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RESEARCH ARTICLE

KNOWLEDGE, ATTITUDE AND PRACTICES OF PHARMACOVIGILANCE AMONG HEALTHCARE PROFESSIONALS IN A MEDICAL AND DENTAL INSTITUTE: A COMPARATIVE STUDY

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ABSTRACT

Background: Pharmacovigilance deals with the detection, assessment, understanding and prevention of adverse effects, particularly long term and short-term adverse effect of medicines. Objectives: To assess knowledge, attitude and Practice among health professionals about Pharmacovigilance and barriers towards reporting adverse drug reactions.

Material & Methods: It was a cross-sectional, questionnaire based survey. The participants were Under Graduates, Interns & post graduates pursuing their courses in dental & medical field. The assessment regarding knowledge, attitude and practice was done by questionnaire having 23, 8 & 8 items respectively. Five point Likert scale was used to evaluate attitude and practice. 07 questions for under reporting the adverse drug reactions, with an option to tick multiple options were also included. Demographic data of the participants was also collected. Unpaired't' test was used to assess the statistical differences.

Results: A total of 397 out of 605 Study subjects responded in medical, and similarly 203 out of 283 in dentistry. Among medical and dental subjects 9% and 36.4% have never heard the term pharmacovigilance. Overall 3% and 5.4% had taken special training in pharmacovigilance, respectively. The mean knowledge, attitude and practices scores were higher in medical compared to dental professions but only mean practices scores was found statistically significant.

Conclusion: The underreporting of ADRs was due to lack of knowledge and poor practice. Even though the attitude was good but still it has to improve among dental students by appropriate curriculum changes and continuing education programs in medical students.

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INTRODUCTION

Pharmacovigilance is a branch of pharmacology which deals with the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term adverse effect of medicines (Lihite, 2015). World Health Organisation (WHO) has defined Adverse Drug Reactions (ADRs) as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function" (International drug monitoring: the role of national centres, 1972).

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Throughout the world ADRs are one of the most common cause of morbidity of varying magnitudes & mortality, therefore monitoring or surveillance of ADRs is the necessity in present scenario. Recent studies suggests that ADRs are the fourth major cause of hospitalisation/death in USA (Lazarou, 1998). In India ADR monitoring programme was formally introduced in the year 1986 with 12 regional centres. The inadequate ADR reporting led to the initiation of National Pharmacovigilance programme (NPvP) by Government of India, but due to some unforeseen circumstances this programme was temporarily suspended. Again in 2010 a nationwide programme "Pharmacovigilance programme of India" (PvPI) was launched (Kalaiselvan, 2014 and Gupta, 2010). Initially only 22 ADR Monitoring centres (AMCs) were there, this number is continuously increasing and presently 179

AMCs are existing under PvPI in the country (http://ipc.nic.in/showfile.asp?lid=448&EncHid= retrived on 10 Mar 2016). In India all health care contributors (Doctors, nurses, pharmacists etc) as well as participants (patients) can report an ADR to the CDSCO (Central Drugs Standard Control Organization) by filling the form which is easily available (Upadhyaya, 2012). Inspite the continuous effort by the Pharmacovigilance Programme of India (PvPI) towards instilling the culture of ADRs reporting still there is high prevalence of underreporting and studies suggests that only 6-10 % of all ADRs are reported (Khan, 2013 and Muraraiah, 2011). Pharmacovigilance has gain its importance over the last three decades not only in terms of reporting ADRs but also in actual increase in several hospital admissions due to ADRs (Wu, 2003; Von Laue, 2003 and Radhakrishnan Rajesh, 2010). Pharmacovigilance supports health care system by early detection of ADRs as well as also assist in identification of risk factors associated and mechanism responsible for ADR (Pimpalkhute, 2012). With effective communication pharmacovigilance permit for the fact based application of drugs and having the prospective for preventing many ADRs related hospitalization (Radhakrishnan Rajesh, 2010). Base of successful pharmacovigilance is spontaneousreporting of ADRs. India is lagging in spontaneous reporting because of which nation's contribution to the UMC (Uppsala Monitoring Centre) database of WHO is scanty(Jose, 2006). In 2013 India's share to WHO-UMC's vigibase was only 2%, despite this India was at 7th position among top 10 countries to global vigibase (Lihite, 2015).

