

Knowledge, attitude and practice towards pharmacovigilance among ayurveda physicians and teachers of Gujarat State: A cross sectional study

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ABSTRACT

Aim: The aim of this study was to assess the knowledge, attitude, and practice towards pharmacovigilance for Ayurveda among the teachers and practitioners working in Ayurveda colleges of Gujarat State. **Materials and Methods:** A survey questionnaire with 29 questions covering points like participants' knowledge, attitude and practice towards pharmacovigilance, adverse drug reaction reporting, and misleading advertisements related Ayurveda drugs was developed in Google form format. The study was carried out during December 2020 and January 2021. Question-wise analysis was made and their percentage value was calculated with the help of a Microsoft Excel spreadsheet in MS Office 2010. The result was presented using simple frequencies with percentages in appropriate tables. **Results:** Results from this study show that majority of the respondents were having a good knowledge regarding the concept of pharmacovigilance and ADRs in terms of their definitions and purposes. But, a complete knowledge regarding the structure of present national and international pharmacovigilance programme, reporting the ADR and its format were still lacking among majority of the participants. An encouraging attitude towards reporting of adverse drug reaction of ASU&H drugs and teaching of Pharmacovigilance for all the healthcare professionals by majority of the participants was observed. Further maximum participants opine a mandatory rule for reporting of ADR by Physicians, Pharmacist and Nursing staff. A major part of respondents (78.03%) opine that poor quality of drug, medication errors, prescription errors, dispensing errors are part of Pharmacovigilance under drug-related problems. The observed positive attitude is not being reflected in term of practice i.e., reporting of ADR related to Ayurveda drugs. One-third of the participants reported their experience about adverse drug reactions during their professional practice, out of which very few have reported ADRs. Difficulty in deciding or identifying the ADR and lack of time to report ADR is one of the major factor discouraging the participants from reporting ADRs. A large number of respondents were also not familiar with reporting misleading advertisements. **Conclusion:** Findings of this study reflects a good knowledge of the participants about the concept of Pharmacovigilance but unfamiliarity about the programme. The positive attitude towards practice of Pharmacovigilance and ADR reporting can be converted to foster pharmacovigilance practice through series of awareness programmes.

Keywords: ADR, awareness, AYUSH, knowledge, pharmacovigilance, practice

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Introduction

Pharmacovigilance is an important element of any medical intervention which aims at enhancing patient safety by

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assessing the risk-benefit profile of medicines.^[1] It is defined by WHO as “The science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems”.^[2] Considering the significance of this area, Department of AYUSH, Ministry of Health and Family Welfare, Govt. of India started National Pharmacovigilance Programme for Ayurveda, Siddha and Unani Drugs in the year 2008.^[3] Ministry of AYUSH, Govt. of India, in 2018 with inclusion of Homoeopathy reintroduced the programme under Central Sector scheme for promoting “Pharmacovigilance of Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs”.^[4]

In the year 2008, monitoring of safety of Ayurveda Siddha and Unani (ASU) drugs was initiated under a national level programme at Institute for Post Graduate Teaching and Research in Ayurveda (IPGT& RA), Jamnagar, a constituent institute of Gujarat Ayurved University, which is first of its kind institute dedicated to Ayurveda Education and Research. In the present academic session 2021-22, total 24 Ayurveda institutes have been granted conditional permission in Gujarat by the central government for taking admission to Ayurveda education.^[5]

Though the programme has started more than 12 years back in Gujarat, the number of Adverse Drug Reaction (ADR) on ASU&H drugs reported in the state, under pharmacovigilance programme is negligible. This less reporting of ADRs may be due to either the firm belief among teachers and practitioners that ASU&H drugs are safe or their lack of knowledge about the concept and importance of Pharmacovigilance.

Primary care physicians represent the first contact point within the health care system when a patient encounters a health problem. They are an essential part of the health care system by their contribution in reducing morbidity, emergency room visits, and hospitalizations. Considering the number of patients seen daily by primary care physicians it is essential to determine if there are gaps in the knowledge, attitudes, and practices in order to develop strategies that will address such gaps. Findings from various studies have revealed that ADR reporting by healthcare providers is linked to their knowledge, attitude, and practice about pharmacovigilance.^[6] A published study among Ayurveda Pharmacists conclude that, even though there was a positive attitude toward ADR reporting, limited knowledge about the importance of the program needed to be addressed through educational initiatives, regular sensitization, and awareness programmes.^[7] But, till date no such studies have been reported which could establish the cause and relationship of low reporting of ADR among Ayurveda Primary Care Physicians. Hence, this study was planned to assess the knowledge, attitude, and practice of Ayurveda teachers and practitioners of Gujarat State which may be further beneficial in taking necessary steps to improve the documentation and reporting culture.

Materials and Methods

Type of study

This is a cross-sectional, questionnaire based study aimed to assess knowledge, attitude, and practice towards pharmacovigilance and adverse drug reaction reporting among Ayurveda physicians and teachers working in different Ayurveda colleges of Gujarat state, India.

Sampling method and source of data

Convenience sampling method was used in which Ayurveda physicians and teachers working in different Ayurveda Colleges of Gujarat state were requested to provide their responses.

