Abusive use and legal drug addiction: a bioethical view

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Abstract

The undue consumption of legal drugs, particularly medications, increases significantly worldwide. This study aims at addressing issues involving medications abusive use and addiction, from bioethics' perspective. It consists of a critical review from the SciVerse Scopus and Virtual Health Library (VHL) databases. After reading the selected material, some bioethical dilemmas were identified in professional-patient relationship, in research with humans and, finally, in the interests of the mar]et. We conclude that the main findings refer to the power of media influence defining patterns of medications consumption, to the loss of patient autonomy when he becomes abusive or dependent user, interfering in his trust relationship with the health professional, besides the economic interests of pharmaceutical companies related to clinical trials and the manipulation due to personal interests of some health professionals.

Key words: Substance-related disorders. Substance abuse detection. Pharmaceutical preparations. Drug and narcotic control. Bioethics.

Resumo

Uso abusivo e dependência de drogas lícitas: uma visão bioética

0 consumo indevido de drogas licitas, especialmente de medicamentos, aumenta significativamente em todo o mundo. Este estudo objetiva abordar questões que envolvem o uso abusivo e a dependência das medicações, sob a perspectiva bioética. Consiste em uma revisão crítica a partir das bases de dados da SciVerse, Scopus e da biblioteca Virtual em Saúde (BVS). Após a leitura do material selecionado, foram identificados alguns dilemas bioéticos na relação profissional-paciente, nas pesquisas com seres humanos e, por fim, nos interesses de mercado. Conclui-se que os principais achados referem-se ao poder da influência midiática como definidora de padrões de consumo de medicações, a perda da autonomia do paciente quando se torna usuário abusivo ou dependente, interferindo na sua relação de confiança com o profissional de saúde, além dos interesses econômicos das indústrias farmacêuticas relacionados aos ensaios clínicos e a manipulação a partir de interesses pessoais de alguns profissionais de saúde.

Palavras-chave: Transtornos relacionados ao uso de substâncias. Detecção do abuso de substâncias. Preparações farmacêuticas. Controle de medicamentos e entorpecentes. Bioética.

Resumen

Uso abusivo y dependencia de drogas llcitas: una vision bioéfica

El consumo indebido de drogas licitas, especialmente de medicinas, aumenta de forma significativa en todo el mundo. Este estudio tiene por objeto abordar cuestiones relacionadas con el uso abusivo y la adicción a medicinas, bajo la perspectiva bioética. Consiste en una revisión crítica a partir de las bases de datos de la SciVerse, Scopus y de la Biblioteca Virtual en Salud (BVS). Tras la lectura del material seleccionado, fueron identificados algunos dilemas bioéticos en la relación profesional-paciente, en las investigaciones con seres humanos y, finalmente, en los intereses del mercado. Se concluye que los principales hallazgos se relacionan al poder de la influencia de la media como definidora de estándares de consumo de medicinas, a la pérdida de autonomía del paciente cuando se convierte en usuario abusivo o dependiente, lo cual interfiere en su relación de confianza con el profesional de salud, más allá de los intereses económicos de las industrias farmacéuticas relacionados a los ensayos clínicos y a la manipulación a partir de intereses personales de algunos profesionales de salud.

Palabras-clave: Trastornos relacionados con sustancias. Detección de abuso de sustancias. Preparaciones farmacéuticas. Control de medicamentos y narcóticos. Bioética.

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The improper use of drugs has been a public health problem in several segments of society, due to the association between the use and the social damage that comes from it. According to the World Health Organization (WHO), about 10% of the urban centers use these substances abusively, regardless of gender, age, level of education or purchasing power [1].

While the use of illegal drugs is increasing more and more, some legal drugs, specially medications, have their status increasingly supported by a consumption culture, in which the financial capital invested does not give room to unhappiness. The solution seems to be seeking for a balance between happiness and confidence through prescription drugs[2].

In 2002, in the United States of America (USA), the National Institute on Drug Abuse, a division of the National Health Institute, discovered that approximately four million people, almost 2% of the population over 12 years old, uses medications without prescription, including painkillers, sedatives and tranquilizers. The American mental health and substance abuse management services did a national research about drug use and health, discovering that 6.2 million people, that is, 2.6% of the people of the same age, were using psychotherapeutic drugs without any prescription. In ten years, from 1990 to 2000, the number of users initiating the use of illegal drugs or drugs with potential for abuse, including painkillers, has increased from 628,000 to 2,700,000 [3].

