

Knowledge, Attitudes and Practices of Dentists on Medical Devices: Study in the Region of Dakar, Senegal

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Abstract: The aim of this study was to test the level of knowledge, attitudes and practices of the dental surgeon on medical device in the region of Dakar. This was a descriptive and cross-sectional study covering 130 dental surgeons practicing in the region of Dakar, selected following stratified sampling. One stratum grouped 60% of the sample that worked in dental public structures. Another stratum gathered 40% of the sample who were dentists working in private dental structures. More than half of the dental surgeons (53.8%) have at least observed once an adverse effect case with a predominance of allergy (42%). The prevailing attitude was to stop or removal of the material. However, more than 86% of the sample have never reported or notified any adverse effects following use of any material. Almost 9/10th of the surveyed sample (88.5%) have never been trained on medical device vigilance. These results strongly advocate for the integration of medical device vigilance in the current health monitoring system and for an improved awareness in notifying and spontaneously reporting adverse effects observed in the use of medical device. More than half of the dental surgeons (48.40%) do not define the medical device vigilance.

Keywords: Medical Device, Medical Device Vigilance, Dentist

1. Introduction

Medical device (MD) has significantly been used in dental care or often concurrently during these last years. In some cases, these MD can even constitute the bulk of the treatment but differ from drugs by their principal mode of action other than pharmacological, immunological or metabolic; however they can contain a drug for an ancillary action [1]. Nevertheless, there are no perfect materials; when inserted into a living tissue, interactions may occur with biological systems with which they are in contact. These interactions may result in a biological response, which vary depending on the material and conditions to which it is subjected [2]. Medical device can cause unpredictable effects in the medium or long term; this could be due to mechanical defects, manufacturing or use problems. These adverse effects are common and can affect the patient's

integrity. So many adverse effects implicating some MD have been reported, namely inflammatory reactions, oral or extra-oral irritations, allergies. A Norwegian study found half of the dental surgeons suffering from reported occupational health problems, such as skin diseases (40%), eye problems, respiratory and systemic complaints (13%) [3]. A study was conducted from 2000 to 2004 to identify common allergens associated with contact dermatitis in dental care. The most common oral manifestations were cheilitis and perioral dermatitis (25.6%), oral lesions (15.7%), lichenoid reactions (14.0%), granulomatous (10.7%) [4].

To tackle this problem, many countries have a health monitoring system for medical devices. To improve the safety of patients and practitioners, medical device vigilance serves as a monitoring station for any DM as soon as it is commercialised; this consists in the monitoring of incidents or risks of incidents

resulting from the use of medical devices by means of preventive and /or appropriate corrective measures [5]. However in Senegal, medical device vigilance is still not integrated in the organization of health monitoring. Is health monitoring collecting a satisfactory level of information in comparison to medical device vigilance? This work is a contribution to a better understanding of medical device vigilance as well as participating in a better management of adverse reactions occurring in the use and handling of medical devices in the daily practice of dentistry. The objective of this work was to test the level of knowledge, attitudes and practices of the dental surgeon on medical device in the region of Dakar.

2. Methods

2.1. Framework and Type of Study

The investigation took place in the region of Dakar that concentrates more than half of the dentists in Senegal. There are 220 dentist offices in the region of Dakar approved by the Ministry of Health. Thirty of them are public and 190 are private. These offices are distributed into 7 districts and 31 municipalities. It was a cross sectional and descriptive study.

2.2. Studied Population

The studied population included a total of 264 dentists from whom 190 work in private offices and 74 in public offices in Dakar.

2.3. Selection Criteria

The dental surgeons included in this study were all those who have obtained the degree of Doctor of Dental Surgery, practicing at the time the survey took place and who have agreed to participate in the study. The dental surgeons who were not included in this study were all those who have refused to participate in the data collection.

