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- Evidence hierarchies relating to hand surgery: current status and improvement

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- Translation and cultural adaptation of the revised foot function index for the Portuguese language: FFI-R Brazil

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Lowering blood pressure is a priority in Brazil and worldwide

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In November 2017, the American Heart Association (AHA) and the American College of Cardiology (ACC) launched new guidelines for detecting, treating and controlling hypertension.[1] Recommendations from US researchers have been reaching significant broad audiences through several guidelines that have been disseminated worldwide. Starting in the 1970s, the US National Institutes of Health (NIH) issued seven guidelines relating to management of high blood pressure[2]. However, in 2014, the NIH declined to issue new instructions and asked these American professional associations to update the approach to hypertension.

The cornerstone of the new guidelines has come from the results of the Systolic Blood Pressure Intervention Trial (SPRINT). This was a large randomized clinical trial that revealed that the risks of all causes of deaths and of new cases of cardiovascular diseases were lower only at blood pressure levels lower than the previous cutoff of 140 mmHg for systolic blood pressure (SBP) and 90 mm for diastolic blood pressure (DBP).[3]

The data from SPRINT reaffirmed what had been seen in several observational studies that showed that people with prehypertension were at higher risk. The most relevant data had come from the Framingham Heart Study in 2001: the 10-year cumulative incidence of cardiovascular disease among people with prehypertensive blood pressure levels (SBP of 130 to 139 mmHg, DBP of 85 to 89 mmHg, or both) in the age range from 35 to 64 years was 4% (women) and 8% (men); and at ages of 65 years and over, the incidence was 18% (women) and 25% (men).[4]

Briefly, based on risk findings and clinical trial experience, these guidelines recommend that for individuals with average SBP ≥ 130 mmHg or average DBP ≥ 80 mmHg, accurate outpatient clinic and home blood pressure monitoring measurements are needed. Use of drugs after the diagnosis is recommended for everyone with SBP ≥ 140 mmHg or DBP ≥ 90 mmHg. Among people presenting SBP values ranging from 130 to 139 and DBP from 80 to 89, use of medicines is recommended for those with high cardiovascular risk, diabetes, chronic kidney disease or previous cardiovascular diseases.[1]

From our point of view, there are two essential points to be discussed with all physicians and healthcare providers in Brazil.

1. The diagnosis of hypertension does not need to be immediate. A sequence of blood pressure measurements taken at home or in an ambulatory setting should be the gold standard, and not the office blood pressure. At first glance, the impression obtained is that the range of blood pressures that are deemed to be hypertensive has been significantly increased. However, the spread of home and ambulatory blood pressure measurements will reduce the level of values obtained, in comparison with the blood pressure measured in the physician's office, which was the source of the survey data addressing hypertension.
2. The aim in lowering high blood pressure is to reduce the incidence and recurrence of cardiovascular diseases. Consequently, a general approach to risk factors is fundamental for all patients and mandatory for people who are tagged with the diagnosis of hypertension. Thus, the need to calculate the overall risk will demand information about smoking, diabetes, renal function and previous cardiovascular diseases.

It is always necessary to remember that the most crucial issue regarding lowering of blood pressure to curb the burden of cardiovascular diseases relates to primordial prevention. Thus, there remains

the need to reduce the high intake of salt in Brazil,[5] and the high mortality rate among people with previous cardiovascular conditions that arises from the lack of secondary prevention in this country.[6]

It now becomes necessary for the previous analyses in several Brazilian epidemiological studies to be rerun. These studies include the Brazilian Longitudinal Study of Adult Health (ELSA-Brasil),[7] Bambuí Cohort Study of Aging, [8] Pelotas (Brazil) Birth Cohort Study,[9] Prospective Urban Rural Epidemiology,[10] First National Survey of Indigenous People's Health and Nutrition[11] and 2013 National Health Survey.[12] The aim in so doing will be to identify the impact of the 2017 ACC/AHA high blood pressure guidelines, in accordance with the different population subsets evaluated by those studies.

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Addiction to work and factors relating to this: a cross-sectional study on doctors in the state of Paraíba

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ABSTRACT

CONTEXT AND OBJECTIVE: Addiction to work is one of the new behavioral phenomena present in organizations and it is characterized by excess work and compulsion to work. This phenomenon may give rise to different sicknesses and may affect different professionals, including doctors. Thus, the aims of this study were to analyze the factorial validity and internal consistency of the Dutch Work Addiction Scale (DUWAS); to evaluate the prevalence of addiction to work among doctors in the state of Paraíba; and to investigate factors relating to addiction to work among these doctors.

DESIGN AND SETTING: This was an exploratory, descriptive cross-sectional study with a quantitative approach conducted in municipalities in the state of Paraíba.

METHODS: Data were gathered between June and October 2015, by applying a questionnaire containing sociodemographic questions and the Work Addiction Scale.

RESULTS: The results showed that the Work Addiction Scale has internal consistency and factorial validity and that, in the population studied, only one factor was pointed out: addiction to work. Most of the doctors were not addicted to work; among the addicts, the addiction was not excessive; and the addiction had a positive correlation with the number of shifts done and a negative correlation with age.

CONCLUSION: Greater attention to this phenomenon is required and further research on this topic is needed in order to elucidate the harm caused by addiction to work in daily medical practice.

INTRODUCTION

With a focus on greater agility and competitiveness, organizations have begun organizational policies and practices that place higher value on professionals who have dedicated more of their time to work.[1] To meet capitalist market demands, professionals tend to work to exhaustion in order to reach organizational targets and consequently obtain desirable professional success. Thus, work tends to be the main reason to live and exist, which creates the new phenomenon of workaholism, i.e. addiction to work[1] or working excessively.[2-3]

Addiction to work may be considered to be one of the most recent behavioral vices, although no addiction-inducing substance is present.[3-4] It is a form of psychosocial damage characterized by working excessively, because of an irresistible need or wish to work more and more[5]. Thus, it involves compulsion to work.[6]

These phenomena may be subjectively experienced as loss of control, in which the work addict continues working despite the known negative consequences, which are similar to those relating to psychological, physical and social disorders.[7] The consequences of addiction to work include cardiovascular and dermatological problems, cephalalgias, myalgias, sexual disorders,[8] depression, high-level anxiety[9] and poor satisfaction with life and with work performance.[10]

Because of the severe health complications that addiction to work causes, it has received great attention from researchers.[11] However, research on this topic has been hindered by a lack of consensus regarding the definition of this term and how it is evaluated.[1,7] Moreover, there is poor knowledge about the number and kind of people affected by addiction to work and insufficient research with relevant samples.[7]

Addiction to work in the Brazilian context, factors relating to this and assessments of its consequences have been little explored in the Brazilian scientific literature. This shows that there is a need for greater scientific production concerning this topic.

Regarding the characteristics that describe addiction to work, this problem can be correlated with medical practice. Thus, it becomes relevant to evaluate the extent to which doctors may be vulnerable to addiction to work and the factors that might be related to this phenomenon.

In addition to academic relevance, the current study may provide practical contributions through increasing the knowledge of addiction to work and its correlations in Brazil. Specifically, through knowing to what extent physicians are work addicts, strategies to help these professionals improve their health and quality of life may be deployed.

OBJECTIVES

The study aimed to analyze the factorial validity and internal consistency of the Dutch Work Addiction Scale (DUWAS); to evaluate addiction to work among doctors in the state of Paraíba; and to investigate factors relating to addiction to work among these doctors.

METHODS

This was an exploratory analytical cross-sectional study with a quantitative approach. The population consisted of doctors in the state of Paraíba, Brazil, in the municipalities of João Pessoa, Pombal, Guarabira, Bayeux, Santa Rita, Cabedelo, Campina Grande, Sousa, Cajazeiras, Monteiro, Itaporanga, Piancó, Catolé do Rocha, Belém do Brejo dos Santos, São Bento and Patos. This study was approved by the Ethics Committee for Research on Human Beings of Lauro Wanderley University Hospital, Federal University of Paraíba. Data collection was performed only after approval had been obtained from this committee, under the number CAAE 39156114.0.0000.5183.

The sample size was calculated based on the number of physicians registered at the Regional Medical Council of Paraíba (6,100) by using a simple random sampling plan, considering a margin of error of 3% and a confidence level of 95%. Thus, the sample size was equal to 909. As it was possible to interview more physicians than the total of sample size calculated, the final sample size was 1,110 physicians.

Doctors from Sertão, Borborema, Agreste and Mata were selected to ensure the representativeness of the sample selection. It needs to be highlighted that in choosing these municipalities for inclusion, the number of doctors present at these locations was taken into consideration, because in some places there was either minimal presence of professionals or even none at all. These physicians met the following inclusion criteria: they were active during the data-gathering period; they signed a free and informed consent statement; and they were interested in participating in the study and did so willingly.

Data were gathered between June and October 2015. Sociodemographic information (age, sex, race, marital status, income, religion and number of shifts) and data relating to the Work Addiction Scale were sought. Each work shift was considered to consist of 12 working hours.

The main researcher was directly responsible for applying the questionnaire and coordinating the corresponding activities, counting on cooperation from other previously trained researchers. The average time taken to gather data from each individual was 20 minutes.

The Dutch Work Addiction Scale (DUWAS) was originally created by Schaufeli et al.[12-14] It is composed of 7 items (e.g. "I am usually busy"; "I have many issues under my control"; and "I feel guilty when I am not doing anything else"). The questions are answered on a four-point scale, ranging from never (1) to every day (4). These aim to show how the person feels at work, i.e. how much he experiences. Theoretically, this measurement covers two main dimensions: compulsive work and excessive work.

The Brazilian version adapted by Carlotto and Miralles[15] follows the same instructions and response format. However, it contains 10 items: 5 for each dimension, which are answered using a four-point scale (on which 1 = never and 4 = every day). The results from this adaption have provided justifications for using this scale, including a goodness-of-fit index = 0.95, comparative fit index = 0.98, root mean square error of approximation = 0.04 and internal consistency in which the minimum Cronbach's alpha exceeded the cutoff point of 0.70.

Because we did not find any data relating to measurement of addiction to work among doctors, we decided to take into consideration not only the Portuguese version of the scale but also exploratory analyses that aimed to identify the underlying (componential) factorial structure.

The mean point on the scale (2.5) was used to consider whether addiction to work was present, chosen as the mean between the two cut-off values proposed by Schaufeli.[12] Thus, the doctors whose mean score was greater than or equal to 2.5 were considered to be addicted to work. Those whose mean scores were less than 2.5 were not considered to be addicted to work.

Data were originally formatted using the Microsoft Excel software and were then converted to .sav format in the Statistical Package for the Social Sciences (SPSS) (version 18). Descriptive statistics, e.g. frequency distribution, mean and standard deviation, were produced. These were useful for ascertaining the profile of the sample participants. In addition, we also calculated the following: Kaiser-Meyer-Olkin (KMO) criterion, based on measurement of the adequacy of the factorial analysis; Bartlett sphericity test, which determines whether correlations exist among the variables; Cattel criterion, which presents the most important variables in the factorial analysis in ascending order; Cronbach's alpha, which evaluates instrument consistency; correlation tests to evaluate addiction to work and demographic variables; mean comparison tests (t tests);

and association tests (chi-square and Fisher). The significance level was taken to be 5% ($P < 0.05$).

RESULTS

Although 1,110 physicians were initially interviewed at hospitals, in their shifts and healthcare centers, only 1,108 were included in the final sample: 2 were excluded due to incomplete answering of the questionnaire, making it impossible to perform correlation analysis. The majority of the participants were male (53.30%). The largest proportion of the individuals (27.17%) aged between 31 and 40 years, followed by participants between 51 and 60 years (20.40%). A minority was over 60 years of age (15.79%). Most participants stated that their monthly salary was seven or more minimum wages (92.50%) (**Table 1**).

The largest proportion of the doctors performed 10 shifts (each with 12 working hours) per month (38.18%), followed by those who did 11 to 20 shifts (35.74%). The average was of 12.10 shifts per month (standard deviation, SD = 10.03). A very small proportion (3.16%) stated that they did 31 shifts or more.

Parameters for addiction to work

As a first step, we decided to check the adequacy of the factorial analyses through an inter-item correlation matrix. The KMO (0.88) and Barlett sphericity test results [χ^2 (45) = 3831.36; $P < 0.001$] showed that these analyses were adequate for the data. Thus, we opted to perform principal component analysis (PCA).

The analyses showed that there were two components with eigenvalues greater than one (4.45 and 1.22; Kaiser criterion) that together explained 56.7% of the total variance. **Figure 1** shows the graphical distribution of the eigenvalues, which is a more consistent criterion for defining the number of factors to be taken out (Cattel criterion).

As can be seen from **Figure 1**, the first component is evident, standing out from the others. However, regarding the other components, no relevant difference was observed; the second component is practically aligned with the others, thus suggesting that its presence may not be so clear. Because of these findings, it was considered that only one component existed, thus defining its extraction.

It was found that the saturations (factorial charges) were substantially consistent, ranging from 0.60 (item 10: "It is difficult to relax when I am not working") to 0.70 (item 6: "I dedicate more time to work than to my friends, hobbies or pleasant activities"). Thus, it seems plausible to accept that there was only one dimension for addiction to work, which presented the eigenvalue of 4.45 and explained 44.5% of the total variance. The internal consistency (Cronbach's alpha) of this group of items for measuring the same construct was 0.86, thus emphasizing its pertinence. Likewise, the homogeneity coefficient, i.e. the mean inter-item correlation, was 0.38. This ranged from 0.23 (item 9 with items 1 and 4) to 0.61 (items 7 and 9).

In summary, it can be accepted that the Work Addiction Scale evaluated a general factor gathering together the factorial validity and evidence for internal consistency in the group studied here, which can be simply named "addiction to work". All the results from

Table 1. Doctors' distribution according to sex, age, race, marital status, income, religion and number of shifts worked. Paraíba (PB), 2016 (n = 1108)

Variable	Frequency	Percentage	Mean	Median	Standard deviation
Sex					
Male	591	53.3			
Female	512	46.3			
Not informed	5	0.4			
Age (years)					
From 21 to 30	200	18.17			
From 31 to 40	301	27.07			
From 41 to 50	200	18.08	44.42	43	13.89
From 51 to 60	226	20.32			
Above 60	175	15.83			
Not informed	6	0.53			
Race					
White	681	61.5			
Black	22	2			
Brown	397	35.8			
Other	4	0.4			
Not informed	4	0.4			
Marital status					
Single	254	22.9			
Divorced	91	8.2			
Married	713	64.4			
Widow	22	2			
Other	25	2.2			
Gross monthly income					
4 to 6 minimum wages	79	7.2			
7 to 9 minimum wages	115	10.5			
10 or more minimum wages	910	81.9			
Not informed	4	0.4			
Religion					
Catholic	823	74.3			
Evangelical	132	12			
Spiritist	56	5			
Agnostic	39	3.5			
Other	47	4.2			
Not informed	11	1			
Number of shifts worked					
Up to 10	423	38.31			
11 to 20	396	35.7			
21 to 30	94	8.45	12.1	10	10.03
31 to 40	35	3.15			
Above 40	11	0.99			
Not informed	149	13.39			

these analyses thus showed that the general score from the Work Addiction Scale, obtained through summing its 10 items, could be considered to be the sole variable. This could then be analyzed.

Addiction to work among doctors

In the present analysis, most of the physicians were not addicted to work (610 in total). From the average scores for addiction to work in each group (addicts and non-addicts), it was seen that the non-addicts had an average score of 1.95 (SD = 0.32), and the addicts had a score of 2.50 (SD = 0.37). Thus, it could be confirmed that even in the group of addicts, the addiction was not strong, given that the addiction score was only 2.5.

Factors relating to addiction to work

Addiction to work was positively and weakly correlated with the number of shifts worked ($r = 0.20$; $P < 0.001$); and it showed a negative, weak correlation with age ($r = -0.20$; $P < 0.0001$). Income did not show any significant correlation with addiction to work ($r = -0.01$; $P > 0.05$).

It was not possible to show any association between categorized addiction to work and the variables of sex, race, marital status and religion, with the confidence level taken to be 95%.

From these findings, it seems evident that addiction to work was influenced by the number of shifts worked and the doctors' ages. On this basis, the younger the doctor was, the greater the chances were of being addicted.

DISCUSSION

The results from this study showed that the Work Addiction Scale has internal consistency and factorial validity, and that it evaluates a single general factor that can be named "addiction to work", which is more precise than bi-dimensional evaluation. These findings are contrary to the results found by Carlotto and Miralles,[15] who found that bi-dimensional evaluation of compulsion to work and excessive work was coherent.

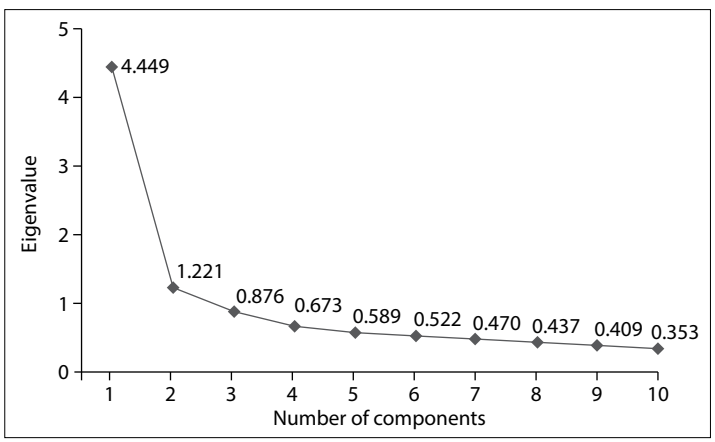

Figure 1. Distribution of eigenvalues on the work addiction scale.

In an evaluation on the factorial validity and internal consistency of the Brazilian Work Addiction Scale, it was observed that compulsion to work and excessive work were related but independent dimensions.[15] However, the group studied and the research locality differed from those of the present study, which may have contributed towards the divergence of these results.

Nevertheless, the study in which the factorial structure of the 10-item version of the Dutch Work Addiction Scale (DUWAS) was investigated demonstrated that this measurement could be applied rapidly and had good factorial validity for all the professions and nations measured. Moreover, it has showed that the DUWAS-10 subdimensions were highly correlated, thus making it possible to use them as a one-dimensional measurement for addiction to work.[16]

That study[16] also showed that the degree of addiction to work can be assessed through four dimensions that are subdimensions of compulsion to work and excessive work: "working frantically" and "working long hours" to explain excessive work and "obsessive work drive" and "unease if not working" to explain compulsion to work.

In the light of these variabilities, further studies replicating the results obtained through using workers in a diversity of professional categories, in different regions of Brazil and in dissimilar organizational and sociocultural contexts, are recommended. These would take into consideration the specificity of each group.[15]

The current study showed that, although present, the addiction to work was not strong. The fact that most of the professionals evaluated only had up to 10 monthly shifts may have influenced the scores for addiction to work. The addicts dedicated many hours to their professional practice, but this was not a constant factor in the group studied.

In another study, doctors considered that their work was one of the most important things in their lives, and that it fulfilled their economic and emotional needs and their pleasure and status, self-satisfaction and self-valorization. These factors motivated them, were complementary and made life more attractive, and may have influenced their non-addiction to work.[17]

A qualitative study involving eight doctors showed that they did not fulfill the characteristics of workaholism, although the interviewees worked exhaustingly long hours and had difficulties regarding taking vacations, having leisure time, being with their families and disassociating their thoughts from their work. However, on certain occasions, some traces were observed, but they were not significant enough to affirm that these doctors were workaholics.[17]

A case study using a quantitative approach analyzed a sample of 25 collaborators within a medical healthcare cooperative, using a self-reporting questionnaire consisting of 24 questions. The results showed that there were many workers who might become workaholics, but that only four of them were considered to be workaholics.[1]

However, this does not mean that these professionals are also worklovers. A worklover is a person who is always satisfied with his work, and this is not a common occurrence among healthcare professionals, including physicians.[17]

An analysis on 2,115 resident Dutch physicians showed that unfavorable work conditions, work overload, conflicts, overwork, presentism and burnout syndrome were related to addiction to work. In addition, it showed that addicts recovered less easily, felt less fulfilled, were unhappy and had a colder relationship with their patients. Thus, the combination of compulsion to work and excessive work was detrimental both to doctors and to the institution in which they work.[18]

A study carried out among doctors in the northeastern states of Brazil and published by the Federal Medicine Council showed that doctors in Paraíba mostly considered that their working conditions were fair or good, and that they were satisfied with the work that they were doing. They also believed that their working day and pay had improved in relation to previous years.[19] These factors may contribute towards a lack of addiction to work.

In view of these favorable working conditions and reasonable salaries, plus low wear and tear relating to transportation within the doctors' municipalities, i.e. without the hectic pace of larger centers (which means that they do not waste so much time on commuting), a healthy routine encompassing work, home and family becomes established. This favors biopsychosocial and economic balance among physicians in Paraíba and frees them from being absorbed into addiction to work. Moreover, because they are close to the countryside, they can enjoy moments of leisure, when they have become established.

Addiction to work among doctors was correlated positively with the number of shifts worked and negatively with age in the present study. Thus, the more shifts worked monthly and the younger the doctor was, the greater the addiction to work was. Workaholics tend to work compulsively and to work more than what is required within their work environment, for greater financial return and professional status and because of the organizational culture.[20] These factors may influence the relationship between the number of shifts and work addiction.

This study showed also that intense dedication to work involved a great number of hours taken to conclude activities. If different demands are under these individuals' control, more time is required and this means greater addiction to work.[21] The fact that younger physicians need to achieve professional status and excel in the job market may make them work intensively, with longer working hours, thus dedicating more time to work and giving up leisure time. This increases their chances of developing addiction to work. However, it has been suggested that young workers who do not have a family are more likely to gain professional achievement and receive little social criticism if they work excessively, in comparison with older workers who are married and have children. The latter attributes contribute towards decreasing addiction to work.[22] A study conducted on a Portuguese group showed that younger people seem to work less excessively than older ones.[23] In that study, there was no significant correlation between addiction to work and the income variable, or even any associations with the variables of sex, race, marital status and religion.

It is important to point out that, in many cases, low income threatens workers' personal, family and social stability and, in searching for better work conditions, they dedicate more time to work, which may make them become workaholics. However, in comparing medical activities with other professions in Brazil, it needs to be highlighted that medical activity is well remunerated, and that this may influence the lack of correlation between addiction and income.

The findings from the present study were similar to those from a previous study that showed that there was no relationship between the dimensions of addiction to work and the variables of income, sex and marital status, among others.[24] A study conducted among academic groups showed that addiction to work had a negative correlation with age, wages and marital status and a positive correlation with the kind and size of the family.[25]

Addiction involves behavioral vices without substance, and it is necessary to differentiate this from real addiction to work, since this behavior may generate mental, physical, social and family consequences, besides affecting work performance.[26] Different people have considered work to be the most important factor in their lives, for different reasons such as: the need to survive, professional and personal fulfilment or even financial reasons. Consequently, some people have shown greater predisposition towards developing addiction to work.[1] So far, no treatment for addiction to work has been proposed, and it is therefore necessary to conduct further studies in this area.[27]

Moreover, there is a need for additional studies in relation to considering work as one of the predictors of sickness, especially nowadays, when work is considered to be a privilege, and not a personal right. Only advances of science within this field may provide the credibility that is required for there to be any kind of influence on public policies for workers and any contribution towards international scientific outcomes relating to addiction to work.[15]

This study has limitations, since the findings cannot be generalized to the medical profession in general because only one Brazilian state was analyzed. In addition to this, the analysis only considered the relationship between addiction and the variables of sex, age, income, race, marital status, religion and working hours. Other studies evaluating relationships with other variables such as presence of children, length of time as a professional and leisure time are also necessary.

This phenomenon requires closer attention. Further research that can elucidate the damage caused by addiction to work within daily medical practice and which can create strategies for diminishing addiction to work and its consequences needs to be developed to investigate the presence of addiction to work among doctors in other Brazilian regions and the factors that influence it.

FINAL REMARKS

In keeping with the traditional characteristics of Northeasterners, of love for the land and contact with nature, the bucolic life of rural areas is an incentive for physicians, once they have become established, to acquire the hobby of spending weekends enjoying the countryside or farms near their homes and having moments of pleasure, which contribute towards increasing their wellbeing. The pleasure of being together with their relatives, and with the soil, animals and plants, relieves the tension of the day-to-day routine and is an excellent impediment to work addition.

As expected, the higher the number of shifts worked was, the greater the addiction to work was, but the greater the age was, the less the addiction was. Since addiction is due to repetition, it is believed that when doctors take on more and more shifts, they get into a vicious cycle and become liable to take up the repetitive act of working more and more. They thus compromise their good sense of knowing how to impose limits and refuse additional job offers, and consequently let themselves be swallowed up by the addiction.

Regarding the predominance of addiction in the younger age group, it is likely to be due to the natural impulses of youth, consisting of "I want everything", "I can do everything" and "I crave everything". It may even be due to a certain degree of ambition to quickly ascend socially and economically through the product of their work, i.e. the more they work, the more they earn and the richer they can become.

Another aspect of this might be due to the long duration of medical school. Because medical courses are full-time, they do not allow young people to enter profitable employment during the six years of the course, plus another four to six more years of medical residency. When doctors finally become free to enter the job market, the will to "roll up the sleeves and get to work" manifests itself more intensely, and the long-held desire to "make money" is shown, sometimes even to an exaggerated extent.

CONCLUSION

The work addiction scale that best suited the population studied here considered excessive work and compulsion to work to be dependent variables. Therefore, the scale is unifactorial.

Most of the physicians evaluated were not addicted to work, and, even in the group of addicts, the addiction was not strong, given that the addiction score was only 2.5. This may have been because these physicians considered that their working conditions were favorable and because they were satisfied with what they were doing.

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Short Mood and Feelings Questionnaire for screening children and adolescents for plastic surgery: cross-cultural validation study

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KEY WORDS:
Adolescent.
Self-image.
Surgery, plastic.
Depression.
Triage.

ABSTRACT

CONTEXT AND OBJECTIVE: Patient-reported outcome measurements assessing the emotional state of children and adolescents who seek plastic surgery are important for determining whether the intervention is indicated or not. The aim of this study was to cross-culturally adapt and validate the Short Mood and Feelings Questionnaire (child/adolescent and parent versions) for Brazilian Portuguese, test its psychometric properties and assess the emotional state of children and adolescents who seek plastic surgery.

DESIGN AND SETTING: Cross-cultural validation study conducted in a plastic surgery outpatient clinic at a public university hospital.

METHODS: A total of 124 consecutive patients of both sexes were selected between September 2013 and February 2014. Forty-seven patients participated in the cultural adaptation of the questionnaire. The final version was tested for reliability on 20 patients. Construct validity was tested on 57 patients by correlating the Short Mood and Feelings Questionnaire (child/adolescent and parent versions) with the Strengths and Difficulties Questionnaire and the Rosenberg Self-Esteem scale.

RESULTS: The child/adolescent and parent versions of the Short Mood and Feelings Questionnaire showed Cronbach's alpha of 0.768 and 0.874, respectively, and had good inter-rater reliability (intraclass correlation coefficient, ICC = 0.757 and ICC = 0.853, respectively) and intra-rater reliability (ICC = 0.738 and ICC = 0.796, respectively).

CONCLUSIONS: The Brazilian-Portuguese version of the Short Mood and Feelings Questionnaire is a reproducible instrument with face, content and construct validity. The mood state and feelings among children and adolescents seeking cosmetic surgery were healthy.

INTRODUCTION

Childhood and adolescence are difficult times because of the enormous pressure imposed by society on people to conform to arbitrary standards of physical appearance.[1,2] Standards of beauty help to shape thoughts, which may lead to discrepancy between what is conceived as ideal and the actual personal reality and also to higher demand for plastic surgery.[3]

Physical and emotional changes during adolescence may lead to dissatisfaction with physical appearance.[4,5] At present, adolescents tend to seek esthetic and surgical procedures influenced by their peers or to improve interpersonal relationships and increase their feelings of inclusion in a social group.[4]

According to the American Society of Plastic Surgeons, about 283,000 cosmetic plastic surgeries were performed on adolescents aged between 13 and 19 in 2012.[6] In Brazil, there was an increase of 141% in the number of plastic surgical procedures performed on adolescents between 14 and 18 years.[7,8] The most common cosmetic procedures sought by girls, both in Brazil and worldwide, are liposuction and breast augmentation, and by boys are gynecomastia and otoplasty for correction of prominent ears.[4,6] According to some authors, improvement in physical appearance is directly associated with increased self-esteem and self-confidence among adolescents.[1,9]

Thus, indications for plastic surgery may help some adolescents who feel different and uncomfortable in their own body to break out of social isolation.[4,9] In fact, plastic surgery leads to psychological changes by modifying the physical appearance, and therefore is considered to be a psychological intervention.[10-12] Thus, its impact is not only esthetic but also, especially, psychosocial. It is known that esthetics produces individual and social wellbeing.[9,13]

Body dysmorphic concerns may result in social anxieties and emotional conflicts among children and adolescents.[1,2] Moreover, the presence of physical characteristics and appearance differing from the cultural standard of beauty may trigger bullying, which in turn causes psychological disorders among vulnerable individuals. Thus, the perception of a defect or flaw in physical appearance may contribute towards development of a mental disorder in individuals with neurobiological vulnerability and psychological fragility.[3]

Depression is the most common psychological disorder in contemporary society,[14] with a prevalence of 2% among children and 4% to 8% among adolescents.[14,15] The World Health Organization reported that depression is the most common disorder among children and adolescents between 10 and 19 years of age and is the predominant cause of disability in both genders. Suicide is one of the three leading causes of death in this age group.[16] Mental health problems during childhood and adolescence are common and may be associated with various difficulties, including behavioral, emotional, social and academic functioning problems, thus affecting the development and use of potential resources.[17]

Excessive concern regarding appearance may conceal psychopathological states that are not always easily identified and may lead to iatrogenic and medico-legal problems if neglected.[18] Thus, validation of patient-reported outcome measurements can help in rapidly screening and identifying depression among children and adolescents, since psychological disorders may not only affect their emotional, social and academic life,[19] but also influence patient satisfaction with the results of surgery.[20,21]

OBJECTIVE

To translate, culturally adapt and validate the Short Mood and Feelings Questionnaire (child/adolescent and parent versions)[22] for Brazilian Portuguese; to test the psychometric properties, reproducibility and validity of the instrument; and to assess the emotional state of children and adolescents who seek plastic surgery.

METHODS

This study was approved by the Institutional Research Ethics Committee of Universidade Federal de São Paulo (approval number 32664) and was conducted in accordance with the Brazilian Ethical Review System for research involving human beings. It also conformed to the 1964 Declaration of Helsinki and its subsequent amendments. Written informed consent was obtained from all patients and their parents or legal representatives after the procedures had been fully explained to them and prior to their inclusion in the study. Patient anonymity was assured. This study was conducted between September 2013 and February 2014.

Patients were consecutively recruited at the Plastic Surgery Outpatient Clinic of the "Jesus" Municipal Hospital and Barra Day Hospital in Rio de Janeiro (Brazil). The parents or legal representatives of the patients also participated in the study. The eligibility criteria were that patients of both sexes, aged between 8 and 17 years, showing preoccupation with physical appearance associated with subjective distress, and who were seeking plastic surgery, could be included. The exclusion criteria were lack of ability to understand the interview questions and presence of psychotic disorders.

A convenience sample (non-probability sample) of all consecutive patients who met the study criteria was selected to participate in the study. We assessed the highest possible number of eligible patients during the study period; none declined participation. Out of the 124 patients admitted, 47 participated in the cultural adaptation of the scale, 20 were included in the reliability analysis on the final version of the instrument and 57 participated in the construct validity assessment. The construct validity was assessed through correlating the Short Mood and Feelings Questionnaire, in its child/adolescent and parent versions, with the Strengths and Difficulties Questionnaire and the Rosenberg Self-Esteem scale. The participants in each phase were not included in the other phases of the study.

The number of patients participating in the cultural adaptation, reliability and validity phases was similar to that used in previous studies evaluating the psychometric properties of social construct measurements in plastic surgery populations,[23-29] and was in accordance with the methodology internationally accepted and used for translation, cultural adaptation and validation of instruments.[30-34] According to Sapnas and Zeller,[34] the traditional protocol for determination of an adequate sample size based on power analysis is not appropriate for studies assessing the psychometric properties of social construct measurements; a total sample size of 50 subjects or more is adequate for representing the study population.[34]

The instrument

The present study was conducted after Dr. Angold, the author of the original version of the Short Mood and Feelings Questionnaire, granted permission to translate, culturally adapt and validate the instrument for Brazilian Portuguese.