Inclusion and exclusion criteria

Teachers and Physicians presently working Ayurveda colleges, state of Gujarat, from both government, private and autonomous sector, who are willing to participate and give their consent for participation irrespective of age, sex and experience were included in the study. Participants who were not willing to participate were excluded from the study.

Ethical considerations

This study was under taken after getting ethical clearance from Institutional Ethics Committee (IEC) vide its meeting held on 8 January 2021.

Validity and reliability of the study tool

The survey questionnaire was designed and prepared by referring to previously published literature on KAP studies related to Ayurveda,^[8,9] Pharmacovigilance^[10-12] and healthcare workers^[13,14] with suitable customization for this study. A questionnaire with questions covering points like participants' knowledge, attitude and practice towards pharmacovigilance, adverse drug reaction reporting and misleading advertisement was developed. The questionnaire was reviewed by pharmacovigilance experts, and checked for question's consistencies, clarity and relevance then modified accordingly. A pilot study was conducted with final format initially, among the post-graduate scholars of the institute, to assess the content and face validity of the tool and whether data collection procedures were feasible or not. Data obtained during the pilot study was excluded from the reported study results.

Data collection procedure

Total 29 pretested questions; 13 related to knowledge covering concept, present structure and reporting of ADR, 10 on attitude and 6 on practice, in Google form, were made available to all the targeted participants through email, as part of series of awareness programme being conducted by Intermediary Pharmacovigilance Centre for Ayurveda (IPvC), Institute of Teaching and Research in Ayurveda (ITRA), Jamnagar during December 2020 and January 2021.

Data management and analysis

The survey questionnaire was analysed question-wise and their percentage value was calculated with the help of Microsoft Excel spreadsheet in MS Office 2010. The result is presented using simple frequencies with percentages in appropriate tables.

Results and Discussion

Total 842 working teachers and physicians registered for participating the survey for 17 different Ayurveda collages of Gujarat state. Details of participants with regards to their gender, qualification, service sector and experience are provided in Table 1.

Before starting of the awareness programme total three questions were asked to 842 participants that why they want to participate in the awareness programme on Pharmacovigilance. Details of the responses with regards to their awareness about the present programme and whether they were previously attend the programme are provided in Table 2.

Out of 842 registered participants, 519 participated in the KAP survey yielding a participation rate of 61.64%. Comparatively the participation rate is better among teaching faculty. Physicians, especially private practitioners showed poor participation rate.

Of those who participated in the study, 487 participants consented for the survey and offered their responses yielding a response rate of 93.83%. Majority of the respondents were teaching faculty having less than 10-year experience followed by teaching faculty having more than 10-year experience and medical officers. The response rate was almost equal in all the responded stakeholders. The details of registered participants, participation and response rate is provided in Figure 1.

Knowledge

The details of the observation of the participants on knowledge on Pharmacovigilance is presented in Tables 3-5. Total thirteen questions were designed to evaluate participants' knowledge regarding pharmacovigilance and ADRs reporting.

Majority of the respondents (95.48%) had the knowledge about definition of Pharmacovigilance and opined that it deals with monitoring of drug safety and other drug-related problems. When asked about the rule/act applicable for misleading advertisements only one-fourth of the participants (25.67%) were aware about the fact that, advertising regulation of ASU&H products comes under the ambit of Drug and Magic Remedies Act 1954. Further, more than 30% of the respondents think that misleading advertisements are regulated by Drugs and Cosmetics Rules 1945. Though majority of the participants (64.89%) consider many AYUSH medicines related advertisements in TV, social medias, newspapers, and road side posters claiming cure for various diseases as misleading advertisements, a considerable proportion of respondents (20.94%) are not sure about that. About 73.92% participants were aware about inclusion of blood products, nutraceuticals, cosmetics, medical device and vaccines under the purview of pharmacovigilance. But, 10.47% were not aware that they fall under the purview of pharmacovigilance.

More than half of the respondents (52.16%) answered CDSCO as the monitoring authority of pharmacovigilance for ASU & H Drugs, nearly half of the participants' (47%) does not know that the international centre for Adverse Drug Reaction (ADR) monitoring is located at Sweden. About 55.44% participants think that, ADRs related to ASU & H drugs can be reported to any one among National Pharmacovigilance Centre, Intermediary Pharmacovigilance Centre, and Peripheral Pharmacovigilance Centre or online in the official web site of Pharmacovigilance programme for ASU&H drugs. About 24.06% think that they can

