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Original Article

Pharmacology Section

Prevalence of Adverse Events in Healthcare Professionals Using Personal Protective Equipment to Treat COVID-19: A Web-based Survey

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ABSTRACT

Introduction: Healthcare Professionals (HCPs) involved in managing Coronavirus Disease-2019 (COVID-19) pandemic were instructed to wear Personal Protective Equipment (PPE) to protect themselves from contracting virus. However, PPE use can sometimes lead to adverse events which create greater impact on health status of HCPs. Thus, the prevalence of adverse events and associated risk factors should be estimated for taking necessary preventive measures.

Aim: To evaluate the prevalence of adverse events in HCPs due to PPE use during second wave of COVID-19 in Tamil Nadu, India.

Materials and Methods: A cross-sectional study was conducted in different levels of healthcare centres in Tamil Nadu, India, from April to May 2021. Data were collected using a prevalidated questionnaire from HCPs of any discipline who were directly involved in managing COVID-19 patients. A total of 282 responses were collected through Google forms and proportion of HCPs who experienced adverse events due to PPE and percentage of different adverse events associated with PPE wearing were assessed. Data were analysed using Chi-square test.

Results: Out of 282 respondents of the survey included 224 doctors, 34 nurses and 24 lab technicians with a mean age of 30 years. There were 164 females and 118 males. A total of 177 (62.76%) participants experienced adverse events which included dehydration, thirst and heat, headaches, inability to go to restroom and other urinary/respiratory problems. With respect to duration of exposure to PPE, 163 (57.8%) HCPs had >6 hours/day and 102 (36.2%) had 4-6 hours/day. It was observed that factors such as age, gender, profession, various wards posted for COVID-19 duty and duration of PPE worn daily were significantly associated with adverse events to PPE (p-value <0.05).

Conclusion: The results of the study concluded that higher prevalence of adverse events with PPE was seen among doctors and nurses. Most common encountered adverse events were dehydration, headache and skin problems, which have been associated with prolonged use of PPE.

Keywords: Coronavirus disease-2019, Materiovigilance, Questionnaire, Untoward effects

INTRODUCTION

Coronavirus Disease-2019 (COVID-19), a novel coronavirus disease is a highly infectious acute respiratory disease which has caused a recent major outbreak affecting many countries worldwide [1]. It is caused by a pathogen called Severe Acute Respiratory Syndrome-Coronavirus-2 (SARS-CoV-2) [2]. The pandemic outbreak is initially originated from Wuhan, China in December 2019 and spreads rapidly through transmission from human to human due to close contact with an infected person, with exposure to coughing, sneezing, respiratory droplets or aerosols. The World Health Organisation (WHO) declared that COVID-19 was a "public health emergency of International concern" on 30th January 2020 [3].

Personal Protective Equipment (PPE) complements in control of infection transmission from patients to HCP, other patients and attendants along with other infection control practices. PPE has become pivotal after the emergence of life-threatening infections like severe acute respiratory syndrome, Middle East Respiratory Syndrome (MERS) and COVID-19. There is a substantial need for efficient infection spread control in all healthcare settings [4].

Healthcare Infection Control Practices Advisory Committee (HICPAC), recommends the use of PPE in standard and transmission-based infection control precautions. Standard precautions require the HCPs to anticipate exposures and select appropriate PPEs for use while providing care to patients affected with infectious diseases which are classified as being transmitted through the airborne, contact, or droplet route [5].

The PPE includes disposable N95 masks, goggles, triple layers of medical gloves, a protective face shield, an isolates gown and a medical protective clothing. The use of PPE is associated with high incidence of adverse events such as heat, dehydration, pressure sores, headaches, inability to go to washroom, infections in respiratory tract, urinary tract etc. [6,7]. Most of the adverse events experienced by HCPs while using PPE have not been reported appropriately to concerned personnel who is handling Pharmacovigilance and Materiovigilance Departments due to lack of awareness, time constraint and motivation [8].

Materiovigilance Programme of India (MvPI) was launched in 2015 with an objective to identify and collect the adverse events associated with the use of medical devices and to eliminate the device-related risks through a systematic reporting system [9]. In India, the Medical Devices Rules (MDR) became effective from 1st January 2018. The MDR has significantly influenced the postmarketing surveillance of medical devices, by ensuring their quality and user safety [10].