The Short Mood and Feelings Questionnaire[22] is derived from the Mood and Feelings Questionnaire,[35] which was developed to assess depressive signs and symptoms among children and adolescents between 8 and 17 years of age.[36,37]

The Short Mood and Feelings Questionnaire is a brief self-report instrument for screening for depressive symptoms and for

assessing moods and feelings among children and adolescents; it is also available in a parent version. Thirteen items involving affective and cognitive components are rated on a scale from 0 to 2, where 0 indicates no symptom and 2 indicates depressive symptoms. The total score is calculated as the sum of ratings for the 13 items, with higher scores indicating mental health impairment of greater severity.

Translation

The original version of the Short Mood and Feelings Questionnaire was translated from English into Brazilian Portuguese by two independent translators. Only one of the translators was informed about the objectives of the study, so as to obtain a conceptual rather literal translation of the scale.[30] Both translations were evaluated by a multidisciplinary group composed of two plastic surgeons, a psychologist and an anesthesiologist. All items were checked for possible mistakes made during the translation and were evaluated for content validity. A Brazilian Portuguese consensus version of the questionnaire was then obtained by combining elements from both translations. The consensus version was adequately adapted for linguistic context and care was taken to preserve all essential characteristics of the original instrument. Idiomatic, semantic, conceptual and cultural equivalences were considered during the translation phase.

Next, the consensus version was back-translated into English by two independent translators who did not have any knowledge about the original questionnaire or purpose of the study. Both back-translated versions were evaluated and compared with the original questionnaire by the same multidisciplinary group, to check for possible errors made during back-translation. A consensus back-translated version was created and compared with the original English version, and minor differences were resolved by discussion. This analysis resulted in development of consensus version 1 of the Short Mood and Feelings Questionnaire in Brazilian Portuguese, which was appropriately adapted to the linguistic and cultural context of the target population, while maintaining all the essential characteristics of the original questionnaire in English.

Cultural adaptation or pretesting

Version 1 of the questionnaire was administered to 20 patients and their respective parents, who were interviewed separately, to test for possible failures of the respondents to comprehend the items. After these patients had given informed consent for their participation, they were given the opportunity to express their comprehension of the questionnaire and suggest any changes they considered necessary. All patients and parents understood that the questionnaire items related to emotional state.

The interview data were collected and evaluated by the multidisciplinary team, and then version 2 of the scale was created, including adaptations that were necessary for patients and parents to properly understand all items. When patients failed to understand the meaning of an item, the question was reworded, while always maintaining the same semantic concept, so that the essential structure of the instrument was unchanged.

Version 2 of the scale was then administered to 27 different patients and their respective parents. The final version was obtained when patients, translators and healthcare professionals reached a consensus (**Appendix 1**).

Psychometric evaluation

After translation and cultural adaptation, the final version was tested for internal reliability and for face, content and construct validity, on 20 and 57 target patients and parents, respectively.

Reliability

Cronbach's alpha (α) was used to evaluate the internal consistency and reliability of the instrument. It indicates the degree to which a set of items measures a single latent construct, thus determining the internal consistency or average correlation of items in a survey instrument and estimating its reliability.

Cronbach's alpha ranges from 0 to 1. Alpha values greater than 0.7 indicate acceptable to high reliability.[38,39] When the overall Cronbach's alpha value is low (< 0.7), an item-by-item analysis should be carried out to evaluate whether an item should be excluded from the scale to increase the consistency of the instrument. The item-by-item analysis is performed by observing the correlation of each item with the other items of the instrument (item-total correlation) and by calculating "alpha if item deleted" for each item. If the item-total correlation is low and the alpha value if item deleted is higher than the overall alpha, it may be appropriate to remove this item from the scale.

Test-retest reliability (reproducibility) is the ability of an instrument to produce stable or similar results from repeated administration when no change in the patients' characteristics has occurred.[33] Studies have reported retesting as early as a few hours after baseline testing.[24-28] The longer the time that elapses is, the lower the measured reliability will be, and the more likely it will be that knowledge or attitudes have in fact changed.[40] The instrument was tested for test-retest reliability (reproducibility) in three interviews conducted by two independent interviewers. Twenty patients and parents were interviewed by investigator 1 and the interview was repeated by investigator 2 three hours later, on the same day. After two weeks, the instrument was administered to the same patients and parents by investigator 1 only. Inter and intra-rater reliability analyses were performed. This phase of testing is used to verify the precision of the instrument in measuring the properties for which it was designed.[31,32]

Statistical analysis on test-retest reliability was performed using the intraclass correlation coefficient (ICC) and Pearson's correlation coefficient (r).

Validity

In this study, face validity was determined through a consensus reached by the multidisciplinary group responsible for the Brazilian version of the questionnaire during its cultural adaptation.

Content validity is defined as the degree to which items are representative of the construct of interest. The content validity of the instrument was examined in each phase of the study by the multiprofessional group and determined through reaching a consensus.

Construct validity was tested on 57 patients and respective parents. This is the process in which the correlation of a measurement with other variables is tested for theoretical consistency. Construct validity was tested by comparing the Short Mood and Feelings Questionnaire with scales that are considered to be associated with mood and feelings, using convergent and divergent validity analyses.

Convergent validity refers to the degree to which two measurements of constructs that theoretically should be related are in fact related. Assessment of convergent validity does not require use of a gold standard. It was measured by studying the correlations between domains of the child/adolescent and parent versions of the Short Mood and Feelings Questionnaire and the child and parent versions of the Strengths and Difficulties Questionnaire.[17,41] The Strengths and Difficulties Questionnaire has 25 items grouped into five subscales (emotional symptoms, conduct problems, hyperactivity-inattention, peer problems and prosocial behavior subscales) that assess positive and negative attributes of children and adolescents between 4 and 16 years of age. Higher scores on the prosocial behavior subscale reflect strengths, whereas higher scores on the other four subscales reflect difficulties. The instrument is available in three versions (child, parents and teachers).[17] The correlation between the Short Mood and Feelings Questionnaire and the Strengths and Difficulties Questionnaire was tested using Pearson's linear correlation.

Divergent validity demonstrates that the construct of interest (e.g. depression) is different from other constructs that might be present in the study (e.g. loss of self-esteem). Assessment of divergent validity does not require use of a gold standard. Divergent validity was determined by comparing scores on the Short Mood and Feelings Questionnaire, in its child/adolescent and parent versions, with scores on the Rosenberg Self-Esteem scale,[23] using Pearson's linear correlation. The Rosenberg Self-Esteem Scale is a 10-item measurement of self-esteem distributed over two domains: self-confidence and self-deprecation. The total score ranges from 0 to 30, where 0 indicates the highest level of self-esteem and 30 indicates the lowest level of self-esteem.

The Kolmogorov-Smirnov test was used to test the data for normal distribution. The Wilcoxon test was performed to evaluate differences in mean scores between the child/adolescent and parent versions of the Short Mood and Feelings Questionnaire, because the data were not distributed normally. Student's t test for independent samples was used for comparisons of mean scores in the child/adolescent version of the Short Mood and Feelings Questionnaire, between age groups.

To evaluate the responsiveness of the Short Mood and Feelings Questionnaire, floor and ceiling effects were considered to be present if more than 10% of the respondents achieved the lowest or highest possible score, respectively.

The IBM Statistical Package for the Social Sciences, version 20.0 for Windows (IBM Corp., Armonk, NY, USA), and the Stata 12 software (Stata Corp, College Station, Texas, USA) were used for data analysis. All statistical tests were performed at a significance level of 5% ($P < 0.05$). Data were expressed as mean ± standard deviation (SD).

RESULTS

A convenience sample of 124 consecutive patients of both sexes was selected to participate in the study. No patient declined to participate. The flow diagram showing the initial recruitment and the final sample of patients is shown in **Figure 1**.

Overall, most patients 63.7% (n = 79) were boys; 48.4% (n = 60) were Caucasians; 86.3% (n = 107) had completed their primary education; the mean age was 12.1 ± 2.5 years; and 91.9% (n = 114) of the legal guardians who completed the parent version of the Short Mood and Feelings Questionnaire were the child's natural parents (**Table 1**).

Cultural adaptation or pretesting

The purpose of the cultural adaptation or pretest was to evaluate whether the items of the translated instrument were clearly formulated. Thus, the 47 patients who participated in the pretest were not included in the statistical analysis.

Version 1 of the questionnaire was administered to 20 patients and respective parents. All the respondents understood that the items were about emotional states relating to mood and feelings. However, 20% (n = 4) of the children and adolescents and 15% (n = 3) of the parents did not understand the term "restless" ("inquieto" in Brazilian Portuguese) in item 4 (version 1), so the term was changed to "agitated" ("agitado" in Brazilian Portuguese) in both the child/adolescent and the parent version of the instrument.

The Short Mood and Feelings Questionnaire version 2 was then applied to another 27 children and adolescents and their parents, and the cross-cultural equivalence of the scale was retested. The patients and their parents had no doubts about the questionnaire items and found the instrument easy to understand. The mean time taken to answer the questionnaire was five minutes.

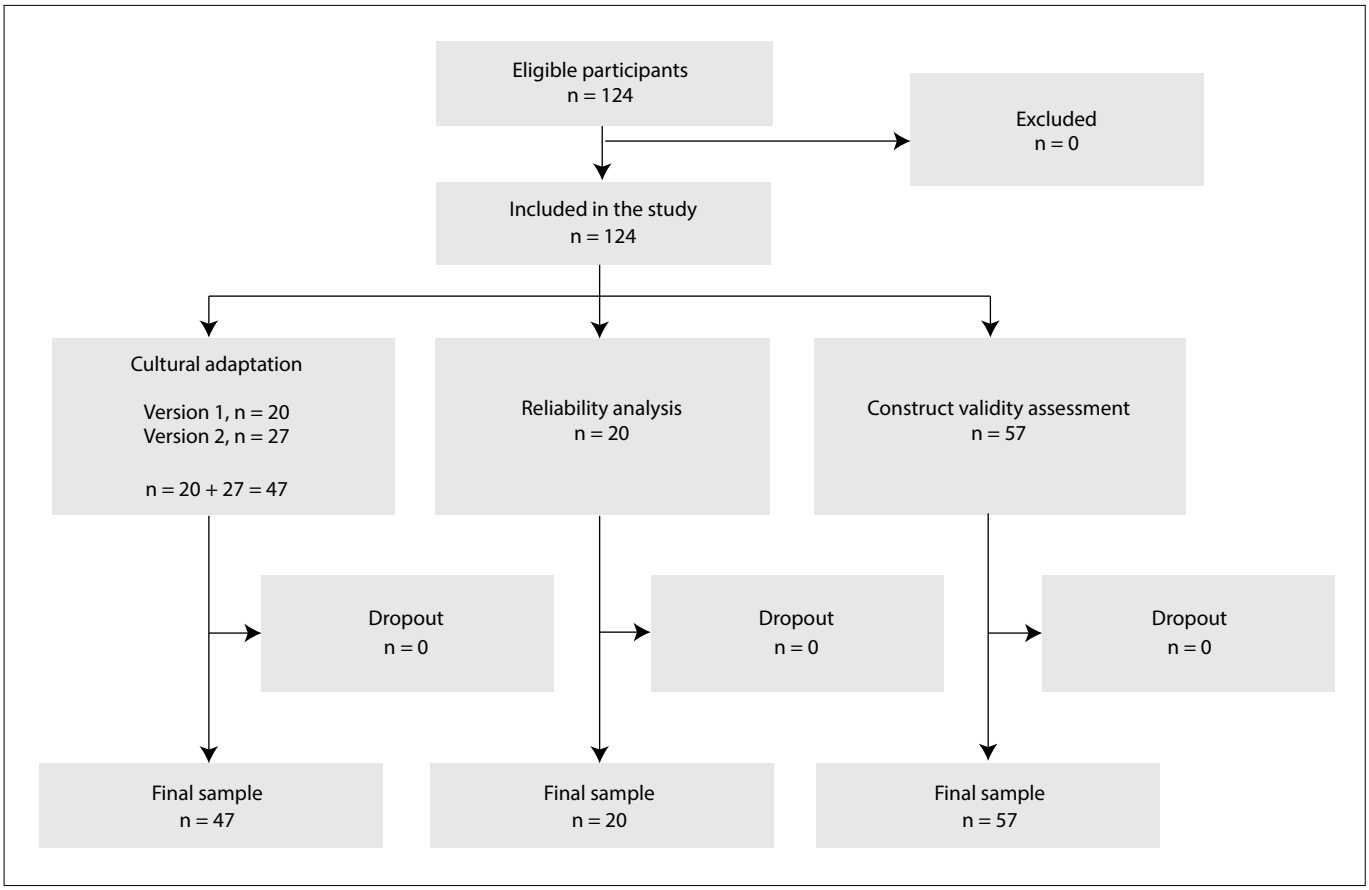

Figure 1. Flow diagram showing the initial recruitment and final sample of patients.

Table 1. Characteristics of the children and adolescents in each phase of the study

Characteristics	Pretest 1 (n = 20)	Pretest 2 (n = 27)	Test-retest (n = 20)	Validity (n = 57)	Total (n = 124)	P[1]
Gender	20 (100%)	27 (100%)	20 (100%)	57 (100%)	124 (100%)	
Girl	10 (50.0%)	8 (29.6%)	6 (30.0%)	21 (36.8%)	45 (36.3%)	0.500
Boy	10 (50.0%)	19 (70.4%)	14 (70.0%)	36 (63.2%)	79 (63.7%)	
Ethnicity	20 (100%)	27 (100%)	20 (100%)	54 (100%)	121 (100%)	
Caucasian	13 (65.0%)	3 (11.1%)	14 (70.0%)	30 (55.6%)	60 (49.6%)	< 0.001
Black/mixed race	7 (35.0%)	23 (85.2%)	5 (25.0%)	24 (44.4%)	59 (48.8%)	
Asian	0 (0%)	1 (3.7%)	1 (5%)	0 (0%)	2 (1.7%)	
Education level	20 (100%)	27 (100%)	20 (100%)	57 (100%)	124 (100%)	
Primary	17 (85.0%)	26 (96.2%)	17 (85.0%)	48 (85.7%)	107 (87.7%)	0.483
Secondary	3 (15.0%)	1 (3.8%)	3 (15.0%)	8 (14.3%)	15 (12.3%)	
Kinship of respondents of the parent version	20 (100%)	27 (100%)	20 (100%)	56 (100%)	123 (100%)	
Son	19 (95.0%)	24 (88.9%)	19 (95.0%)	52 (92.9%)	114 (92.7%)	
Stepson	0 (0%)	1 (3.7%)	0 (0%)	2 (3.6%)	3 (2.4%)	0.419
Brother	0 (0%)	0 (0%)	1 (5.0%)	1 (1.8%)	2 (1.6%)	
Foster child	0 (0%)	0 (0%)	0 (0%)	1 (1.8%)	1 (0.8%)	
Grandson	0 (0%)	2 (7.4%)	0 (0%)	0 (0%)	2 (1.6%)	
Nephew/niece	1 (5.0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.8%)	
Age (years) mean (SD)	12.0 (2.6)	12.3 (2.6)	12.6 (2.5)	12.0 (2.5)	12.1 (2.5)	0.787

[1]Fisher's exact test or analysis of variance. SD = standard deviation.

Questionnaire scores

The mean scores on the Short Mood and Feelings Questionnaire, in the child/adolescent version (n = 77) and the parent version (n = 77) were 6.1 ± 4.4 and 6.9 ± 5.6, respectively. This showed that although the patients were dissatisfied with their physical appearance, they were mentally healthy. No significant difference was observed between scores from the child/adolescent and parent versions of the Short Mood and Feelings Questionnaire (P = 0.407; Wilcoxon test), and only a low correlation was found between the two versions of the instrument (r = 0.268; P = 0.019).

No significant age-related differences in scores from the child/adolescent version of the Short Mood and Feelings Questionnaire were found between children up to 11 years of age and those 12 years and older (P = 0.139; Student's t test), thus showing that age had no impact on the degree of body dissatisfaction.

Internal consistency

The child/adolescent version of the Short Mood and Feelings Questionnaire (n = 77) showed acceptable internal consistency (α = 0.768). All items contributed to the internal consistency of the scale, except for item 4, which showed an α of -0.086, thus indicating almost complete absence of correlation of this item with the others. Deletion of item 4 (I felt very agitated) increased the internal consistency (α = 0.808), as shown in **Table 2**. The parent version of the Short Mood and Feelings Questionnaire (n = 77) showed good internal consistency (α = 0.874), with all items contributing favorably towards the internal consistency of the scale (**Table 2**).

No floor or ceiling effect was present for the child/adolescent and parent versions of the Short Mood and Feelings Questionnaire, thus showing that both versions had good responsiveness.

Test-retest reliability

Inter-rater and intra-rater reliability were investigated in a sample of 20 patients and respective parents. The child/adolescent version of the Short Mood and Feelings Questionnaire demonstrated good inter-rater reliability (r = 0.808; ICC = 0.757; P < 0.001) and intra-rater reliability (r = 0.801; ICC = 0.738; P < 0.001), as seen in **Table 3**. The parent version of the Short Mood and Feelings Questionnaire also had good inter-rater reliability (r = 0.894; ICC = 0.853; P < 0.001) and intra-rater reliability (r = 0.816; ICC = 0.796; P < 0.001), as listed in **Table 4**.

Construct validity

Construct validity was evaluated in a sample of 57 adolescent patients and their parents. There was a low correlation between the child/adolescent version of the Short Mood and Feelings Questionnaire and the child version of the Strengths and Difficulties Questionnaire (r = 0.295; P = 0.044), and a moderate correlation between the child/adolescent version of the

Table 2. Internal consistency analysis. Statistical summary of scores from the child/adolescent and parent versions of the Short Mood and Feelings Questionnaire (SMFQ) (n = 77)

SMFQ items		Child/adolescent version		Parent version	
Cronbach's alpha = 0.768 (child version) Cronbach's alpha = 0.874 (parent version)		Corrected item-total correlation	Cronbach's alpha if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
1.	I felt miserable or unhappy	0.264	0.766	0.669	0.858
2.	I didn't enjoy anything	0.578	0.737	0.457	0.870
3.	I felt so tired that I just used to sit down without doing anything	0.438	0.748	0.354	0.876
4.	I felt very agitated	-0.086	0.808	0.443	0.871
5.	I felt worthless	0.626	0.731	0.700	0.857
6.	I cried a lot	0.423	0.752	0.567	0.864
7.	It was hard to think or to concentrate	0.386	0.754	0.568	0.864
8.	I hated myself	0.444	0.749	0.470	0.869
9.	I was a bad person	0.393	0.755	0.395	0.872
10.	I felt lonely	0.456	0.747	0.610	0.861
11.	I thought that nobody loved me	0.552	0.739	0.645	0.859
12.	I thought that I would never be as good as other children or adolescents	0.462	0.746	0.710	0.855
13.	I did everything wrong	0.421	0.751	0.562	0.864

Short Mood and Feelings Questionnaire and the Rosenberg Self-Esteem scale (r = 0.495; P < 0.001).

A moderate correlation was found between the parent version of the Short Mood and Feelings Questionnaire and the parent version of the Strengths and Difficulties Questionnaire (r = 0.581; P < 0.001).

DISCUSSION

The Short Mood and Feelings Questionnaire[22] is a brief self-report questionnaire that captures specific information about depressive symptoms and can serve as a decision-support system for selecting children and adolescents as candidates for plastic surgery. In contrast to the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5), which is intended for use by psychiatrists in making diagnoses of mental disorders such as depression, the Short Mood and Feelings Questionnaire is a brief, easy-to-use, objective screening tool that can be administered by healthcare professionals in general, thus allowing symptom tracking.

General guidelines for cross-cultural adaptation of quality-of-life instruments were followed to ensure quality in the cross-culturally adapted Brazilian version of the Short Mood and Feelings Questionnaire (**Appendix 1**). Patients and healthcare professionals who were experienced in management of plastic surgery patients participated in the evaluation of this instrument.[30]

The Brazilian Portuguese version of the Short Mood and Feelings Questionnaire was validated in a population sample of esthetic surgery patients (n = 77). The most common complaint among these children and adolescents was prominent ears, as reported by other researchers,[4,6,42-44] and the main motivation for seeking otoplasty was marked psychological and social distress, a finding consistent with previous studies.[42,44] The mean age of 12 years was similar to what was found by Rhew et al.[44] in a validation study on the Short Mood and Feelings Questionnaire.

The 47 patients who were interviewed to assess the cross-cultural equivalence of the translated Short Mood and Feelings Questionnaire[32] found that the instrument was easy to understand. The mean time taken to answer to the questionnaire was five minutes.

The instrument showed good internal consistency (child/adolescent version, $\alpha = 0.76$; parent version, $\alpha = 0.87$), compared with the original instrument (child/adolescent version, $\alpha = 0.85$; parent version, $\alpha = 0.87$),[22] as well as good inter-rater reliability (child/adolescent version, ICC = 0.76; parent version, ICC = 0.85), compared with the original scale (child/adolescent version, ICC = 0.73; parent version, ICC = 0.75),[35] and intra-rater reliability (child/adolescent version, ICC = 0.73; parent version, ICC = 0.79).

Item 4 of the Short Mood and Feelings Questionnaire had to be changed in both the child/adolescent and parent versions, and negatively affected the internal consistency of the scale. Similarly, Lundervold et al.[45] found excellent internal consistency for all items of the Short Mood and Feelings Questionnaire, except for item 4. Sharp et al.[46] reported that items 3, 4 and 7 had no discriminatory power, especially for high scores, but contributed towards screening for patients reporting low scores from the Short Mood and Feelings Questionnaire. The variables of restlessness and tiredness, which are assessed in these items, may be related to changes to sleep-wake pattern during adolescence, resulting from physiological and psychological factors.[47] In this study, the lowest scores reported were for items 3, 4 and 7, which assessed restlessness, tiredness and concentration problems, respectively, which are symptoms of depression.[45] The low scores indicated that despite the distress with their physical appearance, the patients were mentally healthy.

Table 3. Inter and intra-rater reliability of the child/adolescent version of the Short Mood and Feelings Questionnaire (SMFQ-C) (n = 20)

SMFQ-C	Intraclass correlation coefficient (ICC)			Pearson's correlation coefficient		
	ICC	95% CI	P	r	95% CI	P
Inter-rater reliability	0.757	[0.489; 0.896]	< 0.001	0.808	[0.499; 0.971]	< 0.001
Intra-rater reliability	0.738	[0.455; 0.886]	< 0.001	0.801	[0.587; 0.929]	< 0.001

CI = confidence interval; ICC = intraclass correlation coefficient; r = Pearson's correlation coefficient.

Table 4. Inter and intra-rater reliability of the parent version of the Short Mood and Feelings Questionnaire (SMFQ-P) (n = 20)

SMFQ-P	Intraclass correlation coefficient (ICC)			Pearson's correlation coefficient		
	ICC	95% CI	P	r	95% CI	P
Inter-rater reliability	0.853	[0.670; 0.939]	< 0.001	0.894	[0.642; 0.981]	< 0.001
Intra-rater reliability	0.796	[0.561; 0.914]	< 0.001	0.816	[0.472; 0.944]	< 0.001

CI = confidence interval; ICC = intraclass correlation coefficient; r = Pearson's correlation coefficient.

The validity of the instrument was tested by comparing the Short Mood and Feelings Questionnaire with similar tools.[33] The Brazilian versions of the Strengths and Difficulties Questionnaire and the Rosenberg Self-Esteem scale are cross-culturally adapted and validated instruments that measure aspects of mental health. The moderate and low correlations of the Short Mood and Feelings Questionnaire with the Rosenberg Self-Esteem scale and the Strengths and Difficulties Questionnaire, respectively, indicated that the study participants were mentally healthy. The children and adolescents reported a mean score of 9.9 ± 3.9 on the Rosenberg Self-Esteem scale, thus indicating good self-esteem, which is a mental health indicator. Individuals with good self-esteem are less likely to have depression.[12]

The fact that the Strengths and Difficulties Questionnaire assesses various emotional problems and is not specific to depressive symptoms may explain the low correlation between the two questionnaires. The moderate correlation between the parent version of the Short Mood and Feelings Questionnaire and the parent version of the Strengths and Difficulties Questionnaire suggested that parents provided a more rigorous evaluation of both the mental condition of their children[47] and their own subjectivity. However, the correlation between parent and child perception showed that although there was an affective bond between them, there was also independence of affections and presence of individuality. Parents can be a relevant source of information.[9] Children often cannot adequately express their feelings about physical issues that may be affecting them emotionally. This highlights the importance of validating the child/adolescent and parent versions of the Short Mood and Feelings Questionnaire.

Although the Strengths and Difficulties Questionnaire assesses emotional problems and the Rosenberg Self-Esteem Scale measures self-deprecation, these instruments were not designed to specifically measure depressive signs and symptoms among children and adolescents. Thus, the Short Mood and Feelings Questionnaire is a valuable screening tool for rapid and simple detection of mental health impairment among children and adolescents, and may provide support for selecting patients for plastic surgery procedures.

This study was conducted mostly on boys and the main motivation for seeking plastic surgery was prominent ears. This is a limitation on the generalization of the results. Further studies are necessary to test the performance of the Short Mood and Feelings Questionnaire in different populations of children and adolescents.

CONCLUSIONS

The Short Mood and Feelings Questionnaire was translated, culturally adapted and validated for Brazilian Portuguese and was named the "Short Mood and Feelings Questionnaire-Escola Paulista de Medicina/UNIFESP" or SMFQ-EPM/UNIFESP. It is a reliable instrument, showing face, content and construct validity. The Short Mood and Feelings Questionnaire indicated that the mood state and feelings of children and adolescents seeking cosmetic surgery were healthy.

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Appendix 1. Brazilian Portuguese version of the Short Mood and Feelings Questionnaire (SMFQ) for children/adolescents and parents

QUESTIONÁRIO CURTO SOBRE HUMOR E SENTIMENTOS

Versão para autoavaliação

Este formulário se destina a registrar seus sentimentos e ações recentes.

Para cada pergunta, pedimos que marque como você se sentiu ou agiu nas duas últimas semanas.

Se a afirmação refletir seu sentimento a maior parte do tempo, marque a coluna VERDADE. Se for verdadeira apenas algumas vezes, marque a coluna ALGUMAS VEZES. Se a afirmação não se aplicar a você, marque a coluna NÃO É VERDADE.

	Verdade	Algumas vezes	Não é verdade
Eu me senti muito mal ou infeliz			
Eu não gostava de absolutamente nada			
Eu me senti tão cansado/a que só ficava sentado/a sem fazer nada			
Eu me senti muito agitado/a			
Eu me senti como se não valesse mais nada			
Eu chorei muito			
Achei difícil raciocinar ou me concentrar			
Eu me odiei			
Eu fui uma pessoa má			
Eu me senti sozinho/a			
Eu pensei que ninguém me amava de verdade			
Eu pensei que nunca chegaria a ser tão bom/a como as outras crianças/adolescentes			
Eu fiz tudo errado/a			

QUESTIONÁRIO CURTO SOBRE HUMOR E SENTIMENTOS

Versão para avaliação de pais/responsáveis

Este formulário se destina a registrar seus sentimentos e ações recentes.

Para cada pergunta, pedimos que marque como você se sentiu ou agiu nas duas últimas semanas.

Se a afirmação refletir seu sentimento a maior parte do tempo, marque a coluna VERDADE. Se for verdadeira apenas algumas vezes, marque a coluna ALGUMAS VEZES. Se a afirmação não se aplicar a você, marque a coluna NÃO É VERDADE.

	Verdade	Algumas vezes	Não é verdade
Ele/a se sentiu muito mal ou infeliz			
Ele/a não gostava de nada			
Ele/a se sentiu tão cansado/a que só ficava sentado/a, sem fazer nada			
Ele/a se sentiu muito agitado/a			
Ele/a se sentiu como se não valesse mais nada			
Ele/a chorou muito			
Ele/a achou difícil raciocinar ou se concentrar			
Ele/a se odiou			
Ele/a achou que era uma pessoa má			
Ele/a se sentiu sozinho/a			
Ele/a pensou que ninguém o/a amava de verdade			
Ele/a pensou que nunca chegaria a ser tão bom/a como as outras crianças			
Ele/a achou que fazia tudo errado			

Characteristics of role models who influenced medical residents to choose surgery as a specialty: exploratory study

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KEY WORDS:
Education, medical.
Internship and residency.
Career choice.
Faculty.
General surgery.

ABSTRACT

CONTEXT AND OBJECTIVE: Choosing a medical specialty and making decisions concerning a career are difficult processes for medical students and newly graduated physicians. This exploratory study aimed to investigate the influence of role models on the choice of surgery as a career, and to determine the most influential model characteristics.

DESIGN AND SETTING: Qualitative analysis on responses to a self-administered questionnaire, in different teaching-learning settings.

METHODS: Residents from all years of various surgical subspecialties in a university hospital were included in a survey about the factors that determined their choice of surgery. The questions included items on whether a role model had influenced them in choosing surgery, and the personal or professional characteristics of the models that had been most influential. The responses were subjected to qualitative content analysis.

RESULTS: Sixty-four out of 96 medical residents participated. Fifty-three residents (82.8%) acknowledged the influence of role models. Sixteen model characteristics were indicated as important, with 136 mentions. Characteristics classified as technical skills (55%), such as "medical knowledge" and "manual dexterity" predominated over humanistic characteristics (35%), such as "patient-physician relationships" and "ethical behavior". However, this difference was not statistically significant (Fisher test, P = 0.11). There were no age differences regarding the proportions mentioning "technical" and "non-technical" attributes, but female residents mentioned significantly more technical skills than their male colleagues did.

CONCLUSIONS: The influence of role models seems to be an important factor determining the choice of surgery as a career. The influential characteristics of the models include not only technical but also humanistic qualities.

INTRODUCTION

Choosing a medical specialty and making decisions concerning a future career comprise complex and difficult processes for medical students and newly graduated physicians. These processes are important not only for individuals but also for healthcare systems, as they have implications in medical workforce planning.[1,2]

A number of different factors are known to influence medical specialty choice, including gender, personality features, academic interests, specialty characteristics and training demands, curricular and extracurricular past experiences, financial aspects and lifestyle expectations.[1-3] Among these influential factors, role models, such as teachers, tutors and supervisors, to whom medical students and trainees are exposed, embody one of the most important influences on medical specialty choice.[4]

Surgical specialties may be characterized as being physically and mentally demanding careers, with long and hard training periods, and with diminished potential for lifestyle control.[5] Regarding the factors influencing the choice of surgery as a career, an investigation carried out in the United Kingdom among medical students found that, for those interested in surgical specialties, a number of perceived career characteristics, such as completing a clinical attachment in this area, professional prestige, technical challenge and prospects of financial rewards were important factors.[3] An extensive review of published work in Australia found that positive past experiences in a surgical environment, perceived prestige and expectations of higher financial reward were significantly associated with choosing a surgical specialty as a career.[6]

A number of studies have shown that, besides the previously mentioned factors, medical students interested in pursuing surgery as a career, as well as trainees who have already chosen this professional field, have acknowledged the influence of mentors and role models.[7-11] A few studies have attempted to identify characteristics and traits associated with successful mentors and role models.[8-12] Nevertheless, the influence of role models upon the choice of surgery as a career among newly graduated physicians and, in particular, the attributes and characteristics of these models that are more effective in influencing their choice towards a surgical field have not been much investigated.

OBJECTIVE

Therefore, the aim of this exploratory study was to investigate the influence of role models among medical residents who had already chosen surgical specialties, and to identify the most influential characteristics of their role models.

METHODS

Participants and ethics

The study included medical residents from all years (1st to 5th) of the 10 surgical subspecialty training programs of the Department of Surgery of the University Hospital of the Ribeirão Preto Medical School (Faculdade de Medicina de Ribeirão Preto, FMRP). All medical residents were contacted and only those who refused to participate or were away from the Department for electives or congresses were not included.

This was done in accordance with a study project that had been approved by the local Institutional Ethics Committee (Pr. 411/2017). Residents were included after being fully informed about the study aims and were given guarantees regarding anonymity and confidentiality issues.

