Analysis of the adverse events reported to the office of the clinical director at a dental school in Bogotá, Colombia

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ABSTRACT

Dentistry is interested in identifying and controlling adverse events, understood as involuntary injuries to the patient during dental care. The aim of this study was to analyze the adverse events reported to the Office of the Clinical Director at the School of Dentistry at Pontificia Universidad Javeriana (Colombia) during 2011-2012. It was an observational, descriptive study that evaluated 227 dental clinical records of patients who filed a complaint with the Office of the Clinical Director. Of these, 43 were adverse events and were used as the basis for this study. Of the 16,060 patients who received care during 2011 - 2012, 0.26% (43) filed a complaint involving an adverse event, of which 97.7 % were considered preventable. Most of these (76.18%, n= 32) occurred during clinical management of treatments in different specialties, 9.5% (4) were the result of deficient external dental laboratory quality, and 14.32% (6) were due to failure in document management, soft tissue injury, misdiagnosis and swallowing foreign objects. Of the patients involved, 65.2% (28) received care from postgraduate students, with the highest number of cases in the Oral Rehabilitation speciality. The occurrence of adverse events during dental care, indicates the need for information about their origin in order to establish protection barriers and prevent their incidence, particularly in the educational area under the student dental clinic service model.

Key words: *Dentistry, Reporting events, Reporting incidents.*

Análisis de los eventos adversos reportados a Dirección de Clínicas en una Facultad de Odontología de Bogotá-Colombia

RESUMEN

En odontología existe interés por identificar y controlar los eventos adversos, entendidos como las lesiones no voluntarias que ocurren durante la atención odontológica. El objetivo de este estudio fue analizar los eventos adversos reportados a Dirección de Clínicas de la Facultad de Odontología de la Pontificia Universidad Javeriana durante el periodo 2011-2012. Se realizó un estudio observacional descriptivo para el que se evaluaron 227 historias clínicas de pacientes que reportaron una queja a la Dirección de Clínicas, de las cuales en 43 se evidenció la presencia de eventos adversos, a partir de las cuales se registró la información analizada en este estudio. De los 16.060 pacientes atendidos durante el periodo 2011 y 2012, el 0,26% (43) formularon alguna queja que resultó en un evento adverso, de los cuales el 97,7 % se consideraron prevenibles. El mayor porcentaje 76,18 % (32) se presentó durante la gestión clínica de tratamientos en diferentes áreas. El 9,5 % (4), se debieron a fallas en la calidad del trabajo del laboratorio externo; el 14,32% (6) correspondió a eventos generados por fallas en la gestión documental, lesiones de tejidos blandos, fallas de diagnóstico y deglución de objetos extraños. El 65,2 % (28) de los pacientes fueron atendidos por estudiantes de posgrado, con el mayor número de casos en la especialidad de Rehabilitación Oral. La presentación de eventos adversos durante el proceso de atención en odontología, es indicador de la necesidad de conocer su origen para establecer barreras de protección y prevenir su incidencia, especialmente en el área formativa bajo el modelo de atención docencia servicio.

Palabras clave: *reporte de eventos, reporte de incidentes.*

INTRODUCTION

Due to their complexity, health services are considered a high-risk system. There is concern to identify, control and prevent adverse events, which are understood as involuntary unsafe care which unintentionally harms the patient and can be attributed to the healthcare provided but not to the underlying pathology. Adverse events may be caused by human failure or defects in the system. Although some events are considered unpreventable accidents, most of them are considered preventable.[1-4]

When unsafe care does not cause any damage, it is considered a sign or incident, defined as an event

or circumstance which may warn of increased risk of a failure occurring in healthcare[3].

The World Health Organization (WHO)[5] encourages reporting, monitoring and managing adverse events, and highlights the fact that there is little available documentation in dentistry. Given that patients safety is a global sanitary issue and that adverse events occur at all health centers, the WHO, the International Dental Federation and several researchers have conducted a study on safety culture in the field of dentistry, benefitting both professionals and patients[4].

In Colombia, the Ministry of Health and Social Protectionfosters, by means of a quality assurance system, adverse event management and prevention, which must be applied as from the training stage pursuant to the Ministry of Health decree 2376 of the year 2010, which refers to training practice as "an educational institution's planned, organized pedagogical strategy seeking to integrate academic education andproviding healthcare service, with the aim of strengthening and creating competencies and skills in students training under healthcare programs, within a framework promoting the quality of healthcare, responsible, ethical professional exercise"[6].