There are many studies conducted on reporting of adverse events due to medical devices like ventilators, vital signs monitor, incubators, infusion pumps, cardiac implants across various countries. But very few studies have been done on evaluating the adverse events due to PPE which mainly focuses particular symptoms like skin reactions, headache and so on [11-13]. This study primarily focuses on overall rate of adverse events caused by PPE to HCPs in various healthcare centres in Tamil Nadu, India, during this pandemic

situation and also aimed to evaluate the proportion of various adverse events in association with the various cadre of health professionals, duration of shifts and comfortability.

MATERIALS AND METHODS

A cross-sectional study was conducted in different levels of healthcare centres in Tamil Nadu, India, from April to May 2021. Participation was voluntary and anonymous. The study was conducted after the approval from Institutional Human Ethics Committee (Ref: CSP-MED/21/FEB/66/27). Informed consent was obtained from all the study participants. The study was conducted using a prevalidated questionnaire.

Inclusion criteria: Doctors and nurses who had been directly involved in treating COVID-19 patients in 40 healthcare centres in Tamil Nadu, India, during the study period regardless of speciality and experience were included in the study. Lab personnel involved in blood collection and sample processing for COVID-19 patients were also included in the study.

Exclusion criteria: Participants who were not willing to take part in the survey were excluded from this study.

Sample size calculation: The sample size was determined using Cochran sample size formula for categorical data with a 5% margin of error and a 95% confidence interval level together (level of significance, α=0.05) along with the proportion of Adverse Drug Reactions (ADRs) reported from previous literature [14]. Number of participants was derived as 246 respondents, which was the minimum sample size (N) of HCPs required for this study using convenient sampling technique.

$N=Z^2PQ/d^2=(1.96)^2*0.80*(0.20)/(0.05)^2=246$.

Where, Z=95% confidence interval level gives Z value of 1.96

P=Estimated proportion of the population=0.8

Q=1-P

d=desired level of precision (i.e., the margin of error)

Study Procedure

A questionnaire for the survey was drafted based on the previous study by Yu K et al., and modified by the principal investigator of the present study to assess the prevalence of adverse events using PPE among HCPs which consisted of 29 questions with 22 closed ended and seven open ended questions pertaining to the details of basic demographic, training experience, institutional work characteristics, usual practices and availability of PPE, along with perceptions of its adequacy in terms of supply and training in the workplace as well as adverse effects of wearing PPE [15].

Out of 29 questions, 6 (q7, 11, 13, 24, 26, 27) questions were framed regarding knowledge, 3 (q8, 15, 29) regarding attitude and rest were related to practices. The questionnaire was prevalidated for criteria validity, language, understandability, ease of administration and content by faculties of pharmacology (n=4) and experienced physicians from various departments (n=6) in the same institution where the study was conducted excluding principal investigator and co-investigators. Reliability of the questionnaire was measured using Cronbach's alpha score (0.8).

After validation, survey was prepared in e-Google form in english language and was circulated through e-mails and WhatsApp modes. The participants were briefed about questionnaire filling procedure and requested to do the survey after seeking their informed consent and the responses were collected. Data collected were kept confidential.

STATISTICAL ANALYSIS

Data were entered in Microsoft (MS) excel 2020 and analysed using Statistical Package for Social Sciences (SPSS) software version 20.0. Proportions of adverse events in each group of participants (doctors, nurses and lab technicians) were expressed in percentages. Various associations between HCP's duration of shift, demographic and occupational related characteristics and more with adverse events were calculated by Chi-square test. Results were considered statistically significant when the p-value was ≤0.05.

RESULTS

In this survey, 282 HCPs participated comprising 224 (79.4%) doctors, 34 (12.1%) nurses and 24 (8.5%) lab technicians from various medical centres in Tamil Nadu, India. Among 282 participants 164 were females and 118 were males with a mean age of 30 years. Majority of HCPs 201 (71.3%) were working from tertiary health institutions followed by primary healthcare 44 (15.6%) and secondary healthcare 37 (13.1%) [Table/Fig-1].