Study development

The study was carried out during the first six weeks of the 2014 academic year. Residents were approached individually by one of authors (CEP or LER), while in different practice and learning settings used by the various residency programs. After consent had been obtained, a questionnaire form was handed to the participant, who was invited to record his/her answers immediately and anonymously. The participants were instructed to ask the researcher for clarifications if necessary, but none of them needed to do this. The median time spent in answering the questionnaire was 10 min.

Instrument

The questionnaire contained items asking for demographic data and only two single open-ended questions addressing the main objectives of the study:

1. "Do you consider that a surgeon acting as a role model due to his/her knowledge, skills, attitudes and values has influenced you in your medical specialty choice?"
2. If your answer to the previous question was positive: "which were the most influential personal or professional characteristics of your role models?".

Data analysis

Answers to the first question were recorded as "yes" or "no" and expressed as the corresponding percentages. Answers to the second open question were subjected to content analysis using a standard qualitative technique[13] for capturing both the manifest (explicit) and the latent (implicit) meaning of every individual response. The responses were read by two of the authors (CEP and MLVR), who jointly coded each of them into different categories, which were expressed as single keywords or expressions. Coding was based on well-known attributes of role models who influence medical specialty choice.[8-12] Subsequently, the senior author (LEAT) empirically classified the characteristics mentioned into three groups:

1. "Technical skills";
2. "Humanistic characteristics"; and
3. "Miscellaneous".

For the statistical analysis, the latter two classes were aggregated into a category of "non-technical attributes".

Statistical analysis

Differences between the proportions of the characteristics of role models pertaining to the classes of "technical skills" and "non-technical attributes", for the whole sample of participants, as well as between male and female and between "older" and "younger" residents, were analyzed using the nonparametric Fisher exact probability test. For the analysis concerning age, the cutoff point was the participants' median age ("younger" ≤ 28 years; "older" > 28 years). Differences associated with P-values of less than 0.05 were regarded as statistically significant.

RESULTS

Sixty-four out of the 96 current residents (66.6%) were surveyed in this study. Participants from three programs (General Surgery, Vascular Surgery and Upper Digestive Tract Surgery) comprised almost two-thirds of the study sample, whereas the remaining subspecialties (Urology, Neurosurgery, Colo-Proctology, Plastic and Reconstructive Surgery, Pediatric Surgery, Cardiovascular Surgery and Head & Neck Surgery) were represented by at least one resident (median 3; range: 1-8). There were 49 male residents (74.2%) and 17 female residents (25.8%). The median age was 28 years. Forty-nine participants (74.2%) had already completed

a two-year training period in General Surgery either in our institution or elsewhere, before entering a particular local surgical specialty training program.

Fifty-three residents (82.8%) acknowledged that role models influenced them in their medical specialty choice, while eight had a negative answer and three were not sure about this influence. The 53 medical residents acknowledging the influence of role models mentioned 136 remarkable characteristics overall, which were coded into 16 categories. These results are shown in **Table 1**.

These 16 categories were subsequently grouped into three main classes. The "technical skills" class (52.2%) comprised the following categories: technical skills, technical or medical knowledge, decision-making capability/resolvability, objectivity and dexterity. The class of "humanistic" characteristics (31.6%) included the following categories: adequate patient-physician relationship, ethical behavior, modesty, humane treatment, patient-centered concerns and integrity. The class of "miscellaneous" characteristics (16.1%) consisted of the following characteristics: accountability, professionalism, teaching skills, work devotion and austerity.

Although the characteristics classified as "technical skills" were more frequently mentioned than the "non-technical attributes" (52.2% versus 47.7%), this difference did not reach statistical significance (P = 0.11).

There were no significant differences (P = 0.50) between "younger" and "older" participants regarding the proportions of mentions of "technical skills" and "non-technical attributes". However, female residents, who formed nearly one quarter of the sample of participants, accounted for 70.5% of the mentions of "technical skills" (P = 0.03).

Table 1. Remarkable characteristics of role models influencing medical residents who chose a surgical specialty as a career. Data are presented as the number (N) and percentage (%) of the 53 residents mentioning each characteristic

Characteristics	N	%
Technical skills	27	50.9
Technical or medical knowledge	26	49.0
Adequate patient-physician relationship	12	22.6
Ethical behavior	9	16.9
Decision-making capability/resolvability	9	16.9
Modesty	8	15.0
Accountability	6	11.3
Humane treatment	5	9.4
Objectivity	5	9.4
Patient-centered concerns	5	9.4
Professionalism	4	7.5
Austerity	4	7.5
Work devotion	4	7.5
Integrity	4	7.5
Teaching skills	4	7.5
Dexterity	4	7.5

DISCUSSION

The results from this exploratory study confirm that a large proportion of medical residents in training in several fields of surgery do acknowledge being influenced by a role model, and that technical skills were the most influential model characteristic. Additionally, although humanistic qualities were mentioned by a smaller proportion of the participants than the proportion who indicated that technical skills were most influential, they were cited by more than one third of the participants. Altogether, "non-technical" characteristics were cited nearly as frequently as technical qualities (61/136 versus 75/136), as the most prominent feature of role models who exerted an influence on the respondent's choice of surgery as a career.

The finding that the majority of the participants in this study recalled being influenced by a surgeon who acted as a role model is in line with several other published studies.[3,4,7,9,10,14] It is plausible, however, that the fact that our instrument only had two single questions may have biased these results. Indeed, the first direct question on whether a surgeon acting as a role model had influenced the participant's specialty choice could have elicited a positive response bias. However, the percentage of respondents answering positively was comparable to those reported in similar studies using different methods.[3,4,9] Furthermore, the second question, relating to the characteristics of the influential role model is likely to have elicited further thoughts on the topic, and therefore to have had a confirmatory effect regarding the first answer.

The most influential characteristics of role models within surgery, as spontaneously mentioned by the participants of our study, were comparable to those reported by Healy et al.,[10] who used a structured questionnaire to survey both medical students and surgical trainees. These characteristics were grouped into four categories: clinical competence, personal qualities, teaching abilities and research abilities.[10] It is noteworthy that many influential characteristics mentioned in the present study were very similar to those reported by Healy et al.,[10] such as "good surgical technique", "excellent clinical knowledge" and "compassionate and caring". However, the meaning of some characteristics mentioned by participants in the present study, such as "professionalism", "modesty" and "austerity" would deserve clarification through content analysis on data from personal interviews with the respondents. This was beyond the scope of this exploratory study, but may form the focus in further investigations. Nevertheless, it seems that the medical residents in our study were more concerned with non-technical skills than were the surgical trainees included in the study by Healy et al.,[10] even though they were comparable with

the medical students included in their study. This difference can possibly be explained by cultural differences between the respective groups of participants in these studies.

It is well known that the influence of role models is one of the main factors determining medical specialty choice.[3,4,15] This influence appears to be exerted similarly in both surgical and nonsurgical specialties and has been reported in studies from different countries[1,2,3,6,7,14,16] Nevertheless, the findings from a study by Ibrahim et al.[3] suggest that role models are likely to be more influential for those pursuing a surgical specialty than for those interested in nonsurgical fields. Whereas the latter group appears to be more influenced by factors such as length of training and lifestyle, the former group acknowledged the influence of role models, despite also mentioning factors such as prestige and prospects of financial reward.[3]

Role models have been defined as "individuals admired for their ways of being and acting as professionals".[17] Teachers, trainers and also senior trainees may have excellent professional performance, together with humanistic qualities, such that they may serve as role models for students and other trainees within healthcare professions. These same qualities may attract people to seek their professional services.[18-20]

As mentioned in a recent study,[21] it is important to differentiate role models from mentors, since models exert their influence only by example, whereas mentors have a more formal and lasting relationship with students. It appears that the interaction between students and trainees and their role model depends not only on the model's characteristics but also on the choices made by the model's followers.[21] These influences and relationships need to be taken into consideration in the current changing world of professional education. Indeed, over the last few decades, medical and healthcare professionals' education and training have undergone a number of changes that have influenced teacher and trainer roles. In a seminal essay published in 2000, Harden and Crosby[22] described twelve different roles of teachers, which were grouped into six diverse categories according to student or trainee learning scenarios, and included mentors and role models.

Both mentors and role models should be regarded as useful resources when implementing strategies aimed towards recruiting medical students to choose surgical fields as the medical specialties for their careers. These strategies are likely to become increasingly necessary, given that there have been reports of both decreasing numbers of candidates for surgical careers[23] and increasing attrition rates amongst surgical trainees in some countries.[24] It has been suggested that, in planning teaching experiences and in actually teaching, factors that are known to negatively influence the choice of surgery as a career should be worked on, as a way of improving recruitment.[25] Likewise, it has been suggested that medical students should be exposed to positive surgical experiences as early as possible.[9] Nevertheless, the contribution of surgical mentors and role models and the importance of their actions, starting from the earliest phases of medical education, have been greatly stressed.[10]

While a few teachers and other staff may have natural skills and characteristics that favor them as mentors and role models, it is plausible that the necessary attributes could be acquired though systematic learning in teacher development programs, as suggested elsewhere.[22] In this regard, the results from our study suggest that professionals acting as role models are more likely to positively influence potential candidates to a career in a surgical field when exhibiting not only good technical skills and other well-known attributes of good surgeons (such as strongly grounded medical knowledge and decision-making capability), but also more humanistic qualities, including an adequate patient-physician relationship, ethical behavior, modesty, humane treatment and patient-centered concerns. These findings should therefore be taken into account by academic departments of surgery in recruiting teachers and devising teacher development programs.

Furthermore, acquisition of these characteristics should be regarded as a goal within general surgical education and training, since both senior surgical trainees and practicing surgeons may act as role models to influence medical students and junior trainees to pursue a career in a surgical field. Firstly, they should be aware of their potential influence, which has been reported as being underestimated.[26] Additionally, as much as possible, they should be educated to acquire not only the necessary professional skills but also humanistic qualities.

The finding that female residents mentioned technical skills more frequently than did their male colleagues was rather surprising, since among medical students women have tended to show more positive attitudes than men towards humanistic factors involved in healthcare work, such as empathy[27] and patient-centered care.[28] Although this finding deserves confirmation through further studies, it is tempting to speculate whether this trait is particular to female physicians choosing surgery as a career.

This study has two main limitations: the data came from a single training center and the participants comprised a relatively small sample. Nevertheless, many of these residents had completed previous training periods in General Surgery at other institutions throughout the country and the array of characteristics mentioned as having influence were rather diversified. Moreover, notwithstanding the exploratory nature of the present study, its main results and particularly those relating to the influence of a role model on the choice of medical specialty were in line with published data originating from many different centers and countries.

Other study limitations that must be acknowledged relate to the survey instrument and the study sample. Concerning the

questionnaire, no formal validation procedures were applied, and this can be justified by the exploratory nature of this study. Additionally, the first open question, as mentioned earlier and already discussed, could have elicited a positive response bias. Regarding the study sample, it only included surgical residents expressing their retrospective perceptions of the influence of role models on their choices. Further studies also including residents in non-surgical fields such as Internal Medicine and Pediatrics, with the aim of ascertaining reasons for not choosing surgery, may expand the knowledge of factors affecting medical specialty choices, thus revealing characteristics of role models that could favor or even hinder the choice of surgery in particular as a career.

CONCLUSIONS

As in other medical specialties, the influence of surgeons acting as role models comprises an important factor in determining the choice of surgery as a career. The role model characteristics that are regarded as being most influential include not only technical skills, which are intrinsically linked to surgical practice, but also humanistic qualities, such as adequate patient-physician relationship, ethical behavior, modesty, humane treatment and patient-centered concerns.

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Prevalence of thyroid autoantibodies in patients with systematic autoimmune rheumatic diseases. Cross-sectional study

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ABSTRACT

BACKGROUND: Thyroid autoimmunity is more common in patients with rheumatic diseases than in healthy populations. The degree of association seems subject to influence from patients' geographical location. Here, we aimed to ascertain the prevalence of thyroid autoantibodies in a cohort of patients with systemic rheumatic disease and the degree of association between its presence and inflammatory activity.

DESIGN AND SETTING: Cross-sectional observational study in a rheumatology unit.

METHODS: 301 patients with systemic lupus erythematosus (SLE), 210 with rheumatoid arthritis (RA), 58 with scleroderma (SSc) and 80 with spondyloarthritis (SpA) were studied regarding thyroid function (TSH and T4), anti-thyroglobulin (TgAb) and anti-thyroperoxidase (TPOab) and compared with 141 healthy controls. Disease activity in patients with rheumatic disease was assessed through appropriate indexes.

RESULTS: There were more antithyroid antibodies in SLE patients with hypothyroidism (P = 0.01; odds ratio, OR 2.7; 95% confidence interval, CI: 1.20-6.26) and in those without hypothyroidism (P = 0.06; OR 2.4; 95% CI: 1.28-4.55) than in controls. SSc patients also showed P = 0.03 both with antithyroid antibodies and hypothyroidism (OR 3.4; 95% CI: 1.06-10.80) and without hypothyroidism (OR 3.1; 95% CI: 1.11-0.13). RA and SpA patients had the same prevalence as controls (P not significant). Presence of autoantibodies with and without hypothyroidism was not associated with the activity or functional indexes evaluated.

CONCLUSION: SLE and SSc were associated with higher prevalence of thyroid autoantibodies in patients with and without hypothyroidism, unlike SpA and RA. There was no link between thyroid autoantibody presence and disease activity or functional impairment.

INTRODUCTION

Autoantibodies against the thyroid seem to be more common in patients with rheumatic diseases than in the normal population.[1,2] Their appearance may be linked to an associated autoimmune thyroid disease, although sometimes they lack a clear clinical meaning. The major antigens driving the appearance of thyroid autoantibodies are thyroglobulin (Tg), thyroid peroxidase (TPO) and thyroid-stimulating hormone receptor (TSH-R).[3,4]

Tg is a protein from which the thyroid hormones (T3 and T4) are produced. It has four to six epitopes that are believed to be recognized by B cells that are involved in the autoantibody response. TPO, formerly known as microsomal antigen, is an enzyme that catalyzes iodination of the tyrosine residues of thyroglobulin to form monoiodotyrosine and diiodotyrosine.[5] TPO is found on the apical surface and cytoplasm of thyroid follicular cells.[4] Unlike Tg, TPO is capable of inducing antibody-dependent cell-mediated cytotoxicity and is considered to be more specific for autoimmune thyroid disease.[3,4]

The most common autoimmune thyroid disease is Hashimoto thyroiditis, which is characterized by gradual thyroid failure with or without goiter development.[3] Nearly all Hashimoto thyroiditis patients have high serum concentrations of antibodies against one or more thyroid antigens that are produced by lymphocytic infiltrate in the thyroid gland or, to a small extent, by regional lymph nodes or bone marrow.[4]

Hypothyroidism and rheumatic diseases share common clinical findings such as arthralgias, arthritis, myalgias, myopathy and fatigue,[6-8] which need to be correctly diagnosed to be properly treated. Knowing the degree of association between rheumatic and thyroid diseases may help the clinician to make the correct decision. Systemic lupus erythematosus (SLE),[9,10] rheumatoid

arthritis (RA),[11-12] scleroderma (SSc),[13,14] Sjögren's syndrome[15] and spondyloarthritis (SpA)[16] have been associated with increased presence of Hashimoto thyroiditis and/or thyroid autoantibodies. However, the degree of such associations seems to be different according to the sample studied, given that both rheumatic and thyroid diseases are influenced by genetic background and exposure to environment triggers. Moreover, iodine intake is another variable to be taken into account.[5,17] Also, in some of the rheumatic diseases mentioned, such as SpA and SSc, studies in this context are scarce.

In the present study, we aimed to estimate the prevalence of thyroid autoantibodies among patients with systemic rheumatic disease (SLE, RA, SSc and SpA) and its association with disease activity and functional impairment.

METHODS

This was a cross-sectional observational study with a convenience sample, conducted in a single rheumatology unit. The study had previously been approved by the local Research Ethics Committee. All the individuals included signed a consent statement.

Participants in this study presented rheumatic disease in which the onset was after they had reached 16 years of age. To be included, SLE patients needed to fulfill at least four of the classification criteria for SLE published by the American College of Rheumatology (ACR) in 1997.[18] RA patients needed to have at least four of the 1987 classification criteria from the ACR.[19] SSc patients needed to achieve at least nine points in the ACR/2013 (EULAR) classification criteria.[20] SpA patients needed to fulfill the criteria of the Assessment of SpondyloArthritis International Society (ASAS).[21]

All patients were recruited in a single rheumatology unit according to arrival order for routine consultations and willingness to participate in the study, during a two-year period.

The patients' medical files were reviewed for demographic, clinical and treatment data. Blood samples were collected to determine the TSH, T4 and antithyroid antibody levels. The reference values for TSH ranged from 0.4 to 5.0 mU/l and free T4 from 4.5 to 12.0 μg/dl, and both were measured by means of chemiluminescence (Architect, Abbott). Patients were considered to have hypothyroidism when TSH was > 5.0 mU/ml and free T4 < 4.5 μg/dl or when they were using thyroid replacement therapy. Serum autoantibody levels for Tg and TPO were determined by means of immunometric assays (INOVA-KIT, Quanta Lite, Inova Diagnostics, San Diego, CA, USA). Test results were considered positive if the levels were > 50 IU/ml for TPOab (antithyroid peroxidase antibodies) and > 325 IU/ml for TgAb (antithyroglobulin antibody), as specified by the manufacturer.

At the time of blood collection, the SLE patients' disease activity and cumulative damage index was determined through the SLE disease activity index (SEDAI)[22] and the Systemic Lupus International Collaborating Clinics/American College of Rheumatology damage index (SLIIC/ACR),[23] respectively. For RA patients, the Disease Activity Score-28 using the erythrocyte sedimentation rate (DAS28-ESR)[24] and the Health Assessment Questionnaire (HAQ)[25] were used to quantify disease activity and the corresponding functional status. For SpA patients, data from the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)[21] and the Bath Ankylosing Spondylitis Functional Index (BASFI)[21] were gathered. For SSc patients, the Rodnan modified index (Rodnan-m)[26] was measured to evaluate the degree of skin involvement, and the Medsger index[27] to evaluate the degree of systemic involvement.

Patients from gynecology and ophthalmology units, without known inflammatory or autoimmune disease, were included as controls. They were included according to the order in which they arrived for consultations and according to whether they were willing to participate in the study. To be included, these individuals needed to live in the same geographical area as the patients. The patients and controls were from the same hospital, which only attends patients through the Brazilian National Health System.

The data were gathered into frequency and contingency tables. Rheumatic disease patients with thyroid autoantibodies were evaluated in two main groups: those with anti-TPO antibodies and hypothyroidism (who possibly presented Hashimoto thyroiditis) and those with antibodies without thyroid dysfunction (who possibly presented polyclonal activation of B cells). Logistic regression models were built to study associations between rheumatic diseases and (a) positivity for anti-TPO antibodies with hypothyroidism and (b) positivity for antithyroid antibodies without hypothyroidism (individuals who were negative for antithyroid antibodies were the reference group). The models were adjusted for age, gender and tobacco exposure, since these might affect the prevalence of thyroid autoimmunity.[17] Positivity for or absence of thyroid autoantibodies was used as the dependent variable. Comparisons of activity and harm indexes for rheumatic diseases according to the presence of antithyroid antibodies were made using the unpaired t test, or the Mann-Whitney test for pairs of samples, or one-way analysis of variance (ANOVA) and the Kruskal-Wallis test for groups of three samples, according to data distribution. The significance level used was 5%.

RESULTS

As shown in **Table 1**, a total of 649 individuals with rheumatic diseases were included: 301 patients with SLE; 210 with RA (61% seropositive); 58 patients with SSc (62% limited, 32.8% diffuse form and 5.2% sine scleroderma); and 80 patients with SpA (66.2% with ankylosing spondylitis, 11.2% with psoriatic arthritis and 22.5% with other forms). Over the study period, 141 controls were included. **Table 1** also demonstrates that SLE and SSc patients had higher prevalence of antithyroid antibodies, either with or without hypothyroidism.

Table 2 shows a comparison of prevalences of presence of TPO autoantibodies with hypothyroidism (presumably Hashimoto thyroiditis) and presence of autoantibodies (TPO and/or Tg) without hypothyroidism (most likely with polyclonal activation of B cell) among rheumatic disease patients, in relation to controls. In **Table 2**, it can be seen that SLE and SSc patients (but not SpA and RA patients) had higher prevalence of antithyroid autoantibodies than that of controls. **Table 3** shows that there was no association between presence of thyroid antibodies and the functional and/or activity indexes of these diseases.

During the period of observation (mean time of 11.1 ± 8.9 years for RA, 9.8 ± 6.1 years for SLE, 10.4 ± 8.5 years for SpA and 8.8 ± 7.18 years for SSc) none of our patients developed thyroid cancer.

DISCUSSION

Clustering of specific autoimmune diseases such as thyroiditis and systemic autoimmune diseases such as rheumatic diseases in the same patient is commonly noted,[8] although the reasons for these associations are not completely clear. A common genetic background is one of the proposed explanations for this link.[8] Another explanation that has been put forward is that there may have been exposure to a common triggering event such as a pollutant or a viral infection. In this regard, infections due to the Epstein-Barr virus[28] and tobacco exposure[17] have been implicated in both situations.

The results from the present study showed that SLE and SSc patients had greater quantities of antithyroid antibodies with or without hypothyroidism than did healthy controls. This higher prevalence had already been noted in several other studies, as detailed below.

Table 1. Epidemiological data and prevalence of antithyroid antibodies (ATA) in rheumatic disease patients (n = 649)

	SLE N = 301	RA N = 210	SSc N = 58	SpA N = 80	Controls N = 141
Female gender	282 (93.6%)	191(90.9%)	55 (94.8%)	33 (41.2%)	130 (92.1%)
Median age in years (with IQR)	42 (31-51)	53 (47-61)	56 (39-61)	49 (44-57)	39 (28.5-52)
Hypothyroidism	49 (16.2%)	34 (16.1%)	16 (27.5%)	12 (15%)	16 (11.3%)
At least one ATA	99 (32.8%)	41 (19.5%)	21 (36.2%)	12 (15 %)	23 (16.3%)
Anti-TPO with hypothyroidism	38 (12.6%)	24 (11.4%)	12 (20.6%)	9 (11.2%)	8 (5.6%)
Anti-TPO without hypothyroidism	12 (4.3%)	8 (3.8%)	3 (5.1%)	0	12 (8.5%)
Anti-Tg without hypothyroidism	43 (14.2%)	8 (3.8%)	3 (5.1%)	3 (3.7%)	7 (4.9%)

N = number; IQR = interquartile range; SLE = systemic lupus erythematosus; RA = rheumatoid arthritis; SSc = scleroderma; SpA = spondyloarthritis. TPO = thyroid peroxidase; Tg = thyroglobulin.

Table 2. Comparison of the prevalence of hypothyroidism plus TPO antibodies and the prevalence of positivity for thyroid autoantibodies without hypothyroidism, between patients with rheumatic diseases and controls*

	Anti-TPO with hypothyroidism	Anti-TPO and/or anti-Tg without hypothyroidism
Systemic lupus erythematosus	OR = 2.7 (1.20-6.26); P = 0.01	OR = 2.4 (1.28-4.55); P = 0.06
Rheumatoid arthritis	OR = 1.7 (0.62-4.66); P = 0.29	OR = 1.3 (0.56-3.00); P = 0.53
Scleroderma	OR = 3.4 (1.06-10.80); P = 0.03	OR = 3.1 (1.11-0.13); P = 0.03
Spondyloarthritis	OR = 1.1 (0.88-1.02); P = 0.99	OR = 0.49 (0.05-4.05); P = 0.50

*corrected according to age, gender and tobacco exposure. Individuals who were negative for antithyroid antibodies were the reference group. OR = odds ratio, with 95% confidence interval in parentheses; TPO = thyroid peroxidase; Tg = thyroglobulin.

Table 3. Comparison of activity and functional indexes for rheumatic diseases in patients with and without antithyroid autoantibodies (ATA)

		Total Sample	Anti-TPO with hypothyroidism	ATA without hypothyroidism	Without ATA	P
SLE	SLEDAI (median [IQR])	0 [0-2.0]	0 [0-2.0]	0 [0-1.5]	0 [0-2.0]	0.45
	SLICC/ACR (median [IQR])	2.0 [1.0-4.0]	2.0 [1.0-3.0]	2 [1.0-4.0]	2 [1.0-4.0]	0.89
RA	DAS28-ESR (mean ± SD)	3.7 ± 1.3	4.2 ± 1.6	3.6 ± 1.1	3.6 ± 1.3	0.18
	HAQ (median [IQR])	1.1 [0.6-1.6]	1.2 [0.6-2.0]	1.0 [0.5-1.1]	1.1 [0.5-1.6]	0.72
SSc	Rodnan-m	15.0 ± 10.1	11.1 ± 9.8	15.3 ± 7.4	15.8 ± 10.8	0.70
	Medsger index (median [IQR])	5.0 [4.0-7.7]	5.5 [3.0-9.0]	4 [3.0-7.0]	6 [4.0-8.0]	0.43
SpA	BASDAI (mean ± SD)	3.8 ± 2.4	4.8 ± 2.6	*	3.7 ± 2.3	0.20
	BASFI (mean ± SD)	4.2 ± 2.7	5.4 ± 2.8	*	4.0 ± 2.7	0.17

*number too low. SLE = systemic lupus erythematosus; SLEDAI (SLE disease activity index); SLIIC/ACR = Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index; RA = rheumatoid arthritis; DAS28-ESR = disease activity score 28 using erythrocyte sedimentation rate; HAQ = Health Assessment Questionnaire; SSc = Systemic sclerosis; Rodnan m = Rodnan modified; SpA = spondyloarthritis; BASDAI= Bath Ankylosing Spondylitis Disease Activity Index; BASFI= Bath Ankylosing Spondylitis Functional Index. SD = standard deviation; IQR = interquartile range.

Regarding SLE, a Colombian study[5] found that the prevalence of hypothyroidism was 12% in their cohort, thus corroborating our findings. A meta-analysis by Pan et al.[29] showed that their SLE patients were positive for Tg antibodies 2.9 times more frequently and for TPO antibodies 2.2 times frequently than healthy controls. In another study,[30] it was observed that antithyroid antibody levels correlated with serum levels of other antibodies that are characteristic for SLE, such as anti-Sm, ribonucleoprotein (RNP) and dsDNA antibodies. However, those authors did not study the influence of presence of these antibodies on the clinical profile of the disease. Kumar et al.[31] found that the presence of thyroid dysfunction was greater in patients with high degrees of disease activity, as measured using SLEDAI, while other studies had contrary findings.[32,33] We did not find any association either with activity or with the cumulative harm index. However, the disease activity of our SLE patients was quite low, with median SLEDAI of zero.

One interesting finding from the present study, which had already been observed by Viggiano et al.,[34] is that in SLE patients without hypothyroidism, anti-Tg antibodies were more common than anti-TPO antibodies. This outcome was unique to SLE patients, given that it was not found in the other rheumatic diseases studied here. Since anti-Tg antibodies are less specific for autoimmune thyroid disorder,[4] it is possible to assume that their appearance may, at least partially, be due to unspecific polyclonal activation of B cells. Fluctuating levels of antithyroid antibodies over time have been reported in some SLE patients,[32] thus validating this hypothesis. Nevertheless, it is possible that patients with persistently elevated antithyroid antibodies will progress to thyroid disease in the future, considering that these may be found in serum many years before the disease appears.[35]

A profile similar to SLE was found in SSc patients, with higher prevalence of thyroid autoantibodies with or without hypothyroidism than in controls. SSc patients showed a higher odds ratio for the presence of antithyroid antibodies. According to the literature, the percentage of antithyroid antibodies in SSc ranges from 12 to 52%[36-41] and the percentage of hypothyroidism from 2.4 to 26%.[38,42] A previous study showed that presence of hypothyroidism in SSc patients was associated with higher prevalence of pulmonary hypertension.[13]

It is important to highlight the high prevalence of thyroid autoimmunity in SLE and SSc cases in daily practice, since this is associated with higher prevalence of thyroid cancer.[43,44] High frequency of papillary thyroid cancer in SSc patients in this context was noted by Antonelli et al.[44] They hypothesized that this link could be due to the association of thyroid cancer with the chronic inflammatory process from thyroiditis or to a role played by a common proto-oncogene that activates the pathway of extracellular signal-regulated kinases (ERKs) found in SSc and in thyroid cancer. Tissue fibrosis (the hallmark of SSc) is also linked to increased rates of tumor appearance.[44] Regarding SLE, findings from a meta-analysis by Zhang et al.[43] that included seven studies revealed that the overall standardized incidence rate for thyroid cancer was 2.2 times higher than in controls. None of our SLE patients has developed thyroid cancer so far.

In the present study, we did not find that thyroid autoantibodies, either with or without thyroid dysfunction, were more common in either RA or SpA than in controls. A study on an Italian population showed high occurrence of thyroid autoantibodies with low prevalence of hormonal alterations.[45] A meta-analysis on the prevalence of thyroid autoantibodies showed that there was increased prevalence of Tg and TPO antibodies, with OR of 3.1 and 2.3 respectively.[11] Nevertheless, when a subgroup analysis according to patients' geographical location was done, it showed that the American RA population did not have an increased rate of antithyroid antibodies, thus emphasizing the need for local studies. In addition, El Sheriff et al.[2] found that thyroid disorders were significantly more common in SLE patients (50%) than in RA patients (15%).

Some authors have been unable to link thyroid autoantibodies with any specific clinical profile for RA.[35] Others noted that RA patients who were positive for TPO antibodies showed greater progression of carotid intima media thickness, thus suggesting that this antibody may amplify the cardiovascular risk in this disease.[46] However, another research group described thyroid autoantibodies as being more common in RA patients with high disease activity, as measured through DAS 28, anemia and seropositivity.[35] We found a tendency towards an association for TPO antibodies and hypothyroidism with disease activity. However, judging disease activity in RA through instruments that use tender and swollen joint counts, such as DAS-28, may be misleading in this context. It has been reported that patients with autoimmune thyroid disease may have rheumatic manifestations even without glandular dysfunction.[2] Arthralgia and even arthritis of small joints such as the wrist and hand are found in patients with thyroid autoimmunity without concomitant connective tissue disease.[7,35] Punzi et al.[47] observed antimicrosomal antibodies in the synovial fluid of patients one year prior to antibody detection in serum, and one year prior to the diagnosis of hypothyroidism. Another interesting observation is that RA patients with secondary fibromyalgia or chronic widespread pain had more TPOab than did those without this.[12] It is possible to speculate that the articular component of thyroid autoimmunity may contribute towards increasing the painful symptoms.

SpA has been studied much less in this context. Contrary to our findings, Peluso et al.[16] found that thyroid disorder was more common in SpA patients than in controls and they correlated this with occurrences of peripheral arthritis and long-duration disease. These authors did not report what influence drug treatment had

on their sample, but others have noted that the frequency of thyroid disorder was lower in SpA patients receiving anti-TNF-alpha treatment.[48] The same was observed in RA patients using adalimumab.[49] This may at least partially explain the dissimilarity of these results. In our sample, 17.5% (14/80) of our SpA patients were on anti-TNF drugs. The different ethnic backgrounds of the samples studied may be another explanation.

Our study had a cross-sectional design, and this is one of its limitations. As already mentioned, patients with persistent autoantibody positivity, especially anti-TPO, may develop thyroid disease in the future.[35] Also, the study design did not allow us to prove any causal association. Likewise, we were unable to determine what influence antirheumatic immunosuppressive drug treatment has on antibody positivity. Further studies, with longitudinal monitoring and higher numbers of patients are needed to answer these questions. On the other hand, it should be stressed that this study included a control group that was from the same geographical region as the patients, with similar exposure to iodine deficiency, and that all data were corrected for gender, age and tobacco exposure.

CONCLUSION

It was found in our sample that SLE and SSc are diseases associated with higher prevalence of thyroid autoantibodies in patients with and without hypothyroidism. This was not seen in our SpA and RA samples. No link could be established between the presence of thyroid autoantibodies and the results from any of the instruments used to measure inflammatory activity and functional impairment in these cases of rheumatic diseases.

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Use of a child health surveillance instrument focusing on growth. A cross-sectional study

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KEY WORDS:
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Health records, personal.

ABSTRACT

BACKGROUND: Proper use of a child health handbook is an important indicator of the quality of care provided to children at healthcare services. This study aimed to evaluate the use of child health surveillance tool (by health professionals?), especially focusing on growth.