The potential harm that a patient may suffer when receiving care from personnel undergoing dental care training has not been measured widely. Further knowledge of the frequency of this kind of error and fostering a culture of systematically reporting incidents will serve as a basis to design new, efficient tools to measure the occurrence of incidents, and most importantly, preventing them.[4,7] The School of Dentistry where this study was conducted provides care to patients under the teaching-service model, where pedagogical practices at all levels of training – low, medium and high – are provided, according to the complexity of the treatments required, at theoretical, pre-clinical and clinical levels. Dental services at the School include a portfolio offering General Dentistry and the specialties Oral Surgery and Pathology, Maxillofacial Surgery, Endodontics, Periodontics, Orthodontics, Pediatric Dentistry and Oral Rehabilitation.

Adverse events occur during or as a result of clinical procedures, which should therefore be subject to management tools and methodologies to reduce or prevent them. This would impact the costs of lack of quality, and contribute to safe, efficient, people-centered care as essentialin training human resources in Dentistry[8,9]. This study was performed as a contribution to the Patient Safety Program, with the aim of analyzing the adverse events filed with the Office of the Clinical Director at the School of Dentistry at Pontificia Universidad Javeriana during 2011-2012.

MATERIALS AND METHODS

During 2011-2012,we analyzed 16,060 patients who received care at undergraduate and postgraduate services at the clinics. Of these, 227 dental clinical records were found in which patients filed a complaint with the Office of the Clinical Director and requested a review of their current treatment condition or their further care. We analyzed them to determine whether there had been any risk situations which mighthave caused an incident or adverse event, finding 63, including20 with signs of unsafe care and 43 with occurrence of an adverse event, defined in the opinion of the experts in the Institutional Technical-Scientific Committee.

Using an *ad-hoc* form, we recorded patient demographics (age, sex, occupation); type of adverse event; complexity of treatment; number of students and their level (undergraduate/postgraduate); specialty of postgraduate students; support services from dental laboratories; failures before, during and after treatment in the clinical, academic and administrative spheres; and management of instruments, supplies and equipment. In addition, we considered time of treatment as a factor of non-conformance and clinical risk affecting the proper evolution of treatments.

After collecting the information, we classified the adverse events detected. The analysis is supported by descriptive statistics.

RESULTS

Of the 16,060 patients who received care during 2011 and 2012, 0.26% (43) filed a complaint which has resulted in an adverse event. Of these,62.7% were female, while regarding age, 4.8% were under 18 years old, 57.1% were between 19 to 59 years old and 38.1% were over 60 years old.

Occupation was classified according to patient's activity at the time of the event, without considering schooling education level, 42.2% working, 48.9% homemakers, students or pensioners, and 7% with no recorded data. None had any physical or mental disability impacting the occurrence of the event.

Of the 43 adverse events detected, only one was classified as unpreventable, in which the treatment

failed because bone regeneration was not viable despite the fact that the morning C-terminal telopeptide (CTX) value was within normal limits. Individual biological response was the determining factor in the occurrence of the event.

Of the adverse events classified as preventable (9.7%), most (52.38%,n = 22) occurred during clinical management of prosthetic treatments, with the most common cause being fracture of prosthetic material after cementing. In second place, 23.8% (10) of the events were related to clinical management in other areas, the most frequent being excessive drilling. In third place, 9.5% (4) were failures in the quality of work from the external dental laboratory, and the remaining 14.32% (6) were caused by failures in document management, soft tissue injury, misdiagnosis and swallowing foreign objects (Table 1).

Regarding the level of the students providing clinical care, 34.8% (15) patients received care from undergraduate students and 65.2% (28) received care from postgraduate students, mainly in Oral Rehabilitation speciality (Fig. 1).

It is important to use and follow clinical and learning guidelines as academic support within the care model at the School. We found that these guidelines had been used to support clinical practice in 97.6% (42) of the cases and not used in 2.3% (1). Regarding the degree to which the recommendations in these guidelines were followed, we found that they had been followed by 11.62% (5), not followed by 53.48% (23), and there was no report in the dental clinical records for 34.8% (15).

Complaints about dissatisfaction with care provided within the teaching-service model at the School were classified according to cause. It was found that the 83.72% (36) of the complaints were due to clinical care, while for 11.62% (5) it was due to clinical-administrative errors caused by students, such as delays in care or evolution of treatment, not calling the patient after the inter-semester period or unpunctuality. Right of petition for clinical and administrative cause were 2.3% each, being a resource used by very few patients, and were filed due to dissatisfaction with the type of clinical care received. Administrative complaints exclusive not were found. (Fig. 2).

