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Original Article

Legal Aspects of Dental Antibiotic Prescriptions: A Descriptive Study in a Large Brazilian City

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Abstract

Objective: To quantify the antimicrobial drugs most commonly prescribed by dentists since the institution of legal controls in Brazil and to identify the presence of errors in the legal requirements of some of these drugs. **Materials and Methods:** This is a cross-sectional study of dental antibiotic prescriptions at 69 drug stores in a chain of pharmacies in Belo Horizonte, Brazil. A calculated sample of dental antimicrobial drug prescriptions was selected using simple random sampling from a total of 31,105 prescriptions. The following data were analyzed: the type of antimicrobial drug; the presence of a prescription in accordance with the Common Brazilian Nomenclature (DCB); the name, gender, age and address of the patient; the name, signature, address, telephone number, Regional Dental Council registration number and stamp of the prescriber. After double entry in the Epi-Data program, a descriptive analysis was performed using SPSS version 19.0. **Results:** A total of 366 dental antimicrobial drug prescriptions were analyzed. The majority of the antimicrobial drugs prescribed were from the penicillin group (71.9%; CI95% 67.0-76.2), 99.7% of which were amoxicillin with or without clavulanic acid. The second most commonly prescribed drugs were the macrolides (16.7%; CI95% 13.2-20.8). The majority (92.8%) had 3 to 5 errors. The most frequent errors were as follows: spelling of the drug name not in accordance with the DCB (72.1%), and the absence of patient information such as age (99.7%), gender (99.8%), and address (87.0%). **Conclusion:** Antimicrobial drugs of the penicillin and macrolide groups were prescribed most often by dentists, and the majority of those prescriptions had three to five errors, with spelling of the drug name not in accordance with the DCB and missing patient information as the most common errors.

Keywords: Drug prescriptions; Inappropriate prescribing; Antimicrobials; Dentistry.

Introduction

The prescription of antibiotics has been subject to special control, with a copy of each prescription kept on file at the pharmacy, in Brazil since 2010 by Resolution of the Collegial Directorship no. 44 [1]. The most recent determinations are described in the Resolution of the Collegial Directorship - RDC no. 20 from May 5, 2011, which among other topics, states that the prescription must contain identifying information for the prescriber and for the patient as detailed in Law no. 5991/73 [2,3]. RDC no. 20 further states that antimicrobial drugs must be prescribed according to their generic name, in accordance with the Common Brazilian Nomenclature - DCB. Article 5 of RDC no. 20 details the information that must be present on the prescription: the patient's "name, age, gender and address;" the prescriber's "name with registration number with the Regional Dental Council or the name of the institution, complete address, telephone number, signature and stamp."

Data from Brazil [4] and other countries such as the United Kingdom, Iran and India [5, 6, 7] show that dentists incorrectly prescribe antimicrobial drugs in both legal and pharmacological terms. The consequences of this practice are observed in patient health and in treatment cost.

Errors in medical prescriptions are part of an area of research designated as "medication errors," which are any avoidable errors that lead to the inappropriate use of medicines or that put the patient at risk with the use of medicines [8]. These errors can be grouped according to the processes that led to the error, which include the prescription, the transcription, the dispensation, the administration and the patient follow-up [9]. This study is focused only on the prescription stage.

In the US, it is estimated that 1% - 2% of hospital admissions are the result of medication errors [10]; in Spain, such errors are responsible for 4.7% of admissions to health services [9]. In Brazil, in a study performed in 2009, the number of medication errors leading to patient admission was quantified as 9.2%. Most were due to missing information about the dosage and means of administration; there were also writing errors, duplicated items and doses that were higher than normal, among others [8]. In a study of prescription errors conducted in four Brazilian hospitals, the authors found that only one hospital used the generic names for all of its prescriptions; in another, only 38% of the 248 prescriptions written were complete [11].