DESIGN AND SETTING: Cross-sectional study carried out in the context of the Family Health Strategy in two municipalities in Paraíba, Brazil.

METHODS: Three hundred and twenty-one children under five years of age from areas covered by health workers were included in the study. Mothers answered a questionnaire asking for information on sociodemographic characteristics. Growth charts, records of iron and vitamin A supplementation and notes on immunization schedules registered in the instrument were analyzed. In the case of children for whom the third version of the child health handbook was used, the association between completion of this handbook and sociodemographic characteristics was analyzed.

RESULTS: All the parameters studied showed high frequencies of inadequate data entry, ranging from 41.1% for the weight-versus- age chart to 95.3% for the body mass index-versus-age chart. Higher frequency of inadequate data entry was found among children aged 25 months and over and among those living in areas of these municipalities with minimal numbers of professionals in the healthcare teams.

CONCLUSIONS: The use of a child health handbook to monitor children's growth in the municipalities studied appeared to be faulty. Data entry to this instrument was better at locations with larger healthcare teams.

INTRODUCTION

Healthcare for children comprises development of health promotion and preventive care actions through highly qualified assistance, in order to contribute to adequate child growth and development, and to maintenance of health and quality of life.[1] Primary healthcare services are the preferred gateway to the system, and links from this level to higher levels of care need to be established so as to offer comprehensive healthcare.[2,3] From this perspective, child health handbooks, established in 2005 to replace the child card, stand out as an integral surveillance tool for children's health, with periodic recording of anthropometric data in charts.[4-6] At present, these handbooks offer the possibility of monitoring the evolution of weight, head circumference, height and body mass index, according to age groups, using curves developed by the World Health Organization for children up to the age of 10 years.[5-7]

Use of a specific instrument for monitoring children's health is not exclusive to Brazil. Other countries such as the United Kingdom, Sweden, Greece, Portugal, France, Canada, Indonesia, Japan, Australia, New Zealand and the United States (some states) also use similar technologies, thus showing the relevance of such tools.[8] In Indonesia, for example, this instrument has been the principal means of keeping health records since 2004 and its use has been correlated with better child immunization coverage.[9]

Proper use of a child health handbook, with complete and correct recording of information, not only is essential to the dialogue between healthcare professionals and users regarding its content but also can result in adherence and appreciation of the instrument by families, as well as shared responsibility for actions.[10,11] With handbook data at hand, both parents and healthcare professionals have the opportunity to monitor the entire process of children's growth and development, thus enabling early identification of health problems such as malnutrition and delayed

growth, so that these do not become irreversible.[4,7] Thus, use of a handbook is an important indicator of the quality of care provided to children at healthcare services.[5,11] However, studies on this topic have noted that a variety of circumstantial difficulties may exist and have emphasized the need for further research.[7,11,12]

The objective of the present study was to evaluate the use of child health surveillance, especially focusing on growth.

METHODS

This was a cross-sectional study carried out in two municipalities in the state of Paraíba. These municipalities were chosen based on their similarities regarding factors such as geographical location (metropolitan region of the state capital, with access to the service network available in the city), degree of urbanization (almost 100%), sociodemographic indicators, economic resources and tradition regarding organization of primary healthcare services (the "family health strategy" covers nearly 100% of the population). Municipality 1 has a population of 57,944 inhabitants, of whom 4,596 are children under five years of age. This municipality has a healthcare system composed of 19 family health strategy teams. Municipality 2 has a population of 99,716 inhabitants, of whom 7,862 are children under five years of age. Its healthcare system is composed of 28 family health strategy teams. There were more healthcare professionals (general physicians and pediatricians, nurses and nutritionists) for every 1,000 inhabitants, within the Brazilian National Health System (Sistema Único de Saúde, SUS), in municipality 1 than in municipality 2 at the time of this study, and the family health strategy teams are larger in municipality 1, with inclusion of nutritionists.

Children under five years of age were the study population. For the present study, a convenience sample was used, obtained from the sample of a larger study of which this formed part, which had the aim of evaluating healthcare service users' perceptions about the quality of children's health care. Parameters obtained from another study evaluating the quality of healthcare offered to children within the family health strategy, according to patients' point of view, in the city of Montes Claros (Minas Gerais),[13] were used to estimate the sample size in the major study.

In each municipality, nine family health strategy teams were randomly selected to represent at least one third of the total number of teams. Each team contributed 18 children on average. For the total sample, two criteria were followed:

1. An intentional sample of all nursing services that were part of routine visits on the day of data collection, on a typical working day; and
2. Selection of 18 out of all the children referred to healthcare services by community health workers, according to their work routine, to be included in the study based on the number of children intentionally sampled.

At the end of the data collection period, the sample consisted of 321 children under five years old, of whom 153 were from municipality 1 and 168 from municipality 2. Of this total, five children (one from municipality 1 and four from municipality 2) attended the healthcare unit without taking their handbook or card. Therefore, there were 316 evaluations for this study.

Data collection was carried out in the healthcare units between July and December 2014. The field team was composed of healthcare professionals and students who had had previous experience of fieldwork, and the team was supervised by a trained professional. The quality control for the study included: training and standardizing of interviewers, building an instruction manual and carrying out a pilot study in the city of Campina Grande, Paraíba.

The data collection included application of a questionnaire to the children's mothers to obtain information on sociodemographic characteristics (child's sex and age; mother's age, employment and education level; number of people in the household; benefits received through the family grant program; and family income). The child's age was calculated as the difference between the consultation date and the child's date of birth. The municipality was also considered among the independent variables.

In order to assess the use of the child health surveillance tool by the health professionals, the interviewers analyzed the version that the interviewees had (use of the third version of the child health handbook was considered appropriate) and the records relating to growth (head circumference for age according to the head circumference-versus-age chart; weight for age according to the weight-versus-age chart; height for age according to the height-versus-age chart; and body mass index [BMI] for age according to the BMI-versus-age chart); supplementation (with iron according to the corresponding annotation table and with vitamin A according to the corresponding annotation table or the space for recording the vaccines); and vaccination (completeness of the vaccination table according to the space destined for this purpose).

The records were considered adequate when they were in accordance with the recommended standards, according to the child's age at the time of the survey. The following recommendations established by the Ministry of Health were used: growth charts in accordance with the minimum number of visits indicated;[14] preventive supplementation with iron in accordance with the national iron supplementation program;[15] preventive supplementation with vitamin A in accordance with the national vitamin A supplementation program[16] (**Figure 1**) and vaccination in accordance with the surveillance instrument itself. The height-versus-age curve was verified among children who had the second and third versions of the handbook. The BMI-versus-age curve was verified among the children who had the third version of the handbook. Supplementation with iron was verified in the annotation table for preventive iron and vitamin A supplementation. Vitamin A supplementation was

verified in the annotation table for preventive iron and vitamin A supplementation or in the annotation table for vaccines.

In the case of children who had the proper instrument at hand, i.e. the third version of the child health handbook (n = 259), the completion of the instrument was classified as adequate or inadequate. To this end, a scoring system that allowed comparisons between different locations and over time was used.[17] In order to calculate the score, a value of one was attributed for items correctly entered and zero for items incorrectly entered, and the total score was expressed as the sum of the values for these items. Thus, variation from 0 to 7 points was accepted, such that values closer to 7 indicated better completion. A score greater than or equal to four points (57.1% of the items correctly filled out) was established as the cutoff for adequate completion. This cutoff point was based on the statistical distribution of scores, given that no information on this cutoff point was encountered in the literature.

Data were organized in spreadsheets and double-entered. The validate application of the Epi Info software, version 3.3.2, was used to analyze data consistency, thus generating the final database used in the statistical analysis.

Estimates of prevalence ratios (PR) and their respective 95% confidence intervals (CI) were used to analyze the association between completing the third version of the child health handbook and sociodemographic characteristics. For adjustment of confounding factors, we used Poisson regression with robust variance adjustment. Variables that were associated with the level of 25% ($P < 0.25$) in bivariate analysis were included in multivariate analysis, in which P values according to the chi-square test were considered.

In all statistical analyses, the significance level accepted was 5%. Analyses were performed using the Statistical Package for the Social Sciences (SPSS) software, version 13.0.

This study was approved by the Ethics Committee of the State University of Paraíba, under protocol number 19689613.3.0000.5187.

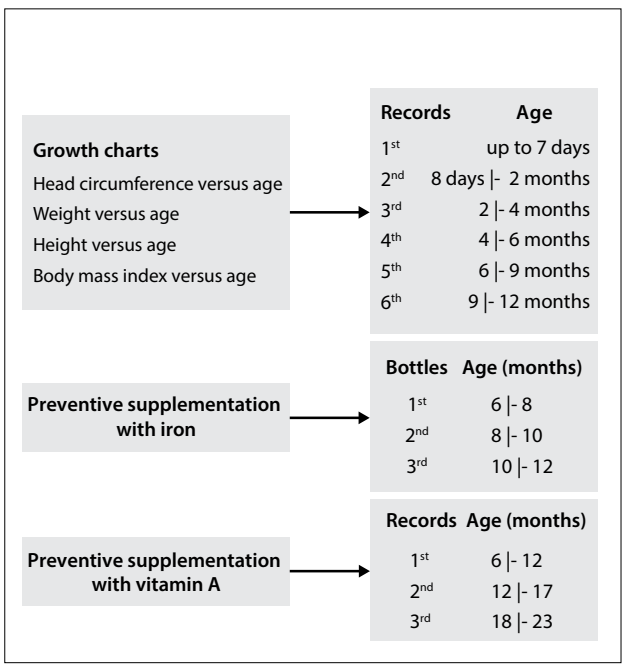

Figure 1. Adequacy parameters considered in determining the adequacy of records in growth charts and in charts on preventive iron and vitamin A supplementation, according to the child's age.

RESULTS

Among the 321 children studied, the majority (75.1%) were under 25 months of age. A high frequency of households with four or more people (67.0%) was observed. The vulnerability of the population was also evident in the proportion of the families enrolled in the family grant program (59.8%) and the proportion with family income below two minimum monthly wages (27.8%) (**Table 1**).

Among the children who had the instrument at hand (316), 18% had inadequate versions (i.e. out-of-date versions). Regarding completion, all the parameters studied showed high frequencies of inadequate data entry, ranging from 41.1% for completion of the weight-versus-age chart to 95.3% for completion of the BMI-versus-age chart (**Table 2**).

Table 1. Sociodemographic characteristics of children under five years of age assisted by healthcare teams within the family health strategy in two municipalities in the state of Paraíba, 2014

Variables	n	%
Sex		
Female	157	48.9
Male	164	51.1
Age (months)		
< 25	241	75.1
25-60	80	24.9
Maternal age (years)		
< 21	78	24.8
≥ 21	237	75.2
Maternal employment outside the home		
No	246	76.6
Yes	75	23.4
Maternal education		
Unable to read, write or do math in writing	67	20.9
Able to read, write and do math in writing	254	79.1
Number of people in the household		
≥ 4	215	67.0
< 4	106	33.0
Benefits received through the family grant program		
No	129	40.2
Yes	192	59.8
Family income		
< 2 minimum monthly wages	88	27.8
≥ 2 minimum monthly wages	228	72.2
Municipality of residence		
Municipality 2	168	52.3
Municipality 1	153	47.7

Table 3 presents the analyses on the associations between sociodemographic characteristics and completion of the child health handbook. The results show that there were statistically significant differences regarding the variables of child's age and municipality of residence.

Through fitting the Poisson regression model, as shown in **Table 4**, it was observed that being a child under 25 months of age was a protective factor against inadequate data entry in the handbook (PR = 0.65; 95% CI: 0.53-0.80). Furthermore, children living in municipality 2, in relation to those living in municipality 1, had a higher frequency of inadequate data entry (PR = 1.55; 95% CI: 1.33-1.78).

DISCUSSION

It was observed that, even though nine years have elapsed since implementation of use of the child health handbook,[5] 15.2% of the children in this study were still using the child card that preceded this. This result raises questions about the replacement of the card and the distribution of the handbook, as reported in a previous study.[18]

The results from the present study show problems relating to recording of growth charts, which have also been found in other places in Brazil.[5,18-20] These findings suggest that there is non-compliance with the minimum number of consultations recommended by the Ministry of Health for the first five years of life,[14] as also suspected by other researchers,[21] and/or suggest that monitoring of growth has not yet received proper attention among healthcare professionals.[5]

The abovementioned situation, especially the disuse of height and body mass index charts, is a cause for concern because of the nutritional status of Brazilian children, which is characterized by coexistence of significant prevalence of growth retardation and overweight.[22] These disorders, when untreated during childhood, can have irreversible consequences.[23] This is why monitoring of growth is so essential.[7]

The higher percentage of completion of the weight-versus-age chart, compared with the other growth charts in this study, has been reported in a similar manner by other researchers, in Brazil[18,24] and in other countries.[8] This finding may be related to the fact that weight-versus-age curves have been used for a long time, i.e. since the implementation of the child card in 1984. It may also be associated with inclusion of new curves with concepts that are unfamiliar to professionals, such as representation as z scores.[6]

With regard to information on head circumference, the results from the municipalities studied here showed lower frequencies of correct data entry than was reported in other cities.[4,18] These low percentages need to be analyzed with caution, because deviations from the recommended measurements may be associated with neurological diseases, such as microcephaly and hydrocephaly, which need better evaluation and referral.[15]

Like in previous studies,[20] a low percentage of completion of the height-versus-age chart was seen in the present study. Non-availability of equipment and lack of professional training for making height measurements are possible factors relating to this problem.[25] Systematic evaluation of the height-for-age index deserves greater attention at healthcare facilities because linear growth is an important expression of health and of the coverage of public policies.[26]

In this study, almost all BMI-versus-age charts were inadequately filled out. There is a lack of analyses in the literature in this regard.[23] An evaluation of the medical records of children under two years of age in Cuiabá (Mato Grosso) showed that only 22.7% of the documents had registered BMI.[27] Use of BMI is recommended from the time of birth onwards as a control measurement regarding overweight and adiposity, and as a predictor of obesity in adulthood.[23]

The greater adequacy of completion of data entry in the child health handbook among younger children that was observed in the present study has similarly been reported in previous investigations.[24] This can possibly be explained by the higher frequency of scheduling of consultations during children's first months of life, as a reflection of the greater biological risk that is typical of this extremely young age.[23,24] Moreover, during the first year of life, children receive most of their vaccines, thus implying that there is a need to return to the healthcare service more often, which gives rise to opportunities for use of this instrument.[20] It should be noted that the Poisson regression with robust variance that was used in the present study to obtain this result has been

Table 2. Child health surveillance instrument: version at hand and level of completion among children under five years of age who were treated by healthcare teams within the family health strategy in two municipalities in the state of Paraíba, 2014

Variables	n*	%
Version of the instrument at hand		
Child card	48	15.2
1st or 2nd version of CHH	9	2.8
3rd version of CHH	259	82.0
Head circumference-versus-age chart		
Adequate	81	30.2
Weight- versus-age chart		
Adequate	186	58.9
Height-versus-age chart		
Adequate	107	40.1
Body mass index-versus-age chart		
Adequate	12	4.7
Iron supplementation score		
Adequate	8	3.7
Vitamin A supplementation score		
Adequate	141	65.6
Vaccine score		
Adequate	149	47.2
Score for completion of the instrument†		
Adequate (≥ 4 correct items)	110	42.5

CHH = child health handbook; *values that differ from the total were due to the version of the instrument used and/or the child's age; †completion level among children who had the third version of the child health handbook.

suggested as an appropriate method for cross-sectional designs with binary outcomes, which should be based on calculation of prevalence ratios.[28]

Considering the particular features of the municipalities analyzed, it is possible that the significant difference in the rate of inadequate completion of data entry in the child health handbook that was observed between these two municipalities was related to differences between them regarding the structure of larger teams and the training of professionals to work within primary healthcare and develop food and nutrition actions. Both of these municipalities had adequate availability of materials, inputs and equipment, including anthropometric instruments and handbooks. These conditions may favor interaction and minimize the influence of factors that hinder completion of the handbook, at least as far as food and nutrition issues are concerned. Experiences from other countries have shown that interactions among primary healthcare professionals promote improvement of growth monitoring and, in turn, the nutritional

Table 4. Adjusted association (Poisson regression) between inadequate completion of data entry in the child health handbook and sociodemographic characteristics of children under five years of age who were treated by healthcare teams within the family health strategy in two municipalities in the state of Paraíba, 2014

Variables	PR (95% CI)	P
Age (months)		
< 25	0.65 (0.53- 0.80)	0.000
25-60	1.0	
Number of people in the household		
≥ 4	0.88 (0.76-1.02)	0.079
< 4	1.0	
Benefits received through the family grant program		
No	0.95 (0.82-1.10)	0.051
Yes	1.0	
Municipality		
Municipality 2	1.55 (1.33-1.78)	0.000
Municipality 1	1.0	

PR (95% CI) = prevalence ratio (with 95% confidence interval).

Table 3. Association between level of completion of data entry in the child health handbook and sociodemographic characteristics of children under five years of age who were treated by healthcare teams within the family health strategy in two municipalities in the state of Paraíba, 2014

Variables	Total (n = 259)		Level of completion				PR (95% CI)	P
			Inadequate (< 4 correct items)		Adequate (≥ 4 correct items)			
	n	%	n	%	n	%		
Sex								
Female	129	49.8	71	55.0	58	45.0	0.92 (0.74-1.13)	0.419
Male	130	50.2	78	60.0	52	40.0	1.0	
Age (months)								
< 25	205	79.1	109	53.2	96	46.8	0.72 (0.59-0.88)	0.006
25-60	54	20.9	40	74.1	14	25.9	1.0	
Maternal age (years)								
< 21	64	25.3	36	56.3	28	43.8	0.98 (0.77-1.26)	0.901
≥ 21	189	74.7	108	57.1	81	42.9	1.0	
Maternal employment								
No	203	78.4	114	56.2	89	43.8	0.90 (0.71-1.14)	0.395
Yes	56	21.6	35	62.5	21	37.5	1.0	
Maternal education								
Unable to read, write or do math in writing	50	19.4	32	64.0	18	36.0	1.14 (0.90-1.45)	0.303
Able to read, write and do math in writing	209	80.6	117	56.0	92	44.0	1.0	
Number of people in the household								
≥ 4	170	65.6	103	60.6	67	39.4	1.17 (0.93-1.48)	0.169
< 4	89	34.4	46	51.7	43	48.3	1.0	
Benefits received through the family grant program								
No	104	40.1	54	51.9	50	48.1	0.85 (0.68-1.06)	0.135
Yes	155	59.9	95	61.3	60	38.7	1.0	
Family income								
< 2 minimum monthly wages	68	26.7	41	60.3	27	39.7	1.08 (0.86-1.37)	0.505
≥ 2 minimum monthly wages	187	73.3	104	55.6	83	44.4	1.0	
Municipality								
Municipality 2	127	49.0	98	77.2	29	22.8	2.00 (1.58-2.53)	0.000
Municipality 1	132	51.0	51	38.6	81	61.4	1.0	

P = P-values for chi-square test; PR (95% CI) = prevalence ratio (with 95% confidence interval).

status of children.[29] However, further research in the Brazilian context should be conducted to address the possible matters of controversy.

The need for caution in interpreting the findings from the present study has to be emphasized, given that the responsibility for using the child health surveillance instrument is not restricted to healthcare professionals but should be shared with families.[23,30] Awareness needs to be raised among all parties involved regarding the importance of making proper use of the handbook and of effectively achieving its purpose.[5]

In interpreting the results from this study, some limitations should be considered. Firstly, it should be noted that data entry in the child health handbook was restricted only to some of the parameters included in the instrument. Furthermore, some factors relating to completion of the data entry in the handbook were not considered here, such as birth weight and other conditions inherent to child health, maternal care during the prenatal and postpartum period, the area of residence (urban or rural) and the parents' marital status. Furthermore, because of the attempt to preserve the work routine through use of a convenience sample, the possibility of bias in selecting the sample of children may be presumed.

CONCLUSIONS

Although the child health handbook is one of the most prominent aspects of public health policies in Brazil, the use of this instrument to monitor children's growth within the family health strategy in the municipalities studied is flawed. The precariousness of the records suggests that there is a need to raise awareness about the importance of the handbook and of larger healthcare teams.

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Engagement in physical education classes and health among young people: does sports practice matter? A cross-sectional study

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ABSTRACT

CONTEXT AND OBJECTIVE: Physical education classes aim to promote health but it is unknown whether benefits occur independently of sports practice. The purpose of this study was to examine associations between engagement in physical education classes and physical fitness and obesity according to sports practice among Brazilian students.

DESIGN AND SETTING: Cross-sectional school-based study involving 737 students aged 10-17 years in southern Brazil.

METHODS: Engagement in physical education classes and sports practice were analyzed using a self-report questionnaire. The health indicators analyzed were cardiorespiratory fitness, muscle strength, obesity and combinations thereof. The covariates were sex, age, socioeconomic status, physical activity and sedentary behavior. Prevalence ratios (PR) adjusted for confounding variables were estimated using Poisson regression. Analyses were stratified according to sports practice.

RESULTS: Engagement in physical education classes was associated with achievement of health-related criteria for cardiorespiratory fitness (PR = 1.52), muscle strength (PR = 1.55), obesity + cardiorespiratory fitness (PR = 1.51), obesity + muscle strength (PR = 1.70), cardiorespiratory fitness + muscle strength (PR = 2.60) and the three outcomes combined (PR = 2.43), only among non-sports practitioners, all $P < 0.05$. Engagement in physical education classes was not associated with obesity (PR = 1.00, $P > 0.05$). No associations were found for sports practitioners ($P > 0.05$).

CONCLUSION: Engagement in physical education classes was associated with health among non-sports practitioners. However, to protect students from obesity and promote additional health benefits for sports practitioners, the conventional physical education program offered to the sample studied should be reformulated.

INTRODUCTION

Physical activity is an important health-related behavior in different age groups. It is associated with mental, cardiovascular and bone health, lower adiposity, greater physical fitness, greater motor skills development and better quality of life among children and adolescents.[1] Approximately 70% of Brazilian adolescents are inactive and therefore promotion of physical activity in this age group is necessary.[2] In this context, since schools have a responsibility for promoting physical activity, the subject of physical education takes on an important role in relation to public health among young people,[3] with the aims of increasing the amount of moderate to vigorous physical activity and decreasing students' daily sedentary behavior.[4] In addition, physical education classes have the goal of providing students with knowledge, skills and confidence so that they can be active throughout their lifetime, thus preventing the emergence of health problems.[3,5]

Several observational and experimental studies have been conducted to examine the benefits of physical education classes for schoolchildren's health. Physical fitness and obesity are widely investigated outcomes because of their contribution to cardiovascular, metabolic, musculoskeletal and mental health among young people.[6,7] Experimental studies have demonstrated that intervention programs within physical education classes increase muscle strength[8,9] and cardiorespiratory fitness,[8-10] and decrease the body mass index[8] and prevalence of overweight[11] among children and adolescents. Similarly, an observational study that evaluated 91,236 fifth-grade students in California, United States, found that policies offering physical education classes were associated with better cardiorespiratory fitness.[12]

In analyzing the relationship between physical education programs and health among young people, sports practice is a variable that needs to be considered for two reasons. Firstly, sports practice is associated with habitual physical activity among young people[13,14] and consequently increases their cardiorespiratory fitness and muscle strength,[13,15,16] and decreases their overweight and obesity.[17] Secondly, it has recently been reported that the effects of physical education classes on cardiorespiratory fitness occur only among young people in a poor physical condition,[10] who are probably not sports practitioners. Despite the information provided, studies conducted so far with the aim of examining the relationship between physical education classes and health, as well as those analyzing the effects of intervention programs within physical education classes, have not considered whether the participants were sports practitioners. This limitation prevents knowledge of whether the benefits of physical education classes on health occur among both young people who practice and those who do not practice sports in their leisure time.

OBJECTIVE

The aim of the present study was to examine associations of engagement in physical education classes with physical fitness and obesity, according to sports practice, among Brazilian young people.

METHODS

Ethics

This study was approved by the Ethics Committee for Research Involving Human Beings of the State University of Londrina (Universidade Estadual de Londrina, UEL), Paraná, Brazil, under protocol 312/2011. A parent or legal guardian provided written informed consent through signing a statement in which the aims of the study, details about the procedures, risks and benefits of the study and contact details of the researcher were described.

Study sample and design

This was a cross-sectional study that formed part of a larger epidemiological survey entitled "Physical education and health criteria achievement in Brazilian young people", which was conducted from May to July 2012. The aim of the larger survey was to investigate the association between engagement in physical education classes and health indicators in a representative sample of students in the city of Londrina, Paraná, Brazil.

The study population was composed of students enrolled in state schools in Londrina in 2012. The inclusion criteria were that they needed to:

1. Agree voluntarily to participate in the study;
2. Provide an informed consent statement signed by a legal representative;
3. Be aged between 10 and 17 years;
4. Be enrolled in a state school;
5. Not present any physical or metabolic limitations that would prevent performance of any study procedures; and
6. Undergo all the proposed procedures.

For this study, the sample size was estimated considering a population of 55,475, outcome prevalence of 40%, confidence interval of 95%, design effect of 2, and sample loss of 30%, using the Epi Info 7.0 software. The minimum sample size was estimated as 732 students.

Out of the 965 students invited to participate in this study, 737 met the eligibility criteria and composed the final sample. The students were aged 10 to 17 years and were probabilistically selected through clusters (school and classrooms) that were stratified according to region of the city (north, south, east, west and center), sex and school year. The sampling procedure was performed in two stages. One school from each region of the city was selected randomly and the proportional number of students in the region was assessed using full classrooms (25-30 students).

Data collection and variables

All procedures were carried out at the school in which the participants were enrolled. The questionnaire was answered and the anthropometric measurements were performed in the classroom. The field tests were carried out in the school's indoor sports court. All information was collected within a maximum period of three days.

The independent variables of the present study were sports practice and engagement in physical education classes. Sports practice was analyzed by means of the following question: "In leisure time activities, do you practice sports?", with the following response options: never; rarely; sometimes; frequently; or always. The question was taken from the Questionnaire of Habitual Physical Activity.[18] Participants who answered "frequently" or "always" were considered to be sports practitioners.

Engagement in physical education classes was assessed using two self-report questions:

1. In this semester, did you participate in physical education classes?", with answer options "no", "yes, but only one class per week" or "yes, I participated in all classes". This question presented 90% agreement one month later, through direct observation among 40 students selected from the sample of the present study.
2. "Generally, during physical education classes, how active were you, i.e. did you play, run, jump and throw balls intensely?" with the following response options: "I didn't participate in the classes," "rarely," "sometimes," "often" or "always." This question was adapted from the PAQ-C questionnaire (Physical Activity Questionnaire for Children).

The translation and cross-cultural adaptation of PAQ-C into the Portuguese language, and its reproducibility and concurrent validity, have been described elsewhere.[19] We tested the validity of question 2 for assessing the intensity of classes, by using a perceived exertion scale[20] in eight physical education classes: two classes a week for one month. Students who reported being active during classes presented significantly higher perceived exertion than did those who reported not being active: 4.0 (3.0-5.0) versus 6.5 (4.5-7.5) arbitrary units; $P < 0.05$. Participants who answered that they had participated in all physical education classes and were "often" or "always" active during classes were considered to be engaged in physical education classes. The independent variables presented high reproducibility (agreements of 80% and 93.4%).

Outcomes

The outcomes of the study were cardiorespiratory fitness, muscle strength, obesity and combinations of these outcomes. Cardiorespiratory fitness was evaluated by means of the multistage 20-meter shuttle run test.[21] This is a progressive test and participants are required to run back and forth over a 20-meter distance. The velocity starts at 8.5 km/h and increases by 0.5 km/h each minute until voluntary exhaustion. Upper-limb muscle strength was estimated using the 90° push-up test.[22] The cutoffs used for cardiorespiratory fitness and muscle strength (health fitness zone) were as proposed through Fitnessgram, according to sex and age.[22] Nutritional status was assessed through the body mass index (BMI = body mass/height^2). Measurements of body mass and height were obtained using a digital scale and a portable stadiometer. The cutoff points used to classify obesity were as proposed by the International Obesity Task Force.[23] The above outcomes were analyzed both separately and in combinations.

Covariates

The covariates used to adjust the analysis were sex, age, socioeconomic condition, physical activity and sedentary behavior. Socioeconomic condition was estimated using the questionnaire of the Brazilian Association of Polling Companies. The Questionnaire of Habitual Physical Activity was used to assess physical activity.[18] The following question was used to assess sedentary behavior: "How many hours on average do you watch TV, play video games or use the computer," with the following response options: < 1 hour per day, 1 hour per day, 2 hours per day, 3 hours per day, 4 hours per day or 5 or more hours per day.

Physical education curriculum

In the year during which the study was conducted, the school subject of physical education was taught by a physical education teacher and each student had timetabled classes totaling 100 minutes/week. All schools included in the sample had an indoor sports court. In the state schools of the state of Paraná, the physical education curriculum has the objective of teaching body culture, which is based on the cultural forms of human movement historically produced by humanity. This is based on the assumption that the pedagogical practice of physical education within the school context should turn the different forms of body expression activities into topics, consisting of the following: games, sports, gymnastics, rhythmic activities and martial arts. With the aims of increasing knowledge of reality and establishing relationships between everyday social and cultural phenomena, the curriculum also includes the following articulating elements: body, playfulness, health, world of work, technical and tactical elements, leisure time, diversity and media. This curriculum is the same as in other Brazilian states and details have previously been described.[24]

Statistical analyses

Descriptive statistics were produced, comprising relative frequencies and 95% confidence intervals. The chi-square test was used to analyze the bivariate association between engagement in physical education classes and health indicators. Multivariate analysis was performed using Poisson regression to estimate prevalence ratios (PR) and 95% confidence intervals. The analyses were stratified according to sports practice and independent variables were inserted simultaneously in the final model. Because of the complex sample used and stratifications of the analysis according to sports practice, the multivariate analysis was conducted considering the strata, primary sample units and sample weight, using the "survey" (svy) command of STATA 11.0. In all cases, results were considered significant when $P < 0.05$.

RESULTS

The sample loss from the present study was 23.6%. This loss arose because some of the students did not perform all the study procedures. However, this did not affect the representativeness of the sample, given that missing values had been anticipated in the sample size estimates, and because the losses did not change the proportions among the participants according to sex, age, socioeconomic status or region of the city. Moreover, the losses did not prevent the study from attaining the minimum sample size required to conduct the analysis.

Out of the 737 students, 35% reported practicing sports. Higher proportions of the sports practitioners were males, were aged between 10 and 12 years, were engaged in physical education classes and achieved the health criteria for cardiorespiratory fitness and muscle strength ($P < 0.05$). No differences between the

proportions of sports practitioners and non-practitioners regarding socioeconomic status or obesity were found (P > 0.05) (**Table 1**).

The bivariate analyses are presented in **Table 2**. Among the young people who did not practice sports, positive associations were found between engagement in physical education classes and health criterion achievement regarding cardiorespiratory fitness and muscle strength (P < 0.05). No association was found regarding obesity (P > 0.05). In analyzing combined outcomes, positive associations were found between engagement in physical education classes and the following variables: obesity + cardiorespiratory fitness, obesity + muscle strength, cardiorespiratory fitness + muscle strength and all outcomes combined (P < 0.05). No association was found between engagement in physical education classes and achievement of health criteria for any of the outcomes analyzed, for the participants who were sports practitioners (P > 0.05).

Table 1. Descriptive characteristics of the study participants (n = 737)

	All	Sports practice		P
		No (n = 477) % (95% CI)	Yes (n = 260) % (95% CI)	
Sex				
Male	49.5 (45.9-53.1)	37.6 (33.3-41.9)	71.6 (65.7-76.6)	< 0.001
Female	50.5 (46.8-54.1)	62.4 (58.0-66.7)	28.4 (23.1-34.4)	
Age				
10-12	35.6 (32.2-36.1)	29.2 (25.2-33.3)	47.4 (41.3-53.3)	
13-15	33.6 (30.3-37.1)	34.6 (30.4-38.9)	31.9 (26.5-37.8)	< 0.001
16-17	30.8 (27.5-34.2)	36.2 (32.8-40.6)	20.7 (16.2-26.1)	
Socioeconomic status				
Low	21.6 (18.8-24.7)	23.2 (19.7-27.3)	18.5 (14.2-23.6)	
Medium	62.0 (58.5-65.4)	61.9 (57.4-66.1)	62.1 (55.8-67.6)	= 0.181
High	16.4 (13.9-19.3)	14.8 (11.9-18.3)	19.4 (14.9-24.4)	
Engagement in physical education				
No	26.8 (23.8-30.1)	32.5 (28.4-36.8)	16.4 (12.5-21.5)	< 0.001
Yes	73.2 (69.8-76.2)	67.5 (63.1-71.5)	83.6 (78.4-87.4)	
Cardiorespiratory fitness[1]	45.6 (42.0-49.2)	36.0 (31.8-40.4)	63.4 (57.0-69.1)	< 0.001
Muscle strength[1]	33.6 (30.3-37.1)	27.8 (24.0-32.0)	44.4 (38.3-50.3)	< 0.001
Obesity	5.4 (4.0-7.3)	5.8 (4.0-8.4)	4.7 (2.7-7.9)	= 0.566

[1]Achievement of health status according to the criteria proposed through Fitnessgram; 95% CI = 95% confidence interval of prevalence; P refers to the chi-square test.