Characteristics	Distribution	Participants n (%)
Age (Years)	≤25	27 (9.6)
	26-30	144 (51.1)
	31-40	81 (28.7)
	>40	30 (10.6)
Sex	Female	164 (58.2)
	Male	118 (41.8)
Profession	Doctor	224 (79.4)
	Lab personnel	24 (8.5)
	Nurse	34 (12.1)
Type of institution	Primary healthcare	44 (15.6)
	Secondary healthcare	37 (13.1)
	Tertiary healthcare	201 (71.3)

[Table/Fig-1]: Demographic characteristics of participants (N=282). Data are presented as numbers=n (%)

Out of 282 participants, 123 (43.6%) strongly agreed that they were keen to come to work in COVID-19 wards at this pandemic, while 117 (41.5%) participants strongly agreed that they were worried about transmitting disease to their family and 66 (23.4%) strongly agreed that they were worried about contracting COVID-19 inspite of PPE use [Table/Fig-2].

Knowledge and attitude towards pandemic work		Participants n (%)
Adequate knowledge about transmission	Agree	119 (42.2)
	Neutral	11 (3.9)
	Strongly agree	131 (46.5)
	Strongly disagree	21 (7.4)
I am keen to come to work in COVID wards at this pandemic.	Agree	98 (34.8)
	Disagree	3 (1.1)
	Neutral	55 (19.5)
	Strongly agree	123 (43.6)
	Strongly disagree	3 (1.1)
I am worried about contracting COVID inspite of PPE use.	Agree	104 (36.9)
	Disagree	34 (12.1)
	Neutral	71 (25.2)
	Strongly agree	66 (23.4)
	Strongly disagree	7 (2.5)
I am worried about transmitting disease to my family	Agree	92 (32.6)
	Disagree	26 (9.2)
	Neutral	44 (15.6)
	Strongly agree	117 (41.5)
	Strongly disagree	3 (1.1)

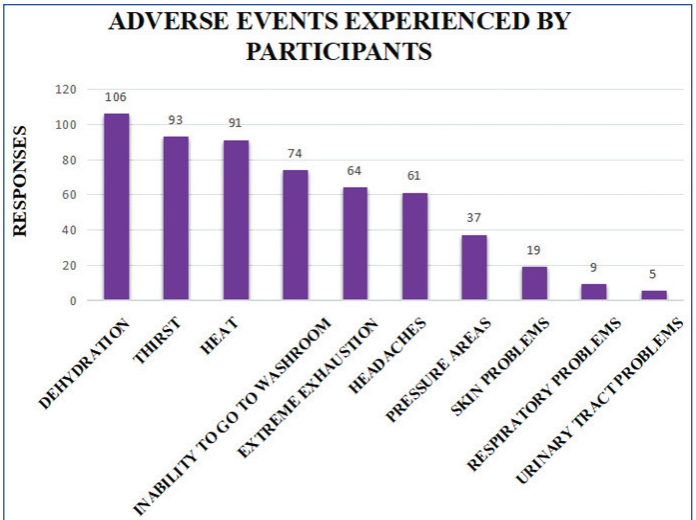
[Table/Fig-2]: Knowledge (one question) and attitude (three questions) of HCPs towards working in COVID-19 pandemic.

A total of 248 of the 282 participants were posted for COVID-19 duty in four different areas under all levels of healthcare of which a greater number of HCPs were posted in COVID-19 wards. Total 34 were doctors posted in primary health centres from remote areas, where they dealt both COVID-19 and non COVID-19 patients. Totally 190 (67.4%) members had undergone proper training in donning and doffing of PPE in their institutions. Majority of the participants i.e., 74 (26.2%) utilised level 4 PPE, apart from level 4 PPE, 116 participants wore one pair of gloves and 166 wore double gloves. the total ADR's reported were 177 (62.76%), out of which 21 were treated on Outpatient Department (OPD) basis. A total of 88 (31.2%) participants were affected with COVID-19 and 35 (12.4%) thought it may be due to PPE failure. Among 282 participants, only 134 (47.5%) participants were aware about reporting in materiovigilance program and only 13 (4.6%) had reported the adverse events due to PPE [Table/Fig-3].