Most common reasons for underreporting of ADR is absence of awareness or alertness about the finding or detection of ADRs and also no financial benefit associated with it. Insufficient knowledge, poor attitudes, Fear of litigation and publishing ambition are another reasons for high degree of underreporting of ADRs (Radhakrishnan Rajesh, 2010; Inman, 2009 and Lopez-Gonzalez, 2009). Studies showed that with introduction of incentives or prize money will increase the voluntary reporting of ADRs by 4.3% preferably by junior doctors (Feely, 1990). Though many studies were published in various part of our country to assess knowledge, attitude & practice of pharmacovigilance (Kalaiselvan, 2014; Upadhyaya, 2012; Khan, 2013; Muraraiah, 2011; Hardeep, 2013; Rehan, 2012 Desai, 2011 and Rehan, 2012), it is vital to assess the present status of health care providers for the continuous improvement in ADR monitoring. Medications that were efficacious in large groups, often fails to perform with same efficacy in different lineage, thus ADR are highly variable and hence limiting factor of highest order in drug therapeutics and development[1]. It is necessary to make our own database for ADR reporting due to various factors like ethnic factor, socio-economic or environmental factors (Muraraiah, 2011).

Previous studies conducted either in India or abroad are focused on either medical or dental group. The present study was undertaken to evaluate the knowledge, attitude and practices in a group of medical & dental; undergraduates, interns & residents of postgraduates of the same institute. Both medical and dental groups are included in this research because both are practising modern medicine (allopathy) & well authorize and capable of reporting ADRs. This study will support in providing numerous approaches for betterment of the PvPI.

MATERIALS AND METHODS

This study was a cross-sectional questionnaire based survey carried out in tertiary care teaching Medical & Dental institute in the central region of India. The study was conducted after getting permission from the Institutional Review Board. The participants selected for this study was Under Graduates (UGs), Interns &Resident Doctors (1st to 3rd year). The purpose and nature of study was explained and necessary consent was acquired from the participants. The questionnaire was self-administered and closed ended. The participants of both medical & dental cadre were gathered in the class and instructions were given to all the participants about filling of questionnaire before the beginning of the exercise and sufficient time was given to them for completing the questionnaire. The questionnaire included self-explanatory consent, basic knowledge of ADRs, barriers for not reporting ADRs, attitudes toward the voluntary ADR reporting system, practices regarding ADR reporting system. With the help of research, observation, theory & expert opinion the content of this questionnaire was created (Streiner, 2014). 50 subjects were given the questionnaire for assessing Cronbach's alpha and split-half reliability before the beginning of this study. Successive revisions of the questions were done for the better understanding and compliance by the subjects. The values for the final questionnaire were 0.79 and 0.83 for knowledge; 0.81 and 0.88 for attitude; 0.88 and 0.93 for practices, respectively. Main study excluded pilot study subjects. Pilot study was performed only to measure reliability and results of pilot study were not included in main study.

So the final questionnaire consisted of total 46 items with 23 questions for knowledge, correct answers were given a score of "01"and for wrong answers score is "00". Eight questions for attitude assessment by using five point Likert scale, scores ranging from five for definitely yes, yes, neutral, no and one for definitely no. Similarly eight questions for practice assessment, scores ranging from five for < 1month, 1-6 months, 6-12 months, > 1year and one for never. The range of possible scores for knowledge, attitude, and practice was 0-23, 8-40, and 8-40, respectively. Additionally seven questions were included for exploring various barriers for underreporting of ADRs, with an option to choose multiple reasons. After completing the data collection it was transferred to MS Excel (MS Office version 2013 developed by Microsoft, Redmond, WA) was employed to perform statistical analysis. Descriptive analysis was performed to know the awareness and perceived barriers for not reporting pharmacovigilance. Unpaired 't' test was used to assess the differences in knowledge, attitude, and practices among both health professionals as well as in academic positions using SPSS version 16.

RESULTS

A total of 397 out of 605 Study subjects responded in medical, with a response rate of 65.83% and similarly 203 out of 283(response rate 71.73%) in dentistry. Among the study subjects, 182 (30%) belonged to undergraduates, 159 (26.5%) and 259 (43%) to interns and to post-graduates. A total of 226 respondents were males (37.6%), while 374 were females (62.3%) with a mean age of 27.6 years (Table 1).