Table 2. Bivariate association analysis between engagement in physical education classes and achievement of health criteria among students

Dependent variables	Engagement in physical education	Sports practice					
		No			Yes		
		%	Crude PR	P	%	Crude PR	P
Cardiorespiratory fitness[1]	Yes	42.6	1.91	0.001	64.4	1.14	0.444
	No	22.1	1.00		57.9	1.00	
Muscle strength[1]	Yes	31.6	1.63	0.012	46.3	0.99	0.547
	No	20.0	1.00		50.0	1.00	
Obesity[1]	Yes	94.5	1.01	0.699	95.4	1.00	0.869
	No	93.6	1.00		94.7	1.00	
Dependent variables combined							
Obesity + cardiorespiratory fitness	Yes	41.2	1.93	0.001	62.4	0.92	0.604
	No	21.4	1.00		57.9	1.00	
Obesity + muscle strength	Yes	31.6	1.77	0.004	42.8	0.97	0.412
	No	18.6	1.00		50.0	1.00	
Cardiorespiratory fitness + muscle strength	Yes	17.9	3.31	0.001	30.4	0.83	0.435
	No	5.7	1.00		36.8	1.00	
All outcomes combined[2]	Yes	16.2	3.04	0.001	23.7	0.92	0.493
	No	5.7	1.00		28.9	1.00	

PR = prevalence ratio; % = relative frequency; P = P for chi-square test; [1]Achievement of health status according to the criteria proposed through FitnessGram; [2]Health criteria combined (cardiorespiratory fitness, muscle strength and obesity).

The results described in the bivariate analysis were maintained after adjustment for the confounding variables (**Table 3**). Young people who reported not practicing sports but being engaged in physical education classes were more likely to achieve the health criteria for cardiorespiratory fitness (PR = 1.52), muscle strength (PR = 1.55), obesity + cardiorespiratory fitness (PR = 1.51), obesity + muscle strength (PR = 1.70), cardiorespiratory fitness + muscle strength (PR = 2.60) and all outcomes combined (PR = 2.43), all with $P < 0.05$. Being engaged in physical education classes was not associated with obesity for those who were not sports practitioners or with any of the outcomes for those who were sports practitioners ($P > 0.05$).

DISCUSSION

The aim of this study was to analyze the association between engagement in physical education classes and some health indicators, according to sports practice among young Brazilians. The novelty of this study was that engagement in physical education classes was associated with cardiorespiratory fitness, muscle strength and combined health outcomes, only among students who did not practice sports. In contrast, engagement in physical education classes was not associated with obesity, independent of sports practice.

Although the present study had a cross-sectional design, the results found regarding participants who were not sports practitioners corroborate previous experimental studies that demonstrated increases in cardiorespiratory fitness[8-10] and muscle strength[8,9] after implementation of intervention programs within physical education classes. Likewise, they corroborate an observational study that was carried out on a representative sample in the American state of California. The results from that study demonstrated that adoption of public policies to promote physical education classes was associated with higher cardiorespiratory fitness among schoolchildren.[12] Despite the information available regarding the relationship between physical education programs and health, none of the studies listed above considered students' sports practice, which limits comparison of the results.

Differently from previous studies, it was sought in the present study to investigate whether engagement in physical education classes was associated with health indicators, among both young people who practiced sports and those who did not. There was no benefit in engaging in physical education classes for the students who were sports practitioners, in relation to any of the variables analyzed. This can probably be explained in terms of the adaptations resulting from the intensity of sports practice. Although sports practice during leisure time was analyzed in the present study, this type of activity is usually performed at high intensities and results in positive cardiovascular and muscle adaptations.[25] Associations between sports practice and cardiorespiratory fitness,[13,16] muscle strength[15] and protection against overweight and obesity have been described.[17] Because young people who practice sports are more active,[13,14] they are probably protected from the outcomes analyzed in the present study. Hence, engagement in physical education classes would not present any additional

Table 3. Multivariate analysis on the association between engagement in physical education (PE) classes and achievement of health criteria among students

Dependent variables	Engagement in PE	Sports practice	
		No	Yes
		Adjusted PR (95% CI)	Adjusted PR (95% CI)
Cardiorespiratory fitness[1,3]	Yes	1.52 (1.03-2.25)	1.12 (0.89-1.41)
	No	Reference	Reference
Muscle strength[1,3]	Yes	1.55 (1.14-2.12)	1.04 (0.43-2.48)
	No	Reference	Reference
Obesity[1,4]	Yes	1.01 (0.95-1.09)	1.00 (0.90-1.12)
	No	Reference	Reference
Dependent variables combined			
Obesity + cardiorespiratory fitness[1,4]	Yes	1.51 (1.07-2.14)	0.87 (0.62-1.21)
	No	Reference	Reference
Obesity + muscle strength[1,4]	Yes	1.70 (1.17-2.47)	0.98 (0.66-1.46)
	No	Reference	Reference
Cardiorespiratory fitness + muscle strength[1,3]	Yes	2.60 (1.24-5.41)	0.89 (0.53-1.35)
	No	Reference	Reference
All outcomes combined[2,4]	Yes	2.43 (1.23-4.78)	1.00 (0.43-2.32)
	No	Reference	Reference

PR = prevalence ratio; 95% CI = 95% confidence interval; [1]Achievement of health status according to the criteria proposed through FitnessGram; [2]Health criteria combined (cardiorespiratory fitness, muscle strength and obesity); [3]Adjusted for sex, age, socioeconomic status, obesity, physical activity and sedentary behavior; [4]Adjusted for sex, age, socioeconomic status, physical activity and sedentary behavior.

benefit. One previous result that reinforces this statement was the finding that a physical education program only increased cardiorespiratory fitness among young people who were in a poor physical condition,[10] who probably were not practicing sports or physical exercise. The results from the present study also indicate that there is a need to estimate sports practice when analyzing the effects of both intervention programs and conventional physical education on the health of young people, in order to better understand the results. However, this methodological procedure is not commonly performed.

In the present study, the outcomes were analyzed separately and in combinations. Analysis on combined outcomes is necessary for two reasons. Firstly, in combining low physical fitness with indicators of high adiposity, there is an increase in cardiovascular risk in comparison with the separate outcomes.[26,27] Secondly, cardiorespiratory fitness, muscle strength and low adiposity are independently associated with cardiometabolic risk[28-30] and thus, it is desirable that young people should fulfill all of these health criteria. Thus, the results showed that engagement in physical education classes was associated with higher probability of achievement of combined health criteria among participants who were not sports practitioners.

It is worth noting that it was difficult to compare the results found with those previously reported, since it has been unusual for studies investigating relationships between physical education classes and health to use combined outcomes. From a public health point of view, this is an important result, given that sports make a large contribution towards total physical activity.[13,14] Students who do not practice sports may perform less daily physical activity and be exposed to the risks of future non-communicable diseases.[2]

Regarding the results relating to physical fitness and combined outcomes, it had been expected that engagement in physical education classes would be associated with obesity among students who were not sports practitioners, but this did not occur. This result corroborates a previous study that demonstrated that school physical education, as typically offered, does not reduce or prevent obesity.[31] Although it has the potential to assist in controlling obesity, there is a need to implement stricter policies to promote physical education.[32] Another point that should be highlighted is that strategies for promoting physical activity in isolation do not demonstrate efficacy in reducing obesity. Obesity-related outcomes were found to be improved in intervention programs with two or three components (i.e. physical activity plus nutrition and physical activity plus both education and nutrition),[33,34] which did not occur in conventional physical education programs as analyzed in the present study.

The present study has limitations that need to be considered in interpreting the results. Although previous studies provided the theoretical basis for demonstrating the effects of physical education classes on students' health, the design used here was cross-sectional, which prevented inferences regarding causality among the associations identified. The main limitation was that engagement in physical education classes was estimated through a self-report questionnaire, which prevented accurate measurement of the intensity of classes, in comparison with objective measurements. However, this limitation was attenuated, given that the instrument used was valid for detecting students who reported higher perceived exertion during classes. Regarding sports practice, although the instrument used showed correlations with the amount of daily physical activity,[35] it presented the limitation of not estimating which types of sports were practiced by these young people, or the volume and intensity of the activities. Despite these limitations, the present study had a representative sample and analyzed a conventional physical education program with outcomes relating to public health, using multivariate analysis. This enables generalization of the results to populations with similar characteristics and similar physical education programs.

Physical education plays an important role in health promotion among young people who do not practice sports, because of the protection that it provides against the risk of low physical fitness. However, to provide protection against obesity and obtain additional benefits regarding the health of young sports practitioners, conventional Brazilian physical education programs require improvement. Future studies aiming towards examining the relationship between physical education programs and health should consider sports practice, in order to better understand the benefits among young people.

CONCLUSION

The benefits of engagement in physical education classes regarding cardiorespiratory fitness and muscle strength were only seen among students who did not practice sports. On the other hand, no association was observed regarding obesity. Benefits were also observed when the variables of cardiorespiratory fitness, muscle strength and obesity were combined for analysis.

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Evidence hierarchies relating to hand surgery: current status and improvement. A bibliometric analysis study

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ABSTRACT

BACKGROUND: Hierarchy of evidence is an important measurement for assessing quality of literature. Information regarding quality of evidence within the Brazilian hand surgery setting is sparse, especially regarding whether research has improved in either quality or quantity. This study aimed to identify and classify hand surgery studies published in the two most important Brazilian orthopedics journals based on hierarchy of evidence, with comparisons with previously published data.

DESIGN AND SETTING: Bibliometric analysis study performed in a federal university.

METHODS: Two independent researchers conducted an electronic database search for hand surgery studies published between 2010 and 2016 in Acta Ortopédica Brasileira and Revista Brasileira de Ortopedia. Eligible studies were subsequently classified according to methodological design, based on the Haynes pyramid model (HP) and the JBJS/AAOS levels of evidence and grades of recommendations (LOR). Qualitative and quantitative data were gathered regarding all studies. Previous data were considered to assess whether the proportion of high-quality studies had improved over time (2000-2009 versus 2010-2016).

RESULTS: The final analysis included 123 studies, mostly originating from the southeastern region (78.8%) and private institutions (65%), with self-funding (91.8%). Methodological assessment showed that 15.4% were classified as level I/II using HP and 16.4% using LOR. No significant difference in proportions of high-quality studies was found between the two periods of time assessed (5% versus 12%; P = 0.13).

CONCLUSION: Approximately 15% of hand surgery studies published in two major Brazilian journals were likely to be classified as high-quality through two different systems. Moreover, no trend towards quality-of-evidence improvement was found over the last 15 years.

INTRODUCTION

The systematic approach of evidence-based medicine involves critical appraisal and stratification into levels of evidence[1-3] as a first step. Classification of research considering its internal validity is important in translating research results into clinical practice.[1,2]

In this regard, stratification of evidence is the key to distinguishing robust high-quality research from biased or low-quality research. Stratification is demanded, given that the number of published studies in the literature is increasing year by year.[4] Poolman indicated that higher quality research is linked to better reporting, which relates to trustworthiness and applicability.[5]

As a basic principle, researchers and practitioners should consider the best evidence available, in making health-related decisions. However, it is often not easy to distinguish good from poorly performed research. Thus, systematic reviews (SRs) are an important tool for combining and summarizing relevant previously published studies.[2,4] Most SRs only consider level I and sometimes level II studies as eligible for data synthesis. Therefore, only highly unbiased studies are eligible for inclusion and final analysis.

In the setting of hand surgery, although there has been an absolute increase in research production, little is known about the quality of the evidence generated. A previous study suggested that higher levels of evidence are related to higher applicability within clinical, academic and educational scenarios.[6]

One Brazilian study from the early 2000s assessed hand surgery studies and demonstrated that only a low proportion provided level I and II evidence, accounting for less than 10% of all the studies analyzed.[7] These data[7] are in accordance with other findings in other settings.[8] Bibliometric analyses, as performed in these two studies,[7,8] are important because they can potentially have an impact on research policies and academic actions and can pinpoint unnecessary or unethical studies.[7,9]

Hypothesis

The hypothesis for the present investigation was that recent studies have improved in terms of scientific methodology, thus moving towards a proportional increase in the numbers of level I and II studies produced.

OBJECTIVES

This study aimed to:

1. Identify hand surgery studies published over the last five years (2010-2016) in the two main Brazilian orthopedics journals: Acta Ortopédica Brasileira (AOB) and Revista Brasileira de Ortopedia (RBO).
2. Classify the types of study and levels of evidence according to evidence-based medicine hierarchies.
3. Compare findings from two different periods (2000-2009 versus 2010-2016) within the same journal using the same methodology.

METHODS

This study was approved by the local ethics committee of our institution (Universidade Federal de São Paulo, UNIFESP) under the number CAAE 60911016.8.0000.5505. The methodology used for this study was similar to that used in the senior author's previous publication.[7]

Search strategy

Using the specific web databases of the two journals (AOB and RBO), two researchers (M.C. and T.B.) independently evaluated all studies published between January 1, 2010, and December 31, 2016. These two prominent journals were chosen since they are national-level journals in Brazil that have an orthopedics scope and are indexed in international research databases (SciELO and MEDLINE).

Studies were initially screened based on their titles and were classified as eligible, potentially eligible or not eligible. The initial inclusion criteria included the presence of the following themes in the titles/abstracts: hand and wrist fractures, peripheral nerve lesions and vascular lesions in the upper limbs, nail bed lesions, brachial plexus lesions, muscle tendon lesions, upper-limb skin coverage, microsurgery, upper-limb pain syndromes, upper-limb congenital malformations, and anatomical and experimental studies. From the methodological perspective, narrative reviews, economic appraisal studies and experimental studies *in vitro* or on animals were excluded.

After this initial screening, eligible and potentially eligible studies were assessed: first using the abstracts and then the full-text articles. These studies were evaluated by the two examiners, who subsequently categorized them according to study type and level[10] of evidence, using two different approaches: the Haynes pyramid of evidence (HP) and the JBJS/AAOS Evidence-Based Practice Committee guideline - levels of evidence and grades of recommendations (LOR).[11] Stratification was conducted after reading the full text of all eligible studies. Any disagreements were resolved by a third evaluator (V.Y.M.).

Haynes pyramid of evidence

We considered that systematic reviews of randomized clinical trials provided evidence at level I; randomized clinical trials, level II; cohort and case-control studies, level III; case series, level IV; and case reports, level V.

JBJS/AAOS Evidence-Based Practice Committee guideline

This guideline, produced jointly by the Journal of Bone and Joint Surgery (JBJS) and the American Academy of Orthopaedic Surgeons (AAOS), is an improved, robust and detailed version of the previous HP stratification. Its levels of evidence are classified as follows:

Level I

Randomized controlled trial (RCT): a study in which patients are randomly assigned to the treatment or control group and are followed prospectively; or a meta-analysis on randomized trials with homogeneous results.

Level II

Poorly designed RCT: follow up data on less than 80% of patients.
Prospective cohort study (therapeutic): a study in which patient groups are separated non-randomly according to exposure or treatment, with exposure occurring after the study started.
Meta-analysis on Level II studies.

Level III

Retrospective cohort study: a study in which patient groups are separated non-randomly according to exposure or treatment, with exposure occurring before the study started.
Case-control study: a study in which patient groups are separated according to the current presence or absence of disease and examined for the prior exposure of interest.
Meta-analysis on Level III studies.

Level IV

Case series: a report on multiple patients with the same treatment, but no control group or comparison group.

Level V

Case report (a report on a single case), expert opinion or personal observation.

For all the studies ultimately included, we obtained information regarding the journal (AOB or RBO); geographic location of the study (south, southeast or north plus northeast plus center-west of Brazil); number of authors; and funding. Case reports were excluded from the analysis.

Statistical analysis

Descriptive statistics consisting of the mean (following by standard deviation) and proportions were produced. Fisher's F test was used to evaluate the proportions between the two periods of assessment. We considered P-values < 0.05 to be statistically significant.

RESULTS

Study characteristics

A total of 1200 papers in the journals' databases were screened. From these, 123 (10.2%) were eligible for the current study. Sixty-three were retrieved from Acta Ortopédica Brasileira (51.2%) and 60 (48.8%) from Revista Brasileira de Ortopedia. The agreement between the observers for inclusion of the studies was 98.8%. **Table 1** depicts the results from the data retrieved covering the period 2010-2016 and historical data from the previous study (2000-2009) on the same subject and journals.[7] The data distribution in the two periods did not show any differences in the assessed outcomes between these periods (2000-2009 versus 2010-2016), since the confidence intervals overlapped for all relevant data.

Most studies were from private institutions (65%), were self-funded (91.8%) and were conducted in Brazil's southeastern region (78.8%). The distribution of the studies conducted in other countries (12 studies) was: Turkey (4 studies), Portugal (3 studies) and others (5 studies; one each from China, Colombia, Uruguay, Italy and a multicenter study).

Evidence hierarchy assessment

Haynes pyramid of evidence

Considering the standard classification as published by Haynes, most of the studies were considered to present evidence at level IV/V. No systematic reviews of randomized trials (RCTs) on hand surgery were recognized. However, we found 7 RCTs and 12 case-control/cohort studies, which encompassed 15.4% of the total number of studies considered, as shown in **Graph 1**.

JBJS/AAOS Evidence-Based Practice Committee Guideline

The more comprehensive criteria proposed by the Journal of Bone and Joint Surgery showed a similar trend. Level I, II and III studies encompassed 16.4% of the total number of studies assessed. As occurred with the HP assessment, the majority of the studies were level IV and V. **Graph 2** shows the distribution of the studies according to this classification.

Comparison with historical data from previous study: 2000-2009 versus 2010-2016

In our previous report (2000-2009), we recognized 83 studies and only four were considered as presenting level I or II according to HP. There were no statistical differences (Fisher's F test, P = 0.13) in the proportion of published studies with level I or II evidence between 2000-2009 (4/83) and 2010-2016 (14/123).

DISCUSSION

Our study characterized the current panorama of hand surgery research published in Brazilian journals. Two different criteria were used to classify these studies. We first used the extended pyramid model proposed by Haynes in 2006. Each of these levels should build systematically from lower levels and provide substantially more useful information for guiding clinical decision-making.[10] Secondly, the JBJS/AAOS Evidence-Based

Table 1. Study characteristics - qualitative and quantitative data

	2010-2016			2000-2009		
	N or mean	%	SD	N or mean	%	SD
Study origin						
Public	42	34.1		40	51.1	
Private	80	65.0		36	45.5	
Both	1	0.9		3	3.4	
Number of authors per article						
Total	5.05		1.48	4.49		1.48
AOB	5.00		1.64	4.35		1.54
RBO	5.11		1.33	4.75		1.35
Origin						
Southeast	97	78.8		38	74.6	
South	8	6.5		9	17.6	
North/Northeast	6	4.9		4	7.8	
Other countries	11	8.9		0	0	
Multicenter	1	0.9		0	0	
Funding						
Self-funded	113	91.8		75	67.2	
External (public agencies)	9	7.3		3	2.8	
External (industry)	1	0.9		1	1.4	

SD = standard deviation; AOB = Acta Ortopédica Brasileira; RBO = Revista Brasileira de Ortopedia.

Practice Committee Guideline.[11] This was created by a task force of representatives from the AAOS Evidence-Based Practice Committee and the Journal of Bone and Joint Surgery, with the aim of providing the best answers to questions about interventions, in a timely manner. As far as we know, this was the first study to include both evidence hierarchy criteria in the same investigation.

We demonstrated that approximately 15% of the available research may be considered to present high quality-evidence (level I or II). In comparison with our previous analysis (2000 to 2009), a trend towards improvement of evidence was identified, although this was not statistically significant. Our findings reflect the challenge of conducting high-quality studies relating to hand surgery, such as blinded RCTs.

Classifying studies within the hierarchy of evidence is important as a first step. However, some published data have proven that RCTs may be prone to a great variety of systematic errors, which means that analysis on the internal validity of each study is an essential measurement for assessing its quality.[12] Bias assessment is another means of rating research and may be standardized using specific tools. However, to our knowledge, there is no consensus in the literature regarding the application of such assessments.[13]

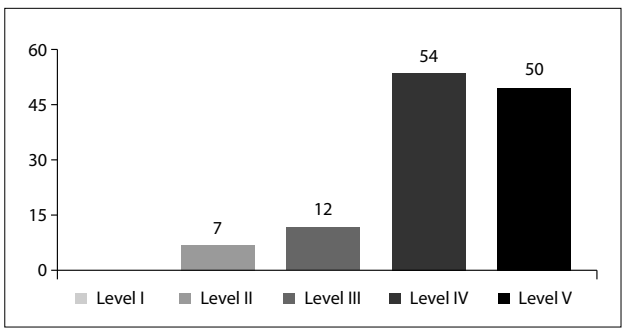
Recent research conducted on papers published in other journals, such as Plastic and Reconstruction Surgery, Journal of Plastic, Reconstructive and Aesthetic Surgery, Journal of Hand Surgery – European Volume, Journal of Hand Surgery – American Volume, Journal of Bone & Joint Surgery and Bone & Joint Journal, has demonstrated similar low rates of high-quality studies (11.2%). This shows that the data regarding hand surgery are in line with data from other specialties.[14]

Another study reviewed all online articles published in 2010 in The Spine Journal (TSJ), Spine, European Spine Journal (ESJ), Journal of Neurosurgery: Spine (JNS) and Journal of Spinal Disorders and Techniques (JSDT). It found that 27.9% of the articles were of high quality and that spinal surgery journals with higher impact factors contained higher proportions of studies of better quality.[15]

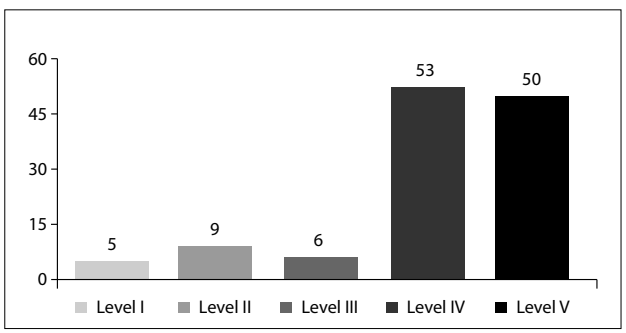
Research on the neurosurgical literature from 2009 to 2010 demonstrated that only 10.3% of the studies were of high quality. Only 1 in 10 of the studies was classified as presenting a high level of evidence.[16]

Research in the palliative medicine literature has shown that there was an increase in the proportion of studies presenting a high level of evidence among all published articles, from 0.08% in 1970 to 0.38% in 2005. However, it does not show the quality of the studies, only the quantity.[17]

Finally, our findings may not reflect the current status of Brazilian hand surgery research. We believe that the quantity of RCTs may have been underestimated, given that relevant high-quality research tends to be published in high-impact journals, with greater visibility and academic impact. Broader analysis on this subject might explore these phenomena in the future.



Graph 1. Distribution of studies as proposed using the Haynes model.



Graph 2. Distribution of studies according to the JBJS/AAOS Evidence-Based Practice Committee Guideline.

CONCLUSIONS

Approximately 15% of hand surgery studies published in two major Brazilian journals are likely to be classified as high quality through two different classification systems. In addition, no trend towards improvement of the quality of evidence over the last 15 years was found.

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Smoking among adolescents is associated with their own characteristics and with parental smoking: cross-sectional study

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This study was developed in the city of Londrina (PR), Brazil

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ABSTRACT

BACKGROUND: This study aimed to analyze the association between smoking during adolescence and the characteristics of smoking and alcohol consumption among their parents.

DESIGN AND SETTING: Cross-sectional study in Londrina (PR), Brazil.

METHODS: The subjects comprised 1,231 adolescents aged 14-17 years. The adolescents and their parents answered a self-report questionnaire that asked for sociodemographic information and data on smoking and alcohol consumption. Multiple logistic regression models were used to analyze associations between smoking among adolescents and their characteristics (age, sex, period of the day for attending school, alcohol consumption and socioeconomic level) and their parents' characteristics (smoking, alcohol consumption, age and education level), adjusted according to the adolescents' characteristics (sex, age and socioeconomic level).

RESULTS: The prevalence of smoking among adolescents was 3.4% (95% confidence interval, CI: 2.4-4.4). Adolescents whose mothers or fathers were smokers were 2.0 and 2.5 times more likely to be smokers, respectively. The prevalence of smoking among adolescents with a smoking mother was 7.1% (95% CI: 2.6-10.7) and a smoking father, 5.4% (95% CI: 1.6-8.5). There were significant associations between smoking adolescents and age [5.2% (95% CI: 3.3-6.6)], studying at night [9.6% (95% CI: 4.0-15.5)] and alcohol consumption [69.0% (95% CI: 55.0-83.0)]. It was observed that the number of alcoholic beverage doses consumed was higher among smoking adolescents (P = 0.001).

CONCLUSION: Adolescent smoking was associated with smoking by their parents, regardless of the gender of the parents or adolescents. Age, alcohol consumption and studying at night are characteristics of adolescents that can contribute towards smoking.

INTRODUCTION

Smoking is considered to be a behavior that puts health at risk.[1] Several studies have demonstrated a strong relationship between smoking and various types of diseases in the adult population, such as carotid calcification[2] and other cardiovascular problems, like stroke.[3] However, this type of behavior has been detected not only among adults, but also in young populations. In a study conducted in Saudi Arabia, Al-Zalabani and Kasim[4] observed that the prevalence of smoking was around 15% among the young people who they evaluated.

Adolescent smoking is increasing in poorer countries. Smoking in adulthood may start during adolescence, which demonstrates the importance of studies addressing this issue.[5] Tavares et al.[6] and Barreto et al.[7] highlighted that adolescence is a period of great exposure and vulnerability to consumption of substances such as tobacco and alcohol, with frequent experimentation by adolescents. Consequently, determining the factors that could cause this type of behavior among adolescents is important. Another aspect that has been investigated is whether adolescents' household environment might contribute to such behavior.

In a study on adolescents aged 13-18 years, Vázquez-Rodríguez et al.[8] reported that parental smoking was associated with smoking among their children. Similar results were observed in some studies in which adolescent smoking was more prevalent among those whose parents were smokers.[9,10] Tondowski et al.[9] showed that approximately 45% of adolescents who reported frequent tobacco use had fathers or mothers who smoked. In addition, it has been shown that smoking during adolescence may be linked both to use of illicit drugs such as marijuana and to use of licit drugs such as alcohol.[11-15]

The majority of previous studies have only examined parental smoking as a risk factor. However, other lifestyle variables such as alcohol consumption and sociodemographic characteristics such as the parents' ages and educational levels, also need to be considered. One of the hypotheses is that the parents' characteristics other than smoking may also be associated with smoking among adolescents. Moreover, it needs to be emphasized that the characteristics of the adolescents themselves should also be considered in order to eliminate possible confounding factors, since late adolescence[16] and being male[17] tend to be more associated with smoking, and socioeconomic level may also be associated, depending on the characteristics of each country.[18]

Studies that investigate lifestyle habits between parents and children can contribute towards health promotion actions, if these relationships are observed in the family environment. Therefore, the aim of the present study was to analyze the association between smoking during adolescence and the lifestyle characteristics (smoking and alcohol consumption) of parents or family members who live with adolescents.

METHODS

Sample

The sample of this study formed part of a larger study that looked at risk factors for health among adolescents at public schools in the city of Londrina (PR), Brazil, and among their parents. To contact the adolescents, the Londrina Department of Education was first contacted in order to explain the objectives of the study. Subsequently, the Department identified the six largest public schools in the central region, which receive adolescents from different areas of the city (north, south, east, west and central areas). Subsequently, the researchers contacted the principals of the schools that were invited to participate in the study to explain the objectives of the study. After authorization from the schools' directors, contact was made with all classes of students aged 14-17 years in these schools.

To calculate the sample, the prevalence of smoking among adolescents was taken to be 15%,[4] and a tolerable error of 3% and power of 80% were used. Since the sample was selected through clusters, a design correction of 1.5 was used. To anticipate possible losses from the sample, 10% was added to the sample calculation. Thus, the minimum sample required was 870 adolescents. In the end, the study included 1231 adolescents (716 girls and 515 boys) aged 14-17 years.

Adolescents and their parents or family members who agreed to participate in the study signed a free and informed written consent form. This study was approved by the Research Ethics Committee of the institution responsible for this study (procedural number: 0.181.0.268.000-10; register number: 367.801).

The adolescents took the consent form home for their parents to sign and thus authorize the adolescent to participate in the study. Along with this consent form, they also took the parents' questionnaire with them, so that their parents could answer this instrument at home. The parents' questionnaire contained questions about their lifestyle habits (among them smoking and alcohol consumption) and sociodemographic variables (sex, age and schooling level). In total, 1,202 mothers and 871 fathers answered the questionnaire. Subsequently, the adolescents were evaluated at school.

Smoking and alcohol

Smoking status was ascertained through analysis of participants' smoking behavior.[19] If individuals replied that they had smoked cigarettes within the previous 30 days, they were considered to be smokers. The number of cigarettes that these individuals consumed in a typical week was also established.

Alcohol consumption was obtained through questions based on the questionnaire of the Brazilian Center for Psychotropic Drugs (CEBRID),[20] which assesses the frequency and quantity of alcoholic drinks consumed. Adolescents and parents or family members who reported consumption of more than 1-2 doses (each dose corresponded to 250 ml of beer or 40 ml of distilled beverages in this study) on more than 1-2 days a week were classified as high consumers. The cutoff points used in this study were adapted from Moreira et al.[21] These instruments demonstrate good reproducibility values: kappa = 0.81 for smoking and kappa = 0.83 for alcohol consumption.

Anthropometric variables

The adolescents were measured wearing light clothing and no shoes. Weight was measured using a portable scale (Plenna; precision of 0.100 kg) with a capacity of 150 kg. Height was measured using a portable stadiometer (Sanny; precision of 0.1 cm) with a scale in centimeters. The anthropometric characteristics of the adolescents were evaluated by two previously trained evaluators. The procedures were applied in accordance with the recommendations of Gordon et al.[22] To assess the participants' nutritional status, the body mass index (BMI) was calculated as the ratio between the weight and height squared. The adolescents' nutritional status was classified in accordance with the values proposed by Cole et al.[23] Overweight among the parents was determined based on the cutoff points of the World Health Organization, and adults with BMI greater than or equal to 25 kg/m^2 were classified as overweight.[24]

Sociodemographic variables

The parents' educational level was evaluated as the number of years of study reported over the course of their lives. Parental schooling was divided into terciles, such that lower education level was considered to be up to 8 years of study; medium education level, from 8 to 12 years; and higher education level, more than 12 years.

Parental age was determined as the difference between the date of data collection and birth date. Subsequently, age was divided into terciles.

To define the families' economic class, the 2011 Brazilian economic classification criteria of the Brazilian Market Research Association (ABEP) were used.[25] Householders' education level and the presence and quantity of certain rooms, assets and domestic employees in the homes analyzed were considered (color TV, VCR or DVD player, radio, number of bathrooms, car, washing machine, housemaids, refrigerator and freezer). At the end of this instrument, a scoring system is provided in which the individual is classified according to economic strata, such that higher scores represent higher economic strata.

Statistical analysis

The data characterizing the sample were presented as means and standard deviations stratified according to smoking status (smoker or nonsmoker). Analysis on the association between the dependent variable (smoking adolescents) and the independent variables was performed using the chi-square test.

