Background and Objective: Inadequate knowledge and underreporting of medical device-associated adverse events (MDAEs) were observed among health-care professionals (HCPs) in studies carried out in other countries. In India, HCP’s knowledge, attitude, and practice (KAP) regarding materiovigilance have not been explored extensively. Hence, the present study was carried out to assess KAP of materiovigilance among nurses working in a tertiary care teaching hospital in South India. Materials and Methods: This is a descriptive, cross-sectional study conducted among nurses. A self-administered, validated questionnaire was distributed to 420 nurses. Data were analyzed using the Statistical Package for the Social Sciences software version 21.0. Kruskal–Wallis test was used to compare KAP score of materiovigilance among the study participants. Results: A total of 400 (95.2%) responses were received. About 65.7% (n = 263) of nurses were having adequate knowledge about the various aspects of materiovigilance and 80.5% (n = 322) of nurses had a positive attitude toward MDAE reporting. However, only 18 (4.5%) of nurses have reported about MDAEs. Further, factors such as uncertainty on how to report a MDAE and concerns about their legal issues significantly led to underreporting of MDAEs. Conclusion: The transition of adequate knowledge and positive attitude to good practice of MDAE reporting was lacking among the study participants. Hence, with due consideration of these deficits and the various factors influencing MDAE reporting, it is necessary to conduct periodical workshops and training sessions for HCPs to enhance their spontaneous reporting of MDAEs.

Keywords: Materiovigilance, medical device-associated adverse event, medical device vigilance
to October 2019.[7] Spontaneous reporting of MDAEs by health-care professionals (HCPs) and other stakeholders is the fundamental element for successful functioning of medical device surveillance system.[8] Poor knowledge, attitude, and practice of MDAE reporting was observed among HCPs in studies carried out in other countries.[9,11,12] In India, HCP’s knowledge, attitude, and practice (KAP) regarding materiovigilance has not been explored extensively. With the implementation of MvPI and the increasing use of medical devices, it is essential to assess the awareness and practice of MDAE reporting among the Indian HCPs. Hence, the present study was carried out to assess KAP of materiovigilance among nurses in a tertiary care teaching hospital in South India.

**Materials and Methods**

**Study design and setting**

This is a questionnaire-based cross-sectional study conducted among nurses in Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, a tertiary care teaching hospital in South India with a MDAE monitoring center under MvPI. The study protocol was approved by the Institutional Ethics Committee (Human studies, Reference number: JIP/IEC/2019/0159), and it was carried over a period of 5 months from June 2019 to November 2019.

**Study tool: Questionnaire development and validation**

A self-administered, structured questionnaire was developed in English based on the previous studies conducted in the field of medical devices vigilance in other countries.[8-11] Seven experts in the field of pharmacology working at different medical colleges in South India independently reviewed the study tool for assessing its content validity. Minor modifications were done based on their comments. The items with content validity index (CVI) ≥0.86 were included and the final scale CVI of the 15-item questionnaire was 0.91.[13-15]

The questionnaire was pilot-tested on a group of 50 nurses to evaluate the relevance, feasibility, comprehensibility, and clarity of the items. The responses obtained from the pilot study participants were not included in the final analysis of study results. Cronbach’s alpha coefficient was estimated to assess the internal consistency of the items included in the questionnaire. The Cronbach’s alpha value of the questionnaire was 0.75, suggesting its adequate internal consistency.[16]

The questionnaire consisted of two parts, part one comprised of questions on sociodemographic details of the participants (age, gender, and years of work experience). Part two comprised of 15-item questionnaire to assess the knowledge of materiovigilance (Question no: 1-5), attitude toward MDAE reporting (Question no: 6-10), practice of materiovigilance (Question no: 11-14), and factors influencing MDAE reporting (Question no: 15). The “knowledge” section consisted of five closed-ended questions. A score of 0 and 1 was given for each wrong and correct response, respectively, and total knowledge score for each participant varies from 0 to 5. Median knowledge score was used to categorize the participants overall knowledge level. Respondents who scored ≥median knowledge score were categorized as having adequate knowledge and those with scores less than the median score were categorized as having inadequate knowledge. Three-point Likert scale type of questions was included in “attitude” section and a score of 2, 1, and 0 was given for each question with agree, neutral, and disagree responses, respectively. For two questions in “attitude” section (Question no: 8,9) which were negatively framed, reverse scoring was followed. The total attitude score for each participant varies from 0 to 10. Participants with a total attitude score ≥7.5 (75% of maximum score) were considered to have a positive attitude toward MDAE reporting. The “practice” section consisted of closed-ended questions with dichotomous (yes/no) responses. A score of 1 (maximum score-4) was given to each question if the participant had encountered, managed, and reported MDAEs. Total score for KAP (minimum 0 to maximum 19) was calculated for each participant. For question no: 15, the participants were asked to select the factors which might encourage and discourage their reporting of MDAE.