In the case of Brazil, there is a pharmacy for each three thousand inhabitants, over double what is recommended by the WHO. For the local social reality, legal drugs seem to be so present in the culture as food, and people suffer for not having access to either of them[4]. Even though it is possible to consider the proper, intelligent use of medication as highly cost-effective technology, at the same time it can increase health related costs, leading to different reactions that, according to WHO data, are responsible for 15% to 20% of hospitals expenditures, due to complications caused by its improper of abusive use [4].

Thus, it is necessary to pay more attention to legal drugs, more specifically medication, considering that its abusive use has become a increasingly common daily habit, causing an addiction invisible to the public policies since it involves not only morally acceptable issues, even justifiable to a certain point, but also generate immense profit to the pharmaceutical and biomedical industries.

With that focus, the goal of this study is to approach issues that involve the abuse and addiction to medication under a bioethical perspective.

Method

It is a descriptive study, in which a critic review was done on the database of SciVerse Scopus and the Virtual Health Library (BVS), from the Health Science Descriptors (Decs) bioethics and AND "drug dependence" and bioethics AND drugs to Scopus, and bioethics AND "drug addiction" and bioethics AND drugs to BVS.

The research was done in May 2011. Some inclusion criteria were used in order to limit the study: published in the last six years (2006 to 2011); in English, Spanish or Portuguese. Relevant approaches for the research's goal on the abstract; title that includes at least one of the following words: bioethics, ethics or drugs and to be available online. As exclusion criteria: to be a literature review articles, monograph, essay, thesis and anything that approached the use of drugs associated with mental disease.

Results and discussion

As a result of the research, nine articles were used: seven in English, one in Spanish and one in Portuguese (Tables 1 to 3).

After reading the selected material, bioethical dilemmas were identified involving issues like the influence of advertisements, subliminal advertisement and the impact of over-the-counter medication and, finally, pharmaceutical research. All those issues are factors that might contribute to the abuse and addiction to medication.

Table 1. Research results, 2006

Author(s)	Title	Conclusion	Periodic
Caplan AL	*Ethical issues surrounding forced, mandated, or coerced treatment*	The study shows that the moral of the story lays on the challenge of opening the doors for mandatory treatment, which, ironically, is done in the name of autonomy. If, at the end of a mandatory treatment, some drug addicts feel increase and improvement in their autonomy and self-determination after a series of medications, then it is justified, ignoring temporarily their autonomy. It may push the current ethics to the limit, but the mandatory nature of the treatment, in the name of autonomy, is not as immoral as some people might consider.	*Journal of Substance Abuse Treatment*
Newland SE	*The role of bioethics in the international prescription drug market: economics and global justice*	The association between the economical policies and the commercialization of medication requires solution involving human rights theory and the economic theory and the relationship between bioethicists and economists to reach a fair sharing of medication in the global market, as well as to guarantee the future innovation of scientific progress.	*Penn Bioethics Journal*

Table 2. Research results, 2007

Author(s)	Title	Conclusion	Periodic
Miller J	*The other side of trust in health care: prescribing drugs with the potential for abuse*	It approaches the awareness of the clinical-medical meaning of trust and distrust, as well as the many factors that influence the moral principles of these attitudes with respect to medication prescription.	*Bioethics*
Fagundes MJD, Soares MGA, Diniz NM, Pires Jr., Garrafa V	*Análise bioética da propaganda e publicidade de medicamentos*	The future of medication publicity in the country depends on the strictness and commitment of the State when implementing education, regulation and inspection policies, specially with respect to prescription based on the requirements of the World Health Organization (WHO) and on the rational consumption by the population.	*Ciência & Saúde Coletiva*
Selgelid MJ	*Ethics and drug resistance*	The case of resistance to drugs shows additional reasons for those traditionally mentioned by bioethicists. For health treatments as something special, the political decisions influence directly in its distribution.	*Bioethics*