Subsequently, two multivariate models were created and were analyzed through binary logistic regression. The association between smoking adolescents and their own characteristics (sex, age, period of the day for attending school, day or night, socioeconomic status and alcohol consumption) was analyzed. The association between smoking adolescents and the characteristics of their mothers and fathers was analyzed. In the first model, unadjusted smoking among adolescents was analyzed in relation to their mothers and fathers' smoking, alcohol consumption, age and education level. In the second model, which was adjusted according to the adolescents' characteristics, the sociodemographic variables of the adolescents that might be potential confounders were considered (sex, age and socioeconomic status). Although only the adolescents' ages presented P values lower than 0.200, it was decided that, in analyzing the association with smoking, the adolescents' sex and socioeconomic status would be inserted as adjustment variables. This was done to ascertain whether the possible associations between smoking and the variables analyzed would be independent of these confounding factors.

The significance level used for all analyses was $P \leq 5\%$. The confidence interval (CI) used was 95%. The analyses were performed using the Statistical Package for the Social Sciences (SPSS) software, version 15.0.

RESULTS

The prevalence of smoking in the sample of this study was 3.4% (95% CI: 2.4-4.4), which was equivalent to 42 adolescents. The average number of cigarettes smoked by the adolescents interviewed was 0.29 per month with no difference between boys and girls (P = 0.351). The prevalence of smoking among the mothers was 12.1% (95% CI: 10.5-14.2) and among the fathers, 17.9% (95% CI: 15.3-20.4). Smoking mothers consumed more alcohol than did mothers who did not smoke. Fathers who smoked presented lower weight, lower BMI and higher alcohol consumption than did fathers who did not smoke. Mothers and fathers with fewer years of schooling were more likely to be smokers. The prevalence of smoking was higher among fathers and mothers of medium socioeconomic status. **Table 1** presents information regarding sample characterization. It can be seen that the highest average of alcoholic beverages consumed in doses were higher among smoking adolescents.

Table 2 shows the significant associations between smoking among adolescents and later adolescence, studying at night and alcohol consumption. Older adolescents (16-17 years) presented higher levels of smoking behavior (5.2%; 95% CI: 3.45-6.82) than younger adolescents (1.6%; 95% CI: 0.56-2.61) (P = 0.002). The adolescents who studied in the evenings presented higher prevalence of smoking (9.6%; 95% CI: 4.0-15.5) than those who studied during the day (3.2%; 95% CI: 1.94-3.91). Smoking adolescents presented higher frequency of alcohol

Table 1. Characteristics of the sample according to smoking status

	Adolescents			Mothers			Fathers		
	Mean (SD)			Mean (SD)			Mean (SD)		
	Nonsmoker	Smoker	P-value	Nonsmoker	Smoker	P-value	Nonsmoker	Smoker	P-value
Age (years)	15.53 (1.06)	16.2 (0.9)	**0.001**	43.2 (7.0)	43.6 (8.1)	0.532	45.9 (7.4)	44.8 (7.5)	0.098
Weight (kg)	21.5 (13.0)	62.9 (13.0)	0.155	68.1 (12.8)	66.7 (12.7)	0.205	82.8 (14.2)	78.5 (14.6)	**0.001**
Height (cm)	166.61 (9.1)	169.1 (8.6)	0.085	161.3 (6.4)	161.3 (6.3)	0.991	173.0 (6.9)	173.4 (7.4)	0.568
Alcohol (doses)	0.42 (0.1)	2.0 (0.2)	**0.001**	0.4 (0.1)	1.1 (0.3)	**≤ 0.001**	1.21 (1.1)	2.13 (1.6)	**0.001**
Body mass index (kg/m²)	21.5 (3.8)	21.9 (4.0)	0.518	26.1 (4.7)	25.6 (4.5)	0.158	27.6 (4.09)	26.1 (4.38)	**0.001**
Education level (years)	10.5 (1.0)	11.2 (0.9)	**0.001**	8.3 (3.8)	7.3 (3.4)	**0.002**	8.0 (3.5)	6.6 (3.4)	**≤ 0.001**
Socioeconomic level (%)									
High	39.0	38.1		40.2	29.5		44.3	30.1	
Medium	55.4	57.1	0.988	54.7	60.1	**0.003**	52.4	64.1	**0.001**
Low	5.6	4.8		5.1	9.4		3.4	5.8	
Nutritional status (%)									
Normal weight	96.8	95.6	0.496	87.1	88.0	0.682	72.5	86.2	**≤ 0.001**
Overweight	3.2	4.4		12.9	12.0		27.5	13.8	

SD = standard deviation.

consumption: among the 42 adolescents who smoked, 29 (69.0%; 95% CI: 55.0-83.0) consumed alcohol and 7.0% of them (95% CI: 0.65-14.95) consumed alcohol with a frequency of four times a week.

Table 3 shows the associations between adolescents who smoked and mothers or female guardians who smoked. Adolescents whose mothers were smokers were twice as likely to have this habit. The prevalence of smoking among adolescents with smoking mothers was 7.1% (95% CI: 2.6-10.7), compared with 2.3% (95% CI: 1.85-3.86) among adolescents with non-smoking mothers. In both the raw and adjusted analyses on the variables relating to the adolescents, associations between smoking adolescents and alcohol consumption could be seen. There were no significant differences in smoking levels among adolescents between those with older mothers and those with younger mothers, or between those with mothers with lower education levels and those with mothers with higher education levels.

The prevalence of smoking among adolescents with smoking fathers was 5.4% (95% CI: 1.6-8.5). Smoking among fathers was also associated with smoking among adolescents: teens whose fathers smoked were 2.5 times more likely to be smokers (**Table 4**).

Table 5 presents information on the relationship between smoking among adolescents and the smoking habits of both of their parents. There were no associations between adolescent smoking and both parents smoking.

Table 2. Association between adolescents' smoking habits and their characteristics

Characteristics	Odds ratio	95% confidence interval	P-value
Age			
14-15 years	1.00	1.00	1.00
16-17 years	**3.26**	**1.54-6.88**	**0.002**
Sex			
Male	1.00	1.00	1.00
Female	0.71	0.38-1.31	0.277
Period of attending school			
Daytime	1.00	1.00	1.00
Night	**3.21**	**1.49-6.92**	**0.003**
Socioeconomic level			
High	1.00	1.00	1.00
Medium	1.05	0.55-2.01	0.868
Low	0.87	0.19-3.90	0.865
Alcohol consumption			
No	1.00	1.00	1.00
Yes	**6.81**	**3.59-12.90**	**0.001**

Table 3. Association between smoking among adolescents and characteristics of their mothers

Mothers' characteristics	Crude	P-value	Adjusted using adolescents' characteristics*	P-value
Smoking				
No	1.00		1.00	
Yes	**2.44 (1.17-5.11)**	**0.017**	**2.37 (1.23-5.00)**	**0.022**
Alcohol consumption				
No	1.00		1.00	
Yes	**1.90 (1.00-3.60)**	**0.049**	**1.91 (1.00-3.66)**	**0.049**
Age				
≤ 40 years	1.00		1.00	
41-46 years	1.32 (0.63-2.79)	0.455	1.22 (0.57-2.59)	0.727
≥ 47 years	1.27 (0.58-2.78)	0.925	1.37 (0.62-3.03)	0.659
Educational level				
Low	1.00		1.00	
Medium	0.82 (0.36-1.86)	0.645	0.83 (0.35-1.94)	0.729
High	1.10 (0.48-2.48)	0.818	1.08 (0.47-2.50)	0.759

*Adjusted according to the adolescents' sex, socioeconomic level and age.

DISCUSSION

The prevalence of smoking adolescents in this study can be considered low (3.4%) in comparison with other studies.[4,26] In a recent study, Figueiredo et al.[16] observed that the prevalence of smoking in a sample of adolescents aged from 12 to 17 years was 5.7%, considering several Brazilian cities. Their findings were similar to those of the present study and their prevalence can also be considered low. One reason for this low prevalence appears to be related to restrictions on tobacco advertising on the television and to laws prohibiting tobacco use in public places, along with increased prices for cigarettes and increased activity of smoking cessation programs, as shown by Levy et al.[27]

There were no significant differences in the nutritional status of adolescent smokers and nonsmokers in this study. This same relationship was observed for the mothers, but smoking fathers presented lower weight and prevalence of overweight than did nonsmoking fathers. Adolescents are at an early stage of life, at which they have probably not yet established a pattern for nutritional status or smoking habits. Considering the difference in the nutritional status among their fathers, one of the reasons for this that can be considered is nicotine levels, which cause several changes to appetite and metabolic rate, thus giving rise to differences between smokers and nonsmokers.[28] For both fathers and mothers, those with higher average schooling levels presented lower tobacco consumption than did parents with lower schooling levels, possibly because parents with higher education levels have more knowledge about the harm that cigarette smoking can cause.

This study found that adolescents whose mothers or fathers smoked were about 2.0 and 2.5 times as likely, respectively, to have the same kind of behavior, even after various adjustments for potential confounders. It was observed that the habit of smoking among parents was associated with their children's habits, independent of the abovementioned variables. In a study on young Canadians, O'Loughlin et al.[29] also observed that parental smoking was associated with the onset of smoking during their children's adolescence, regardless of parental schooling levels. Similar relationships have been observed in other studies.[9,10]

The fact is that teens tend to replicate their parents' habits. In a recent meta-analysis, Laird et al.[30] observed that adolescents with physically active parents were more likely to be physically active. However, this replication of habits does not seem to occur for healthy habits alone, and a similar relationship regarding smoking habits is observed between adolescents and their parents. One of the hypotheses for this is that these young people may have felt more freedom to experiment with smoking because of the example seen in their homes.

Having a father and/or mother who smokes seems to represent a permissive attitude for adolescents, based on their parents' behavior, thus producing an image that smoking is acceptable and possibly contributing towards a process of initiation of smoking. Nonetheless, in our sample, contrary to expectations, there was no association between smoking among adolescents and both parents being smokers. One of the possible reasons for this finding is that the prevalence of occurrences of both parents smoking at home was low: only 4.4%.

An association was observed between mothers who had the behavior of consuming alcohol and smoking among adolescents. One of the possible reasons for this is the strong relationship between smoking and alcohol. Elicker et al. showed that 39.2% of the adolescents in Porto Velho (RO), Brazil, consumed alcohol for the first time at home.[31] This may be one of the reasons, since alcohol consumption at parties or family meetings would not be characterized as a risk factor for health, but as a normal attitude that could be related to smoking. Perhaps parents who are permissive regarding alcohol use may also be permissive regarding to smoking among young people.

Among the characteristics of adolescent smoking, there were associations with age (being older), alcohol consumption and the period of the day in which adolescents attended school (night). Khuder et al.[32] found that older adolescents were about six times more likely to be smokers than younger adolescents. One reason for this relationship is the transformation that adolescents experience during this stage of life. This is a period in which social relationships are important, and this could contribute towards starting some types of behavior such as smoking, with the aim of achieving acceptance in social groups. Several studies have reported the strong influence that friends have on smoking habits among adolescents.[10,33]

Regarding alcohol consumption, those who consumed alcoholic beverages were six times more likely to be smokers. Several studies have demonstrated significant relationships between smoking and alcohol consumption among adolescents.[13-15] Among the substances found in large quantities in cigarettes, nicotine acts in many areas of the brain. It has been hypothesized that neuronal nicotinic acetylcholine receptors act in a specific brain area that also causes higher propensity towards alcohol use.[34]

Additionally, adolescents who went to school in the evenings were about three times more likely to have a smoking habit than their peers who attended school during the day. This corroborated the findings of Farias Junior et al.[35] who observed that young people who attended classes in the evenings presented a greater chance of being smokers. This relationship was also observed among almost 3,000 adolescents in northern Brazil.[36] Among the reasons that could explain this relationship, the first is that adolescents who study in the evenings have a higher average age than the adolescents who study during the day.

Another characteristic of the adolescents attending school in the evenings is that they tend to work during the day, which aids independence and brings the possibility of buying cigarettes with their own income. The association between adolescents working and smoking has also been reported in another study.[37] A further factor to be considered as a hypothesis, but which was not analyzed in this study, is that at night, several bars and nightclubs, which are often close to where schools are located, are open. This may contribute towards this type of behavior among young people who attend these places.

Table 4. Association between smoking among adolescents and characteristics of their fathers

Fathers' characteristics	Crude	P-value	Adjusted using adolescents' characteristics*	P-value
Smoking				
No	1.00		1.00	
Yes	**2.51 (1.04-6.05)**	**0.039**	**2.58 (1.06-6.28)**	**0.029**
Alcohol consumption				
No	1.00		1.00	
Yes	2.40 (0.88-6.55)	0.085	2.37 (0.86-6.47)	0.095
Age				
≤ 43 years	1.00		1.00	
44-47 years	0.98 (0.35-2.70)	0.978	0.87 (0.31-2.41)	0.665
≥ 48 years	0.57 (0.20-1.56)	0.275	0.46 (0.16-1.28)	0.137
Educational level				
Low	1.00		1.00	
Medium	0.64 (0.64-2.07)	0.465	0.77 (0.23-2.58)	0.725
High	1.20 (0.41-3.55)	0.736	1.33 (0.45-3.95)	0.398

*Adjusted according to the adolescents' sex, socioeconomic level and age.

Table 5. Association between smoking among adolescents and smoking among parents

Both parents' characteristics	Crude	P-value	Adjusted using adolescents' characteristics*	P-value
Smoking				
Neither	1.00		1.00	
Mother or father	1.74 (0.65-4.66)	0.267	1.70 (0.62-4.58)	0.299
Both parents	2.72 (0.59-12.55)	0.198	2.99 (0.62-14.01)	0.165

*Adjusted according to the adolescents' sex, socioeconomic level and age.

The practical application for the present study is that it serves as a reminder to different healthcare agencies regarding the importance of organizing prevention strategies among families, in order to avoid problems caused by smoking in the future. In this regard, the recent findings of West et al.[38] are noteworthy. Through a cohort study conducted over a period of more than twenty years, these authors found that children exposed to parental smoking had higher odds of developing carotid atherosclerotic plaque in adulthood.

The limitations of the present study were, firstly, that the outcome was assessed using a questionnaire, which was self-administered and may have underestimated the prevalence of smoking, since some adolescents may have omitted the fact that they were smokers. In addition, this was an epidemiological cross-sectional study and it was not possible to quantify serum nicotine levels to confirm the presence of the smoking habit among these adolescents and thus to preclude the limitation of potential underreporting of this habit. Another factor to be mentioned is that the sample was not representative of all schools in the city in which the study was conducted. However, the sample was selected from the six largest schools in the central region of the city of Londrina, and these schools receive students from different areas of the city, with large numbers of students, which made the sample more representative.

The strong aspects of this study are its large sample size, and all of the adjustments made in the analysis on the data. It is worth noting that through stratification of the parents according to sex, it became possible to observe the relationships between both the fathers' and the mothers' smoking habits and those of the adolescents.

CONCLUSION

The smoking habit among adolescents was associated both with parental and maternal smoking, regardless of the gender of the parents or adolescents. Factors such as age, alcohol consumption and attending school at night were characteristics among these adolescents that may have contributed towards smoking. Health promotion actions need to focus on the family unit and not on strategies that are isolated from each other.

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A study of pulmonary function in end-stage renal disease patients on hemodialysis: a cross-sectional study

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KEY WORDS:
Kidney diseases.
Respiratory function tests.
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ABSTRACT

BACKGROUND: The aim here was to study acute effects of hemodialysis among end-stage renal disease (ESRD) patients.

DESIGN AND SETTING: Prospective study in tertiary-level care center.

METHODS: Fifty ESRD patients undergoing hemodialysis were studied. Spirometric pulmonary function tests were performed before and after four-hour hemodialysis sessions.

RESULTS: The patients' average age was 45.8 ± 10.0 years; 64% were males and 64% had normal body mass index. Anemia (94%) and hypoalbuminemia (72%) were common. Diabetes mellitus (68%), hypertension (34%) and coronary artery disease (18%) were major comorbidities. Forty-five patients (90%) had been on hemodialysis for six months to three years. The patients' pre-dialysis mean forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV1) were below normal: 45.8 ± 24.9% and 43.5 ± 25.9% of predicted, respectively. After hemodialysis, these increased significantly, to 51.1 ± 23.4% and 49.3 ± 25.5% of predicted, respectively ($P < 0.01$). The increase in mean FEV1/FVC, from 97.8 ± 20.8% to 99.3 ± 20.1% of predicted, was not significant ($P > 0.05$). The pre-dialysis mean forced expiratory flow 25-75% was 50.1 ± 31% and increased significantly, to 56.3 ± 31.6% of predicted ($P < 0.05$). The mean peak expiratory flow was below normal (43.8 ± 30.7%) and increased significantly, to 49.1 ± 29.9% of predicted ($P < 0.05$). Males and females showed similar directions of change after hemodialysis.

CONCLUSIONS: Pulmonary function abnormalities are common among ESRD patients. Comparison of pre and post-hemodialysis parameters showed significant improvements, but normal predicted values were still not achieved.

INTRODUCTION

Chronic kidney disease (CKD) is a worldwide public health problem and comprises the presence of sustained and irreversible abnormality of renal functions and loss of the kidneys' ability to maintain homeostasis. CKD results from different causes of renal injury and can lead to progressive loss of renal function. It may reach end-stage renal disease (ESRD) after a variable period of time following the initiating injury. ESRD is the situation when kidney function is insufficient to sustain life and there is then a need for hemodialysis (HD), peritoneal dialysis (PD) or kidney transplantation, to substitute for native kidney function.[1] ESRD presents not only as progressive and irreversible loss of excretory function of the kidneys but also as a complex syndrome with altered metabolic and endocrine functions. It has effects on almost all body systems, including pulmonary function.[2]

The relationship between the lungs and the kidneys is clinically important for both health and disease.[3] Kidney failure directly and indirectly impacts the mechanical function and ventilation of the lungs, and treatment with drugs and HD are responsible for part of this effect.[4] Patients with ESRD require dialysis in the form of HD or peritoneal dialysis for survival, because these can partially replace the impaired kidney function, reverse the uremic symptoms and preserve patients with ESRD, while they await a definitive solution through kidney transplantation, if possible.[5] Pulmonary function tests have been compared among individuals on HD and peritoneal dialysis and among kidney transplant recipients, and it was found that pulmonary restrictive defect was the most common dysfunction in all these groups.[6]

Further spirometric changes were studied by Lang et al. before and after HD using different dialyzer membranes, and they found that there was no significant difference between pre-HD

and post-HD vital capacity.[7] On the other hand, in a similar study on the acute effects of HD, Rahgoshai et al. demonstrated that pulmonary function, and especially forced vital capacity (FVC), improved after a HD session; while no significant improvements in forced expiratory volume in 1 second (FEV1), FVC or FEV1/FVC ratio were observed.[8]

Dialysis may have beneficial effects at least in the initial stages of some respiratory disorders among CKD patients without primary lung disease. It may lead to improvement of respiratory symptoms and even pulmonary function test values.[9] However, the immune response resulting from contact between blood and bioincompatible dialysis filters may cause complement activation, which can have a deteriorating effect on the respiratory system and can even cause respiratory distress.[10]

HD-related hypoxemia is another issue among ESRD patients. HD can reduce pulmonary edema around the small airways, and this may lead to dilation of the small airways (decreased closing capacity). It also gives rise to improved basal ventilation and perfusion.[11]

The effects of HD on patients with CKD relate mainly to changes to the volume of body fluid, thus leading to reduction of the amount of water in the lungs following dialysis. Hence, HD improves respiratory status but it may cause pulmonary complications as well, due to various pulmonary injuries of multifactorial origin. Moreover, the malnutrition and degenerative alterations that can occur in CKD patients persist, thereby worsening muscle loss and predisposing these patients towards fatigue, with increases in respiratory rate and work.[12]

METHODS

Design: Our study was prospective and was conducted over a one-year period from November 2011 to December 2012, in a tertiary-level care center. It was an observation study. It was conducted on 50 ESRD patients undergoing HD. The study was approved by our institution's research ethics committee.

Inclusion criteria: Ambulatory, clinically stable patients in the age group of 18-60 years, who had been undergoing HD for more than three months, were included in the study.

Exclusion criteria: Patients with histories of smoking (current or previous), acute infection, acute renal failure, chronic lung disease, tuberculosis, skeletal muscle abnormality, decompensated heart failure, arrhythmias or liver cirrhosis, and patients in severe respiratory distress or who were unable to undergo spirometry, as assessed by the clinician administering the treatment, were excluded from the study.

The patients were given explanations regarding the purpose of the study and written informed consent was obtained from them. Individuals' data were recorded on an assessment form. The glomerular filtration rate (GFR) was estimated by using the empirical formula for creatinine clearance (Cockcroft-Gault equation).

HD was performed using the Fresenius Medical Care 4008-S, a German machine. While the patients' blood flow range was variable from 300 to 350 ml/min, the dialysate flow was constant (500 ml/min). Dialysis was done using a biocompatible membrane and bicarbonate buffer. Intra-dialysis ultrafiltration was based on the patients' condition and on their weight gain during the inter-dialytic period.

The pulmonary function tests were performed using a computerized spirometer ("Medicaid Spirometer"). This automatically corrected all gas volumes to body temperature and pressure, saturated (BTPS), i.e. a set of conditions at body temperature, with ambient pressure and with saturation with water vapor. Spirograms (flow volume and volume-time graphs) were produced, along with numerical data and the predicted percentage values for the spirometric parameters. Spirometric variables were recorded 15 minutes before and after the first HD session of the week.

The data obtained were analyzed statistically with the aid of the Statistical Package for the Social Sciences (SPSS) for personal computer, version 11.0, and paired t tests were used for comparative analyses. $P < 0.05$ was taken to be significant and $P < 0.01$ was taken to be highly significant.

RESULTS

This study was conducted from December 2011 to December 2012. A total of 50 patients met our inclusion criteria and were included in the study. The mean age of the study patients was 45.8 ± 10.0 years (range 24 to 60 years). The majority (62%) of the patients were below fifty years of age. Males formed the predominant group among the patients (64%) and 72% of the patients were from a rural background. The majority (64%) of the patients had a normal body mass index (BMI). BMI did not differ statistically according to gender (**Table 1**).

On investigation, 94% of the patients were anemic (hemoglobin < 12 g%). The hemoglobin values ranged from 5.0 to 12.5 g/dl (mean ± standard deviation, SD: 9.5 ± 1.6) among all the patients. For males, the hemoglobin range was 7.5-12.5 g/dl (10.2 ± 1.3), while for females, the values were 5.0-11.0 g/dl (8.3 ± 1.5).

The serum albumin levels ranged from 2.4 to 4.2 gm/dl. The mean serum albumin concentration was 3.28 ± 0.48 and 72% of the patients had hypoalbuminemia. Pre-dialysis serum urea levels ranged from 92.0 to 278.0 mg/dl (163.1 ± 39.1 mg/dl), serum creatinine 4.6-19.7 mg/dl (9.9 ± 3.3 mg/dL) and estimated GFR 3.0-19.8 ml/min/1.73 m^2 (7.8 ± 3.4 ml/min/1.73 m^2). There were no statistical differences in baseline urea and creatinine levels

Table 1. Body mass index status of study patients (in kg/m^2)

Body mass index (kg/m^2)	No. of patients (n)	(%)
Underweight (< 18.5)	10	20
Normal (18.5-24.99)	32	64
Overweight (25-29.99)	8	16
Obese (> 30)	0	0

according to gender, but estimated GFR was significantly higher in males (8.8 ± 3.5 ml/min/1.73 m^2) than in females (6.0 ± 2.3 ml/min/1.73 m^2).

Forty-five patients (90%) had been on HD for six months to three years and only 10% had been on HD for less than six months. The proportions were identical for males and females (**Table 2**). The majority (58%) of the study patients (62% of the males and 50% of the females) were undergoing HD twice a week, while 30% of all the patients (31% of the males and 28% of the females) were undergoing HD three times a week. Eight percent of the study patients were on hemodialysis once a week and another four percent once every two weeks (**Table 3**). 68% of the patients were diabetic before they were diagnosed as having CKD, while 34% were known to be hypertensive and 18% had coronary artery disease.

The percentages of the predicted spirometric parameters (% pred) and changes to spirometric parameters among our study patients after hemodialysis are presented in **Table 4** and **Table 5**.

FVC: The mean FVC of the study patients was 45.8 ± 24.9% pred, i.e. well below the normal predicted values for pulmonary function (normal is more than 80% of the predicted values), determined through spirometry. After HD, the mean FVC increased to 51.1 ± 23.4% pred, and this increase was statistically highly significant (P < 0.01) (**Table 4**).

FEV1: The mean FEV1 of the study patients was 43.5 ± 25.9% pred, which was also well below the normal predicted values (normal is more than 80% of the predicted values). After HD, the mean FEV1 increased to 49.3 ± 25.5% pred, and this increase was statistically highly significant (P < 0.01) (**Table 4**).

FEV1/FVC%: The mean FEV1/FVC% of the study patients was 97.8 ± 20.8% pred. After HD, the mean FEV1/FVC% increased to 99.3 ± 20.1% pred, but this increase was not statistically significant (P > 0.05) (**Table 4**).

Forced expiratory flow **(FEF) 25-75%:** The mean FEF 25-75% of the study patients was 50.1 ± 31% pred. After HD, the mean FEF 25-75% increased to 56.3 ± 31.6% pred, and this increase was statistically significant (P < 0.05) (**Table 4**).

Peak expiratory flow rate **(PEFR):** The mean PEFR of the study patients was 43.8 ± 30.7% pred, i.e. well below the normal range (normal is more than 80% of the predicted values). After HD, the mean PEFR increased to 49.1 ± 29.9% pred, and this increase was statistically significant (P < 0.05) (**Table 4**).

The overall analysis on pulmonary function in our study revealed that the majority of the patients (82%) had a normal FEV1/FVC ratio (> 70%) and low percentages of the predicted FVC value (< 80% pred), which was indicative of restrictive pulmonary disorder. Moreover, 6% had an FEV1/FVC ratio less than 70%, which indicates obstructive respiratory disorder. However, because these patients also had low FVC, they could be included in the category of mixed respiratory disorder. Only 12% of the study patients had pulmonary function in the normal range.

There were no statistically significant differences in any of the spirometric parameters after HD when compared on the basis of gender. Males and females showed similar directions of change after HD (**Table 5**).

DISCUSSION

The mean age of our study patients was 45.8 ± 10.0 years and 62% of them were < 50 years, thus suggesting that CKD had emerged as an early complication of various disorders. The preponderance of males (64%) may have reflected either greater prevalence of CKD among males or, alternatively, poor availability of costly HD treatment for female patients, due to various sociocultural and economic constraints. The mean BMI of the study group was 21.6 ± 3.0 kg/m^2 and 20% had BMI < 18.5 kg/m^2, but the majority

Table 2. Duration of hemodialysis among study patients

Duration of hemodialysis	Males (n = 32)	Females (n = 18)	Total (n = 50)
< Six months	3 (9.4%)	2 (11.1%)	5 (10.0%)
Six months to one year	12 (37.5%)	7 (38.9%)	19 (38.0%)
> One year to three years	17 (53.1%)	9 (50.0%)	26 (52.0%)

Table 3. Frequency of hemodialysis among study patients

Frequency of hemodialysis	Total (n = 50)	%
Three times a week	15	30
Twice a week	29	58
Once a week	4	8
Once every two weeks	2	4

Table 4. Percentage of predicted spirometric parameters among the study patients (before and after hemodialysis [HD]) (n = 50)

Spirometric parameters	Before HD (mean ± SD)	After HD (mean ± SD)	Paired differences				
			Mean	SD	SEM	95% CI	P-value
FVC	45.8 ± 24.9	51.1 ± 23.4	5.3	8.6	1.2	2.8-7.7	< 0.001
FEV1	43.5 ± 25.9	49.3 ± 25.5	5.8	9.4	1.3	3.2-8.6	< 0.001
FEV1/FVC (%)	97.8 ± 20.8	99.3 ± 20.1	1.5	18.0	2.6	-3.6-6.6	0.561
FEF 25-75%	50.1 ± 31.3	56.3 ± 31.6	6.2	20.9	3.0	0.2-12.1	0.043
PEFR	43.8 ± 30.7	49.1 ± 29.9	5.3	13.1	1.9	1.6-9.1	0.006

SD = standard deviation; SEM = standard error of the mean; CI = confidence interval; P-value from paired t-test (two-tailed); FVC = forced vital capacity; FEV1 = forced expiratory volume in 1 second; FEV1/FVC (%) = ratio between FEV1 and FVC x 100; FEF 25-75% = forced expiratory flow in 25-75% of FVC; PEFR = peak expiratory flow rate.
Note: The mean FEV1/FVC (%) of the study patients was 97.8 ± 20.8% of the predicted value.

(64%) of the patients had normal BMI. This was despite chronic illness, but the patients' obvious water retention and edema may have led to their normal BMI.

Anemia (94%) and hypoalbuminemia (72%) were very prevalent. This may have been due to higher levels of renal dysfunction and poor nutritional status, reflecting both an inflammatory state and poor nutritional status among the patients. The high prevalence of these conditions may also have been due to a hypercatabolic state in CKD, caused by accumulation of proinflammatory cytokines and a combination of factors like uremic toxicity, insulin resistance, and amino acid losses[13] during the dialysis procedure, rather than mere lack of a high protein diet.[14]

FVC (forced vital capacity)

The mean FVC of the study group was 45.8 ± 24.9% pred, i.e. well below the normal predicted values for pulmonary function. After HD, the mean FVC increased to 51.1 ± 23.4% pred ($P < 0.001$). Our findings regarding FVC are in agreement with Mehmood.[7,15-17] Decreased FVC, restrictive pattern and reduced airflows have been observed through spirometry, in studies by several authors. Chronic subclinical pulmonary edema due to increased capillary permeability and hypoalbuminemia was considered to be the cause for the decreased FVC.[11,18]

FEV1

The mean FEV1 of our study patients was 43.5 ± 25.9% pred. which was also well below the normal predicted values (normal is more than 80% of the predicted values). It showed a statistically significant increase after HD, to 49 ± 25.5% pred ($P < 0.01$). However, these low FEV1 values were associated with a normal FEV1/FVC ratio in most of our patients, which suggested that the large airways were not affected in situations of chronic renal failure and that the reduction of FEV1 was primarily due to reduction in FVC, as in restrictive pulmonary disease. Reduced FEV1 as observed in our study patients has also been reported by Maehmood et al. and Nascimento et al.[15,16] Inflammation and malnutrition have been found to present significant relationships with reduced pulmonary parameters.[19]

FEV1/FVC percentage ratio

Most of the study patients (82%) had a normal FEV1/FVC ratio (> 70%) and reduced FVC (i.e. < 80% of the predicted values), which was indicative of restrictive pulmonary disorder, while 6% had an FEV1/FVC ratio of less than 70%, thus pointing towards obstructive respiratory disorder. However, the latter patients also presented decreased FVC and could be included in the category of mixed respiratory disorder. Only 12% of the study patients had pulmonary function within the normal range. The mean FEV1/FVC ratio of our patients was 97.8 ± 20.8% pred, and this increased to 99.3 ± 20.1% pred) after HD, but this increase was not statistically significant ($P > 0.05$). In contrast to FEV1 and FVC, there were no significant changes overall or among the subgroups of the study patients regarding the FEV1/FVC ratio after HD, because there was corresponding increase in both parameters (FVC and FEV1). No significant change in this ratio was also observed by Navari et al.[4]

FEF 25-75% (forced expiratory flow over the middle part of FVC)

FEF 25-75% is measured from a segment of the FVC that includes flow from medium and small airways. Decreased flows are common in the early stages of obstructive disease. In the presence of borderline values for FEV1/FVC, a low FEF 25-75% confirms airway obstruction and sometime signals decreased cross-sectional area in the small airways. The mean FEF 25-75% among our study patients was 50.1 ± 31.3% pred and, after HD, it increased to 56.3 ± 31.6% pred, which was a statistically significant increase ($P < 0.05$). Rakovaca et al. found decreased values for FEF 25-75% among ESRD patients.[20] Mahmood et al. also observed decreased values that were indicative of small airway disease, in comparison with their controls.[15]

The improvement in FEF 25-75% that was achieved through HD among our study patients showed that there was a situation of reversible obstruction, comprising removal of excess fluid from the lungs that had been compressing the small airways. However, chronic subclinical pulmonary edema leading to peribronchial fibrosis may also contribute towards the persistent abnormalities in the small airways that are reflected in reduced FEF 25-75% values.