Table 1: Demographics of the participating teachers and physicians

Indicators	Private Practitioner (n=39)	Medical officer (n=97)	Teaching faculty		Total (n=842)
			>10 year experience (n=223)	<10 year experience (n=483)	
Gender					
Male	22 (56.41%)	44 (45.36%)	113 (50.67%)	247 (51.14%)	426 (50.59%)
Female	17 (43.59%)	53 (54.64%)	110 (49.33%)	236 (48.86%)	416 (49.41%)
Qualification					
BAMS	25 (64.10%)	84 (86.60%)	--	8 (1.65%)	117 (13.90%)
MD	14 (35.90%)	9 (9.28%)	159 (71.30%)	421 (87.16%)	603 (71.61%)
PhD	--	4 (4.12%)	64 (28.70%)	54 (11.18%)	122 (14.49%)
Sector					
Govt.	--	33 (34.02%)	52 (23.32%)	68 (14.08%)	153 (18.17%)
Private	39 (100%)	64 (65.98%)	171 (76.68%)	415 (85.92%)	689 (81.83%)
Experience					
>15 years	6 (15.38%)	19 (19.59%)	95 (42.60%)	--	120 (14.25%)
11-15 years	3 (7.69%)	6 (6.19%)	128 (57.40%)	--	137 (16.27%)
6-10 years	9 (23.08%)	16 (16.49%)	--	178 (36.85%)	203 (24.11%)
1-5 years	9 (23.08%)	19 (19.59%)	--	222 (45.96%)	250 (29.69%)
0-1 year	12 (30.77%)	37 (38.14%)	--	83 (17.18%)	132 (15.68%)

Table 2: Responses of registered participants about awareness/training programme on Pharmacovigilance

Questions/Responses	Private Practitioner (n=39)	Medical officer (n=97)	Teaching faculty		Total (n=842)
			>10 year experience (n=223)	<10 year experience (n=483)	
Are you aware about Pharmacovigilance Programme for ASU& H drugs in India?					
Yes	20 (51.28%)	63 (64.95%)	192 (86.10%)	395 (81.78%)	670 (79.57%)
No	19 (48.72%)	34 (35.05%)	31 (13.90%)	88 (18.22%)	172 (20.43%)
Why you are interested for Pharmacovigilance Awareness/Training Programme?					
Unknown about Pharmacovigilance	7 (17.95%)	12 (12.37%)	6 (2.69%)	25 (5.18%)	50 (5.94%)
Want to know basics of Pharmacovigilance	15 (38.46%)	38 (39.175%)	39 (17.49%)	134 (27.74%)	226 (26.84%)
Want to update about Pharmacovigilance	17 (43.59%)	38 (39.175%)	168 (75.34%)	298 (61.70%)	521 (61.88%)
Want to know how and where to report ADR	--	9 (9.28%)	10 (4.48%)	26 (5.38%)	45 (5.34%)
Have you attended any lecture series/training programme in Pharmacovigilance previously?					
Yes	9 (23.08%)	9 (9.28%)	99 (44.39%)	155 (32.09%)	272 (32.30%)
No	30 (76.92%)	88 (90.72%)	124 (55.61%)	328 (67.91%)	570 (67.70%)

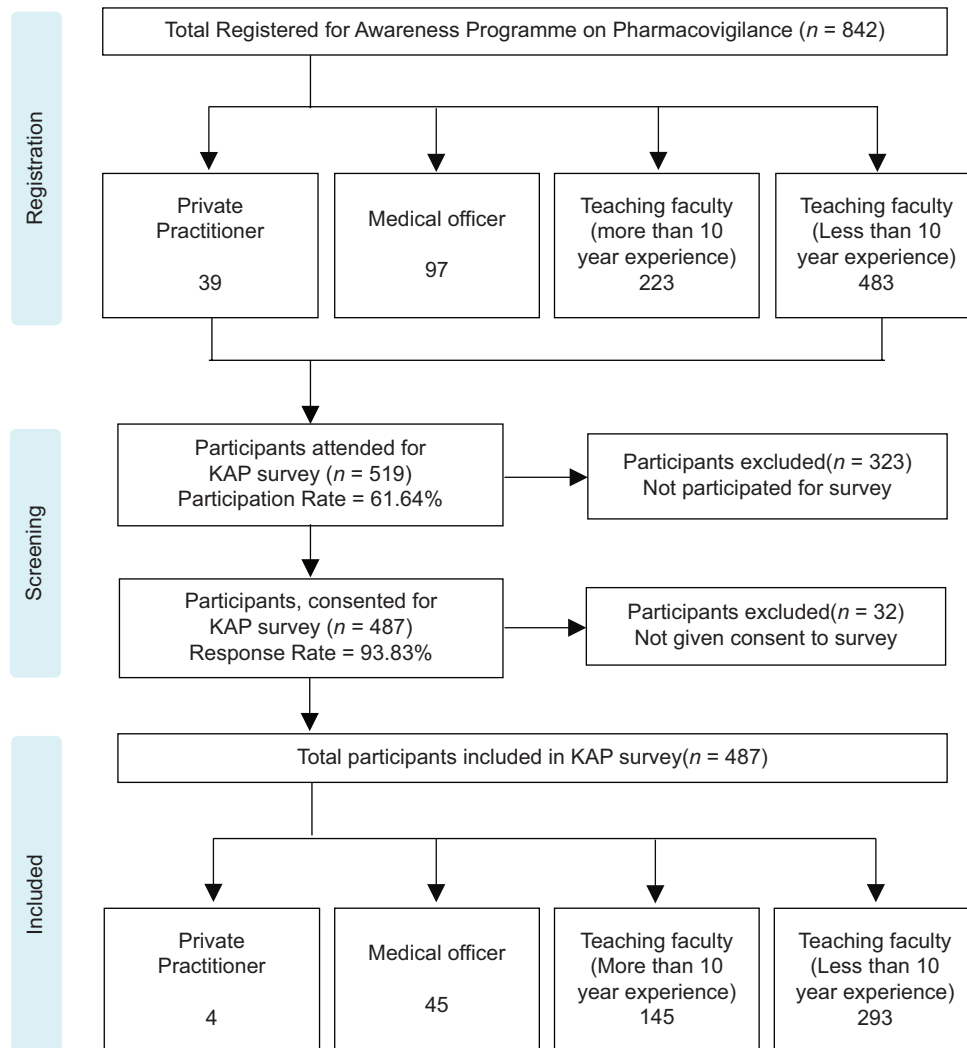


Figure 1: Registration and Participation in KAP survey

be reported at official website of Pharmacovigilance programme only. When asked about the misleading advertisements related