**Study participants**

Nurses employed in various departments of JIPMER, Puducherry, who were willing to give written informed consent were included in the study. Nurses who were not available at the time of distribution of questionnaire were excluded from the study.

**Sample size estimation and sampling technique**

From the pilot study done on 50 nurses, the prevalence of knowledge of materiovigilance was 46%. Using this knowledge prevalence and assuming a confidence interval of 95%, absolute precision of 5%, nonresponse rate of 10%, final sample size calculated for this study was 420. The sample size was calculated using Open Epi software version 3.01. (Open Source Epidemiologic Statistics for Public Health, www.openepi.com). From a sampling frame of 1400 nurses employed at the hospital, simple random sampling technique was followed for achieving the desired sample size (n = 420).

**Data collection**

The study purpose was explained to the nurses and written informed consent was obtained from those who...
were willing to participate in the questionnaire survey. The final version of the questionnaire was distributed to study participants and necessary instructions about filling the questionnaire anonymously were provided to them. To increase the response rate, nurses were requested to return the completed questionnaires immediately on the same day or the next day if they were busy at that moment. To maintain the confidentiality of the data collected, participants were requested to drop the filled questionnaires in a sealed container placed at the nurses’ station.

Statistical analyses
Data on knowledge, attitude, and practice of materiovigilance obtained from the responses of study participants were coded and analyzed using the Statistical Package for the Social Sciences (SPSS version 21.0) (IBM, New York, USA). Kolmogorov–Smirnov test was used to test the normality of the data. Descriptive statistics (frequency, percentages, and median ± interquartile range) were used to present the results. The correct responses for each questionnaire item among the three subgroups of nurses were compared using the Chi-square test. Kruskal–Wallis test was used to compare KAP score of materiovigilance among the study participants. \( P < 0.05 \) was considered statistically significant.

Results

Demographic characteristics
Out of the 420 questionnaires distributed, 400 were completed and returned, a response rate of 95.2% was obtained. Majority of the study participants were females \( (n = 300, 75\%) \) and the mean age was \( 37.76 ± 8.3 \) years. About 59% \( (n = 236) \) of them were nursing officers (NO) with a work experience of <10 years, 21% \( (n = 84) \) were senior NO (SNO) and 20% \( (n = 80) \) were assistant nursing superintendents (ANS) with a work experience of 10–20 years and more than 20 years respectively.

Participants knowledge about materiovigilance
About 83.5% \( (n = 334) \) of them were aware the term materiovigilance and 79% \( (n = 316) \) were able to identify a low-risk medical device. Sixty-seven percent of nurses \( (n = 269) \) were aware about the existence of MvPI and 61% \( (n = 244) \) were aware about the functioning of a MDAE reporting center in the institute. However, only a few of them \( (n = 103, 25.8\%) \) were aware about the location of national collaborating center of MvPI [Table 1]. On comparing the median knowledge score, SNO \( (4\[1], P < 0.001) \) scored significantly higher than others [Table 2]. Based on the overall knowledge level, about 65.7% \( (n = 263) \) of nurses were having adequate knowledge about materiovigilance [Figure 1].

Participants attitude toward materiovigilance
Majority \( (80\%, n = 320) \) of them agreed that reporting of MDAEs is a professional obligation and about 90.8% \( (n = 363) \) of them agreed that reporting of MDAEs would benefit patient care. Around 54.8% \( (n = 219) \) of nurses agreed that even nonserious MDAE should be reported and 67.8% \( (n = 271) \) of them believed that reporting of a single case of MDAE will also improve the health-care system. About 75.8% \( (n = 303) \) of them agreed upon the need for periodical conduct of materiovigilance awareness programs at the institute [Figure 2]. Overall, about 80.5% \( (n = 322) \) of nurses had a positive attitude toward reporting of MDAE [Figure 1] and statistically significant differences in median attitude score were not observed among the three groups of nurses [Table 2].

Participants current practice of materiovigilance
Around 40.3% \( (n = 161) \) of nurses have encountered the occurrence of MDAEs in patients and about 30.8% \( (n = 123) \) have read articles on the prevention of MDAEs. However, a very few of them around 18 \( (4.5\%) \) have reported about MDAEs and only 19 \( (4.8\%) \) nurses have been trained on the process of reporting a MDAE. Overall poor practice of MDAE reporting was observed among nurses in the present study [Figure 1]. On comparing the median practice score, SNO \( (2\[1], P < 0.001) \) scored significantly higher than the other groups of nurses. The median total KAP score of SNO \( (15 \[4], P < 0.001) \) was significantly higher than that of NO \( (11 \[4]) \) and ANS \( (14 \[4.75]) \) [Table 2].