Parameters	Distribution	Participants n (%)
Posted for COVID-19 duty		248 (87.9)
Duty duration	<4 hours	17 (6)
	>6 hours	163 (57.8)
	4-6 hours	102 (36.2)
Posted ward	1. ICU	52 (18.4)
	2. Wards	129 (45.7)
	3. OPD	41 (14.5)
	4. Labs	26 (9.2)
Knowledge about levels of PPE		192 (68.1)
Level of PPE used [16]	Level 1	21 (7.4)
	Level 2	40 (14.2)
	Level 3	57 (20.2)
	Level 4	74 (26.2)
PPE training received		190 (67.4)
Provided with adequate PPE		253 (89.7)
PPE used always	Mask (Surgical, N95)	250 (88.7)
	Gloves	209 (74.1)
	Gown	179 (63.5)
	Face shield	140 (49.6)
	Goggles/safety glasses	128 (45.4)
	Impervious hood	85 (30.1)
Layer (s) of gloves use	One	116 (41.1)
	Two	166 (58.9)
Frequency of hand washing	After wearing PPE	37 (13.1)
	Before wearing PPE	50 (17.7)
	Both	195 (69.1)
Frequency of taking bath/day	>2	42 (14.9)
	1	26 (9.2)
	2	214 (75.9)
Total number of adverse events reported		177 (62.76)
HCPs affected with COVID-19		88 (31.2)
Thought of contracted COVID-19 due to failure of PPE		35 (12.4)
Reuse of the PPE after decontamination		142 (50.4)
Reason for reusing PPE		
Non availability of PPE		29 (10.3)
Non exposure to high-risk patients		46 (16.3)
Shortage of equipments		67 (23.8)
Materiovigilance (MV) program awareness		134 (47.5)
Reported any unwanted reactions to MV		13 (4.6)

[Table/Fig-3]: Details of COVID-19 ward duty and knowledge (five questions).

There were many adverse events experienced by HCPs among which dehydration, thirst and heat were the most common ADRs encountered followed by inability to go to washroom, extreme exhaustion, headaches skin problems and more, as mentioned in [Table/Fig-4].



[Table/Fig-4]: List of adverse events experienced by participants.

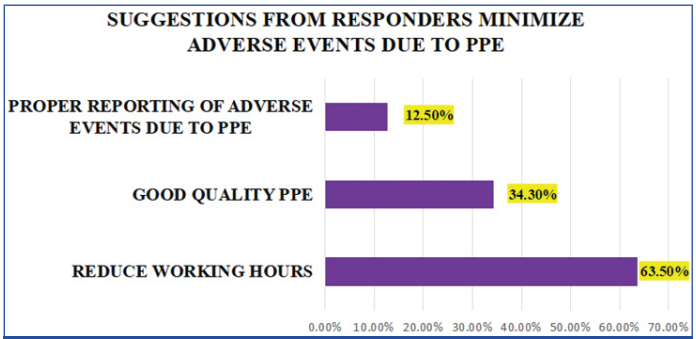
With regard to adverse events, it was observed that females experienced a higher number than males and the same was statistically significant (p-value=0.042). Similarly a statistically significant observation was made that doctors were affected most among the HCPs in working place (p-value=0.046), also HCPs who worked in wards and Intensive Care Unit (ICU) were commonly affected followed by those posted in OPD (p-value=0.038). Duty duration of HCPs were significantly associated with prevalence of adverse PPE events in which professionals working for more than six hours in PPE reported a greater number of adverse reaction (p-value=0.033) [Table/Fig-5].

S. No.	Variables		Adverse events due to PPE		p-value
			Yes n (%)	No n (%)	
1.	Age (years)	≤25	12 (44.4)	15 (55.6)	0.222
		26-30	92 (63.9)	52 (36.1)	
		31-40	53 (65.4)	28 (34.6)	
		>40	20 (66.7)	10 (33.3)	
2.	Gender	Female	93 (56.7)	71 (43.3)	0.013*
		Male	84 (71.2)	34 (28.8)	
3.	Profession	Doctor	149 (66.5)	75 (33.5)	0.035*
		Lab personnel	11 (45.8)	13 (54.2)	
		Nurse	17 (50)	17 (50)	
4,	Type of institution	Primary healthcare	26 (59.1)	18 (40.9)	0.018*
		Secondary healthcare	31 (83.8)	6 (16.2)	
		Tertiary healthcare	120 (59.7)	81 (40.3)	
5.	Posted for COVID-19 duty		156 (62.9)	92 (37.1)	0.898
	Posted ward	ICU	41 (78.8)	11 (21.2)	0.038*
		Wards	74 (57.4)	55 (42.6)	
		OPD	27 (65.9)	14 (34.1)	
		Labs	14 (53.8)	12 (46.2)	
6.	Duty duration	<4 hours	10 (58.8)	7 (41.2)	0.005*
		4-6 hours	115 (70.5)	48 (29.44)	
		>6 hours	52 (50.98)	50 (49.02)	
7.	Level of PPE used	Level 4	11 (52.4)	10 (47.6)	0.0432*
		Level 3	19 (50)	19 (50)	
		Level 2	43 (75.4)	14 (24.6)	
		Level 1	50 (67.6)	24 (32.4)	