to ASU & H Drugs, participants provided diverse opinions. Only 33.26% were having the knowledge that, misleading

advertisements related to ASU & H Drugs can be reported to state licensing authority or GAMA portal of department of consumer affairs. Remaining 45.58% of the participants opted a single option between two. Location of present National Pharmacovigilance Centre for ASU&H drugs was known about half (52.15%) of the respondents. Almost equal numbers to this believe that National Pharmacovigilance Centre is located at ITRA, Jamnagar. The official website of pharmacovigilance program for ASU & H Drugs in India was familiar to only 41.06% of the participants. A major proportion of the respondents (53.18%) opined that, ayushpharmacovigilance.com is the official website designated to pharmacovigilance program.

Regarding the reporting of ADR, majority (84.60%) of the respondents were aware about reporting of ADR by different stakeholders like doctor, pharmacist, nurses etc., can report. However, there are about 11.29% participants who believed that only doctors can report ADR. Further, majority of the participants are aware that, ADR and Side effects (SE) are not same. It is observed that, about half of the participants (51.33%) knew about the specific ADR reporting form for ASU&H drugs while rest of the participants didn't know about the availability of separate ADR reporting form.

Results from this study show that majority of the respondents were having a good knowledge regarding the concept of pharmacovigilance and ADRs in terms of their definitions and purposes [Table 3]. But, a complete knowledge regarding

the structure of National and International pharmacovigilance programme [Table 4], reporting the ADR and its format were still lacking [Table 5]. It is observed that, nearly half of the participants knew about the specific ADR reporting form for ASU&H drugs while rest of the participants didn't know about the availability of separate ADR reporting form. This may be one of the critical observation associated with current ADR under reporting of ASU&H drugs. The trifling information in present curriculum on recent advances in National Pharmacovigilance programme is also one of the reasons for being unfamiliar with the current updates. To overcome these lacunae and to improve their knowledge, awareness programmes and CMEs may be organized at regular intervals. Recent study reports a significant improvement in reporting ADR by healthcare professionals after educational intervention.^[15] Regular awareness programs are the best platforms for the Ayurveda fraternities who are in the field of teaching and clinical practice to preserve their competence and acquire newer developments in their respective field. Further, the awareness can also be developed, among various stake holders, considering their in the form of circulations of written periodicals, newsletter, audio, video, or other forms of electronic media and conducting various competitions like essay, debate etc. Also, ADR reporting guidelines can be made available in the form of booklets and posters at noticeable locations in health care facilities.

Attitude

The data observed about the attitude of the participants toward Pharmacovigilance is presented in Table 6. There were ten

Table 3: Knowledge of participants regarding the concept of Pharmacovigilance

Questions/Responses	Private Practitioner (n=4)	Medical officer (n=45)	Teaching faculty		Total (n=487)
			>10 year experience (n=145)	<10 year experience (n=293)	
Pharmacovigilance deals with					
Monitoring of pharmacy	-	2 (4.4%)	1 (0.69%)	4 (1.37%)	7 (1.44%)
Monitoring of quality of traded drugs	-	1 (2.2%)	6 (4.14%)	-	7 (1.44%)
Monitoring of drug efficacy	-	2 (4.4%)	4 (2.76%)	2 (0.68%)	8 (1.64%)
Monitoring of drug safety and other drug related problems	4 (100%)	40 (88.88%)	134 (92.41%)	287 (97.95%)	465 (95.48%)
In India, which Rule/Act is applicable for Misleading Advertisement?					
Drug and Magic Remedies Act 1954	1 (25%)	10 (22.22%)	35 (24.14%)	79 (26.96%)	125 (25.67%)
Drugs And Cosmetics Rules 1945	1 (25%)	16 (35.55%)	37 (25.52%)	96 (32.76%)	150 (30.80%)
Both of the Above	1 (25%)	9 (20%)	57 (39.31%)	84 (28.67%)	151 (31.00%)
Can't say	1 (25%)	10 (22.22%)	16 (11.03%)	34 (11.60%)	61 (12.52%)
Many AYUSH medicines related advertisements in TV, Social Medias, News Papers, Roadside posters etc., are claiming cure for various diseases. Do you consider them as misleading advertisement?					
Yes	1 (25%)	29 (64.44%)	104 (71.72%)	182 (62.12%)	316 (64.89%)
No	1 (25%)	2 (4.4%)	8 (5.52%)	14 (4.78%)	25 (5.13%)
Maybe	1 (25%)	7 (15.56%)	26 (17.93%)	68 (23.21%)	102 (20.94%)
Can't say	1 (25%)	7 (15.56%)	7 (4.83%)	29 (9.90%)	44 (9.03%)
Does blood products, nutraceuticals, cosmetics, medical device and vaccines comes under the preview of pharmacovigilance?					
Yes	3 (75%)	28 (62.22%)	106 (73.10%)	223 (76.11%)	360 (73.92%)
No	1 (25%)	7 (15.56%)	19 (13.10%)	24 (8.19%)	51 (10.47%)
May be	-	7 (15.56%)	15 (10.34%)	37 (12.63%)	59 (12.11%)
Can't say	-	3 (6.66%)	5 (3.45%)	9 (3.07%)	17 (3.49%)