Antimicrobials are used in dental practice both prophylactically and therapeutically. Thus they are the appropriate drug to prescribe for acute periapical infection, cellulitis and acute ulcerative gingivitis [6]. In the prevention of disease, antimicrobials are used to prevent infective endocarditis, failure of dental implants and, generally, bacteremia [5].

Dentists, like doctors, prescribe antimicrobials in a manner that is both exaggerated and inadequate in situations in which this category of drug is not indicated. In a study performed in Iran, researchers found that 40% of dentists prescribed antimicrobials for problems for which they were not indicated [6]. In an evaluation performed by questionnaire about the prescription standards used by 1,600 dentists in India, researchers found an excess number of antimicrobial prescriptions [7], leading to increases in the cost of therapy.

The cost of drugs in Brazil is one of the major components of the total cost of health services. Families bear a greater part of the cost of drugs than the public health system [12]. However, little research has been performed regarding the quality of prescription medicines with analyses of random samples, especially following changes in the law in that area. The objective of this study is to quantify the antibiotics most commonly prescribed by dentists since the institution of the legal controls over prescribing in 2011, determining whether there are any errors in the legal provisions concerning them.

Material and Methods

This is a descriptive, observational, cross-sectional study analyzing dental antibiotic prescriptions with records retained by pharmacies of the largest chain of drugstores in Belo Horizonte, MG. The company has 120 stores in greater Belo Horizonte, including stores in Betim, Contagem, Lagoa Santa, Nova Lima, Santa Luzia, Sabara, Sete Lagoas and Vespasiano. It is the largest retailer in Minas Gerais and the fourth largest chain of drugstores in Brazil. Their revenue was R\$1.25 billion in 2013, they employ seven thousand, and they serve 40 million customers per year [13].

Data collection was performed in the archive department of this company. Prescriptions of antimicrobial drugs subject to special control (RDC no. 20/ANVISA) that were written by dentists were collected. All of the prescriptions by dentists filed in the period from July 1, 2011 to June 30, 2012 were separated from the medical prescriptions in all of the stores that were in operation at the time of publication of the RDC in the specified period. From the total number of prescriptions, a calculated sample was randomly selected.

From the total of 31,105 prescriptions, using simple random sampling, we obtained a calculated sample of 380 prescriptions. The sample calculation was based on an estimate of the proportions considering that 50% of the estimated proportion of prescriptions had errors. The level of confidence was 95%, and the level of precision was 5%. A total of 434 prescriptions were initially selected, but those from the same dentist or for the same patient were excluded to guarantee the independence of the observations. After removing those with the same dental surgeon or the same patient, 366 prescriptions remained. The accuracy was recalculated to be 5.09%.

The variables analyzed for each prescription were as follows: the name of the antibiotic in conformity to the DCB (yes or no); the patient's name (yes or no), age (yes or no), gender (yes or no), and address (yes or no); the dentist's name (yes or no), signature (yes or no), Regional Dental Council of Minas Gerais (CROMG) registration number (yes or no), and stamp (yes or no); and the address (yes or no) and telephone number (yes or no) of the dentist's office or clinic. These criteria were based on RDC no. 20 from May 5, 2011 [2]. The variables were analyzed by a single researcher specifically trained for this purpose ($Kappa > 0.6$). The drug name was categorized according to specialized literature or in the absence of such information, according to the definition by the National Health Surveillance Agency (ANVISA).

After double entry into the Epi-Data program, a database was created using SPSS version 19.0. The descriptive statistical analysis involved proportion and 95% confidence interval (CI95%) calculations. The study was submitted for approval to the Research Ethics Committee (CAAE - 04645812.9.0000.5149).

Results

Table 1 presents the antimicrobials most commonly prescribed in the 366 dental prescriptions by pharmacological group. The majority (71.9%; IC95% 67.0-76.2) are from the penicillin group; 99.7% of those were amoxicillin with or without clavulanic acid.

Table 1. Frequency of antibiotic prescriptions by dentists in Belo Horizonte, MG, Brazil, 2011-2012.