2.4. Sampling and Sample Size

It was first to identify the location of dental offices according to districts and municipalities within the districts of the region of Dakar. Then a stratified sampling was used and 2 private and public dental offices stratum were formed. In each stratum, dental offices were drawn by simple random sampling. A number of dental offices were selected according to the calculated size. Then finally, all the dental surgeons based in the selected dental offices composed the sample with 40% of public dental surgeons and 60% of private dental surgeons. The size N of the sample was calculated following Schwartz formula: $N = (\epsilon\alpha)^2 pq / I^2$, applicable to cross-sectional studies, where $\epsilon = Z$ score = 1.96; α = risk of error = 0.05; p = theoretical proportion of dental surgeons with a knowledge in medical device vigilance = theoretically set to 50% (in the absence of specific data); q = the complementary probability (=1-p) %, I = Accuracy = 10%. The use of these parameters resulted in a size of $N = 96$. However to deal with potential losses or unusable questionnaire and to increase the power of the study, the size

was increased to 130. Thus the study concerned 78 private dental surgeons and 52 public dental surgeons.

2.5. Data Collection Procedures and Studied Variables

Before starting the survey and administering the questionnaire to the dental surgeons, a pre-test on five dental surgeons was conducted which allowed to observe the reaction of the respondents to the survey, to obtain estimates of the time devoted to the various sections and to validate the questionnaire. The difficulties and ambiguities encountered were corrected in order to prepare for the final survey. The data collection took place from 12/05/2014 to 29/10/2014 and concerned all dental surgeons meeting the selection criteria.

The questionnaire was structured as follows:

- Variables related to sociodemographic characteristics: gender, age, specialty, workplace, years of practice, and most practiced therapeutic acts.
- Variables related to attitudes and practices of dental surgeons in relation with medical devices and their adverse effects: materials more often used, adverse effects cases, report of cases and procedures followed.
- Variables in relation to the knowledge on material device vigilance: meaning, objectives, training, existence of a notification form and the need for monitoring of medical devices after sale.

2.6. Ethical Considerations

Having obtained approval from the Ministry of Health and informed the person in charge of health-care facilities, a questionnaire was devised and administered directly to each dentist. Furthermore, the objectives and importance of the survey were explained to dental surgeons for their consent before administering the questionnaire.

2.7. Data Analysis

SPSS 18 has been used for entry and processing of the data. The results were expressed in actual number and percentage for all variables.

3. Results

In total of 130 dental surgeons participated in the survey.

Table 1. Dental Surgeons' Socio-demographical Characteristics.

Variables	Number	Percentage (%)	
Sex	Male	82	63.08
	Female	48	36.92
Age	25-39 years	50	54.54
	40-59 years	71	7.30
	60 and more	9	19.21
Number of years of practice	Less than 5 years	25	19.21
	5-10 years	35	27.02
	11 and more	70	53.77
Type of Dentist	Specialist	20	15.38
	General practitioner	110	84.62

From the total sample, 63% of dentists were male. The majority of dentist were aged between 25 and 39 years and

were general practitioner (84.62%).

Table 2. Distribution of Dental Surgeons' most used Medical Device.

Medical Devices	Number	Percentage (%)	
Prosthesis	Irreversible hydrocolloid	110	18.45
	Elastomer	99	16.61
	Reversible hydrocolloid	2	0.33
	Others	385	64.61
	Total	596	100
Metals	Nickel-chrome	95	68.84
	Others	57	31.16
	Total	152	100
Conservative dentistry and endodontic (CDE)	Amalgam	117	17.72
	Composite	117	17.72
	GIC*	105	15.75
	MTA*	05	0.75
	Others	316	48.06
Implantology	Total	660	100
	Titanium	09	90
	Others	01	10
	Total	10	100

*GIC: Glass Ionomer Cement, *MTA: Mineral Trioxide Aggregate

In prosthesis, the irreversible hydrocolloids are the most used medical device (18.45%). As regards metals, nickel-chrome was the alloy of choice for 73.08% of the sample. In CDE, amalgam and composite were the most used MD by 17.72% and in Implantology, titanium was the most used MD by 90% of the sample.