Analysis of use of diagnostic aids showed that 88.4% (38) had initial radiographs. Final radiographs were only found in 58.2% (25) of the dental clinical records.

Considering that treatments take longer in the teaching-service care model, we originally considered that the longer the time, the greater the probability of an event occurring, so we checked the average duration of treatments in months. In general, the cases took 1 month to 14 years. In contrast to what we expected, we found that most cases with events had completed the treatment during the first year (20.9%) and almost 70% had been completed within 5 years (Fig. 3).

Under the assumption that the more students taking part in a treatment, the greater the chance of an event occurring, we analyzed the number of students who took part in each adverse event studied. We found that 37% of the cases were conducted by 1 to 5 students, 33% by 6 to 10 students, 19% by 11 to 15 and 11% by more than 16 students. The number of students involved in care of a given patient was not associated to a greater number of adverse events (Fig. 4).

No adverse event wasfound to be related to management of instruments, supplies and equipment.

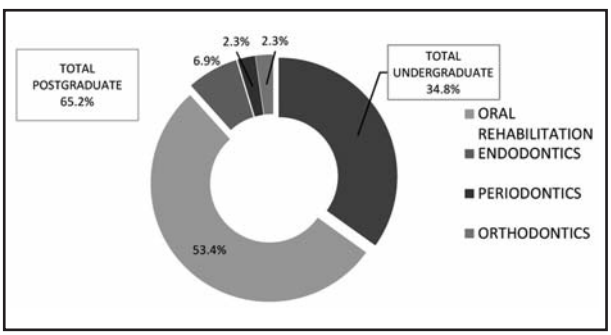

Fig. 1: Distribution of adverse events found according to student training level and specialty.

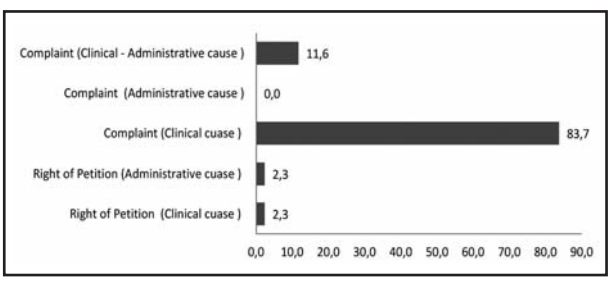

Fig. 2: Classification of complaints filed with the Office of the Clinical Director of the School of Dentistry which correspond to the adverse events found.

DISCUSSION

Given the concern about quality in dental services and that the school of dentistry is a teaching service institution, research has been one of the main purpose since 2008 with the aim of determining the occurrence of incidents or adverse events during care provided by students in different postgraduate courses that could put patient safety at risk, in order to create preventive and control strategies.

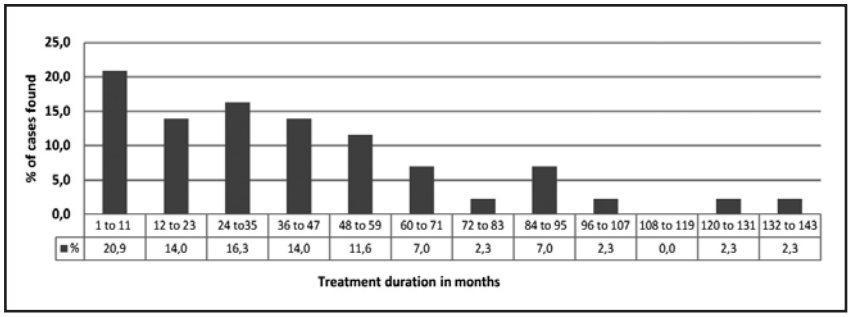

Fig. 3: Percentage of cases according to treatment duration in months.

Worldwide, there is little scientific literature on adverse events in dental care, and the wide variety in both in theory[3] and methodology forstudying adverse events make progression the subject difficult in dentistry.