8.	Layer(s) of gloves use	One	60 (51.72)	56 (48.28)	0.0013*
		Two	117 (70.48)	49 (29.52)	
9.	Reuse any of the PPE after decontamination		99 (69.7)	43 (30.3)	0.015*
10.	Comfortable wearing PPE	Comfortable	6 (26.1)	17 (73.9)	0.001*
		Manageable	88 (59.1)	61 (40.9)	
		Uncomfortable	83 (75.5)	27 (24.5)	
11.	Frequency of hand washing	After wearing PPE	16 (43.24)	21 (56.76)	0.004*
		Before wearing PPE	39 (78)	11 (22)	
		Both	122 (62.56)	73 (37.44)	
12.	Frequency of taking bath/day	1 time	13 (50)	13 (50)	<0.00001
		2 times	150 (70.09)	64 (29.9)	
		>2	14 (33.33)	28 (66.67)	

[Table/Fig-5]: Statistical association of risk factors for adverse events.
Except in S. no 5,7, all other parameters were tabulated for N=282
*p-value <0.05 was considered as statistically significant

Suggestions from responders, indicated reduction in working hours, improvement in quality of PPE and proper reporting of adverse events to minimise adverse events due to PPE [Table/Fig-6].



[Table/Fig-6]: Suggestions from participants to minimise adverse events due to PPE.

DISCUSSION

Even though, treatment protocols have been frequently revised and recommended for management of COVID-19, due to the uncertainty of the infection status of patients, HCPs mandatorily require PPE during their whole duty hours to break the transmission chain [17]. The present study estimated the prevalence of ADRs with PPE use among HCPs while treating COVID-19 patients with an objective of gaining knowledge about the commonly encountered untoward events associated with PPE use.

From this study, the overall adverse event rate for healthcare personnel was found to be 62.76%. About 71.87% doctors have reported greater number of adverse events compared to nurses (58.3%) and lab professional (52.94%) (p-value=0.046). Considering workplace, individuals from secondary care institutions suffered a larger quantum of adverse events due to PPE accounting to 83.8% than tertiary (59.7%) and primary institutions (16.1%). Similar findings were noted in previous studies [18,19].

The present study has shown, 88.7% participants had adequate knowledge about transmission of COVID-19 which correlates with a study conducted by Zhang M et al., in China which showed about 89% of HCPs had sufficient knowledge of COVID-19 [20]. The present study also assessed the attitude of participants towards contracting COVID-19 inspite PPE use has shown that 23.4% had a negative attitude and 41.5% worried about transmitting disease to their family. These findings have not been reported earlier. Also, 67.4% participants from the current study had undergone proper training in donning and doffing of PPE. These results nearly match with a study conducted by Pandey S et al., in which 75.6% respondents achieved adequate training [21].

The present study revealed more number of ADRs (42.55%) reported by HCPs who worked more than six hours/day and about 27.61% by HCPs who worked for 4-6 hours/day. The results of the current study coincides with Desai SR et al., who had shown decreased number of adverse events with reduction in the duration of duty to four hours for nurses [22]. Participants who wore two layers of gloves had higher proportion of adverse events with 68.7% followed by one layer of gloves use with 61.3% (p-value <0.05).

Considering comfortability with PPE, 149 (52.8%) HCPs have reported that wearing PPE was manageable and 110 (39%) reported it as uncomfortable which were in line with the study conducted by Yildiz CC et al., who observed that 23.15% HCPs reported that wearing aprons, masks, goggles and gloves were uncomfortable [23].