Table 5. Change in spirometric parameters among patients after hemodialysis

Spirometric parameter	Male (n = 32)		Female (n = 18)		P-value
	Increase		Increase		
	N	%	N	%	
FVC	25	78.1	15	83.3	0.941
FEV1	24	75.0	14	77.8	0.901
FEV1/FVC ratio	21	65.6	10	55.6	0.689
FEF 25-75%	17	53.1	13	72.2	0.307
PEFR	19	59.4	11	61.1	0.856

FVC = forced vital capacity; FEV1 = forced expiratory volume in 1 second; FEF = forced expiratory flow; PEFR = peak expiratory flow rate.

PEFR (peak expiratory flow rate)

Among our study patients, the mean PEFR was 43.8 ± 30.7% pred, i.e. below the normal range. After HD, the PEFR increased to 49.1 ± 29.9% pred, and this increase was statistically significant ($P < 0.05$). Mahmood et al. reported that the values among CKD patients on HD were lower than those of normal subjects.[15] Reduced PEFR before and even during HD sessions was observed by Davenport, who attributed this to activation of the complement system for neutrophils, monocytes and platelets following blood membrane interaction, thereby resulting in appreciable airway constriction.[21] In contrast to the findings from our study, normal PEFR values were observed by Lang et al.[7]

CONCLUSION

Pulmonary function abnormalities were common among our study patients, but were significantly ameliorated after HD. The majority of our patients had restrictive and mixed respiratory disorders. In the pulmonary function tests on our ESRD patients, spirometric parameters like FVC, FEV1 and PEFR were less than the normal predicted values (i.e. < 80% of the predicted values) in the majority of these patients. In comparing the pre-HD and post-HD spirometric parameters, there was significant improvement but normal predicted values were still not achieved.

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Translation and cultural adaptation of the revised foot function index for the Portuguese language: FFI-R Brazil

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KEY WORDS:
Foot.
Translations.
Surveys and questionnaires.
Outcome assessment (health care).

ABSTRACT

BACKGROUND: The revised foot function index (FFI-R) is used to evaluate the functionality of patients with conditions that affect the feet. The objective here was to produce the Brazilian Portuguese version of this index.

DESIGN AND SETTING: Translation and validation study conducted at the Federal University of São Paulo, Brazil.

METHODS: The translation and cultural adaptation process involved translation by two independent translators, analysis by an expert committee, back translation into the original language, analysis by the expert committee again and a pretest. The Portuguese-language version was administered to 35 individuals with plantar fasciitis and metatarsalgia to determine their level of understanding of the assessment tool.

RESULTS: Changes were made to the terms and expressions of some original items to achieve cultural equivalence. Terms not understood by more than 10% of the sample were altered based on the suggestions of the patients themselves.

CONCLUSION: The translation and cultural adaptation of the FFI-R for the Portuguese language were completed and the Brazilian version was obtained.

INTRODUCTION

Musculoskeletal injuries in the ankle and foot cause functional limitations that have a negative impact on quality of life.[1] Classification of the degree of dysfunction is fundamental for characterization of patients' status and enables quantification of the effect of treatment.[2] The main assessment tools used to evaluate the functionality of the feet, such as the foot function index (FFI), foot and ankle outcome score (FAOS), foot health status questionnaire (FHSQ) and Manchester foot pain and disability index (MFPDI), were developed in the English language.[3,4] For these assessment tools to be used in different countries with different languages, it is necessary to perform translation and cultural adaption and to test the psychometric properties of the adapted tools.[5]

The FFI is considered to be one of the main assessment tools for evaluation of the functionality of the ankle and foot, because all its psychometric properties have been validated.[1,6,7] Subsequently, adjustments and new domains were added to broaden its scope, thereby creating the revised foot function index (FFI-R).[8] In this version, the visual analogue scale (VAS) was replaced with a Likert scale. The domains and items of the original questionnaire were maintained and others regarding psychosocial characteristics were added. The FFI-R has five domains containing 68 items, with questions relating to pain (11 items), stiffness (8 items), problems (20 items), activity limitation (10 items) and social issues (19 items).[8]

Because of the importance of standardization when using evaluation measurements, questionnaires developed in foreign languages need to be translated and their psychometric properties evaluated, to create equivalence between studies. This process makes it possible for physicians and other professionals working in a given field to obtain a reliable tool for patient evaluations. Thus, the FFI-R can become available for assessing patients with foot and ankle musculoskeletal disorders.

The FFI has been translated and validated for use in several countries, such as Germany, Spain, France, China and Brazil.[9-14] However, the revised version has not yet been translated and culturally adapted to any foreign language based on its original version.

OBJECTIVE

The aim of the present study was to translate and culturally adapt the revised foot function index to the Brazilian Portuguese language.

METHODS

Thirty-five patients participated in this study: the first phase involved 20 volunteers and the second phase involved 15 other volunteers with plantar fasciitis and metatarsalgia. The participants were recruited through announcements in the printed and digital media and through verbal invitation. Their mean age was 25.2 years (range: 18 to 57 years) and females accounted for 57% of the sample. With regard to schooling, 12% had completed higher education and 80% were still studying. This investigation received approval from the human research ethics committee of the institution in which it was conducted (ethics committee no. 327.129) and all the participants signed a free and informed consent statement. The authorization for the use of the FFI-R was obtained from the original authors through electronic mail (**Figure 1**).

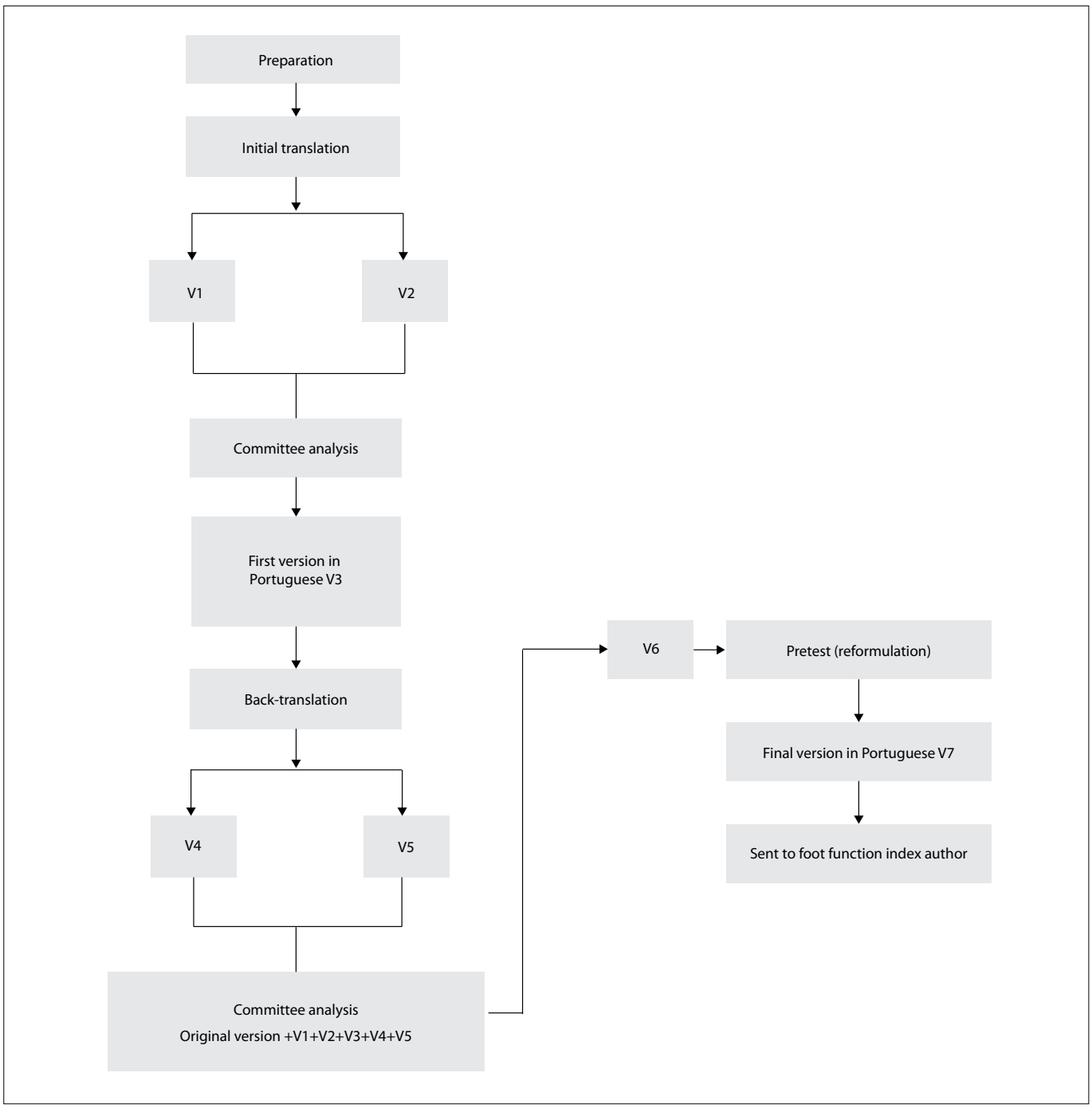

Figure 1. Flowchart of the study.

The translation and cultural adaption of the FFI-R followed the method described by Beaton et al.[15] and the Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were used:[16]

1. Translation;
2. Analysis by an expert committee;
3. Backtranslation into the original language;
4. Analysis by the expert committee again; and
5. Pretest.

The FFI-R was translated into Portuguese by two Brazilian professional translators who were fluent in English. The translators were informed regarding the objective of the study and the two versions of the translation thus produced (V1 and V2) were developed independently.

The two translations and the original questionnaire were compared and discussed by the members of the expert committee, in order to reach a consensual version in Portuguese that maintained the fundamental characteristics of the original questionnaire, thus forming V3. In the backtranslation phase, V3 was translated back into English by two translators whose native language was English and who had no access to the original questionnaire. These versions (V4 and V5) were shown to the expert committee. The committee discussed the differences between all the versions created and the original questionnaire. Inadequate or ambiguous items were altered, changes were suggested and equivalences were determined, regarding the meanings of words, idiomatic equivalence (interpretation of colloquialisms), cultural equivalence (to ensure that the practices mentioned in the questionnaire were common to the new culture to which it would be administered) and conceptual equivalence (to determine the cultural importance of the situations presented in the questionnaire).

Sentences were rewritten as necessary until a consensual version of the index in Portuguese had been obtained. This version was then used in the pretest, which was divided into two parts: V6-1 and V6-2. V6-1 was administered to 20 patients to determine the understanding of the questions. The researcher read aloud the content of the questionnaire to each participant, who then made suggestions if any items required a change (**Table 1**).

Items that did not achieve a level of understanding that exceeded 90% of the volunteers were rewritten, which thus created V6-2. This new version was administered to another 15 patients, who underwent the same procedures as were used for V6-1, until all items in the questionnaire were understood by more than 90% of the patients, which led to the final V7 version. This version was sent to the author of the original FFI-R, who did not suggest any changes.

RESULTS

In the translation phase, the two versions of the translated questionnaire (V1 and V2) were compared and were used to create the first consensual version (V3) (**Table 1**).

In the backtranslation phase, V3 and the backtranslated versions (V4 and V5) were analyzed and compared with the original questionnaire in English in order to develop V6. This stage involved grammatical, semantic and idiomatic changes for cultural adaptation of the questionnaire while maintaining the objective of each item (**Table 2**).

Table 1. Translation phase. Changes in "V1" and "V2" to obtain "V3"

Terms used in items of the original questionnaire	"V1" and "V2"	Modifications that were made to achieve the consensual version "V3"
2 – First stood	V1 - A primeira vez que ficou em pé V2 - Ficou de pé primeiro	Quando você ficou em pé (...) pela primeira vez de manhã
3 – First walked	V1 - A primeira vez que você caminhou V2 - Primeiro caminhou	Quando você caminhou (...) pela primeira vez de manhã
6 – Wearing custom shoe inserts	V1 - usando palmilhas anatômicas V2 - usando dispositivos ortóticos em sapatos sob encomenda	Quando você ficou em pé usando palmilhas anatômicas adaptadas
21 – Walking outside on uneven ground	V1 - Andando do lado de fora em solo irregular V2 - Andando fora em terreno irregular	Andando em solo irregular
27 – Objects weighing more than five pounds	V1 - objetos pesando mais do que cinco libras V2 - objetos pesando mais do que cinco libras (aprox. 2,5 kg)	Objetos pesando mais do que 2 kg
32 – Keeping a regular walking pace	V1 - Mantendo um passo de caminhada regular V2 - Mantendo passada regular de caminhada	Mantendo uma passada regular de caminhada
37 – Hazards in your home	V1 - riscos em sua casa V2 - empecilhos em sua casa	Riscos em sua casa
38 – Operating a vehicle requiring your foot to maneuver	V1 - Operando um veículo que requer seu pé para manobrar V2 - Guiando um veículo que exija manobra com o pé	Conduzindo um veículo que exija o pé para manobrar
45 – Outdoor activities	V1 - atividades externas V2 - atividades ao ar livre	Atividades do lado de fora
62 – Burden of taking medication	V1 - Obrigação de tomar medicamentos V2 - A obrigação de tomar remédios	Obrigação de tomar medicamentos

V1 = translator 1 version; V2 = translator 2 version; V3 = consensual version in Portuguese after translation phase.

In the pretest phase, items that were not understood were altered based on suggestions provided by the patients, thus leading to the final version of the questionnaire in Portuguese (**Table 3**).

DISCUSSION

The translation and cultural adaptation process on the revised foot function index, for use in Portuguese was performed and the Portuguese language version for use in Brazil was achieved. The cultural adaption process for the FFI-R[8] followed the method proposed by Beaton et al.[15] Several other questionnaires that have been translated and validated for the Portuguese language have followed this model, such as the FFI,[9] WOMAC (Western Ontario and McMaster Universities)[17] and FAOS.[18] The questionnaire was administered to a greater number of young, physically active women, which was similar to the method that had been used for the original questionnaire.[8] In the initial phase of translation into the Portuguese language, the term "five pounds" was replaced with 2 kg by the expert committee, since this is the measurement unit for mass that is used in Brazil, thereby allowing patients to correlate the measurement unit with the mass of common objects used in everyday life.

In the back translation, question 35 was discussed during the analysis by the committee because it had been translated in a literal fashion. The expression "keeping your foot clean" in English is quite precise and specific, but when translated into Portuguese, this resulted in "*mantendo o pé limpo*", which caused a lack of understanding. Nevertheless, the committee suggested that this question should be kept in the same format for the pretest phase, to test its clarity in practice. In the first phase of the pretest, approximately 50% of the interviewees had doubts about the meaning and the expression *"mantendo a higiene do pé"* [maintaining the hygiene of the foot] was suggested. After this change, there were no longer any doubts in the second phase of the pretest.

In the backtranslated version of item 62, the committee thought that the original word "burden" did not have the same meaning as the backtranslated word (obligation, from *"obrigação"*). Therefore, the word in the Portuguese version was replaced with "*incômodo*" [inconvenience], to maintain the same idea as in the original word.

With regard to the term *"rigidez"* [stiffness], the interviewees defined it as passive resistance of muscles, tendons, ligaments and fascia, since rigidity is a mechanical property relating to resistance of these tissues to deformation in the absence of muscle contraction.[19]

In the original questionnaire, the Likert scale has a fifth option ("does not apply") for some items. In the second phase of the pretest, this option 5 was added to more items, as shown in **Table 3**, since these items did not apply to the majority of the individuals interviewed. In the sample, 80% of the participants were students at a public university and 12% had completed their university education. Thus, there was no considerable difference with regard to the level of understanding of the questionnaire among the interviewees.

Original questionnaires in English that have been validated for use in Brazil are generally submitted to a pretest process to obtain the final version in Portuguese, as well as to evaluate the psychometric properties, such as reliability and validity, which are applied in interview form. This type of application has been used in Brazil because of the profile of the populations evaluated during the process, most of whom are recruited from public clinics and hospital services. Although the use of two pretest phases is not commonly found in the literature, important questionnaires that have frequently been cited, such as the SF-36,[20] FHSQ[4] and WORC,[19] have also used this model. Pretesting is an important phase in the cultural adaptation process, since it demonstrates patients' interpretation of the items in a questionnaire. Thus, two pretest phases were used for the FFI-R to ensure that the final version would be understood by more than 90% of the patients[21,22] and that the questionnaire would be culturally adapted to the Brazilian population. The psychometric properties of the FFI-R are currently in the test phase to validate the questionnaire for use in Brazil.

Table 2. Back translation phase. Changes in "V4" e "V5" to obtain "V6

Terms used in items of "V3"	Modifications that were made to achieve the pretest version "V6"
8 – Dia típico	Dia normal
11 – Na pior situação	Na pior crise de dor
36 – Dispositivos auxiliares	Dispositivos auxiliares (bengala, muleta ou andador)
37 – Devido aos riscos em sua casa	Devido aos riscos e perigos ao seu pé em sua casa (tapetes soltos, pisos molhados etc.)
38 – Conduzindo um veículo que exija o pé para manobrar	Conduzindo um veículo (carro, moto, bicicleta etc.) que exija o pé para manobrar
56 – Sentiu-se mal	Sentiu-se incomodado
62 – Obrigação de tomar medicamentos	Incômodo de tomar medicamentos

V3 = consensual Portuguese version of V1 and V2; V6 = final Portuguese version, after analyzing the original version, V3, V4 and V5.

Table 3. Modifications to the pretest phase that were made

Items in which terms were "not understood"	Modifications suggested by patients
9 – Quando teve câimbras no pé	Adicionar o item 5, indicando que a pergunta não se aplica
31 – Descendo uma ladeira	Adicionar o item 5, indicando que a pergunta não se aplica.
35 – Pé limpo	"Higiene do pé" e dar exemplos (no banho, cortar unhas etc.)
36 – Dispositivos auxiliares	Adicionar o item 5, indicando que a pergunta não se aplica.
37 – Riscos e perigos	Dar exemplos (tapetes, piso solto etc.)
62 – Incômodo de tomar medicamentos	Adicionar o item 5, indicando que a pergunta não se aplica.
62 – Obrigação de tomar medicamentos	Incômodo de tomar medicamentos

CONCLUSION

The translation and cultural adaptation of the FFI-R for the Portuguese language were completed and the Brazilian version was obtained.

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What do Cochrane systematic reviews say about probiotics as preventive interventions?

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KEY WORDS:
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Probiotics.
Preventive medicine.
Evidence-based medicine.
Evidence-based practice.

ABSTRACT

BACKGROUND: Probiotics have been used for a range of clinical situations and their use is strongly encouraged by the media worldwide. This study identified and summarized all Cochrane systematic reviews about the preventive effects of probiotics in clinical practice.

DESIGN AND SETTING: Review of systematic reviews, conducted in the Discipline of Evidence-Based Medicine, Escola Paulista de Medicina (EPM), Universidade Federal de São Paulo (Unifesp).

METHODS: We included all Cochrane reviews on any probiotics when they were used as preventive interventions and compared with no intervention, placebo or any other pharmacological or non-pharmacological intervention.

RESULTS: 17 Cochrane systematic reviews fulfilled our inclusion criteria and were summarized in this report. None of the reviews included in the present study provided high-quality evidence for any outcome. The benefits from use of probiotics included decreased incidence of antibiotic-associated diarrhea and *Clostridium difficile*-associated diarrhea; decreased incidence of upper respiratory tract infections and duration of episodes; decreased need for antibiotics and absences from school due to colds; and decreased incidence of ventilator-associated pneumonia. Probiotics seem to decrease the incidence of gestational diabetes mellitus, birthweight, risk of vaginal infection and incidence of eczema.

CONCLUSION: Despite the marketing and the benefits associated with probiotics, there is little scientific evidence supporting the use of probiotics. None of the reviews provided any high-quality evidence for prevention of illnesses through use of probiotics. More trials are needed to gain better knowledge of probiotics and to confirm when their use is beneficial and cost-effective.

INTRODUCTION

More than 400 species of microorganisms dwell in the human gastrointestinal tract.[1,2] Balance between them is vital for the host's health. Present-day high usage of antibiotics, together with environmental and physiological factors, can alter this ecosystem. This imbalance can cause illnesses such as diarrhea, which was responsible for 1.31 million deaths in 2015, including 499,000 among children under five.[3,4] Some research has shown that use of probiotics can confer some health benefits, such as treatment for diarrheal disease, prevention of systemic infections and other effects.[2,5]

The 2001 definition from the World Health Organization (WHO) states that probiotics are "live microorganisms which, when administered in adequate amounts, confer a health benefit on the host".[6] They are currently presented by media sources as an attractive health promotion method that prevents or cures a range of clinical situations.[7] Indeed, many trials assessing the effects of probiotics (including using different species of microorganisms) as preventive or therapeutic options for a range of diseases have been conducted and published.[2,5] Consequently, a considerable amount of published data is currently available through MEDLINE. Corroborating this, a search in this database carried out on July 26, 2017, using the MeSH (medical subheading) term probiotics, retrieved 12,370 records, which corresponded to an increase of 278% in the number of records over the last ten years (from December 2007 to July 2017).

The questions that therefore arise are: Should probiotics be indicated for preventive purposes? And if so, for which patients? Which types of probiotics should be used, and at what dose and for how long?

In this review, we identified and summarized all Cochrane systematic reviews about the preventive effects of probiotics in clinical practice.

OBJECTIVE

To summarize the evidence from Cochrane systematic reviews focusing on probiotics for prevention of any disease or condition.

METHODS

Design

Review of Cochrane systematic reviews.

Setting

Discipline of Evidence-Based Medicine of Escola Paulista de Medicina (EPM), Universidade Federal de São Paulo (UNIFESP).

Criteria for including reviews

- Types of studies
  We only included the latest version of completed Cochrane systematic reviews (SR). We excluded any published protocols or any SR marked as "withdrawn" in the Cochrane Database of Systematic Reviews (CDSR).
- Types of participants
  We included healthy participants or those diagnosed with any clinical condition or disease.
- Types of intervention
  This review included any probiotics that were used as preventive interventions and compared with no intervention, placebo or any other pharmacological or non-pharmacological intervention.
- Type of outcomes
  We considered any clinical, social and laboratory outcomes, as evaluated in the systematic reviews that were included.

Search for reviews

We carried out a sensitive systematic search in the Cochrane Database of Systematic Reviews (via Wiley) on July 1, 2017. The search strategy is presented in **Table 1**.

Selection of systematic reviews

Two of the three researchers (VLB, LPDSR and DDB) independently and randomly selected and evaluated all references that were retrieved through the systematic search, to confirm their eligibility in accordance with the inclusion criteria. Any disagreements were resolved by consulting a more experienced author (RR).

Presentation of the results

We presented all the reviews included in this synthesis in a narrative manner (qualitative synthesis). The key points considered were their relevance, methods, results, quality of the body of the evidence for each outcome, and applicability.

RESULTS

Search results

The initial search resulted in 39 reviews and 13 protocols. First, we excluded all protocols. After full-text assessment, we excluded 23 reviews since they either considered use of probiotics to be therapeutic interventions rather than preventive interventions or did not analyze probiotics alone. Thus, 16 Cochrane systematic reviews fulfilled our inclusion criteria and were summarized in this report.

Results from systematic reviews

Among the 16 systematic reviews included, a range of probiotic strains was used. Four systematic reviews tested their use only among adults,[8-11] three only among children[12-14] and five among both adults and children,[15-19] while another four studies did not specify the age range of the population evaluated.[20-23] Two systematic reviews addressed prevention of respiratory diseases,[11,15] nine addressed prevention of gastroenterological diseases,[9,10,13,14,16-18,20,21] three addressed gynecological and obstetric diseases,[8,22,23] one addressed urological diseases[19] and one addressed immunological/allergic diseases.[12] A summary of the reviews included is presented below. The main findings for each comparison and the quality of the evidence (based on the GRADE approach) are presented in **Table 2**.[8-23]

Table 1. Search strategy (July 1, 2017)

#1 "Probiotics" OR "Probiotic" OR "lactobacillus" OR "lactobacilus" OR "lactobacilli" OR "lactobacili" OR "betabacterium" OR "lactobacileae" OR "lactobacilleae" OR "lactobacteria" OR "Lactobacillus acidophilus" OR "Lactobacilus acidophilus" OR "Lactobacillus casei" OR "Lactobacilus casei" OR "Lactobacillus delbrueckii" OR "Lactobacilus delbrueckii" OR "Lactobacillus fermentum" OR "Lactobacilus fermentum" OR "Lactobacillus helveticus" OR "Lactobacilus helveticus" OR "Lactobacillus leichmannii" OR "Lactobacilus leichmannii" OR "Lactobacillus plantarum" OR "Lactobacilus plantarum" OR "Lactobacillus reuteri" OR "Lactobacilus reuteri" OR "Lactobacillus rhamnosus" OR "Lactobacilus rhamnosus" OR "bifidobacterium" OR "lactococcus" OR "streptococcus thermophilus" OR "saccharomyces" OR "bifidobacterium" OR "bacillus subtilis" OR "bacillus licheniformis" OR "bugarian bacillus" OR "enterococcus faecalis" (Probiotics) OR (Probiotic) OR (lactobacillus) OR (lactobacilus) OR (lactobacilli) OR (lactobacili) OR (betabacterium) OR (lactobacileae) OR (lactobacilleae) OR (lactobacteria) OR (Lactobacillus acidophilus) OR (Lactobacilus acidophilus) OR (Lactobacillus casei) OR (Lactobacilus casei) OR (Lactobacillus delbrueckii) OR (Lactobacilus delbrueckii) OR (Lactobacillus fermentum) OR (Lactobacilus fermentum) OR (Lactobacillus helveticus) OR (Lactobacilus helveticus) OR (Lactobacillus leichmannii) OR (Lactobacilus leichmannii) OR (Lactobacillus plantarum) OR (Lactobacilus plantarum) OR (Lactobacillus reuteri) OR (Lactobacilus reuteri) OR (Lactobacillus rhamnosus) OR (Lactobacilus rhamnosus) OR (bifidobacterium) OR (lactococcus) OR (streptococcus thermophilus) OR (saccharomyces) OR (bifidobacterium) OR (bacillus subtilis) OR (bacillus licheniformis) OR (bugarian bacillus) OR (enterococcus faecalis) *in Title, Abstract, Keywords*
#2 #1 *in Cochrane Reviews (complete)*

Moderate quality of evidence

Antibiotic-associated diarrhea among children

The review[13] assessed the efficacy and safety of probiotics for prevention of antibiotic-associated diarrhea (AAD) among children and included 23 RCTs (938 children, aged 0 to 18 years) that compared different types of probiotics versus active treatment, placebo or no treatment. The incidence of antibiotic-associated diarrhea was lower in the probiotic group (relative risk, RR 0.46; 95% CI 0.35 to 0.61; number needed to treat [NNT] 10; 22 RCTs; 3,898 participants; I^2 = 55%; moderate quality of evidence). No adverse events attributable to the treatment were found (2455 participants; 16 RCTs) and there was no difference between probiotics and controls regarding the risk of adverse events for the overall population (risk difference [RD] 0.00; 95% CI -0.01 to 0.01; 16 RCTs; 2455 participants). The authors concluded that there was moderate quality of evidence that probiotics seemed to prevent AAD. However, in some groups of patients such as immunocompromised individuals and others, serious events have been observed, and therefore probiotics should be avoided in these groups. For further details, and to check the probiotics used in each study, refer to the original abstract, available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004827.pub4/full.

Clostridium difficile-associated diarrhea

The review[17] evaluated the efficacy and safety of probiotics for prevention of *Clostridium difficile*-associated diarrhea (CDAD) and included 31 RCTs (4,492 adults and children), with comparisons between probiotics and placebo or no treatment. Probiotics presented benefits for reducing the incidence of CDAD (risk ratio [RR] 0.36; 95% CI 0.26 to 0.51; 23 RCTs; 4,213 participants, moderate quality of evidence) and of adverse events (RR 0.80; 95% CI 0.68 to 0.95; 26 RCTs; 3,964 participants; moderate quality of evidence). There was no statistical difference between the groups regarding the incidence of *C. difficile* infection (RR 0.89; 95% CI 0.64 to 1.24; 13 RCTs; 961 participants; moderate quality of evidence). The authors concluded that, based on the moderate quality of evidence, use of probiotics seemed to be associated with reduction of CDAD and its adverse events. For further details, and to check the form of probiotics used in each study, refer to the original abstract, available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006095.pub3/full.

Very low to low quality of evidence

Acute upper respiratory tract infections

The review[15] evaluated the effectiveness and safety of probiotics for prevention of acute upper respiratory tract infections (URTIs) and included 13 RCTs (3,780 participants) that compared probiotics with placebo. Probiotics presented benefits through reducing the following outcomes:

- the number of people who had one or more URTIs (odds ratio, OR 0.53; 95% confidence interval, CI 0.37 to 0.76; 7 RCTs; 1,927 participants; low quality of evidence);
- the number of people who had three or more URTIs (OR 0.53; 95% CI 0.36 to 0.80; three RCTs; 650 participants; low quality of evidence);
- the duration of the event (mean difference [MD] -1.89; 95% CI -2.03 to -1.75; 3 RCTs; 831 participants; low quality of evidence);
- the need for antibiotics (OR 0.65; 95% CI 0.45 to 0.94; 4 RCTs; 1,184 participants; moderate quality of evidence); and
- missing school due to colds (OR 0.10; 95% CI 0.02 to 0.47; 1 RCT; 80 children; very low quality of evidence).

No difference between the groups was found regarding adverse events (OR 0.88; 95% CI 0.65 to 1.19; 4 RCTs; 1,234 participants; low quality of evidence). The authors concluded that, based on very low to low quality of evidence due to the heterogeneity between studies, use of probiotics may be associated with reductions in the numbers of URTIs, duration of the event, need for antibiotics and missing school due to URTIs. For further details, and to check the form of probiotics used in each study, refer to the original abstract, available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006895.pub3/full.

Bacterial sepsis and wound complications after liver transplantation

The review[16] assessed the effects of different interventions for prevention of bacterial sepsis and wound complications in patients undergoing liver transplantation. Seven RCTs were included in this review, but only two (161 participants) assessed preventive effects of probiotics. There was no difference between probiotics plus prebiotics and selective bowel decontamination regarding the risk of needing retransplantation (OR 2.91; 95% CI 0.12 to 68.81; 1 RCT; 63 participants) or the risk of graft rejection requiring medical treatment (OR 1.94; 95% CI 0.38 to 9.83; 1 RCT; 63 participants). In comparing probiotics plus prebiotics with prebiotics, there was no difference regarding the risk of retransplantation (OR 0.33; 95% CI 0.01 to 7.90; 2 RCTs; 129 participants) or the risk of graft rejection requiring medical treatment (OR 0.69; 95% CI 0.12 to 3.84; 1 RCT; 63 participants). The authors' conclusion was that there was no evidence to support use of probiotics for reducing wound complications and bacterial sepsis in patients with previous liver transplantation. For further details, and to check the probiotics used in each study, refer to the original abstract, available at: http://

Table 2. Characteristics, main findings and quality of evidence from systematic reviews focusing on patient-directed interventions with probiotics

Population and aim	Comparison	Benefits and harm of probiotics	Quality of evidence (GRADE approach)
Pediatric patients receiving antibiotics[13]	Probiotics versus placebo	Benefits: decreased incidence of antibiotic-associated diarrhea Risk of some adverse effects in immunocompromised, severely debilitated and other patients	Moderate
Adults and children receiving antibiotics[17]	Probiotics versus placebo or no treatment	Benefit: decreased incidence of adverse events relating to *Clostridium difficile*-associated diarrhea No benefit regarding incidence of *Clostridium difficile* infection	Moderate
Adults, children and the elderly[15]	Probiotics versus placebo	Benefit: decreased incidence of upper respiratory tract infections, duration of episodes, need for antibiotics and missing school due to colds No difference in adverse events	Very low to low
Patients undergoing liver transplantation[16]	Prebiotics alone or plus probiotics versus selective bowel decontamination; Prebiotics plus probiotics versus prebiotics	Benefits: prebiotics plus probiotics decreased the proportion of participants with infections and the number of infectious episodes No benefit regarding mortality, need for retransplantation, graft rejection, intensive care unit stay or hospital stay	Very low
Patients after liver resection[9]	Probiotics alone or plus prebiotics versus placebo or prebiotics plus probiotics postoperatively	No benefit regarding mortality	Low
Patients with quiescent ulcerative colitis[20]	Probiotics versus placebo or mesalazine	No benefit regarding prevention of relapses and adverse events	Low
Patients undergoing ileal pouch-anal anastomosis for chronic ulcerative colitis[10]	Probiotics versus placebo or other treatment	No benefit regarding prevention of pouchitis.	Very low
Patients susceptible to urinary tract infection and healthy people[19]	Probiotic versus placebo; probiotics versus antibiotics; probiotic versus no treatment	No benefit regarding symptomatic bacterial urinary tract infection	Low
Patients receiving mechanical ventilation[11]	Probiotics versus placebo	Benefit: decreased incidence of ventilator-associated pneumonia No effects regarding intensive care unit mortality, in-hospital mortality, incidence of diarrhea, length of intensive care unit stay, duration of mechanical ventilation or antibiotic use	Very low to low
Women with HIV-infection for prevention of vulvovaginal candidiasis[23]	Probiotics versus placebo or clotrimazole	No benefit regarding prevention of vulvovaginal candidiasis infection	Low
Infants with family history of allergy or food hypersensitivity and healthy infants[12]	Probiotics alone or plus prebiotics versus placebo	Benefit: decreased incidence of infant eczema No benefit regarding food hypersensitivity, asthma, atopic eczema, allergic rhinitis, food allergy or urticaria	Not assessed
Pregnant women without metabolic or chronic diseases[8]	Probiotics versus placebo or diet	Benefit: probiotics decreased both the rate of gestational diabetes mellitus and the birthweight No benefit regarding death (abortion, intrauterine fetal death, stillbirth or neonatal death), risk of premature birth or cesarean delivery rate	Not assessed
Patients with Crohn's disease[18]	Probiotics versus placebo or other treatment	No benefit regarding reduction of the risk of relapse after surgically-induced remission, compared with use of aminosalicylates or azathioprine. Risk of some adverse effects from *Lactobacillus GG*	Not assessed
Infants born at gestational age of less than 37 weeks or weighing less than 2500 g at birth, or both[14]	Probiotics versus placebo or no treatment	Benefit: decreased incidence of severe necrotizing enterocolitis and mortality among preterm infants No effect regarding nosocomial sepsis	Not assessed
Patients undergoing surgery related to Crohn's disease[21]	Probiotics versus placebo	No benefit regarding clinical recurrence, severe endoscopic recurrence or any endoscopic recurrence	Not assessed
Pregnant women[22]	Probiotics versus placebo or acetic acid	Benefit: decreased risk of vaginal infection No effect regarding prevention of preterm birth	Not assessed

onlinelibrary.wiley.com/doi/10.1002/14651858.CD006660.pub3/full.