Factors influence reporting of medical device-associated adverse events
The various factors which were perceived to influence reporting of MDAEs are listed in Table 3. About 70% \( (n = 280) \) and 42% \( (n = 168) \) of them opined that periodical conduct of workshops, training sessions on materiovigilance at the institute level, and easy access to reporting forms would encourage MDAE reporting, respectively. Among the discouraging factors, 45% \( (n = 180) \) of nurses were concerned about the legal
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and punitive actions which might arise due to MDAE reporting. Around 45% (n = 180) opined that they had doubts on how to fill MDAE form and were concerned that the report might be incorrect.

**DISCUSSION**

Globally, the existence of a well-structured, active surveillance system for medical devices is considered to play a vital role in promoting their safe use and quality. Furthermore, all these measures tend to improve patient safety and health-care system.\(^{[17-19]}\) Creating awareness among stakeholders on the importance of MDAE reporting is one of the main objectives of MvPI.\(^{[3,20]}\) Moreover, studies conducted in other countries among HCPs have observed the lack of knowledge and poor practice of MDAE reporting.\(^{[11,12,21]}\) Therefore, the

**Table 1: Knowledge, attitude, and practice of materiovigilance among nurses**

| Knowledge, attitude, and practice associated questions                                                                 | Correct response | P         |
|--------------------------------------------------------------------------------------------------------------------------|------------------|-----------|
| Total (n=400), n (%)                                                                                                        | Nursing officers (n=236), n (%) | Senior nursing officers (n=84), n (%) | Assistant nursing superintendents (n=80), n (%) |
| Definition of materiovigilance                                                                                              | 334 (83.5)       | 198 (83.9) | 70 (83.3)       | 66 (82.5)       | 0.95       |
| Example of low risk medical device                                                                                            | 316 (79)         | 173 (73.3) | 80 (95.2)       | 63 (78.8)       | <0.001*    |
| Aware about MvPI                                                                                                             | 269 (67.3)       | 155 (65.7) | 60 (71.4)       | 54 (67.5)       | 0.62       |
| Aware about the presence of MDAE reporting center at the institute                                                          | 244 (61)         | 147 (62.3) | 57 (67.9)       | 40 (50)         | 0.05*      |
| Location of national collaborating center of MvPI                                                                             | 103 (25.8)       | 42 (17.8)  | 32 (38.1)       | 29 (36.3)       | <0.001*    |
| Reporting MDAE is a part of duty of health-care professionals                                                               | 320 (80)         | 190 (80.5) | 63 (75)         | 67 (83.8)       | 0.35       |
| MDAE reporting system would benefit patient care                                                                             | 363 (90.8)       | 217 (91.9) | 74 (88.1)       | 72 (90)         | 0.55       |
| One report of MDAE will make no difference in health-care system                                                            | 271 (67.8)       | 159 (67.4) | 68 (81)         | 44 (55)         | 0.01*      |
| Only MDAE that cause persistent disability should be reported                                                                 | 219 (54.8)       | 129 (54.7) | 49 (58.3)       | 41 (51.2)       | 0.66       |
| Materiovigilance awareness program can be conducted periodically to all health-care professionals                            | 303 (75.8)       | 170 (72)   | 61 (72.6)       | 72 (90)         | 0.02*      |
| Have you ever experienced MDAE occurring in a patient during your professional practice?                                    | 161 (40.3)       | 31 (13.1)  | 62 (73.8)       | 68 (85)         | <0.001*    |
| Have you read any article on prevention of MDAE?                                                                             | 123 (30.8)       | 41 (17.4)  | 52 (61.9)       | 30 (37.5)       | <0.001*    |
| Have you ever reported any MDAE?                                                                                            | 18 (4.5)         | 4 (1.7)    | 11 (13.1)       | 3 (3.8)         | <0.001*    |
| Have you ever been trained on how to report MDAE?                                                                            | 19 (4.8)         | 4 (1.7)    | 14 (16.7)       | 1 (1.3)         | <0.001*    |

*P<0.05 statistically significant calculated by the Chi-square test. MvPI: Materiovigilance programme of India, MDAE: Medical device-associated adverse event

**Table 2: Comparison of knowledge, attitude, and practice scores of materiovigilance among different categories of nurses**

| Score | Nursing officers (n=236) | Senior nursing officers (n=84) | Assistant nursing superintendents (n=80) | P        |
|-------|--------------------------|-------------------------------|------------------------------------------|----------|
| Knowledge, median (IQR) | 3 (1)                    | 4 (1)                        | 3 (1)                                    | <0.001*  |
| Attitude, median (IQR)  | 8 (3)                    | 9 (3)                        | 9 (3)                                    | 0.409    |
| Practice, median (IQR)  | 0 (1)                    | 2 (1)                        | 1 (1)                                    | <0.001*  |
| Total score, median (IQR)| 11 (4)                   | 15 (4)                       | 14 (4.75)                                | <0.001*  |