Table 3. Research results, 2009

Author(s)	Title	Conclusion	Periodic
Amatriain RMC	*La investigación con drogas en seres humanos: antecedentes y estado actual*	Due to constant irregularities on the clinical trial procedures controlled in different phases, ethical supervision is essential to guarantee the rights of the participants of the trials. An important fact is the creation of independent committees in multidiscipline researches with execution power.	*Revista de la Asociación Médica Argentina*
McKay T, Timmermans S	*The bioethical misconception: a response to Lidz*	Bioethicists have been giving priority to the participants' autonomy and the ability to separate care from the investigation. The need for clinical trials reflects the faults on the US health and policies in the drug field. Clinical trials become an opportunity for social equality for excluded populations, even though it is temporary.	*Social Science & Medicine*
Timmermans S, McKay T	*Clinical trials as treatment option: bioethics and health care disparities in substance dependency*	Even though random clinical trials are imperfect substitutes for clinical care, they are a fragile, sporadic niche in the therapeutics of a country with fundamental problems in healthcare access.	*Social Science & Medicine*
Forlini C, Racine E	*Disagreements with implications: diverging discourses on the ethics of non-medical use of methylphenidate for performance enhancement*	Medicine, health and society need to prepare for an increase in the use of non-prescribed medication; the legislation on the use of non-prescribed drugs needs to be developed, as well as the distribution of this medication and the education of health professionals and the population on the danger of using these drugs incorrectly.	*BMC Medical Ethics*

Advertisement influence

Medication advertisement associated to pharmaceutical industry and medical interests constitute factors that might influence the prescription and the irrational use of medication [5-8]. To Lefévre [9], the capitalist society lives, in hegemonic way, the idea that the only way of being healthy is to consume health. Thus, advertisement became a broadly used means of transmission to strengthen the association established between health and medication, leading people to indiscriminate use.

The option of using advertisement comes from its power to create a positive public opinion to a certain product, guiding human behavior in a certain sense. Because the influence nature of this communication means and the risks deriving from the incorrect use of medication were recognized, advertisement referring to these products now, in Brazil, is regulated by the National Agency of Sanitary Vigilance (Anvisa) through Resolution RDC 96, of December 17, 2008. The document discusses advertisement, publicity, information and other practices whose goal is to disclose and promote commercially industrialized medications regulated by the Anvisa that don't need prescription and that can be sold without a medical prescription [10].

Under this context, advertisement of non-prescriptive medication can be broadcasted specially by mass means communication. However, those that are sold only with a prescription should aim just health professionals capable to prescribe or dismiss those products; they can be done, for example, in current journals, through the mail and congresses promoted and financed by the pharmaceutical industry, that usually focus in a certain drug that is being promoted[11].

Any kind of advertisement about medication sold with medical prescription aiming general public is forbidden. This prohibition becomes, in a certain way, compatible with the market logics, if you take into consideration the difficulties of the population with respect to access to medical appointments and, consequently, to medication requirement, there is no reason to promote those substances. Thus, the biggest investment is on the over-the-counter medication advertisement.

The problem is that the constant advertisement campaigns for non-prescriptive medication, aiming the general public, can also influence the consumption pattern of the population [12].

What makes the medication the main health symbol in this context, confirming the concept of symbolic merchandise for the medication, proposed by Lefévre [9]. Thus, in this market rationale, the individual is not just a mere user, he is a consumer, turning the referred legal drug highlighted in comparison to other therapeutics. In that sense, Anvisa RDC 96/08 sets forth in Article 26 that it is forbidden to suggest medication as the sole therapeutic resource or make someone believe that health habits are necessary, as well as medical appointments [10].

This investment on the advertisement aiming people that have problems with accessing healthcare passes by a short discussion on the principle of autonomy. Under this aspect, the individual must act on knowledge, and not by external coercion, protecting his autonomy. What happens is that, often, the weakness caused by the process of illness can compromise the exercise of freedom keeping the individual's freedom to be expressed [13]. It means that an ill person, kept from his right to health care, finding commercial facilities for medication and with a consumption culture that overrates medication, therapeutics overrates ends up becoming one more follower of self-medication, having his autonomy unprotected due to lac of other therapeutic option.

This market perception of the medication as the only treatment alternative has made self-medication common behavior, a practice that has turned into a public health problem, since it exposes patients to risks that are often unnecessary. Thus, the percentage of people that use those substances is increasing in a global scale[14] and some factors are considered by Kamat and Nichter [15] as key to that increase: the growth of the pharmaceutical market, marketing investments and the increase on the number of pharmacies, creating a competition for the client, especially when the management of the pharmacy is not under the responsibility of a pharmacist.

