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An Evaluations of Knowledge, Attitude and Practice of Invasive Medical Device Adverse Event or Reaction Reporting in Nashik Zone Hospitals

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Abstract: ***The current prospective observational study of three-month duration was designed to evaluate the Knowledge Attitude and Practice among health care person (doctors & nurses) and layperson (a person who under gone through the process) working towards adverse event of medical device reporting and Materiovgilance. A questionnaire which was suitable for assessing the basic Knowledge, Attitude and the Practice (KAP) of Materiovigilance was designed and distributed two time for pre and post study into the healthcare professionals and layperson in Nashik zone hospitals. Out of the 600-questionnaire given, 550 responding were the 220 healthcare professionals working in the hospital and 330 layperson who used the medical devices, from 91.66% responses provided from both groups where the healthcare group 36.66% from (n= 220) and layperson group 55.33% from (n=330). The study showed that the knowledge of healthcare professionals in general was less information about the Materiovigilance Programme for India and also about and its members, National centres and reporting medical device adverse event pre-study after seminar about materiovgilance after that improvement occur into knowledge attitude into post study. The results of the study strongly suggest that underreporting of medical device adverse events is associated with gaps in the knowledge and attitudes.***

Keywords: Medical device adverse event and MDAE reporting, healthcare professionals, layperson, KAP, Materiovigilance

1. Introduction

The term “medical device” has been defined by the World Health Organization (WHO) as any instrument, apparatus, reagent for in vitro use, implant, device for tissue cutting or wound covering, highly sophisticated computerized medical equipment, software or other related or similar materials which are intended to be used for diagnosis, prevention, monitoring, treatment of disease. Although, the medical devices provide immense benefits to the patients, but the use of medical devices may also lead to some significant potential risks, sometimes life threatening [1], [2]. The term “vigilance” means close monitoring of the possible adverse effects. Materiovigilance is the study of adverse events associated with the use of medical devices. It deals with the close monitoring of medical devices after post marketing phase [3],[4]. The risks that are associated with the use of medical devices include harmful effects, in particular, on the patients/users/healthcare professionals, interactions with other substances, certain contraindications and malfunctions [5], [6]. The risks can also include falsifications, technical defects and reduced efficacy. This makes it essential to have a regulatory program to monitor these associated adverse effects [7],[8],[9].

Materiovigilance is the study and follow up of incidents that might result from the use of medical devices. It enables to identify the adverse events associated with the use of medical devices as all the devices may have certain degree of risk and can cause some problems under specific circumstances [1],[4],[10]. Monitoring the safety of these devices enables dangerous devices to be withdrawn from the market and to eliminate faults in medical devices with the intention to constantly improve the quality of the devices and providing patients and consumers with increased safety [5]. Materiovigilance refers only to medical devices whereas pharmacovigilance refers to medicines. The Materiovigilance program of India was launched on 6 July 2015 at the Indian Pharmaceutical Commission, Ghaziabad by DCGI in order to track the medical devices and the associated adverse effects to ensure the safety, provide awareness, generate data, and promoting the patient safety [11].

Scope and objective of Materiovigilance:

- To improve the protection of health safety of the patients, users and create a nationwide system for patient safety monitoring also data base evidence about safety of medical devices [3].
- To support Central Drugs Standard Control Organization (CDSCO) in the decision-making process on the use of medical devices also communicate with stakeholders about reducing or minimize the risk of medical device and safety information on the use of medical device [12].
- To bring solutions for the advancement of the use of the medical device and true up national centre of excellence for Materiovigilance activities, informed about stakeholders about the need and significance of medical devices adverse events (MDAE) reporting [3].
- To examine the proposed framework, and its implication, for the Indian medical device vigilance system to global harmonization, i.e., Global Harmonization Task Force

(GHTF) and monitoring the risk benefit ratio of medical devices used [13].