Table 3. Distribution of Adverse Effects and Dental Surgeons' Attitudes.

Medical Device and Adverse Effects	Number	Percentage (%)	
Occurrence Report of Adverse Effect Cases	70	53.80	
Observed Manifestation	Allergy	29	42.00
	Pain	17	24.60
	Inflammation	9	12.40
	Infection	4	05.30
	Sensitivity	11	15.70
Dental Surgeons' Attitudes	Removal of Material	57	43.85
	Manipulation change	20	15.83
	Drug prescription	4	03.80
	Patient referral	34	26.15

70 dental surgeons (53.8%) claimed to have been at least once faced with an adverse effect case implicating a MD in their professional practice. And Allergy was the most reported adverse effect, which affected 42% of the sample. The prevailing attitude of dental surgeons (43.8%) was to stop and remove the material.

Table 4. Notification Procedure and Medical Device Vigilance Knowledge of the Surveyed Dental Surgeons.

Medical Device and Adverse Effects	Number	Percentage (%)	
Occurrence Report of Adverse Effect Cases	18	13.80	
Notification Procedure	Sending letter	06	03.54
	Telephone	07	04.00
	Sending mail	05	03.35
Address where notification has been reported	Department head	9	06.92
	Order of Dentists	2	1.77
	Oral health department	7	05.82
Training in medical device vigilance	15	07.6	
Defining medical device vigilance	Correct answer	10	26.90
	Wrong answer	22	16.90
	Don't know	63	48.40

From the total sample 13.80% of the surveyed sample has notified cases of adverse effects observed. Only 7 dental surgeons used the phone (4%) and the others wrote a letter or report (7%). More than half of the dental surgeons (48.40%) do not define the medical device vigilance.

4. Discussion

4.1. Limitations of the Study

A total of 130 dental surgeons participated in the survey. However, we met some difficulties namely: the refusal of some dental surgeons to receive us; others required that we leave them the questionnaire so that they could fill it later; others still found it too long and had not enough time for us. This is reflected on the duration of the inquiry, which was extended. To reach the calculated size, the questionnaire was photocopied twice with no return from dental surgeons.

The study sample is indicative since the region of Dakar concentrates more than $\frac{3}{4}$ of dental structures in the country. The survey allowed studying the use of medical device by dental surgeons and assessing their level of knowledge on medical device vigilance.

4.2. Socio-demographical Characteristics

In this survey, 63% of dentists were male; this is representative of the source population in Senegal. The mean age was 43 years. The average number of years of practice was 13 years and 6 months. These findings are consistent with the results in Mbaye's study 2010 [6].

4.3. The Most Used Medical Devices

In prosthesis, although dental surgeons had a large number of impression materials, it turns out at the end of this study that irreversible hydrocolloids were the most used medical device (18.45%), followed by elastomers (16.61%). This can be justified by the fact that these materials have a short contact time with tissues which is certainly an advantage from a toxicological point of view [7] and by their ability to offer many use options to adapt to different clinical indications.

Reversible hydrocolloids, first elastic impression materials in dentistry, were the least used by 0.33% of the surveyed population. This is due to the handling technology and treatment time that has to be quick because there is no middle of storage satisfactory enough to preserve them over an hour [8]. As regards metals, nickel-chrome is the alloy of choice for 73.08% of the sample. According to Wataha (2002), the protective oxide layer that is formed in-between is resistant to corrosion and wear [9]. However, in literature, nickel is responsible for the majority of allergic reactions of the mucous membrane of mouth; Among 2,000,000 new patients treated each year in Orthodontics in North America, 2000 to 4000 2000 exhibit sensitivity to nickel-chromium [10]. In CDE, amalgam and composite are the most used MD by 17.72% of the sample, followed by GIC and MTA users with respectively 15.75%, and 0.75%. However, MTA is a material that presents many clinical indications because of its inductive capacity in

hard tissue formation. But because of its high cost, few dentists use it [11, 12]. In implantology, titanium is the most used MD by 90% of the sample. Probably its osseointegration and mechanical qualities like hardness, lightness and resistance justify this high level of use [13].