As an example, among the features of the people in developing countries, you can say that the economic rationality and the precarious access to public health services bring the population to purchase medication without prior medical appointment and prescription, using these substances, many times, in an incorrect and abusive manner. This behavior causes increase on the resistance to medication, and consequently, more spending in public health [3,7,8].

The difficulty for the population to access health services harm the bioethical principle of justice, that highlights the role of society and organized social movements in bioethics, compensating the different and conflicted interests of collective life [13]. Thus it is expected that the distribution of the benefits of health service to be fair, equitable and universal, guaranteeing every citizen's rights. Since this is not the reality in our country, the influence of advertisement and the consumption culture bring Brazilians to use free purchase of medication as a therapeutic alternative.

Among the most used medications in the context of self-medication is, majorly, the painkillers (47%), anti-inflammatory drugs (16%) groups and, with just 14% of the medication used, antibiotics, anti-depressive and anti-allergic drugs [14]. Those percentage bring to supposition that if the investment in advertisement of over the counter medication was smaller, its irrational use would also decrease.

The ethical dilemma presented in this category consists of the freedom in medication advertisement, on the influence of the pharmaceutical industry and in the global economic interests, needs to be discussed when the issue is medication abuse and addiction [11]. In this aspect Soars [16] considers essential to deepen, debate and mobilize the population and the professionals involved in the sense of forbidding medication advertisement in our country, whether prescriptive or non-prescriptive, considering that only the economical interests of the manufacturers justify the broadcasting of such publicity campaigns [16].

Subliminal advertisement and the impact of non-prescriptive medication

The relationship between the prescriber and the patient should be a partnership, converting health into a shared value, without any coercion, manipulation and disappointment. [3]. Pepe and Castro [11] state that the importance of the prescriber lays on the fact that he or she is the one responsible for the indication of medication based on the interpretation of what the patients tells him or her. The patient, in turn, is the one that is going to describe what he or she feels and follow, or not, the doctor's indication. Thus both of them have experience and expectations that allows them to make decisions about the prescription and use of a certain medication. In this context, bioethics allows us to recover the principles of beneficence and non-malefaction as inherent aspects of healthcare.

Beneficence means to do others good. In healthcare, the practice of beneficence consists of having the professional make his or her best to the patient, using all knowledge and technical abilities aiming to maximize the benefits of the treatment. With pertinence to non-malefaction, the professional has the obligation of not causing any harm to the patient - a referential for which actions are contained in the expression *primum non nocere*, meaning that, above all, you shouldn't cause harm to the patient[13]. Thus, these principles pass by the professional responsibility of assessing if the benefits of the prescribed medication are bigger than the risks of it causing any harm, what configures an ethically correct action in the relationship between the professional and the patient.

These relationships are often manipulated by the pharmaceutical industry, influencing the prescriber in his or her way of prescribing and with the patient being induced to abusive use of medication. Fagundes and collaborators [6] and Selgelid [8], for instance, state that the influence of advertisement can change the professionals' prescription standards. These subtle changes bring to the idea that medications are merchandise that should be offered the same way as other assets and services. This perspective, guided by the rules of free market, ends up inducing people to abusive use of legal drugs due to market incentive.

Under those ethics, article 52 of RDC Anvisa 96/08[10] states: *Companies may not grant, offer promise or distribute gifts, benefits and advantages to prescribing professionals, to the ones that have a role in direct costumer sales, as well as the general public.*

Regarding the users, there are those that will do anything to get a controlled prescription book, offering bribe and even sexual favors, and using several schemes of turning a "no" into a "yes" "[3]. And that is exactly what many pharmaceutical industries intend in some cases even training patients to be part of their advertisement, broadcasted over communications media or promoted by flyers, ads, and websites. These advertisement campaigns – usually disguised as "medical advice" – even offering tips in order to patients make the physician moved to induce him or her into prescribing the medication [,6,8]. Because of the high potential for abuse that can come from those promotion strategies for purchase, professionals should develop sharp clinical ability and ethics to recognize the manipulating role of the media, to learn to say no to users' requests and still keep them in treatment [17].