In present study, most common problems encountered with PPE use were found to be dehydration (59.9%), thirst (52.5%), heat (51.4%), inability to go to washroom (41.8%), skin reactions (31.6%), headache (21.6%) and pressure areas (13.1%) due to PPE use. An 83.7% reported excessive sweating after activity with PPE in this study which was identical with a study conducted in Spain which accounted about 70% participants experienced excessive sweating after duty hours [23]. Results from similar studies have been summarised and compared with present study in [Table/Fig-7] [18,19,24-26,27-29].

In addition to the periodical training about proper usage of PPE among frontline healthcare workers, enhancing the quality of PPE and reducing the working hours with PPE can prevent the potential risks due to PPE use. Awareness about common ADRs with PPE use and importance of reporting untoward events to the concerned authority should be educated among HCPs.

Author's name and publication year	Place of study	Number of participants	Conclusion
Tabah A et al., 2020 [18]	Worldwide	2711	Adverse effects of PPE were associated with longer shift durations and included heat (51%), followed by thirst areas (44%), headaches (28%), inability to use the bathroom (27%) and extreme exhaustion (20%).
Chowdhury S et al., 2022 [19]	Bangladesh	438	48.76%, 28.47% and 60.15% of all participants suffered from skin, oral and neurological problems due to face masks.
Jiang Q et al., 2020 [25]	China	4306	Overall prevalence of skin injuries was 42.8%. About 47.3% participants who worked more than four hours reported higher number adverse events due to PPE.
Ozkok Akbulut T et al., 2021 [24]	Turkey	702	Adverse skin reactions were reported by 79.5% of the respondents and 72.5% reported adverse events who wore two layer gloves than 55.9% in one layer gloves.
Unoki T et al., 2020 [26]	Japan	976	79.4% respondents reported sweating and headache due to dehydration because of PPE use.
Agarwal A et al., 2020 [27]	North India	278	The most common problems associated with using PPE kits was excessive sweating (100%), fogging of goggles, spectacles, or face shields (88%), suffocation (83%), breathlessness (61%), fatigue (75%), headache due to prolonged use (28%),
Lim E et al., 2007 [28]	China	212	37.3% participants reported headaches associated with PPE (Conducted during SARS outbreak).

Ong JJ et al., 2020 [29]	Singapore	158	128 (81%) respondents developed de novo PPE-associated headaches.
Present study, 2023	India	282	Overall adverse event rate reported was 62.76% with highest prevalence in doctors and nurses who worked for more than 6 hours/day with PPE. Most common events in this survey were found to be dehydration (59.9%), thirst (52.5%), heat (51.4 %), inability to go to washroom (41.8%), skin reactions (31.6%), headache (21.6%) and pressure areas (13.1%) due to PPE use.

[Table/Fig-7]: Summarised results of similar studies from various countries [18,19,24–26,27-29].

To emphasise the importance of reporting adverse events associated with medical devices like PPE, ventilators etc., the Government of India initiated MvPI in 2015 to ensure safety of medical devices which is currently being coordinated by National Co-ordinating Centre, Indian Pharmacopoeia Commission (IPC) at Ghaziabad with a collaborating centre at Sree Chitra Tirunal Institute of Medical Sciences and Technology (SCTIMST) in Thiruvananthapuram. IPC has rolled out PPE adverse event reporting form as part of the MvPI for promoting patient and health worker safety [30].

Limitation(s)

This study may have response and recall bias as the adverse events reported by respondents could not be validated by clinicians. Possible associated risk factors in their daily life outside working place were not included. Quality of PPE and working environment of different participants which were not ascertained in the study design may have influence on the outcome of the study.

CONCLUSION(S)

The present study has concluded that the prevalence of adverse events with PPE use were more among HCPs especially doctors and nurses who worked more than six hours/day with PPE and the most common encountered adverse events were dehydration, inability to go to washroom, headache and skin problems. Thus, the study emphasise the need in reduction of working hours and providing a safe and secure working condition for the HCPs. This can be further supported by creating awareness among HCPs and prompt adverse event reporting through MvPI which ensures adequate protection and mitigates the harmful effects to the extent possible.

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Authors contribution: KPG: Principal investigator, prepared the study design, designed the questionnaire, collected, tabulated and analysed the data and prepared the manuscript. RK: Instrumented the preparation of questionnaire, reviewed the study plan, data analysis and carefully reviewed and edited the manuscript. SR: Analysed the results, prepared, reviewed and edited the manuscript. KP: Reviewed and edited the manuscript.

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