Materiovigilance program of India (MvPI)

The MvPI is required to regulate the quality, efficacy, safety and availability of medical devices. The medical device rules, 2017 was brought to regulate the manufacture, import, sales, distribution of medical devices and came into force from 1 January 2018 [8], [14]. The Central Licensing Approving Authority in October 2005, declared 10 devices to be considered as drugs. Medical devices which are classified as drugs include cardiac stents, drugs eluting stents, contraceptive implants, catheters, bone cement, i.e. cannula, intraocular lenses etc. [8],[13]. The MvPI aims at monitoring adverse events associated with the medical devices (medical device associated adverse events). In this program, the IPC functions as a national coordinating center and CDSCO as a regulator. The MvPI includes all private and public health care delivery system as well as the e-reporting system [10]. The MvPI was approved by Ministry of Health and Family Welfare on 10/2/15 and it was launched on 06/7/15 by DCGI at IPC, Ghaziabad, India [1],[5],[15]. The MvPI aims to collect the safety data in a systematic manner so that the recommendations and regulatory decisions on safe use of medical devices can be taken based on the data generated in Indian Population.[16] The programme is meant to monitor medical device associated adverse events (MDAEs) and create awareness among healthcare professionals about the importance of MDAEs reporting in India and monitoring the benefit-risk profile of the medical devices[18] .It is also meant to generate independent, evidence based recommendations on the safety of medical devices and further to communicate the findings to all the key stakeholders in the country and the stakeholders of the Pharmacovigilance Programme of India (PvPI)[12,19].

Objective

The objectives of our study were as follows:

1) To assess the KAP (Knowledge, Attitude & Practice) on Health care professionals about Invasive medical devices & Materiovigilance Programme.
2) To assess the KAP (Knowledge, Attitude & Practice) on Lay Persons about reporting adverse of the Invasive medical devices.

2. Materials and Methods

A questionnaire based cross-sectional, observational study was conducted in departments of various specialties hospitals, Nashik zone. Written infromed consent was taken from the survey. Institutional review board approval was also obtained prior to starting the study. The questionnaire was prepared to investigate knowledge, attitude and practices of healthcare professional& Layperson. The respondents were allowed to strike multiple options wherever applicable. The questionnaire consisted of questions included in previous studies that examined the knowledge and attitude of healthcare professional and Layperson, about medical device adverse event reporting [20,21,22]. The questions were distributed as follows: 5 questions were related to knowledge, 5 questions were related to attitude and 5 questions were related to practice. Also, questionnaire distributed two time for pre and post study into the healthcare professionals and layperson.in pre study basic information of study given and fill questionnaire through the healthcare professional& Layperson. In post study explaining the purpose of the study, through the seminar. They were requested to complete the questionnaire and give it back immediately to maximize the response rate. The sample size 600 were 550 given responds into that 220 Healthcare professional334 Layperson. The study was conducted over a period of 3 months from Jan 2020 to Mar 2020. The responses to the questionnaire were analyzed by performing descriptive statistics. A descriptive analysis of the data was done using SPSS software version 26. Data analysis was carried out using Microsoft Excel spreadsheet and percentage of observations was noted.

3. Result

Out of the 600 questionnaires given both groups, 550 questionnaires were returned, 91.66% provided their response. 50 (8.34%) were not included in the analysis because of incomplete information. All the calculations were done by using the SPSS software. Demographic details of the participants involved in the study was categorized based on gender distribution, age distribution, professional status the results of which were thoroughly analyzed and reported in Table.1.

Table 1: Demographic Details of the Healthcare Professional& Layperson

Sr. No.	Demographic details	No. of participants
1	**Gender Distribution**	
	I] Healthcare person	
	1) Male	105 (48%)
	2)Female	115 (52%)
	II] Layperson	
	1)Male	182 (55%)
	2)Female	148 (45%)
2	**Age group distribution**	
	I] Healthcare professional	
	1)22 to 30	53 (24%)
	2)31 to 45	68 (31%)
	3)46 to 60	75 (34%)
	4) 60 above	24 (11%)
	II] Layperson	
	1)18 to 30	112 (34%)
	2) 31to 45	99 (30%)
	3) 46 to 60	73 (22%)
	4)60 above	46 (14%)
3	**Job role**	
	1)Doctors	90 (41%)
	2)Nurse staff	108 (49%)
	3)Other	22 (10%)

In our study 48% & 55% respondents in healthcare professional and layperson male group also 52% & 45% respondents in healthcare professional and layperson female group. As per age group healthcare professional age group 22 to 30 year shown 24%, age group31 to 45 year shown 31%, age group 46 to 60 year shown 34% & above 60 year shown 11% respondents. As per age group layperson age group 18 to 30 year shown 34%, age group31 to 45 year shown 30%, age group 46 to 60 year shown 22% & above 60 year shown 14% respondents. As per Job role Doctors 41%,

Nurse staff 49% & other 10% respondents in different hospitals in Nashik zone.