One of the most relevant results in this study was the low frequency (0.26%) of adverse events found during analysis of clinical records of dissatisfied patients who filed a complaint with the Technical-Scientific Committee, relative to total number of patients who received care at the School clinics. The cases filed were the most severe or those involving legal implications. However, there is consensus in the literature that cases are under-recorded, under-reported and unsystematized, so adverse events cannot always be analyzed in-depth.[10]

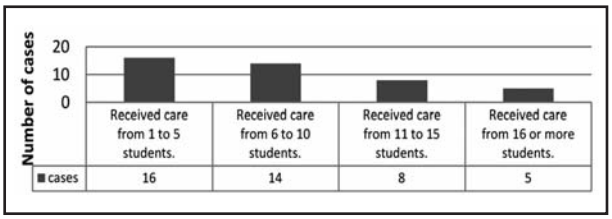

Fig. 4: Adverse event cases classified according to number of students involved in patient care.

One of the problems that creates uncertainty about the real frequency of adverse events is under-reporting, as expressed by Thusu et al.[11], who conducted a one-

Table 1: Preventable adverse events caused by failures before, during and after treatment.

Event according to cause	Type	% (n)
Events in clinical management of prosthetic treatments	Implant screw breakage Fault in hybrid bar design Prosthetic material fracture after cementing Uncemented prosthesis or part of prosthesis Repetition of prosthetic work with unspecified cause Repetition of prosthetic work due to misfit Repetition of prosthetic work due to faulty design	52.38 % (22)
Events in clinical management of treatments in other fields of dentistry	Tooth loss due to endodoncy Excessive tooth drilling Loss of permanent tooth follicle during extraction of temporary tooth Endodontic file breakage Anesthetic needle breakage	23.8 % (10)
Failures in quality of external laboratory work	Loss of ceramic material Broken abutments in removable partial denture Repetition of prosthesis	9.5 % (4)
Failures in document management	Mismanagement of referrals and transfers	4.78% (2)
Soft tissue injury	Burn on lip from electric scalpel Gum injury when placing post-surgical staple	4.78 % (2)
Misdiagnosis	Misdiagnosis	2.38 % (1)
Swallowing foreign objects	Swallowing implant screwdriver	2.38 % (1)

year study based on dental reports from the database of the United Kingdom's National Patient Safety Agency. They found a low rate of reports on dental incidents, possibly due to the voluntary nature of reporting and the reluctance of dental practitioners to disclose incidents for fear of some kind of professional inconvenience.

A study conducted on the database from the Spanish Observatory for Dental Patient Safety (OESPO), analyzed 415 law suits and reported that 40% were caused by errors (conscious event), 40% by complications and 20% by accidents (conceptually defined as an adverse event). It concluded that the use of this source has limitations because dentists report few adverse events since they perceive their procedures as being less complex than medical procedures and not life-threatening, although the same study found 11 cases of death attributed to the dentist's confidence during treatment (allergy, endocarditis caused by lack of prophylaxis, hemorrhages in anticoagulated patients and infections in immunocompromised patients, among others), pointing to the need for detailed clinical records[10,] Obadan et al.[12] report that 24.1% of adverse events required that the patient be transferred to an emergency department, of which 11.1% resulted in death of the affected patient.

In our study, the most severe event (2.38%) of the 43 found was due to swallowing a prosthodontic screwdriver. The patient was taken to emergency room and the device had to be removed under medical care at a hospital. Although events such as this are infrequent, they are important because of their potential complications which may lead to death of a patient. There are reports of a wide range of ingested items, such as fixed prosthesis, orthodontic items[13,14]metal restorations, crowns, cores, endodontic files, and ultrasonic tips, among others[15.]

In their analysis of the those cases, Obinata et al found that ingestions occurred more frequently during treatment of lower molars, and suggest keeping the patient's head inclined towards the side being treated so that objects fall in the buccal pouch. Cases of ingestion occurred more frequently when the procedures were performed by professionals with less than 5 years of experience. Therefore, and considering the risk created by these accidents, dentists should take meticulous precautions and be prepared to deal with this kind of emergency[15.] When there is inhalation, the risk is greater, so it is suggested that dental offices should have emergency protocols for dealing with it promptly[14.] In addition, patients at greater risk of ingestion or aspiration of objects should be identified and extra precautions takento prevent such complications. Zitzmann et al.[16]provide guidelines for managing inhaled or ingested objects during dental treatment.

In addition to the issue of underreporting, the source of information on which an analysis is based modifies the casuistic and results found on the subject. The other methodologies most frequently used for detection and analysis of adverse events are direct review of clinical records and surveys. These methods usually increase the number of events reported. Our research group conducted a study on adverse events in the field of endodontics, finding reports in 74.4% of the records analyzed over two years. It is interesting to note that most of them (81.3%) are considered preventable[17]similarly to the current study, in which only one event was not preventable.