Pharmacological group	Frequency	Percentage (IC95%)
Penicillins	263	71.9 (67.0-76.2)
Macrolides	61	16.7 (13.2-20.8)
Aminoglycosides	11	3.0 (1.7-5.3)
Quinolones	10	2.7 (1.5-5.0)
Lincosamides	8	2.2 (1.1-4.3)
Cephalosporins	4	1.1 (0.4-2.8)
Metronidazole	3	0.8 (0.3-2.4)
Cotrimoxazole	2	0.5 (0.2-2.0)
Fosfomicin	1	0.3 (0.0-1.5)
Nitrofurantoin	1	0.3 (0.0-1.5)
Rifamycin	1	0.3 (0.0-1.5)
Tetracycline	1	0.3 (0.0-1.5)
Total	366	100.0

The frequency of the presence of each legal parameter of the prescriptions is shown in Table 2.

Table 2. Legal aspects of antibiotic prescriptions in Belo Horizonte, MG, Brazil, 2011-2012.

Presence of the variable	Frequency	Percentage (IC 95%)
DCB	264	72.1 (67.3-76.5)
Patient name	365	99.7 (98.5-100)
Patient gender	2	0.5 (0.2-5.0)
Patient age	1	0.3 (0.0-1.5)
Patient address	13	3.6 (2.1-6.0)
Name of the prescriber	361	98.6 (96.8-99.4)
Signature of the prescriber	361	98.6 (96.8-99.4)
Office or clinic address	323	88.3 (84.6-91.2)
Office or clinic telephone number	315	86.1 (82.1-89.2)
Regional Odontological Council (CROMG) registration number	360	98.4 (96.5-99.3)
Stamp	348	95.1 (92.4-96.9)

Table 3 shows the variation in the number of errors identified in dental prescriptions. None of the prescriptions were correct in every aspect of the established legal requirements for the prescription of antimicrobials.

Table 3. Number of errors identified in prescriptions in Belo Horizonte, MG, Brazil, 2011-2012.

Number of errors	Frequency	Percentage (IC 95%)
Two	8	2.2 (1.5-5.0)
Three	212	57.9 (52.8-62.9)
Four	93	25.4 (21.2-30.1)
Five	35	9.6 (7.0-13.0)
Six	14	3.8 (2.3-6.3)
Seven	2	0.5 (0.2-5.0)
Eight	2	0.5 (0.2-5.0)

Discussion

This study shows that dentists mostly prescribe antimicrobials from the penicillin group, utilize the DCB and according to Brazilian legal requirements, commit many errors in writing prescriptions.

Amoxicillin with or without clavulanic acid was the antimicrobial most commonly prescribed by dentists in the sample (73.0%). These results are similar to those found in Brazil [10] and in several other countries in the last 14 years [7,16].

Due to their similarity or suitability to the bacterial spectrum and their mechanisms of action, effective antibiotics that can be considered correctly indicated for use include those from the penicillins, cephalosporins, macrolides and tetracyclines, as well as clindamycin and metronidazole, for oral infections. The last two have a predominantly anaerobic antibacterial spectrum. Support can be found in the specialized literature for their use for oral infections that are characterized as anaerobic; clindamycin substitutes amoxicillin for patients who are allergic to beta-lactams [17]. There is also support in the literature for the use of tetracycline and metronidazole, especially in periodontics [18].

However, it is strange for dentists to prescribe quinolones, which are more often used in the treatment of infections of the genitourinary tract and the respiratory tract and of traveler's diarrhea. The same can be said for cotrimoxazole and nitrofurantoin, which have very specific indications such as urinary infections, toxoplasmosis and granuloma inguinale [14]. Medicines containing neomycin and gentamicin, associated with rifamycin and a corticosteroid, which are also prescribed, are generally used cutaneously and therefore should not be prescribed by dentists. This practice likely demonstrates the inappropriate use of antimicrobials and undoubtedly contributes to the worldwide problem of growing bacterial resistance.