KAP study of healthcare professionals -

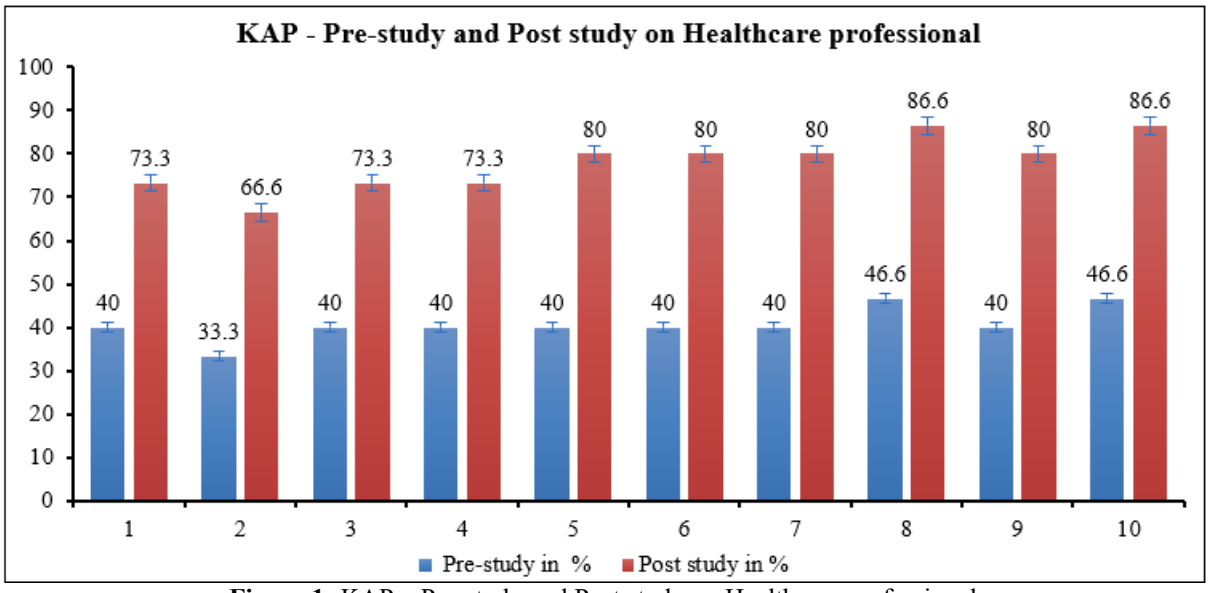

Figure 1: KAP – Pre-study and Post study on Healthcare professional

The response shows by healthcare professionals in pre-study KAP 40.6% ratio of the KAP 33.3% to 46.6. Were as KAP 40.6% divided into knowledge - 42.62%, attitude - 40.98%, practice -16.40%. After that lecture and seminar giving to the healthcare professionals about invasive medical device events reporting and again taken response than result shown KAP 66.6 up to 86.6 also KAP increase 78.6% which divided into knowledge - 40.67%, attitude -33.90%, practice - 25.43%. Difference in pre-study and post study shown by healthcare professionals in KAP increase up to 38%. There was mixed response of healthcare professionals (physician, nurse staffs, others) from different hospitals in Nashik city which distributed as per job role and given the responses were registered. Healthcare professionals shown correct answer response during the KAP pre study 33.3% to 46.6 and After seminar on invasive medical device adverse event. In KAP post study correct answer response rate 66.6% to 86.6, improvement during KAP pre-study and post study 38%. Whereas physician show correct response rate during KAP pre-study 46.6% and which increase during KAP post study 86.6%. Nurse staff show correct response rate during KAP pre-study 33.3% and which increase during KAP post study 66.6%. other show correct response rate during KAP pre-study 40% and which increase during KAP post study 73.3% shown in figure no 10 and table no7. Overall correct response rate during KAP pre - study 37.33% (Knowledge 46.39% Attitude 35.71% Practice 17.81%) which increase during Post study 75.53% (Knowledge 44.13% Attitude 29.40% Practice 26.47%) shown in fig.2