Infections after liver resection

The review[9] assessed the benefits and harm of different interventions for prevention of infectious complications and improving the outcomes after liver resection. Seven RCTs were included, but only two RCTs (125 participants) evaluated probiotics as preventive interventions. One of these compared use of prebiotics and probiotics versus placebo and found that there was no difference in mortality (RR 0.36; 95% CI 0.10 to 1.35; 44 participants). The other RCT, with 81 participants, compared use of preoperative and postoperative prebiotics and probiotics versus use of postoperative prebiotics and probiotics and found that there was no significant difference in mortality (RR 0.39; 95% CI 0.15 to 1.00). Both of these studies presented low quality of evidence.

The authors' conclusion was that there was no evidence to support or refute the use of any type of treatment to decrease the frequency of infectious complications after liver resection. For further information, refer to: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006933.pub2/full.

Maintenance of remission in ulcerative colitis

The review[20] assessed the efficacy and safety of probiotics for prevention of relapses in cases of ulcerative colitis. Four RCTs (587 participants) were included and these showed the following: probiotics versus mesalazine: no difference between the groups regarding the risk of relapse (OR 1.33; 95% CI 0.94 to 1.90; 3 RCTs; 555 participants; low quality of evidence) or the incidence of adverse events (OR 1.21; 95% CI 0.80 to 1.84; 2 RCTs; 430 participants; moderate quality of evidence); probiotics versus placebo: no difference between the groups regarding the risk of relapse (OR 0.27; 95% CI 0.03 to 2.68; 1 RCT; 32 participants; moderate quality of evidence). The authors concluded that there was insufficient evidence to support use of probiotics for preventing relapses in cases of ulcerative colitis. For further details, and to check the form of probiotics used in each study, refer to the original abstract, available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007443.pub2/full.

Pouchitis after ileal pouch-anal anastomosis for ulcerative colitis

The review[10] assessed the effectiveness of different interventions for prevention of pouchitis after ileal pouch-anal anastomosis in cases of chronic ulcerative colitis. Thirteen RCTs were included in this review, but only two studies were about the use of probiotics. One RCT assessed prevention of pouchitis in patients with ileal pouch-anal anastomosis and showed that there were no benefits from using *Bifidobacterium longum*, in comparison with placebo (RR 1.43; 95% CI 0.66 to 3.11; 1 RCT; 12 participants; very low quality of evidence).

Another outcome assessed related to treatment of acute pouchitis. One RCT with 20 participants compared the use of *Lactobacillus GG* with placebo and there was no difference in clinical improvement (RR 3.95%; CI 0.14 to 65.9), with very low quality of evidence.

The authors' conclusions, based on the very low quality of evidence, was that probiotics did not seem to prevent pouchitis after ileal pouch-anal anastomosis in cases of chronic ulcerative colitis or to have any effect in treatments for patients with acute pouchitis. For more information about the other types of treatment in this study, refer to this link: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001176.pub3/full.

Urinary tract infections

The review[19] evaluated the effects of probiotics for prevention of urinary tract infections in susceptible or healthy adults and children. Nine RCTs (735 participants) were included and these showed that there was no difference in the risk of symptomatic bacterial urinary tract infection, in comparisons of use of probiotics versus placebo (OR 0.82; 95% CI 0.60 to 1.12; 6 RCTs; 352 participants) or use of probiotics versus antibiotics (OR 1.12; 95% CI 0.95 to 1.33; 1 RCT; 158 women).

The authors concluded that, based on the few studies available, which were of small size (low quality of evidence), there was no benefit from using probiotics, in comparison with placebo or no treatment. For further details, and to check the probiotics used in each study, refer to the original abstract, available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008772.pub2/full.

Ventilator-associated pneumonia

The review[11] assessed the effects of probiotics for prevention of ventilator-associated pneumonia (VAP). Eight randomized clinical trials (RCTs) (1,083 adults) that compared use of probiotics with placebo, usual care and multiple treatment arms were included. Probiotics were shown to present some benefit regarding reduction of the incidence of VAP (odds ratio, OR 0.70; 95% CI 0.52 to 0.95; 8 RCTs; 1,018 participants; low quality evidence). No difference was found between the probiotics and control groups in relation to the following outcomes,:

- intensive care unit (ICU) mortality (OR 0.84; 95% CI 0.58 to 1.22; 5 RCTs; 703 participants; very low quality of evidence);
- in-hospital mortality (OR 0.78; 95% CI 0.54 to 1.14; 4 RCTs; 524 participants; very low quality of evidence);
- incidence of diarrhea (OR 0.72; 95% CI 0.47 to 1.09; 4 RCTs; 618 participants; low quality of evidence);
- length of ICU stay (mean difference, MD -1.60; 95% CI -6.53 to 3.33; 4 RCTs; 396 participants; very low quality of evidence);

- duration of mechanical ventilation (MD -6.15; 95% CI -18.77 to 6.47; 2 RCTs; 203 participants; very low quality of evidence); and
- antibiotic use (OR 1.23; 95% CI 0.51 to 2.96; 1 RCT; 259 participants; low quality of evidence).

The authors concluded that, based on the low quality of evidence, use of probiotics may be associated with reduction in VAP. For further details, and to check the probiotics used in each study, refer to the original abstract, available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD011513.pub2/abstract.

Vulvovaginal candidiasis in HIV-infected women

The review[23] aimed to assess the effects of many antifungals that are administered vaginally or orally, including probiotics, for treatment and prevention of vulvovaginal candidiasis (VVC) in HIV-infected women. Two trials (431 participants) on use of probiotics as preventive interventions were included. No difference regarding this outcome was found in comparisons of probiotics versus clotrimazole (RR 1.11; 95% CI 0.45 to 2.76; low quality of evidence) or versus placebo (RR 0.54; 95% CI 0.26 to 1.13; low quality of evidence). The authors' conclusion was that no implications for practice could be determined. For other results from this review, refer to this link: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008739.pub2/full.

Quality of evidence not assessed

Allergic disease and food hypersensitivity among children

The review[12] assessed the effect of probiotics for prevention of allergic disease relating to food hypersensitivity among infants. It included 12 RCTs that compared use of probiotics with placebo or use of probiotics plus prebiotics with placebo. The overall results from the pooled data showed that the incidence of infant eczema was reduced in the probiotics group (RR 0.82; 95% CI 0.70 to 0.95; 5 RCTs; 1,477 participants; I^2 = 63.6%). However, these studies were heterogeneous and there was no statistical difference when the analysis was limited to atopic eczema (RR 0.80; 95% CI 0.62 to 1.02). There was also no significant difference regarding the other outcomes evaluated. The authors concluded that there was insufficient evidence to support use of probiotics for preventing allergies or food hypersensitivity among infants, given that the findings were inconsistent and there were many follow-up losses. For further details, and to check the form of probiotics used in each study, refer to the original abstract, available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006475.pub2/full.

Gestational diabetes in women without metabolic or chronic diseases

The review[8] evaluated the effects of probiotics for prevention of gestational diabetes mellitus (GDM). One RCT (256 pregnant women) was included and it found that there were benefits from use of probiotics (compared with placebo or diet) for reducing the rate of GDM (RR 0.38; 95% CI 0.20 to 0.70; 225 women) and for reducing the birthweight (MD -127.71 g; 95% CI -251.37 to -4.06; 256 women). No difference between the groups was found for the following outcomes:

- death (OR 2.00; 95% CI 0.35 to 11.35; 256 women);
- risk of premature birth (RR 3.27; 95% CI 0.44 to 24.43; 238 women);
- cesarean delivery (RR 1.23; 95% CI 0.65 to 2.32; 218 women).

All the infants included in this study were within the normal range for birthweight. The authors concluded that use of probiotics seemed to be associated with reduction in GDM. However, they considered that further studies would be required to confirm these results. For more details, and to check the form of probiotics used in each study, refer to the original abstract, available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009951.pub2/full.

Maintenance of remission of Crohn's disease

The review[18] assessed the effectiveness of probiotics for maintenance of remission in cases of Crohn's disease. Seven RCTs, comparing use of probiotics versus placebo, were included. In evaluating the risk of relapse among adults, there were no differences between the following:

- *E. coli* Nissle and placebo (RR 0.43; 95% CI 0.15 to 1.20; 1 RCT; 20 participants);
- *Lactobacillus GG* and placebo after surgically-induced remission (RR 1.58; 95% CI 0.30 to 8.4; 1 RCT; 37 participants) or medically-induced remission (RR 0.83; 95% CI 0.25 to 2.80; 1 RCT; 9 participants);
- *Lactobacillus GG* and maintenance therapy with aminosalicylates or azathioprine (RR 0.67; 95% CI 0.13 to 3.30; 1 RCT; 24 participants).

Regarding the risk of relapse among children, there was no difference between *Lactobacillus GG* and placebo (RR 1.85; 95% CI 0.77 to 4.40; 1 RCT; 75 participants).

Regarding the risk of adverse events, *Lactobacillus GG* was associated with a risk of adverse events in comparison with maintenance therapy using aminosalicylates or azathioprine (no numerical data provided). A small RCT found that, at the end of the study, there was no difference in use of *Saccharomyces boulardii* plus conventional maintenance therapy versus placebo

plus conventional maintenance therapy for relapses, according to the clinical disease activity index (CDAI) (RR 0.17; 95% CI 0.02 to 1.23).

The authors concluded that there was no evidence that probiotics were beneficial for maintenance of remission in cases of Crohn's disease. For further details, and to check the probiotics used in each study, refer to the original abstract, available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004826.pub2/full.

Necrotizing enterocolitis in premature newborns

The review[14] assessed the efficacy and safety of probiotics for prevention of severe necrotizing enterocolitis (NEC) or sepsis in premature infants. Twenty-four RCTs, comparing use of probiotics with placebo or no treatment, were included. Probiotics showed some benefit regarding reduction of the incidence of severe NEC (RR 0.43; 95% CI 0.33 to 0.56; 20 RCTs; 5,529 infants) and all-cause mortality (RR 0.65; 95% CI 0.52 to 0.81; 17 RCTs; 5,112 infants). Comparison between use of probiotics and placebo or no treatment showed that there was no statistical difference in the incidence of nosocomial sepsis (RR 0.91; 95% CI 0.80 to 1.03; 19 RCTs; 5,338 infants). The authors concluded that use of enteral probiotics seemed to be associated with reduction of severe NEC and mortality among premature infants. For further details, and to check the form of probiotics used in each study, refer to the original abstract, available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005496.pub4/full.

Postoperative recurrence of Crohn's disease

The objective of the review[21] was to evaluate the medical therapies for prevention of postoperative recurrence of Crohn's disease. It included 23 RCTs, but only 4 RCTs were about probiotics. These RCTs found that there was no difference between probiotics and placebo regarding the risk of clinical recurrence (RR 1.41; 95% CI 0.59 to 3.36; 3 RCTs; 213 adults), risk of severe endoscopic recurrence (RR 0.96; 95% CI 0.58 to 1.59; four RCTs; 333 adults) or risk of any endoscopic recurrence (RR 0.98; 95% CI 0.74 to 1.29; 3 RCTs; 213 adults). The authors concluded that there was no difference in effect between use of probiotics and placebo. For information on the other medical therapies included in this review, refer to this link: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006873.pub2/full.

Preterm labor

The review[22] assessed the effectiveness and safety of probiotics for prevention of premature labor and delivery and included three RCTs (344 pregnant women) that compared use of probiotics with acid acetic and placebo. The following results were found: use of probiotics reduced the risk of vaginal infection in comparison with the controls (acetic acid or placebo) (RR 0.19; 95% CI 0.08 to 0.48; 88 pregnant women); comparison of use of probiotics plus dietary counselling versus control (placebo plus dietary counselling or placebo only) showed that there was no difference between the groups regarding birth at gestational ages of less than 32 weeks (RR 0.65; 95% CI 0.03 to 15.88; 1 RCT; 238 pregnant women) or birth between the gestational ages of 32 and 37 weeks (RR 3.95; 95% CI 0.36 to 42.91; 1 RCT; 238 pregnant women).

The authors concluded that use of probiotics seemed to be associated with lower risk of vaginal infection during pregnancy and that there was insufficient evidence to support their use for prevention of premature birth. For further details, and to check the form of probiotics used in each study, refer to the original abstract, available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005941.pub2/full.

DISCUSSION

This overview found that despite increasing marketing of probiotics, there are still few systematic reviews on the preventive use of probiotics and there is a scarcity of high-quality randomized trials. None of the reviews included in the present study provided high-quality evidence for any outcome.

Many clinical trials assessed in this study showed very low or low quality of evidence. Another point that needs to be noted is the huge variety of probiotics that have been considered in RCTs. This made it difficult to identify the individual effect of each probiotic agent, and also precluded meta-analyses.

Most of the studies focused on gastrointestinal diseases. We found that there were some benefits from use of probiotics, with moderate quality of evidence, regarding their use for decreasing the incidence of antibiotic-associated diarrhea among children[13] and the incidence of *Clostridium difficile*-associated diarrhea among adults and children.[17] Other benefits that were observed with very low or low quality of evidence were that use of probiotics decreased the incidence of infections and the number of infectious episodes in patients undergoing liver transplantation.[16] The benefit of decreased incidence of severe necrotizing enterocolitis and mortality among preterm infants was noted in another review, but the quality of its evidence could not be assessed.[14]

In relation to respiratory diseases, probiotics showed some benefits regarding decreased incidence of upper respiratory tract infections and duration of episodes, the need for antibiotics and missing school due to colds,[15] and regarding the incidence of ventilator-associated pneumonia in patients receiving mechanical ventilation.[11] These studies were classified as presenting very low or low quality of evidence, using the GRADE approach.

In three systematic reviews about gynecological and obstetric diseases, we found that there were some benefits in relation to decreasing the rate of gestational diabetes mellitus, decreasing both the birthweight[8] and the risk of vaginal infection,[22] although the quality of evidence could not be assessed. One RCT found that there was a benefit in relation to reducing the incidence of eczema among infants with a family history of allergy or food hypersensitivity and among healthy infants.[12]

Despite the potential benefits of probiotics, we did not find any high-quality evidence that could change clinical practice or recommendations for their use. Furthermore, some probiotics may be harmful in groups of patients such as those presenting immunosuppression, severe debilitation and other such conditions. On the other hand, it is important to examine the number needed to treat (NNT) and to analyze the cost-effectiveness of use of probiotics. Goldenberg et al. concluded that the NNT to prevent one case of diarrhea was ten. Thus, in this example, probiotics reduced the number of cases of diarrhea even with only a few patients treated.[13] To prevent *Clostridium difficile*-associated diarrhea, 29 patients would need to be treated.[17]

Our systematic review has the advantage of the number of studies included, given that the topic of probiotics is currently a matter of debate and that there are uncertainties regarding their effectiveness. Another advantage is that it summarizes the evidence relating to probiotics and their use that has been gathered in the Cochrane Library, which is recognized as the largest database of systematic reviews, given that the information about probiotics is distributed among many studies.

This overview has some limitations. Our search was conducted in a single database, even though the Cochrane Library is recognized as the most important database of systematic reviews. The limited data available is a consequence of the small number of papers, and the low quality of evidence is related to the small sample sizes and bias of the RCTs. Another point that should be noted is the huge variety of prebiotics that have been considered in RCTs, which led to difficulty in identifying the individual effect of each probiotic agent, and also precluded meta-analyses. The NNT was not determined in some reviews, which made it more challenging to analyze cost-effectiveness.

Regarding the implications for practice, our study summarizes the use of probiotics as a preventive intervention for some clinical settings and shows the situations in which there is a real benefit. From this, healthcare professionals can decide when to indicate probiotics for patients and can improve outcomes in their hospitals. For example, probiotics can be used to reduce the incidence of vaginal infection during pregnancy and to decrease the incidence of VAP. On the other hand, probiotics should not be recommended when there is uncertainty about their benefits and harm.

Here, we make it clear that much needs to be done in relation to studying probiotics. Firstly, basic research is needed in order to elucidate the pathophysiological links between different diseases and use of probiotics. Secondly, RCTs with high-quality evidence are needed, with larger sample sizes and better control over variables. Thirdly, research on the cost-effectiveness of use of probiotics needs to be stimulated, because their use must be analyzed in terms of their consequences for health and economic repercussions.

CONCLUSION

This overview included 16 Cochrane systematic reviews about the use of probiotics as preventive measures within clinical practice. There was little scientific evidence to support the use of probiotics. None of the reviews provided high-quality evidence for preventive action achieved through use of probiotics and each review analyzed only a few randomized controlled trials.

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AIM AND EDITORIAL POLICY

Indexing and scope

São Paulo Medical Journal (formerly Revista Paulista de Medicina) was founded in 1932 and is now published bimonthly by the Associação Paulista de Medicina. It accepts articles in the fields of clinical health science (internal medicine, gynecology & obstetrics, mental health, surgery, pediatrics, epidemiology and public health). Articles will be accepted in the form of original articles, narrative reviews, case reports, short communications and letters to the editor. Papers with a commercial objective will not be accepted.

The journal's articles are indexed in MEDLINE, LILACS, SciELO, Science Citation Index Expanded, Journal Citation Reports/Science Edition (ISI) and EBSCO Publishing.

The Journal's peer review policy and procedures

After receipt of the article through the electronic submission system, it will be read by the Editorial Team, who will check whether the text complies with the journal's Instructions for Authors. The Journal has adopted the CrossRef Similarity Check system for identifying plagiarism and any text that has been plagiarized, in whole or in part, will be rejected.

When the format of the manuscript is deemed acceptable, the Editorial Team will submit the article to the Editor-in-Chief who will assign at least two reviewers/referees with expertise in the theme, to assess it. The authors will then receive the reviewers' evaluation and will be required to provide all further information requested and the corrections that may be necessary. Changes to the text should be highlighted, accompanied by a letter answering the referees' comments, point by point.

Once the Editorial Team has received the revised manuscript, the text will be sent to the Editor-in-Chief for a decision. Manuscripts that are suitable for publication according to their scientific merit will be considered "accepted." However, all of them will subsequently be scrutinized to check for any problems regarding sentence construction, spelling, grammar, bibliographical references and other matters that may arise. The authors should contribute towards improving the manuscript by making it as readable as possible. Lastly, the Editorial Team will provide page proofs for the authors to approve. No article is published without this final procedure.

São Paulo Medical Journal does not charge authors for publication: there are no submission fees for the evaluation of articles. The Journal is an open-access publication that does not charge the readers, either. Articles accepted for publication become the journal's property for copyright purposes, in accordance with the Creative Commons attribution-type BY.

THE MANUSCRIPT AND TYPES OF ARTICLES

General guidelines: for all types of articles

All manuscripts must be submitted in English with a covering letter signed by the corresponding author. The letter must contain the following five essential items relating to the manuscript:

1. a declaration that the manuscript is original and that the text has not been nor will be submitted for publication in any other journal.
2. a statement that the manuscript has been approved by all authors, who agree to cede the copyrights to the Journal, disclose all sources of funding and declare all potential conflicts of interest.
3. a statement that implementation of the study was endorsed by an Internal Review Board (Ethics Committee), including the date and number of the approval (in the case of original articles).
4. a brief description of contributorship.
5. a list of a minimum of five potential referees outside of the authors' institutions.

The Journal recommends that all articles submitted must comply with the editorial quality standards established in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (available at www.icmje.org).[1] This means that each type of study must be described in accordance with the specific quality guidelines for papers reporting on clinical trials (CONSORT),[2] systematic reviews and meta-analyses (PRISMA),[3,4] observational studies (STROBE),[5,6] case reports (CARE)[7] and accuracy studies on diagnostic tests (STARD).[8,9]

Abbreviations must not be used, even those in everyday use. Drugs or medications must be referred to using their generic names, avoiding casual mention of commercial or brand names. All drugs should be followed by the dosage and posology used. Any product cited in the Methods section, such as diagnostic or therapeutic equipment, tests, reagents, instruments, utensils, prostheses, orthoses and intraoperative devices must be described together with the manufacturer's name and place (city and country) of manufacture in parentheses.

Grants, bursaries and any other financial support for studies must be mentioned separately, after the references, in a section named "Acknowledgements." This section should also be used to acknowledge any other contributions from individuals or professionals who have helped in producing the study. The Journal supports the position taken by the International Committee of Medical Journal Editors (http://www.icmje.org) regarding authorship. This body's recommendations should be read to obtain clarifications regarding the criteria for authorship.

For any manuscript, all statements in the text that do not result from the study presented for publication in the São Paulo Medical Journal but from other studies must be accompanied by a quotation of the source of the data. All statements regarding health statistics and epidemiological data should generally be followed by references to the sources that generated this information, even if the data is only available electronically.

Articles must also include an abstract and three to five keywords in English. The keywords must be selected from the MeSH list only, available from: https://www.ncbi.nlm.nih.gov/mesh (no other keywords will be accepted).

Texts must be submitted exclusively through the Internet, using the electronic submission system, which is available at http://mc04.manuscriptcentral.com/spmj-scielo. Submissions sent by e-mail or through the post will not be accepted.

Authorship

Authors of articles published in São Paulo Medical Journal should all have contributed actively to the discussion of the study results and should review and approve the final version to be released. The corresponding author is the primary guarantor of all ethical issues relating to the manuscript, before, during and after its publication. However, São Paulo Medical Journal considers that all authors are held fully responsible for the study, regarding the accuracy or integrity of data and data interpretation in the text.

All authors should create an ORCID ID record (in www.orcid.org) before submitting their article and link the submission to their existing ORCID ID in the electronic submission system. ORCID identifications help to distinguish researchers with similar names.

During submission, the authors will be asked to indicate the names of three to five referees. All of them should be from outside the institution where they work and at least two should preferably be from outside Brazil.

FORMAT

Title page (cover page)

The title page must contain:

1. Type of paper (original article, review or updating article, short communication or letter to the editor).
2. Title of the paper in English, which must be brief but informative.
3. Full name of each author (the editorial policy of the São Paulo Medical Journal is that abbreviations of authors' names must not be used; therefore, we ask that names be stated in full or omitted, without using abbreviations); his/her background (Physician, Pharmacist, Nurse, Dietitian or another professional description, or undergraduate student); and his/her position currently held (for example, Master or Doctoral Student, Assistant Professor, Associate Professor or Professor, but not Head of Department, Dean, Provost or Rector), in the department and institution where he/she works, and the city and country (affiliations).
4. Place where the work was developed.
5. Date and venue of the event at which the paper was presented, if applicable, such as congresses or dissertation or thesis presentations.
6. Sources of support in the forms of finance for the project, study bursaries or funding for purchasing equipment or drugs. The protocol number for the funding must be presented.
7. For Brazilian authors, all grants that can be considered to be related to production of the manuscript must be declared, such as fellowships for undergraduate, master and doctoral students; along with possible support for postgraduate programs (such as CAPES) and for the authors, such as awards for established investigators (*Produtividade* - CNPq), accompanied by the respective grant numbers.
8. Description of any conflicts of interest held by the authors. We recommend that the item "Conflicts of interest" at http://www.icmje.org should be read to obtain clarifications regarding what may or may not be considered to be a conflict of interest.
9. Complete postal address, e-mail address and telephone number of the author to be contacted about the publication process in the Journal (the "corresponding author"). The author should also indicate a postal address, e-mail address and telephone number that can be published together with the article.

Main document

Second page: abstract and keywords

The second page must include the title and a 250-word abstract in English (case reports with 100 words). Do not cite references in the abstract.

Use the following headings:

1. Background: Describe the rationale for the study including the research question or the scientific hypothesis.
2. Design and setting: Declare study design correctly,[11] and the setting.
3. Methods: Describe methods briefly.
4. Results: Describe primary results with quantitative results describing the sampling strategy.
5. Conclusions: Make a succinct statement of data interpretation answering the research question presented previously.
6. Clinical Trial Registration. Mandatory for clinical trials, optional for observational studies. List the URL, as well as the Unique Identifier, on the publicly accessible website on which the trial is registered.

Insert 3 to 5 key words after the abstract, with terms differing from the title. The words must be chosen from the Medical Subject Headings (MeSH) list of Index Medicus, which is available at http://www.ncbi.nlm.nih.gov/sites/entrez?db=mesh.

Text

- Typical main headings include Introduction, Methods, Results, Discussion and Conclusion. The authors can use short subheadings too.
- Number the pages.

- Abbreviations must be avoided.
- A maximum of 3000 words in the main text, from the Introduction to the Conclusions; 1000 words for short communications.
- Maximum number of figures and/or tables is 5
- Maximum number of references is 35 (except for systematic reviews).

References

São Paulo Medical Journal uses the reference style known as the "Vancouver style," as recommended by the International Committee of Medical Journal Editors (ICMJE). Follow the instructions and examples at www.icmje.org, item "References", for the format.

In the text, the references must be numbered in the order of citation. The citation numbers must be inserted after periods/full stops or commas in sentences, and in superscript (without parentheses or square brackets). References cited in the legends of tables and figures must maintain sequence with the references mentioned in the text.

The reference list should be inserted after the conclusions and before the tables and figures. In the list of references, all the authors must be listed if there are up to and including five authors; if there are six or more, the first three should be cited, followed by the expression "et al." For books, the city of publication and the name of the publishing house are mandatory. For texts published on the internet, the complete uniform resource locator (URL) or address is necessary (not only the main home page of a website or link), so that by copying the complete address into a computer internet browser, the journal's readers will be taken to the exact document cited, and not to a general website.

Figures and tables

Images must be submitted at a minimum size that is reproducible in the printed edition. Figures should be sent a resolution of 300 DPI and/or minimum size of 2500 pixels (width) and be recorded in ".jpg" or ".tif" format. Do not attach images inside Microsoft PowerPoint or Microsoft Word documents. Failure to send the original images at appropriate sizes leads to paper rejection before peer review.

Graphs prepared in Microsoft Excel (do not send them in image formats) spreadsheets must be accompanied by the tables of data from which they have been generated.

All the figures and tables should be cited in the text.

All figures and tables must contain legends or titles that precisely describe their content and the context or sample from which the information was obtained (i.e. what the results presented are and what the kind of sample or setting was). The reader should be able to understand the content of the figures and tables simply by reading the titles (without the need to consult the text), i.e. titles should be complete.

For figures relating to microscopic findings (i.e. histopathological results), a scale must be embedded to indicate the magnification used. The staining agent should be specified in the figure legend.

Original articles

Clinical trials; cohort, case-control, prevalence, incidence, accuracy and cost-effectiveness studies; case series (i.e. case reports on more than three patients analyzed together); and systematic reviews with or without meta-analysis, are considered to be full-text original articles, with a maximum of 3000 words.

Short communications are reports on the results from ongoing studies or studies that have recently been concluded for which urgent publication is important. They should be structured in the same way as original articles.

Short communications and case reports must be limited to 1000 words (from the introduction to the end of the conclusion). The abstracts in short communications should not be structured and have a maximum of 100 words.

Authors will be required to comply with the guidelines for writing each type of original article, as follows:

1. Observational articles: STROBE Statement[5,6]
2. Clinical trials: CONSORT Statement[2]
3. Accuracy studies on diagnostic tests: STARD Statement[8,9]
4. Systematic reviews of the literature and meta-analyses: PRISMA[4]
5. Case reports: CARE[7]

São Paulo Medical Journal supports the clinical trial registration policies of the World Health Organization (WHO) and the International Committee of Medical Journal Editors (ICMJE) and recognizes the importance of these initiatives for registration and international dissemination of information on randomized clinical trials, with open access. Thus, since 2008, manuscripts on clinical trials have only been accepted for publication if they have received an identification number from one of the clinical trial registers (the options are stated at http://www.icmje.org). The identification number should be declared at the end of the abstract. Authors of randomized clinical trials must thus register their studies before submitting them for publication in the São Paulo Medical Journal.

Results from cases with DNA sequences must be deposited in appropriate public databases. The protocol number or URL can be requested at any time during the editorial review. Publication of other research data in public repositories is also recommended, since it contributes towards replicability of research, increases article visibility and possibly improves access to health information.

Short communications, case reports, case series and narrative reviews

Short communications and case reports must be limited to 1000 words (from the introduction to the end of the conclusion), a maximum of five references and one figure or table. They should be structured in the same way as original articles. Individual case reports should contain the following sections: Introduction, Case Report, Discussion and Conclusion. Reports on case series constitute observational studies and these should be structured in accordance with the norms of the STROBE Statement.[5]

Both short communications and case reports must be submitted with abstracts and keywords. The abstracts in short communications should not be structured and have a maximum of 100 words.

The São Paulo Medical Journal is interested in publishing rare or instructive case reports, accompanied by a systematic search of the literature, in which relevant studies found (based on their level of evidence) are presented and discussed.[11] The search strategy for each database and the number of articles obtained from each database must be shown in a table. The access route to the electronic databases used should be stated (for example, PubMed, OVID, Elsevier or Bireme). For the search strategies, MeSH terms are appropriate to be utilized for Medline, LILACS, and Cochrane Library. DeCS terms must be used for LILACS. EMTREE terms must be used for Embase. Also, for LILACS, the search strategy must be conducted using English (MeSH), Spanish (DeCS) and Portuguese (DeCS) terms concomitantly. The search strategies must be presented exactly as they were used during the search, including parentheses, quotation marks and Boolean operators (AND, OR, and NOT) the search dates should be indicated in the text or in the table.

Narrative reviews may be accepted by the São Paulo Medical Journal provided that a systematic search is made, and they should be structured as Original Articles. The search strategy and results should be presented as described above for case reports. By invitation from the Editor-in-Chief, narrative reviews addressing historical personal or collective experiences relating to clinical health sciences, epidemiology and public health may be accepted, but with no more than two authors.

Individual case reports should contain Introduction, Case Report, Discussion and Conclusion. Case reports should be structured in accordance with the norms of the CARE Statements.[7] Case reports published in São Paulo Medical Journal must be submitted with abstracts and keywords.

Letters to the editor

Letters to the editor may address articles published in the São Paulo Medical Journal publication or may deal with health issues of interest. Case reports must not be submitted as letters. In the category of letters to the editor, the text has a free format, but must not exceed 500 words and five references.

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