Table 1. Distribution of the study subjects according to gender and academic position

	Academic			Mean Age (in Years)	Gender		Total n (%)
	Under-graduate n (%)	Intern n (%)	Post-graduate n (%)		Male n (%)	Female n (%)	
Medical	107(17.8)	86(14.3)	204(34)	26.2	161 (26.8)	236 (39.3)	397(66.1)
Dental	75(12.5)	73(12.1)	55(9.1)	25.7	65 (10.8)	138 (23)	203(33.8)
Total	182(30)	159(26.5)	259(43)	25.9	226 (37.6)	374 (62.3)	600(100)

Table 2. Awareness about term Pharmacovigilance

	Never heard the term N (%)	Familiar with the term N (%)	Understand the term N (%)	Took special training in Pharmacovigilance N (%)	Total N (%)
Medical	36 (9%)	140 (35.2%)	209 (52.6%)	12 (3%)	397 (100%)
Dental	74 (36.4%)	70 (34.4%)	48 (23.6%)	11 (5.4%)	203 (100%)
Total	110 (18.3%)	210 (35%)	257 (42.8%)	23 (38.3%)	600 (100%)

Table 3. Overall Knowledge, attitude and practices among both professions by using Mann Whitney U Test

Variables	Profession	N	Mean	SD	p value
Knowledge	Medical	397	9.40	3.76	0.050
	Dental	203	6.58	3.19	
Attitude	Medical	397	31.16	5.63	0.104
	Dental	203	30.56	4.93	
Practices	Medical	397	20.27	10.03	0.033*
	Dental	203	16.92	9.49	

*p<0.05

Table 4: Comparison of knowledge, attitude and practices of both professions according to different academic position by using Mann Whitney U test

		Undergraduate Mean (SD)	Intern Mean (SD)	Postgraduate Mean (SD)
Knowledge	Medical	7.99(2.85)	8.52(3.59)	9.08 (3.98)
	Dental	7.95(4.52)	8.45(4.10)	8.45 (4.12)
	p value	0.076	0.06	0.05
Attitude	Medical	30.25(4.08)	32.77(3.68)	33.58(4.05)
	Dental	28.86(6.10)	29.92(4.14)	31.95(4.49)
	p value	0.107	0.084	0.098
Practices	Medical	18.12(8.82)	19.62(7.07)	20.30(7.39)
	Dental	13.53(10.08)	21.27(10.06)	21.45(9.34)
	p value	0.01*	0.04*	0.05

Table 2 shows that among medical and dental subjects 9% and 36.4% have never heard the term pharmacovigilance, 35.2% and 34.4% were familiar with the term, 52.6% and 23.6% understood the term completely and 3% and 5.4% had taken special training in pharmacovigilance, respectively. From table 3 & 4 it was observed that, the mean knowledge scores were higher in medical (9.40 $\pm$ 3.76) compared to dental professions (6.58 $\pm$ 3.19).

And no statistical significant difference for knowledge scores was observed between them (p=0.050) and also between various academic levels (p>0.05). For attitude the mean scores were 31.16 ± 5.63 (medical) and 30.56 ± 4.93 (dental) and the difference between was statistically insignificant (p=0.104) and even in various academic levels the same pattern was seen (p>0.05). However, the mean scores for behaviour were 20.27 ± 10.03 (medical) and 16.92± 9.49 (dental) and the difference between the groups was statistically significant (p=0.033) and when further academic levels were analysed it was observed that this statistically significant difference was for undergraduate and interns of medical and dental professions (p<0.05) whereas among postgraduates the difference between both professions were statistically insignificant. Despite of the statistically significant difference in between the dental and medical professionals, there was an indication of overall positive attitude as majority of participants among both the professions, responded in Yes or Definitely Yes category for the questions of attitude. In terms of practice, the frequency of obtaining information regarding Pharmacovigilance from various sources was more than a year in both the professions. Around 40% of the health professionals had never attended any workshop/programs related to Pharmacovigilance as shown in Table 5 and 6.

Table 7 shows various perceived barriers felt by the respondents for reporting ADRs. Maximum subjects found it difficult to decide whether a certain reaction is ADR or not in both medical and dental professions (53.65% and 47.78%). Among medical profession 39 % felt lack of confidence to discuss ADR with colleagues, and 34.5% had concerns that report maybe wrong. Similarly among dental profession 37.93% had concerns that report maybe wrong.