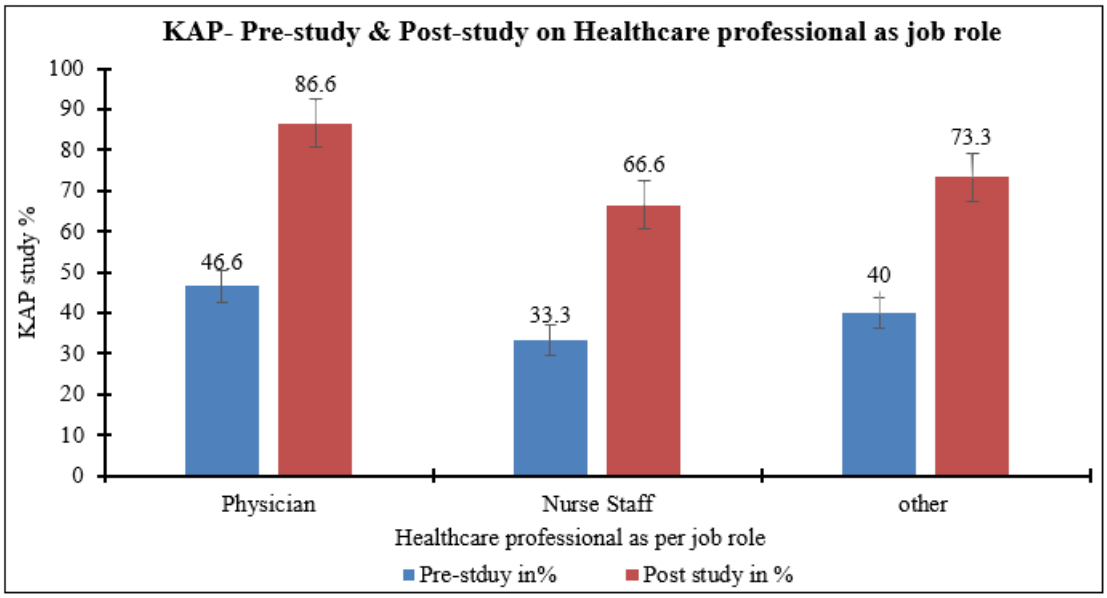

Figure 2: KAP- Pre-study & Post-study on Healthcare professional as job role

KAP study of Laypersons

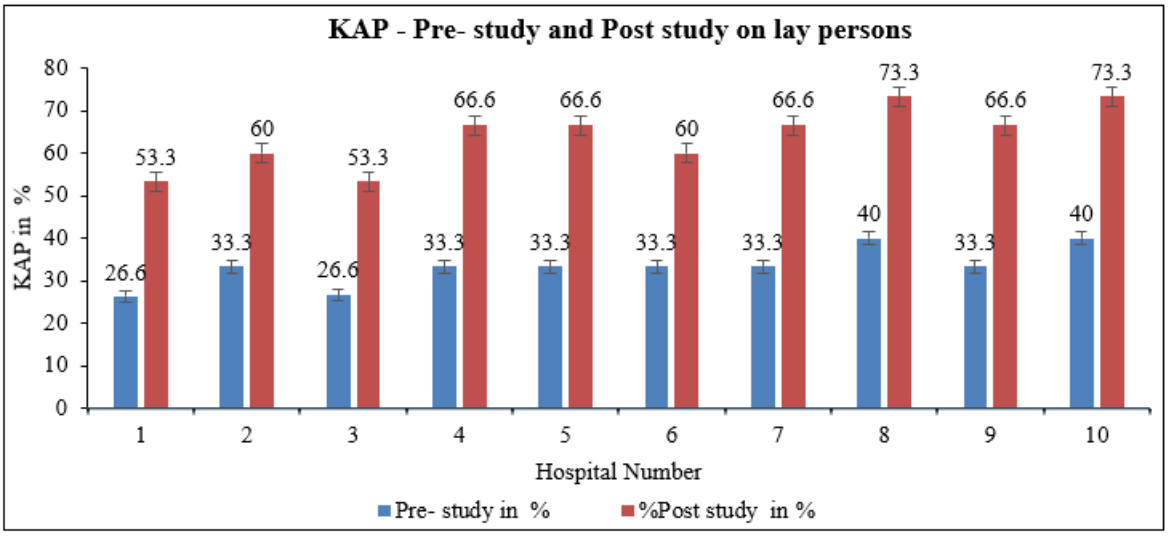

Figure 3: KAP Pre-study and post study on Laypersons

It has been observed that response for KAP study given during pre and post study from laypersons in different hospitals of Nashik city. Assuming the fact that surveys were administered for laypersons shown positive intension during solve questionnaire the KAP pre -study and post study. Laypersons given correct response of KAP pre study overall average 26.3 % to 33.33 % and after the seminar given about medical device adverse event, KAP post study given correct answer response rate overall average 53.3% to 73.3% which mean improvement during KAP per-study to post study 31.33%.If as per beds size wise laypersons divided than 50beds size hospitals KAP pre-study 29.8 %, post study 58.3% and improvement during pre-study to post study 28.5%. 100beds size hospitals KAP pre-study 33.3%, post study 64.4% and improvement during pre-study to post study 31.1%. 200beds size hospitals KAP pre-study 36.65%,post study 69.95% and improvement during pre-study to post study33.3 %. 300beds size hospitals KAP pre-study40 %, post study 73.3% and improvement during pre-study to post study 33.3%. which shown in figure1 and table no 1.It was evident from the survey that most of the laypersons have knowledge & positive attitudes towards reporting medical adverse event of invasive medical devices.

4. Discussion

The present study was a questionnaire-based study which assessed the KAP of Healthcare professionals and laypersons towards medical device adverse events and materiovigilance. A number of studies suggest that healthcare professionals' attitude toward medical device adverse events reporting is a significant determinant of the good knowledge positive attitude.[23],[24] The existence of National Materiovigilance programme in India was known to almost all the respondents. The healthcare professionals had better knowledge regarding materiovigilance compared to laypersons. This was in contrast to results seen in other studies showing where doctors had a better knowledge [8]. 