The media still associates the use of some medication with the improvement of intellectual performance and well-being, with statements like "better life through chemistry" or "quick solution for problems of the in-a-hurry society we live in" or "wonder drug" or "smart drugs" [7]. The information produced and promoted to the professionals and consumers aren't always exempt, making indispensable a critical attitude towards them, since health professionals and prescribers have, under their responsibility, direct or indirectly, the patient's health[18].

Therefore it is essential that they always seek access to reliable, updated sources about the medication, especially because certain information sources tend to make those professionals into true non-*critical consumers* [19].

With the intent to discourage this practice, the Anvisa RDC 96/08 forbids advertisement of non-prescriptive medication that have a name, image and/or voice of a person whose features are easily recognized by the public due to being famous, stating or suggesting the use of that medication, as well as using direct or indirect language relating the use of medication with alcohol or food excess, to physical, intellectual, emotional or sexual performance or to the beauty of a person – except when approved by Anvisa [10].

Pharmaceutical Research

Due to some vulnerabilities to which developing countries are exposed, there is another bioethical dilemma involving abuse and addiction to medication. As a consequence of the market interests, researchers have to do clinical trials for consolidating new medication [20,21]. This opens possibilities for research in developing countries, because, in those places, you don't need to follow completely the ethical standards – like in India, where there are no requirements for the treatment of patients and payment for participating in the research is ridiculously low 20.

In the case of Brazil, this kind of research is regulated by Law 196/96 of the National Health Board (CNS). It is based on the four basic referentials of bioethics: autonomy, non-malefaction, beneficence and justice, among others and aims assuring the rights and duties regarding the scientific community, the subjects of the research and the State[22]. Thus, for a research to be considered ethic, the human dignity must be respected, maximum benefits and minimum risks and damage should be provided, as well as to avoid preventable damage, to have social relevance and to assure equal consideration of the interests involved.

Due to that, Lima [23] asked the following question: should our ethical research standards depend on the place it is done? Many official entities and investigators defend the use of placebo in developing countries, claiming individuals are treated according to the care standards of their countries – that is, nothing. Accepting a standard treatment different from that used in the country sponsoring a study, results in a double ethical standard for research – or *double standard.*

This term refers to doing research used due to the place where it is done. In developing countries, where there are signs of fragility, like poverty, trials considered unacceptable in developed countries are done. The advocates of the ethics of the *double standard* believe that the income inequality is data comprising our societies; thus, a social structure that comes before scientific research. Under this argument, the parameters socially available of treatment and health care are considered ethical, and not necessarily the best within the scientific possibilities. At the same time, there are researchers that defend that the ethical principles that guide scientific research would not be relative to that point [24].

In this context, bioethicists show the inherent dangers of associating care to research. Among the risks of this situation, it's highlighted the fact that researchers don't always have interest in the treatment itself, because their main goals are to subscribe and to keep the most people possible on the research. Additionally, not every participant is duly informed of the kind of intervention to which they will be put through – and many are motivated by the desperation of getting rid of the addiction, what makes the situation even worse [25]. That fact hurts the autonomy of these subjects, since they find themselves with no other therapeutic option.

Bero and Rennie [26] state that, between 1980 and 1986, 61% of clinical trials done in California were done under this condition and often the studies of cost-effectiveness in the USA are created by the marketing department of pharmaceutical industries – not the research department. As shown by Márcia Angell [27], most laboratories in the USA have turned into huge marketing machines for products with questionable benefits, drifting away from their original mission of discovering and manufacturing medication. The author also reveals that these

laboratories depend on institutions financed with public resources for doing research and that they change clinical trials to make their products seem better than they really are, using lawyers to extend the exclusive marketing rights granted by the government.

Bioethics in professional attitude

From the results discussed in the categories above, it is essential to make a short statement about health professionals' attitude towards these dilemmas, based on the principles of bioethics - based principle.

The term bioethics refers to biomedical ethics, that is, the ethics of the professional role related to human beings, reconsidered and demanded upon the moral dilemmas that come from technological development. The operationalization of the principle-based bioethics is possible upon the application of the principles of beneficence, non-maleficence, justice, and respect to the autonomy when resolving the dilemmas and conflicts created in the context of health professionals' performance [28].