Table 5. Comparison of responses for attitude among both the professionals by Chi-square test (*p<0.05; Significant)

Questions (Do you think)	Profession	Definitely No (%)	No (%)	Neutral/no idea (%)	Yes (%)	Definitely Yes (%)	P Value
Doctors should update their knowledge about Pharmacovigilance?	Dental	1.48	2.46	13.30	39.90	42.86	0.002*
	Medical	3.27	1.01	9.57	29.72	56.42	
Doctors have professional obligation to report an ADR?	Dental	0.00	6.40	28.08	41.87	23.65	0.002*
	Medical	4.28	6.30	21.66	35.01	32.75	
Doctors should coordinate with other health professionals to strengthen Pharmacovigilance activities?	Dental	0.00	3.94	19.70	47.29	29.06	0.008*
	Medical	2.77	2.27	14.61	41.56	38.79	
Institutions should conduct continuing education programs related to Pharmacovigilance?	Dental	2.96	7.88	23.65	41.87	23.65	0.043*
	Medical	3.53	5.79	19.65	35.26	35.77	
Practitioners should maintain accurate and complete records of any ADR occurring because of any prescription?	Dental	3.45	5.42	21.18	47.29	22.66	0.128
	Medical	7.56	9.07	20.65	43.32	19.40	
Report of only one ADR makes no significant contribution to ADR database?	Dental	10.34	33.50	39.90	13.30	2.96	0.001*
	Medical	23.68	17.63	24.69	27.20	6.80	
Doctors should report all ADR's of newly marketed drugs?	Dental	1.97	5.42	18.72	48.77	25.12	0.079
	Medical	3.02	2.27	18.14	43.32	33.25	
Pharmacovigilance should be included in undergraduate syllabus?	Dental	1.48	5.42	21.18	42.36	29.56	0.116
	Medical	2.77	3.02	17.38	38.54	38.29	

Table 6. Comparison of responses for practices among both the professionals by Chi-square test

Questions (How often do you)	Profession	Never (%)	>1 year (%)	6-12 months (%)	1-6 months (%)	<1 month (%)	P Value
Obtain information related to Pharmacovigilance from the internet	Dental	38.92	13.30	11.82	18.23	17.73	0.049*
	Medical	0.00	35.01	10.33	14.11	27.71	
Obtain information related to Pharmacovigilance from various scientific journals	Dental	39.90	15.76	15.76	17.73	10.84	0.066
	Medical	35.52	13.60	13.60	28.72	8.56	
Maintain accurate patient records to facilitate ADR identification	Dental	38.92	14.78	17.24	18.23	10.84	0.715
	Medical	36.52	13.85	18.89	21.91	8.56	
Attend workshops / programs regarding Pharmacovigilance	Dental	40.89	15.27	12.81	18.72	12.32	0.122
	Medical	41.06	16.37	16.62	19.65	6.30	
Obtain information about Pharmacovigilance that is specific to your geographical area	Dental	42.86	15.27	13.30	18.23	10.34	0.041*
	Medical	38.54	11.59	23.43	18.64	7.81	
Obtain information related to role of Medical/Dental professionals in Pharmacovigilance	Dental	37.93	17.73	20.20	14.29	9.85	0.149
	Medical	37.78	12.09	22.42	20.15	7.56	
Obtain information related to reporting of ADR	Dental	39.41	14.78	15.27	18.23	12.32	0.476
	Medical	35.52	13.35	19.90	21.16	10.08	
Obtain information related to emotional and psychological reactions of individuals who are victims of ADR	Dental	38.42	15.27	15.27	17.73	13.30	0.048*
	Medical	36.02	10.58	22.67	21.66	9.07	

*p<0.05; Significant

Table 7. Perceived barriers for pharmacovigilance

Perceived barriers	Medical		Dental	
	N	(%)	N	(%)
Concerns that the report may be wrong	137	34.51	77	37.93
Difficulty in deciding whether it is ADR or not	213	53.65	97	47.78
Lack of time to fill an ADR form	113	28.46	65	32.02
Report may generate extra work	134	33.75	55	27.09
Lack of confidence to discuss ADR with colleagues	155	39.04	45	22.17
No financial benefits	99	24.94	35	17.24
Procrastination and disinterest in reporting of any ADR	109	27.46	37	18.23

DISCUSSION

Among the various methods utilised by drug regulatory agencies throughout the world to reduce the incidence of ADRs related hospital admission, morbidity and mortality: cheapest, safest and earliest is the pharmacovigilance (Ting, 2010 and Elkalmi, 2011). That is why this study was planned to assess the difference in knowledge, attitude and practice of pharmacovigilance among medical and dental professionals at various level in their professional stage. This is first ever study comparing the knowledge, attitude and practice (KAP) of pharmacovigilance among the medical and dental health professionals. Many studies have been conducted for assessing KAP in health care professionals but there is dearth of literature assessing the same among undergraduates, interns and postgraduates of medical and dental health professionals.