98% of doctors and 96% of nurses have experienced medical device adverse events in their professional practice but reporting of such medical device adverse events to the materiovgilance centre. Similar results were seen in the study conducted in India 70.8% of the health care providers (doctors, nurses and pharmacists) felt that medical device adverse events reporting should be made mandatory and a study showed only 15%of respondents had reported an ADR previously study [24,25]. Most of the medical professionals had seen materiovigilance from, but very few were trained on how to fill and report it to the materiovgilance centre. This was similar in comparison with other study 71% of the physicians did not know where and how to report a medical device adverse event whereas, in a study shows 50% and 89% of respondents respectively knew about reporting center [24, 25].

When the healthcare providers were questioned about the factors discouraging them from reporting medical device adverse events, most of healthcare professionals and laypersons had difficult to decide whether medical device adverse events has occurred or not, most of healthcare professionals said lack of time as a reason to report in the KAP pre-study after seminar given medical device adverse events there were improvement shown by them. In this study, all of medical professionals are ignorant of various aspects of materiovigilance and adverse events of medical devices. When the KAP scores were compared between the KAP pre and post study of healthcare professionals and layperson whereas, healthcare professionals need to be trained adequately because medical device adverse events comes first to their notice and they are always in contact with the patients. Therefore, the study suggests that there is need for continuous education and training to improve the knowledge. And give acknowledgement note on reporting medical device adverse events might change the attitudes towards materiovigilance and medical device adverse events reporting system among the healthcare providers. And compulsorily keeping an medical device adverse events reporting from in all patient file at the hospital will be more helpful in reporting of the same. Which might help in improving the ongoing materiovigilance activities in at the hospital.

5. Conclusion

This study concluded that healthcare professionals had good knowledge and positive attitude towards materiovigilance and medica device adverse events reporting, but unfortunately the actual practice of medical device adverse events reporting is still deficient among them. The reporting of medical device adverse event can be achieved with a combined effort by all the medical professionals, which can be improved by adequate training and motivation.

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