It is suspected that dentists, like doctors, prescribe antimicrobials in an exaggerated and inadequate manner in situations in which antibiotics are not indicated. In a study conducted in Iran, the authors found that 40% of dentists prescribed antimicrobials for localized floating edema and other problems that do not call for the use of antimicrobials [6]. Similar results were found in India, with the prescription of antimicrobials for irreversible pulpitis and acute apical periodontitis approaching 72% of cases [7]. On the other hand, another study showed that most professionals correctly prescribed antimicrobials for acute periapical infection, cellulitis, and acute ulcerative gingivitis [6].

A Cochrane systematic review concerning the treatment of oral diseases demonstrated that for apical periodontitis, anti-inflammatories but not antimicrobials are recommended [19]. Penicillin has no effect on pain and swelling after the endodontic treatment of necrotic teeth [20]; for the treatment of irreversible pulpitis, it was not possible to determine the beneficial effects of antimicrobials on pain [21]. A meta-analysis demonstrated that in chronic or aggressive periodontitis, the antimicrobials amoxicillin, metronidazole and doxycycline, at low dosages, significantly increased adherence of the teeth to the gums and reduced the depth of periodontal pockets [22].

In 2007, the American Heart Association (AHA) published new guidelines for the prevention of infective endocarditis, stating that the standard use of 2 g of amoxicillin one hour before dental procedures prevents reinfection in the valves of patients carrying the disease. They defined other therapeutic strategies in the case of allergy to penicillin and if the use of oral antimicrobials is not possible. They established the cardiological conditions of patients and specific dental procedures that justify the use of prophylaxis [17]. Such protocols serve as the basis for various other medical societies, but controversies remain regarding the necessity of this type of prophylaxis due to the lack of evidence regarding whether its benefits outweigh the health risks and financial costs [23].

Systematic reviews reveal that in the development of infectious complications after tooth extraction, antimicrobials reduce the risk of dry sockets and pain without any significant difference in the outcome regarding fever, edema or trismus in the groups; however, there was an increase in minor, transitory side effects in the group that received the drugs compared with a placebo [24]. Scientific evidence suggests that a single oral dose of amoxicillin reduces the failure of implants [25]. The use of antimicrobials before the standard installation of only one implant does not improve the outcomes for the patient, nor does it reduce post-surgery complications [26].

One must be careful when discussing the reasoning behind therapy choices because there are no compelling indications for the prescriptions for the disease being treated; additionally, neither the record concerning the International Classification of Diseases (ICD) nor other information clarifies the reasons to prescribe antimicrobials.

Regarding the legal aspects, the results show that more than one in four prescriptions [27.9%] do not conform to the requirements to prescribe according to the DCB because either the

trade name is used or the name of the drug is misspelled. This could be because the prescriber does not know the official name. This result is different from a 2010 Brazilian study in which all of the drugs were prescribed by their generic name [10], probably because the data were collected from a public primary care facility. Nonconformity to the requirement to prescribe using the generic name should preclude the dispensing of the medicine [27], even though the names “amoxillin”, “amox”, “amoxixilin” are very easy to recognize as amoxicillin, which is the antimicrobial most commonly prescribed in this study.

The pharmaceutical industry expends enormous resources to advertise medications that are both controlled and sold over the counter. For this reason, the trade name of the medicine is an important factor to the prescriber making the decision [28]. The establishment of generic drugs in this country was important in creating competition between drug producers, contributing to lowering costs and to rational drug use because “its nomenclature does not change according to economic interests, as can happen with the trade names” [4].

The disregard for generic names could be a risk factor leading to other mistakes in the prescription of therapeutic drugs [11]. Prescribing by the trade name is prohibited in Law 9.787/99 and can increase the cost of treatment because in some cases, medicines with brand names are more expensive than generics. Higher treatment cost could be responsible for lower adherence to the drug therapy, especially in developing countries and in lower income groups.