The early clinical exposure of the undergraduates in their current curriculum makes them also an important group in reporting ADRs and hence even they were included apart from interns and postgraduates (http://www.dciindia.org.in/Rule_Regulation/BDS_Course_Regulation_2007_alongwith_Amendments.pdf and http://www.mciindia.org/tools/announcement/MCI_booklet.pdf). The mean knowledge, attitude and practice scores were low in all the categories of both the medical and dental subjects, similar results were found in other studies (Hardeep, 2013; Desai et al., 2011). However, relatively scores are better in medical than dental subjects, the probable reason could be that pharmacovigilance is not an integral part of dental education curriculum.Though there is a difference in mean knowledge and attitude of both the professions it was not statistically significant this suggest that if proper training is imparted to dental subjects chances are

there that improve ADRs reporting will be seen among them. The scores increased progressively from undergraduates (UGs) to postgraduates (PGs) because PGs are in close contact with patient than UGs and duration of contact is also more in PGs. The current study showed that out of 600 subjects 110 were those who never heard the term pharmacovigilance similar results were seen in studies conducted in other developing countries (Desai, 2011; Gupta, 2011; Madhan, 2009 and Oshikoya, 2009). Whereas studies conducted in developed countries better scenario of pharmacovigilance were observed in health care professionals (Bateman, 1992; Milstein, 1986), this suggest that lack of system reinforcement to train the health care providers in ADRs reporting. In our study, Less than 04% of subjects specialised on pharmacovigilance which was in accord to Khan et al (Khan, 2013). They suggested that there was increase in spontaneous ADRs reporting by educational intervention and hence regular training in pharmacovigilance will help in reducing hospitalisation due to ADRs.

In our study main reason for underreporting of ADRs by both medical and dental respondents was found to be difficulty in deciding whether it is an ADR or not, which is due to low level of their clinical knowledge{9.40 & 6.58}. This was followed by lack of confidence in discussing ADRs and concerns that the report may be wrong by medical and dental subjects respectively. The fear of superiors and inadequate knowledge creates a sense of lack of confidence lagging them behind in discussing the ADRs. Fear has been identified as a potential risk factor in underreporting of spontaneous ADRs. This obstacle can be alleviated by informing health care providers that such reactions are part of natural course of therapy and they are not held responsible for any such incidences suffices if they are adheres to the principle of rational drug use and simultaneously number of ADRs will also reduce if drugs are used rationally[8]. Conversely our results were in contrast to other studies showed that lack of time was the most discouraging factor for underreporting of ADRs (Radhakrishnan Rajesh, 2010; Chatterjee, 2006**)**. Few of the respondents in our study perceived that one of the barrier as no financial incentives. There are studies which has suggested that financial incentives will improve the ADRs reporting system even for serious and also those associated with newer drugs, which in normal course of events go unreported[17]. However some authors have also given their concerns not accepting this to be an appropriate solution as this will result in over-reporting, to obtain financial rewards[13].

Limitations

Interpretation of results have to be regarded in light of limitations. Primarily only one dental and medical institute under one university were included in this study, which cannot be the representative of entire nation's institutes, thus limiting the generalizability. Secondarily one must remember the fundamental limitations of the questionnaire based survey that is whether such survey are assessing the actual application of pharmacovigilance of the respondents or not. Moreover, there are studies which showed that knowledge, attitude and practices might not always have a linear relationship and thus to explore these relationship in regard to pharmacovigilance various other designs of studies must be conducted other than questionnaire based studies (Deolia, 2011). More studies should becarried out to assess the KAP relating to the pharmacovigilance by some better tools.

Conclusion

The underreporting of ADRs was due to lack of knowledge and poor practice this was strongly concluded by our study. Our study was also able to find out the various reasons responsible for underreporting of ADRs. Attitude of the study participants was good showing their interest towards training programmes on pharmacovigilance. National Co-ordination Centre (NCC) should not only recommend medical, pharmacy and nursing councils of India but also dental council of India to include pharmacovigilance in their respective educational curriculum, as dental institutes are also flourishing in India with same frequency as of medical institutes. There is also a need for providing continuing education programs for medical & dental professionals on pharmacovigilance in India and development of rules and regulations for those who do not report ADRs among the various categories of health care professionals. It is anticipated that our study results will help in future for curriculum designing & planning intervention for policy makers and regulatory bodies to strengthen pharmacovigilance.

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