Table 4: Knowledge of participants regarding structure of National and International Pharmacovigilance Programme

Questions/Responses	Private Practitioner (n=4)	Medical officer (n=45)	Teaching faculty		Total (n=487)
			>10 year experience (n=145)	<10 year experience (n=293)	
In India, who is monitoring pharmacovigilance for ASU & H Drugs?					
CDSCO, New Delhi	1 (25%)	18 (40%)	62 (42.76%)	173 (59.04%)	254 (52.16%)
CCRAS New Delhi	1 (25%)	9 (20%)	26 (17.93%)	36 (12.29%)	72 (14.78%)
Ministry of AYUSH, New Delhi	2 (50%)	11 (24.44%)	55 (37.93%)	78 (26.62%)	146 (29.98%)
CCIM, New Delhi	-	7 (15.56%)	2 (1.38%)	6 (2.05%)	15 (3.08%)
The international centre for Adverse Drug Reaction monitoring is located at					
Unites States of America	-	16 (35.55%)	58 (40%)	79 (26.96%)	153 (31.42%)
United Kingdom	-	1 (2.22%)	18 (12.41%)	40 (13.65%)	59 (12.11%)
France	-	2 (4.4%)	2 (1.38%)	11 (3.75%)	15 (3.08%)
Sweden	4 (100%)	26 (57.78%)	67 (46.21%)	163 (55.63%)	260 (53.39%)
Where to report an ADR related to ASU&H drugs?					
National Pharmacovigilance Centre for ASU&H drugs	1 (25%)	13 (28.89%)	27 (18.62%)	68 (23.21%)	109 (22.38%)
Intermediary Pharmacovigilance Centre for ASU&H drugs	-	3 (6.66%)	-	11 (3.75%)	14 (2.87%)
Peripheral Pharmacovigilance Centre for ASU&H drugs	-	10 (22.22%)	11 (7.59%)	28 (9.56%)	49 (10.06%)
Online in the Official web site of Pharmacovigilance programme for ASU&H drugs	-	4 (8.88%)	15 (10.34%)	26 (8.87%)	45 (24.06%)
Any one of the above	3 (75%)	15 (33.33%)	92 (63.45%)	160 (54.61%)	270 (55.44%)
Do you know how to and to whom misleading advertisements related to ASU & H Drugs should be reported?					
State Licensing Authority	-	15 (33.33%)	26 (17.93%)	72 (24.57%)	113 (23.20%)
GAMA portal of Department of Consumer Affairs	2 (50%)	12 (26.66%)	27 (18.62%)	68 (23.21%)	109 (22.38%)
Any one of the above	2 (50%)	10 (22.22%)	61 (42.07%)	89 (30.38%)	162 (33.26%)
Can't say	-	8 (17.78%)	31 (21.38%)	64 (21.84%)	103 (21.15%)
In India, the present National coordination centre for pharmacovigilance program for ASU & H drugs is situated at					
AIIA, New Delhi	2 (50%)	26 (57.78%)	71 (48.96%)	155 (52.90%)	254 (52.15%)
IIRA, Jamnagar	1 (25%)	17 (37.78%)	70 (48.27%)	134 (45.73%)	222 (45.58%)
BHU, Varanasi	-	-	1 (0.69%)	1 (0.34%)	2 (0.41%)
NIA, Jaipur	1 (25%)	2 (4.4%)	3 (2.07%)	3 (1.02%)	9 (1.84%)
The official website of pharmacovigilance program for ASU & H Drugs in India is?					
Ayushpharma.com	-	1 (2.22%)	2 (1.38%)	6 (2.05%)	9 (1.84%)
Ayushsuraksha.com	2 (50%)	19 (42.22%)	58 (40%)	129 (44.03%)	200 (41.06%)
Ayushpharmacy.com	-	0	-	5 (1.71%)	5 (1.02%)
Ayushpharmacovigilance.com	2 (50%)	25 (55.56%)	85 (58.62%)	153 (52.22%)	259 (53.18%)

questions related to the attitudes of the participants towards ADR reporting and Pharmacovigilance. Among the 487 participants, 37.78% believe that mixopathy (combination of more than one drug therapy) can cause ADR. An equal number of participants (37.17%) think that, this may be a cause for ADR. This attitude of health professionals regarding safety of combined use of medicines from different systems could produce potential adverse outcomes. Hence, it is essential for all health professionals to study the safety profiles of medications before prescribing them and be vigilant in reporting any suspected ADRs to the PV centres. Reporting suspected ADRs for combined medications promotes a deeper understanding of their safety profile in a real clinical setting. About 54.41% participants think that ADR reporting is professional obligation for them. It is also encouraging that, majority of the participants (95.48%)