*P<0.05 statistically significant calculated by the Kruskal-Wallis test. IQR: Interquartile range

**Table 3: Factors influencing medical device-associated adverse events reporting (n=400)**

| Factors influencing MDAE reporting | Number of nurses, n (%) |
|-----------------------------------|-------------------------|
| Encouraging factors               |                         |
| Conducting workshops and training sessions on materiovigilance at the institute | 280 (70) |
| Quick and easy access to MDAE reporting forms | 168 (42) |
| Motivation and co-operation among the health-care professionals | 144 (36) |
| Discouraging factors              |                         |
| Doubts on what to fill and how to report MDAE | 180 (45) |
| Concerns about legal issues of reporting | 180 (45) |
| Nonavailability of MDAE reporting forms at the moment when needed | 100 (25) |
| Reporting might become an additional workload | 100 (25) |

MDAE: Medical device-associated adverse event
present study was conducted to evaluate the KAP of materiovigilance among nurses working at a tertiary care hospital in South India.

A response rate of 95.2% was observed in this study and it is very high on comparing with the response rates reported in previous studies.[9,10,11] In the present study, 65.7% (n = 263) of participants had adequate level of knowledge regarding the various aspects of materiovigilance. This is comparatively higher than the values reported in similar studies done by Mohamed et al. in Tunisia and by Meher et al. in Romania.[10,11] Majority of the participants (80.5%, n = 322) in our study had positive attitude toward MDAE reporting and a similar trend was observed in the studies done by Mohamed et al. and by Meher et al.[10,11] The high response-rate, adequate knowledge, and positive attitude toward materiovigilance observed in our study participants are affirming indications of their interest and sense of responsibility as prime stakeholders under MvPI.

In the current study, although 40.3% (n = 161) of nurses had experienced the occurrence of MDAE in patients during their professional practice, but only 11.2% (n = 18) of them had reported about MDAEs and this result is consistent with the findings observed in previous studies.[9-12] The factors influencing MDAE reporting were also assessed in our study. Among them, factors such as uncertainty on how to report a MDAE and concerns about their legal issues significantly led to underreporting of MDAEs. These deficits clearly indicate the need for conduct of workshops and training sessions to sensitize and motivate the HCPs on spontaneous and regular reporting of MDAEs encountered. Moreover, it is also essential to evaluate the impact of these training sessions by periodical analysis on the quality of the reports received at the MDAE monitoring centers.[22]

Although majority of the nurses had a positive attitude toward MDAE reporting, some participants (9.7% and 20%) felt that only serious MDAEs should be reported and reporting one MDAE will not have a significant impact on health-care system, respectively. Small group discussions and training sessions can be conducted at regular intervals to clarify these misconceptions.[23] Further, an increase in the reporting of MDAEs by HCPs has been observed after the implementation of feedback sessions regarding MDAE reporting.[24,25] Regarding the factors which might encourage MDAE reporting, nurses have suggested the regular conduct of workshops, continuous medical education, and training sessions at the institute. In addition to these sessions, availability and easy access to MDAE reporting forms, co-operation, and motivation among HCPs were the other factors suggested by the participants to improve MDAE reporting.

On comparing the total KAP scores based on the years of work experience, SNO had significantly scored higher than the other participants. This might be due to their encounter of more MDAEs in patients than the junior level nurses, active involvement in managing patients, and in measures taken toward the prevention of MDAEs.[9]

Other measures which can be tried to promote MDAE reporting are the display of posters, newsletters at nursing stations regarding information on what has to be done when MDAE is encountered. On the other hand, HCPs must be sensitized on the availability of MDAE reporting forms at IPC website, which can be downloaded and used to hasten and ease the entire reporting process.[26] By introducing materiovigilance in undergraduate curriculum, the significance of medical device surveillance can be kindled at an early stage in the minds of future HCPs.

There are some limitations to our study. First, only one group of HCPs was included in this study. Second, it was a single-center study. Multicentric, large scale prospective studies including all groups of HCPs might be conducted in future for further validation of our findings. The impact of awareness programs and training sessions on MDAEs reporting among HCPs can also be evaluated further.

**Conclusion**

In the present study, it has been observed that nurses working at a tertiary care teaching hospital at South India had adequate knowledge on the various aspects of materiovigilance and positive attitude toward MDAE reporting. However, the transition of this knowledge and attitude to good practice of MDAE reporting was lacking among the study participants. Hence, with due consideration of these deficits and the various factors influencing MDAE reporting, it is necessary to conduct
periodical workshops and training sessions for HCPs to enhance their spontaneous reporting of MDAEs.

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Conflicts of interest
There are no conflicts of interest.

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