A study by Hiivala et al.[4] used an internet survey of dentists who worked at public and private institutions. It reports 872 patient safety incidents, of which 53% were considered adverse events, 45% incidents and 13% severe events potentially causing permanent damage, as a result of factors caused by application of local anesthesia, allergic reaction, exposure to radiation and extracting wrong teeth, among others. Anotherstudy conducted on the database of adverse events reported to national supervision and administrative institutions in the healthcare sector found that 32% occurred at private dental offices, 62.9% were preventable, 4.1% not preventable and 33% could not be evaluated[18.]

The most frequent types of adverse events have been reported in most fields of dental care. In our study, the highest frequency occurred in clinical management of prosthetic treatments, with 52.4%, followed by another clinical management treatments in other fields of dentistry, 28.8%. These results were similar to those reported by Hivalla et al.[18], who rank prosthodontics in first place with 16.4%, restoration 9.5%, implants 8.4%, endodontics 6.6%, orthodontics 3.6% and periodontics 1.8%. Similarly, Tiwana et al.[19] report events in the field of prosthodontics in first place. Perea-Perez[10] finds the highest frequency of events in the

field of implantology, followed by endodontics, oral surgery, prosthodontics and orthodontics.

A range of factors have been found to influence the occurrence of an adverse event. For example, poor management of the patient's medical records considered relevant to patient safety, as well professional skill during the clinical interview, particularly regarding sensitive issues such as HIV[20.] Our study only found one adverse event as a result of diagnosis (2.38%), which occurred due to the lack of a comprehensive diagnosis. Tiwanaet al.[19]found insufficient or erroneous records in 35.6% and in complete medical recordsin 15.1%. Considering the importance of diagnostic help such as diagnostic support and follow-up of treatments, the School of Dentistry policy is that all patients begin with an initial radiograph.It was found that approximately 10% of the cases did not have radiographs, which the students may have removed to perform the diagnosis and failed to return to the clinical file. The problem has now been overcome by the use of digital clinical records, which were implemented 4 years ago at the School.

Among other predisposing factors for adverse events are patient care by a large number of students[21] attempting to perform procedures that are beyond the professional's technical skill, lack of consultation with experts, overconfidence in own skills and knowledge, ignoring evidence-based medicine, operator fatigue, lack of awareness of risks, lack of communication leading to procedural errors through mismanagement of referrals and transfers[22] and following guidelines[18,20,21,23]. We looked at these factors during this study, but found no association between the occurrence of adverse events and the demographic variable sage, sex, level or any influence of number of students or use of guidelines. Regarding age, adverse events have been reported more frequently in adults (25-60 years), with no difference between sexes.[12]

Regarding timing, we found that most events occurred within the first 5 years of treatment, including the inter-semester periods, given the modality of university service provided. In a study on dentists, Hiivala et al.[18] found a time of 17 months, with adverse events attributed mainly to communication breakdowns in the organization.

With regard to the main factors that contribute to preventing adverse events for professionals and university teachers, Bailey[20] mentions knowledge of the patient's medical record as having the greatest impact, as well as quality and adequacy of the record-taking. The pedagogical model implemented at our School includes in its clinical-administrative competences, knowledge of how to use the dental clinical record as an essential safety factor when providing service.

Ten years ago, the School implemented patient safety and service quality committees with the aim of providing a safety policy contributing to systematic follow-up, implementing safety barriers, research and knowledge management in the area, with the aim of creating an impact on students in the exercise of their future profession.

One of the weaknesses of the patient safety culture is the lack of understanding of the concept of adverse event and the lack of research, which does not allow learning how to prevent adverse events, guidelines for improving quality such as detailed monitoring of critical biosafety processes and sterilization, proper medication prescription, control of unnecessary radiation and checklists for all surgical procedures, among others, to help improve quality and patient safety[10.]

The greatest impact on the culture of patient safety is achieved through training. It is at theacademy that knowledge is consolidated with principles of ethics and responsibility. Methodical, systematic rigor in the adherence to safe practices by all staff involved in patient care will reduce the occurrence of adverse events.

Clear, prompt communication skills with patients are essential for decision making by patients regarding treatments and contribute to creating trust. There is a need in both dental professionals and students who are undergoing training to gain deeper knowledge and research of adverse events in order to prevent them from occurring again, thus contributing to improving patient safety and student training.

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