think reporting of adverse drug reaction of ASU&H drugs is necessary and Pharmacovigilance should be taught in detail to all the healthcare professionals (95.69%) which is coincides with the study done on resident doctors by Gupta *et al.*^[16] who identified 89.5% participants suggesting necessity of ADR reporting. Similarly another study also finds 82% of prescribing doctors felt the need of ADR reporting.^[17] Approximately 56.47% respondents feel that pharmacovigilance centre should be established in every hospital whereas as per 25.05% respondents, one centre in a city is sufficient. Though a major part of respondents (78.03%) opine that poor quality of drug, medication errors, prescription errors, dispensing errors are part of Pharmacovigilance under drug related problems, 11.70% are not sure about the answer. About 63.86% participants are having the opinion that ADRs may result due to any negligence from

Table 5: Knowledge of participants regarding reporting of ADR and its format

Questions/Responses	Private Practitioner (n=4)	Medical officer (n=45)	Teaching faculty		Total (n=487)
			>10 year experience (n=145)	<10 year experience (n=293)	
Who among the following can report ADR					
Doctor	-	6 (13.3%)	14 (9.65%)	35 (11.95%)	55 (11.29%)
Pharmacist	-	3 (6.66%)	3 (2.07%)	10 (3.41%)	16 (3.28%)
Patient	-	1 (2.22%)	1 (0.69%)	2 (0.68%)	4 (0.82%)
All of the above	4 (100%)	35 (77.77%)	127 (87.59%)	246 (83.96%)	412 (84.60%)
Is Adverse drug Reactions (ADR) and Side effects (SE) are same?					
Yes	-	3 (6.66%)	10 (6.90%)	20 (6.83%)	33 (6.78%)
No	3 (75%)	36 (80%)	119 (82.07%)	248 (84.64%)	406 (83.37%)
Can't say	-	3 (6.66%)	2 (1.38%)	5 (1.71%)	10 (2.05%)
May be	1 (25%)	3 (6.66%)	14 (10%)	20 (6.83%)	38 (7.80%)
Is there any specific ADR reporting form for ASU&H drugs available?					
Yes	2 (50%)	12 (26.66%)	83 (57.24%)	153 (52.22%)	250 (51.33%)
No	1 (25%)	9 (20%)	18 (12.41%)	34 (11.60%)	62 (12.73%)
Can't say	1 (25%)	19 (42.22%)	31 (21.38%)	78 (26.62%)	129 (26.49%)
May be	-	5 (11.11%)	13 (8.96%)	28 (9.56%)	46 (9.44%)

the side of Physician, Nursing Staff, Pharmacist, Attendant or Patients while a considerable number of participants (17.66%) think that, only Physicians are responsible for ADR. 64.89% respondents supported the inclusion of drugs of exclusive Herbal drug origin under the preview of Pharmacovigilance whereas 15.40% believe that it is not necessary. ADR reporting should be made mandatory to Physicians, Pharmacist and Nursing staff as per 85.01% of respondents. In contrast to this, in a questionnaire-based study to evaluate the knowledge, attitude, and practice of pharmacovigilance among doctors practicing alternative systems of medicine in Southern India, only 12.5% thought that reporting an ADR with ASU drugs is necessary.^[9] An equal number of participants are also having the opinion that all the ADRs should be reported irrespective of their seriousness.

Practice

The data observed related to present practice of Pharmacovigilance among the participants is presented in Table 7. Practice of pharmacovigilance is crucial for generating a national safety database of ASU&H drugs. In this study, six questions were designed to investigate participants practice toward pharmacovigilance and ADRs reporting. Only 37.78% participants responded that their institute is having a pharmacovigilance committee. Though more than half the responders (58.93%) were having exposure to reading article on prevention of adverse drug reactions, a substantial proportion of participants (32.24%) have not read any articles related to the topic. It further drags the individual away from the facts and current updates of the programme and also results in non-publishing of research articles, case studies, reviews on the appropriate platform. Even though there are some reputed indexed research journals on pharmacovigilance and ADR reporting, there is no distinct journal dedicated to Pharmacovigilance and ASU&H system of medicine. The experts and policy makers may consider it

as a scope and efforts should be made to publish the same. As per the participants, difficulty in deciding or identifying the ADR (56.47%) is one of the major factor discourage them from reporting ADRs followed by lack of time to report ADR (17.66%). Even 16.84% of respondents opined that a single unreported case may not affect ADR database. This attitude shows the passive perception of some of the health professionals ignoring the importance of reporting ADRs. Some studies reported that, multi-modality approach model is the best intervention to prevent under-reporting, namely reassurance among doctors that reporting has no legal implications, making ADR reporting mandatory in Medical college hospitals.^[18] Only 30.59% of participants have reported that, they have experienced adverse drug reactions during their professional practice. This value is slightly lower than the similar study done by Bhat *et al.*^[19] Approximately 60.16% of participants have not come across any ADR in their practice. This may be due to lack of training or lack of proper follow-up in identifying the ADR. On assessing the practice, it was found that only 6.57% of participants reported ADRs. Majority of the respondents (87.06%) have not reported any ADRs.