4.4. Adverse Effects

During the survey, 70 dental surgeons (53.8%) claimed to have been at least once faced with an adverse effect case implicating a MD in their professional practice. This can be justified by their wide use in dental clinic and the fact that they remain very often in the mouth for several years. Allergy was the most reported adverse effect, which affected 42% of the sample. These allergic phenomena are frequent and their prevalence tends to increase mainly because of the diversity and proliferation of allergenic products and the high growing number of person suffering from [14]. In reality, the WHO as the 4th pathology currently considers allergy in term of prevalence [15]. The prevailing attitude of dental surgeons (43.8%) in front of observed adverse effects cases was to stop and remove the material, for more caution.

In Diouf's 2013 study on pharmacovigilance, the major part of the dentists (77%) had the same idea to stop and change medication in case of adverse reaction [16]. Because of the frequency of occurrence of more or less serious undesirable effects, the major part of dentist respondents found that DM can be dangerous and that their monitoring after placing on the market was essential.

4.5. Medical Device Vigilance and Dental Clinic

The study showed that only 56.9% of the dentists know what a sheet of notification is. These figures are above those obtained among 50.4% of physicians at the UMC of Ibadan in Nigeria [17]. Although efforts have been made at the level of health programs in Senegal, a lack of awareness is noted in the oral health sector. Indeed, 86.02% of the surveyed sample has never notified cases of adverse effects observed. This figure is confirmed by results obtained in similar studies carried out by Aziz *et al* (2007) in Malaysia and Qing *et al* (2004) in China for other health professionals where 81.4% and 62.1% respectively did not report cases although suspecting them as adverse effects [18, 19]. The non-declaration of these adverse effects, or even under notification, is one of the main obstacles to the smooth running of alert programs. This is a common problem to all countries. In developed countries, such as China, a high level of under-reporting is recorded [19]; in Italy doctors had little information concerning adverse effects as well as their systems of notification [20]. Uppsala Monitoring Centre (UMC, WHO) in Sweden, which holds the international database, has got approximately 4.7 million cases of adverse reactions reported from 96 national centres. Despite this number, it is estimated that only 6 to 10% of serious adverse reactions are reported [21]. This under notification delays signal detection and under-estimates the magnitude of the problem. And Mirbaha *et al* (2015), are detected several

barriers, such as lack of knowledge of what should be reported, fear of punishment and criticism, lack of time, lack of teamwork... [22]. These are confirmed by results obtained in study carried out by Polisen *et al* (2015) findings who indicated that fear of punishment, uncertainty of what should be reported and how incident reports will be used and time constraints to incident reporting are common barriers to incident recognition and reporting [23]. However, according to dental surgeons, this non-reporting of adverse events could be explained by the absence of means of notifications; only 7 dental surgeons used the phone (4%) and the others wrote a letter or report; the remaining had no idea of notification procedures and none of the dental surgeons had a declaration form for the adverse effects of DM. Education, training and the implementation of registries were discussed as important initiatives to improve medical device surveillance in clinical practice [24].

5. Conclusion

The prevailing attitude was to stop or removal of the material. However, more than 86% of the sample have never reported or notified any adverse effects following use of any material. Almost 9/10th of the surveyed sample (88.5%) have never been trained on medical device vigilance.

These results advocate for the integration of medical device vigilance in the health monitoring system and improving awareness in notification and spontaneous reporting of cases of adverse effects observed. In addition, developing a notification form will facilitate reporting adverse effect cases with an improved monitoring of medical devices.

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