The association present in the culture between health and the use of medication makes patients to abuse drugs. Due to this reality, health professionals should guide them and their families to avoid such abuse, due to the adverse effects[14], preserving the autonomy of the subjects based on the principle that every adult, aware human being has the right to decide about what is going to be do done with his or her own body.

For Newland [5], bioethics comes from the need to assess human rights and the responsibilities of the market forces towards the population. It becomes necessary to create a minimum standard for care, that range from creation of a public health environment, with clean water and utilities accessible to every citizen, to the sales of medication and/or drugs, avoiding coercive advertisement, specially for the poor population, that has little access to education.

On the process of diagnosis and therapy, familiarity, trust and collaboration are highly implicated in the result of the prescriber's practice. In many cases, the professional is not actively stimulated to think of the patient as a whole, as a biopsychosocial being or to notice the meaning of being ill to the patient, as well as the limit between use and abuse of a certain substance [29]. Besides, the decision-making for prescribing a certain drug is not always moved by interests of care for the user [30], and it should base the practice in an applied ethics, with the goal of meeting and responding better to the users' needs.

It is necessary to identify up to what point trust is preserved in the relationship between the prescriber and the patient. There are several issues that need to be carefully considered, since trust in essential for reaching a fairer treatment that does the least harm possible. Thus mistrust and trust can influence the interpretation of actions and behaviors [3].

So the health system should be aware of the enthusiastic opinions, informing the public and interested parties better. That implicates commitment with public information and an informed debate about the use of non-prescribed medication to improve the issue. Medicine, health, society and ethics need to prepare for the prevalence of the use of non-prescribed medication, improving even more the development of legislation on the use of drugs, as well as the distribution of this medication and the education of health professionals and the population about the dangers of its misuse [7].

Additionally, the prescriber might be influenced by his or her own features or by external factors such as: the place of the appointment, regulating agencies, advertisement, academic community and economical interests[31]. Certain features relating to the patient are also important for the medical decision-taking: their expectations and demands, their families/employers;; their attitude towards health; their physical features like weight or age; their sensitivity to medication; their economical situation and their insertion on the job market [32].

When it comes to work, an interesting extract of the article by Eliane Brum, called *Can you live without legal drugs,* has a statement by a psychiatrist just to induce in the reader new reflections and inquietudes on the bioethical dilemma about the time, work and use of medication:

Because we live in a world where people don't have time to elaborate what is human. Often this kind of situation happens to me in the office. I see a person there asking me for an anti-depressive because they can't work anymore, they can't live their lives anymore. I know that person can't work or live his life anymore because it has become impossible, because he needs time he doesn't have to organize what he has lived. Obviously it's not possible, for example, to process grieving or divorce in a week and then go on like nothing happened. As it's not possible to live without doubts, sadness, frustrations. So I prescribe the anti-depressive and do a serious follow-up with psychotherapy, so that this person can work out his life and stop taking the medication. It's a dilemma and it's not been easy to deal with it, but it's in this world that I work as a psychiatrist. These people only need to handle a life that a human being can't handle [33].

Even though it doesn't go deeper on the labor issues, working conditions of today's society are also a factor that influences the prescription and medication use and/or consumption standards. The constant hurry of activities, stress, the short periods of days off in case of decease, for instance, often don't give time enough so that people can process what is going on in their own lives – what doesn't give the professional much choice besides prescribing medication. Often it is prescribed by the doctor because he or she understands the social reality of the patient and realizes the medication is necessary, not due to clinical demand, but as an answer to the social demand – what, in a certain way, would preserve the principle of non-malefaction avoiding further harm to the health.

Final considerations

From the results of this research, it's possible to see the complexity of the several factors that influence the abuse and addiction to medication, passing by subjective, social, economical and ethical aspects. Among the main bioethical dilemmas found, it is notorious the influence of the advertisement of non-prescriptive medication, that change the standards of prescription as well as the use standards, and the dangers inherent to associating pharmaceutical research and care. In both situations, these realities are ruled by financial interests of the big pharmaceutical industries that often cross the lines of ethics that are essential in the context. In that sense, as an interdisciplinary field, it is important and relevant to have constant bioethical discussions on medication issues.

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Authors' participation
Lais Lira, Luana Andrade and Fabiola Alves worked in research, methodology, conception and final writing. Edite Sena, Rita Boery, and Sergio Donha Yand worked in the conception and final writing.

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