Even a large number of respondents were also not familiar with reporting misleading advertisements which shows the importance and need of continuous awareness generation which can certainly help in improving the reporting rates. This under-reporting of ADRs should be taken more seriously as the cost of treatment of drug-induced adverse effects is an additional cost of pharmaceutical treatment.^[20] This can only be prevented if the health-care professionals inculcate the habit of spontaneous reporting of ADRs, which serves as the core data generating system of pharmacovigilance.^[21] Though various approaches like awareness lectures, conferences, workshops, and post-training reminders were attempted during the past few years, still there

Table 6: Attitude of participants regarding Pharmacovigilance and ADR reporting

Questions/Responses	Private Practitioner	Medical officer	Teaching faculty		Total
			>10 year experience	<10 year experience	
Do you think mixopathy (Combination of more than one drug therapy) can cause ADRs?					
Yes	2 (50%)	19 (42.22%)	46 (31.72%)	117 (39.93%)	184 (37.78%)
No	1 (25%)	8 (22.22%)	23 (15.86%)	45 (15.36%)	77 (15.81%)
May be	1 (25%)	9 (20%)	66 (45.51%)	105 (35.84%)	181 (37.17%)
Can't say	-	9 (20%)	10 (6.90%)	26 (8.87%)	45 (9.24%)
Do you think ADR reporting is professional obligation for you?					
Yes	4 (100%)	21 (46.67%)	89 (61.38%)	151 (51.54%)	265 (54.41%)
No	-	10 (22.22%)	40 (27.59%)	101 (34.47%)	151 (31.01%)
Can't say	-	9 (20%)	10 (6.90%)	25 (8.53%)	44 (9.03%)
May be	-	5 (11.11%)	6 (4.14%)	16 (5.46%)	27 (5.54%)
Do you think reporting of adverse drug reaction of ASU&H drugs is necessary?					
Yes	4 (100%)	38 (84.44%)	141 (97.24%)	282 (96.25%)	465 (95.48%)
No	-	-	1 (0.69%)	1 (0.34%)	2 (0.41%)
Can't say	-	4 (8.88%)	2 (1.38%)	3 (1.02%)	9 (1.84%)
May be	-	3 (6.66%)	1 (0.69%)	7 (2.39%)	11 (2.26%)
Do you think Pharmacovigilance should be taught in detail to all the healthcare professionals					
Yes	4 (100%)	39 (86.67%)	142 (97.93%)	281 (95.90%)	466 (95.69%)
No	-	0	1 (0.69%)	4 (1.37%)	5 (1.02%)
Can't say	-	4 (8.88%)	-	6 (2.05%)	10 (2.05%)
May be	-	2 (4.4%)	2 (1.38%)	2 (0.68%)	6 (1.23%)
What is your opinion about establishing Pharmacovigilance centre/ADR monitoring centre in every hospital?					
Should be in every hospital	3 (75%)	26 (57.78%)	81 (55.86%)	165 (56.31%)	275 (56.47%)
Not necessary in every hospital	-	2 (4.4%)	5 (3.45%)	13 (4.44%)	20 (4.11%)
One in a city is sufficient	1 (25%)	12 (26.67%)	36 (24.83%)	73 (24.91%)	122 (25.05%)
Depends on number of bed size in the hospitals	-	5 (11.11%)	23 (15.86%)	42 (14.33%)	70 (14.37%)
Do you think poor quality of drug, medication errors, prescription errors, dispensing errors are part of Pharmacovigilance, under drug related problems					
Yes	4 (100%)	26 (57.78%)	122 (84.14%)	228 (77.82%)	380 (78.03%)
No	-	2 (4.4%)	6 (4.14%)	22 (7.51%)	30 (6.16%)
May be	-	9 (20%)	14 (9.65%)	34 (11.60%)	57 (11.70%)
Can't say	-	8 (17.78%)	3 (2.07%)	9 (3.07%)	20 (4.11%)
Do you think ADRs result only due to any negligence from the side of					
Physician	-	2 (4.4%)	27 (18.62%)	57 (19.45%)	86 (17.66%)
Nursing Staff	-	-	1 (0.69%)	3 (1.02%)	4 (0.82%)
Pharmacist	1 (25%)	3 (6.66%)	13 (8.96%)	26 (8.87%)	43 (8.83%)
Attendant	-	-	1 (0.69%)	5 (1.71%)	6 (1.23%)
Patients	-	9 (20%)	8 (5.51%)	20 (6.83%)	37 (7.60%)
None	3 (75%)	31 (68.89%)	95 (65.52%)	182 (62.12%)	311 (63.86%)
Is it correct to keep the drugs of exclusive Herbal drug origin under the preview of Pharmacovigilance?					
Yes	3 (75%)	26 (57.78%)	92 (63.45%)	195 (66.55%)	316 (64.89%)
No	1 (25%)	1 (2.22%)	27 (18.62%)	46 (15.70%)	75 (15.40%)
May be	-	10 (22.22%)	18 (12.41%)	31 (10.58%)	59 (12.11%)
Can't say	-	8 (17.78%)	8 (5.51%)	21 (7.17%)	37 (7.60%)
Do you think ADRs reporting should be made mandatory to Physicians, Pharmacist and Nursing staff?					
Yes	4 (100%)	34 (75.55%)	125 (82.21%)	251 (85.67%)	414 (85.01%)
No	-	2 (4.4%)	4 (2.76%)	8 (2.73%)	14 (2.87%)
May be	-	2 (4.4%)	11 (7.59%)	27 (9.22%)	40 (8.21%)
Can't say	-	7 (15.56%)	5 (3.45%)	7 (2.39%)	19 (3.90%)
Which of the following ADR to be reported?					