Identifying information both for the prescriber and for the patient is indispensable on a medical or dental prescription, and the presence of this information has been mandated by Brazilian law since 1973 in article 35 of Law no. 5.991 [3]. The requirements of the name and signature of the prescriber, the CROMG registration number and the stamp were completed in nearly all of the prescriptions analyzed. It is obvious that the name and signature of the prescriber and the CRO registration number legitimize the prescription and make it legally valid. Because the RDC no. 20/2011 does not contain justification for the requirements, the necessity of having the stamp on the prescription is explained in the CFM Resolution no. 1.974/2011 of the Federal Council of Medicine, which addresses the criteria for printed materials: the stamp will be used only as an identifier of the signature on documents that do not have the name of the health professional printed on them [29]. The address and telephone number of the prescriber are reasonable and important requirements because they facilitate communication between the health professional and the patient in the event of any uncertainty.

As for the patient identification, dentists do not show the same care and attention as they do for prescriber data. Only one prescription did not contain the name of the patient, but the majority of prescriptions were incomplete for the other data (age, gender and patient address). The requirement that the age of the patient be registered appears to be based on the possible analysis of harmful effects on patient health. Elderly patients (those over 65 years of age) should receive different dosages than young adults because changes in the processes of absorption, metabolism, distribution and elimination in older patients can affect the pharmacokinetics of the majority of drugs;

furthermore, concomitant diseases can make the prognosis of drug interactions more difficult to assess in the elderly [11].

Including the gender is not generally required by Brazilian law but can be useful for the funding of public policy focused on the use of medicines specifically for women.

Although there were frequent legal errors in only a few of the items studied, not one prescription was fully compliant. This demonstrates that the Brazilian norms are not being followed for antimicrobial prescriptions by the dentists in this study. This is not simply due to lack of awareness of the generic names of the desired medicine. These errors demonstrate lapses in instruction regarding the norms for proper drug prescriptions. Omissions in dental prescriptions were also detected in a study of the quality of drug prescriptions by students from two sections of an undergraduate dental course. The study concludes that there were improvements in prescriptions as students advanced in the course; however, faults remain that are specifically related to the use of prescribed drugs [30].

Not only the dental courses in Brazil should be attentive to this situation, but also the graduates of these courses who need to adopt a proactive attitude, looking to continue their formal education permanently by means of professional development courses and informally by means of constantly reading technical and scientific information such as that found in the journals of the professional Councils and Associations.

A limitation of this study was the difficulty of establishing whether the prescription was appropriate for the clinical and dental situations. This is an area of interest in therapy, especially because of the suspicion that dentists prescribe antibiotics unnecessarily, as was found in several countries [31]. That practice is one of the factors responsible for the increase in bacterial resistance to antimicrobials. Another limitation was that the data used came from only one drug store chain, albeit the largest, in only one city, the capital of Minas Gerais.

A review of the literature suggests that this is the first study to evaluate the quality of prescriptions of antimicrobials after the institution of the Resolution to control them. It also used a random sample of prescriptions from a large chain of drugstores from Belo Horizonte with a very precise methodology. Nevertheless, more studies are necessary to characterize the current state of dental prescriptions of antimicrobials that evaluate pharmacological errors and the appropriateness of their prescription in clinical situations, always in light of the evidence and in line with the protocols instituted by worldwide organizations of recognized scientific repute.

The control of the prescription of antimicrobials tends to favor the rational use of medicines to benefit the patient by means of reducing adverse reactions and the treatment cost, which also benefits the public health sector, as well as reducing the possibility of increasing bacterial resistance. However, as observed from this study, these controls have not been sufficient. Other health measures should be developed with the objective of improving the utilization of antimicrobial drugs for dentists.

Conclusion

The penicillin and macrolide groups were the most commonly prescribed antibiotics by dentists, and most of the prescriptions had three to five errors, the most frequent of which were in the spelling of the name of the antimicrobial, a lack of conformity to the DCB and the absence of patient information.

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