Contd...

Table 6: Contd...

Questions/Responses	Private Practitioner	Medical officer	Teaching faculty		Total
			>10 year experience	<10 year experience	
Serious	-	4 (8.88%)	9 (6.21%)	25 (8.53%)	38 (7.80%)
Moderate	-	8 (17.78%)	7 (4.83%)	10 (3.41%)	25 (5.13%)
Mild	-	-	4 (2.76%)	6 (2.05%)	10 (2.05%)
All	4 (100%)	33 (73.33%)	125 (82.21%)	252 (86.01%)	414 (85.01%)

Table 7: Practice of participants regarding Pharmacovigilance and ADR reporting

Questions/Responses	Private practitioner	Medical officer	Teaching faculty		Total
			Teaching faculty (>10 year experience)	Teaching faculty (<10 year experience)	
Is there any Pharmacovigilance Committee in your Institute?					
Yes	1 (25%)	12 (26.67%)	69 (47.59%)	102 (34.81%)	184 (37.78%)
No	1 (25%)	14 (31.11%)	29 (20%)	78 (26.62%)	122 (25.05%)
Not yet formed	-	6 (13.3%)	29 (20%)	47 (16.04%)	82 (16.84%)
Don't know	2 (50%)	13 (28.89%)	18 (12.41%)	66 (22.53%)	99 (20.33%)
Have you anytime read any article on prevention of adverse drug reactions?					
Yes	4 (100%)	24 (53.33%)	95 (65.52%)	164 (55.97%)	287 (58.93%)
No	-	15 (33.33%)	39 (26.89%)	103 (35.15%)	157 (32.24%)
Can't say	-	4 (8.88%)	5 (3.45%)	4 (1.37%)	13 (2.67%)
May be	-	2 (4.4%)	6 (4.14%)	22 (7.51%)	30 (6.16%)
Which of the following factor discourage you from reporting ADRs?					
No remuneration	1 (25%)	5 (11.11%)	14 (9.65%)	24 (8.19%)	44 (9.03%)
Lack of time to report ADR	1 (25%)	4 (8.88%)	25 (17.24%)	56 (19.11%)	86 (17.66%)
A single unreported case may not affect ADR database	-	10 (22.22%)	26 (17.93%)	46 (15.70%)	82 (16.84%)
Difficult to decide whether ADR has occurred or not	2 (50%)	26 (57.78%)	80 (55.17%)	167 (57.0%)	275 (56.47%)
Have you ever experienced adverse drug reactions in your patient during your professional practice?					
Yes	1 (25%)	6 (13.33%)	53 (36.55%)	69 (23.55%)	149 (30.59%)
No	3 (75%)	29 (64.44%)	74 (51.03%)	187 (63.82%)	293 (60.16%)
Can't say	-	9 (20.0%)	9 (6.21%)	23 (7.85%)	41 (8.42%)
May be	-	1 (2.22%)	9 (6.21%)	14 (4.78%)	24 (4.92%)
Have you ever reported Adverse Drug Reaction					
Yes	1 (25%)	4 (8.88%)	15 (10.34%)	12 (4.10%)	32 (6.57%)
No	2 (50%)	36 (80%)	122 (84.14%)	264 (90.10%)	424 (87.06%)
Don't know where to submit the ADR reporting form	-	3 (6.66%)	5 (3.45%)	11 (3.75%)	19 (3.90%)
Don't know how to fill up the ADR reporting form	1 (25%)	2 (4.4%)	3 (2.07%)	6 (2.05%)	12 (2.46%)
Did you ever report misleading advertisements?					
Yes	2 (50%)	3 (6.66%)	10 (6.90%)	15 (5.12%)	30 (6.16%)
No	2 (50%)	42 (93.33%)	135 (93.10%)	278 (94.88%)	457 (93.84%)

is a need for improving the ongoing Pharmacovigilance activities and teaching at both undergraduate and postgraduate level. All these interventional strategies and regular pharmacovigilance awareness programme/trainings may be planned at their work place for improving ADR reporting.

Conclusion

The findings of this study provide a basis to develop and implement strategies to improve ADR reporting by Ayurveda Physicians. As

per the observations, it is evident that there is a huge gap between the ADR experienced and ADR reported by participants which may provide a basis to develop and implement strategies to improve ADR reporting by different Ayurveda stakeholders like physicians, pharmacists and teachers with a positive attitude to foster pharmacovigilance practice, if proper knowledge is provided.

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Conflicts of interest

There are no conflicts of interest.

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