

Knowledge, awareness, attitude and practice of Indian Homoeopathic Physicians about pharmacovigilance in homoeopathy: A web-based cross-sectional study

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Abstract

Background: Pharmacovigilance (Pv) is the science and activities relating to detecting, assessing, understanding and preventing adverse effects or any other drug-related problems. The subject is essential for developing reliable information on the safety of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy medicines. **Objectives:** This study explored the homoeopathic physicians' knowledge, awareness, attitude and practice (KAAP) towards the Pv programme in homoeopathy. **Methods:** An online cross-sectional survey was conducted among 274 Indian homoeopathic practitioners for 2 months. The study team developed the questionnaire in consultation with three subject experts and the same was circulated as a generated link among different social media handles. The interested participants consenting to the study were directed to the data collection format through an online portal. The data were collected in four domains: KAAP. Descriptive statistics were used in data analysis and independent t-tests for the subgroup analysis. **Results:** A total of 274 homoeopathic practitioners were approached, of which 265 consented to fill out the questionnaire, yielding a response rate of 96.7%. Most of the study participants had obtained low scores in knowledge and awareness of the programme. Statistically significant differences were observed among postgraduates and those with prior training in Pv. The attitude towards acceptance of the programme was relatively high among the participants, but the low awareness led to reduced observations and reporting of the adverse drug reactions (ADRs) in homoeopathy. **Conclusion:** Despite the good attitude of homoeopathic practitioners to the Pv programme, sufficient hands-on training is required to identify and report ADRs in homoeopathy.

Keywords: Adverse drug event, Adverse drug reaction, Homoeopathy, Knowledge; awareness; attitude and practice, Pharmacovigilance

INTRODUCTION

Pharmacovigilance (Pv) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.^[1,2] The Thalidomide tragedy in 1961 was a revelation for the medical fraternity and its stakeholders.^[3] Gradually, the entire world started developing a system of Pv. In 1978, Uppsala Monitoring Centre (UMC) was established in Sweden as the WHO collaborating centre for international drug monitoring that maintains the global database of adverse drug reaction (ADR) reports.^[3] It has been estimated that only 6–10% of all ADRs are reported.^[4] Although India participates in the programme, its contribution to the UMC database is only 2%.^[5] The National Pv Programme (NPP) was launched in 2003 under the Central Drug Standard Control Organization

(CDSCO), Ministry of Health and Family Welfare, Government of India and in 2010, the name was renamed the Pv Programme of India (PvPI).^[6,7] Due to the increased concern by the WHO regarding the safety of traditional medicines, an NPP in Ayurveda, Siddha and Unani (ASU) drugs was initiated by the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), Ministry of Health and Family Welfare, Government of India, in 2008.^[8,9] In 2018, the Pv programme for Ayurveda, Siddha, Unani medicine

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Received: 25 July 2022; **Accepted:** 9 March 2023

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How to cite this article: Purkait R, Bhattacharjee B, Banerjee A, Choubey G. Knowledge, awareness, attitude and practice of Indian Homoeopathic Physicians about pharmacovigilance in homoeopathy: A web-based cross-sectional study. *Indian J Res Homoeopathy* 2023;17(1):21-29.

| Access this article online | |
|---|---------------------------------|
| Quick Response Code: Available in print version only | Website: www.ijrh.org |
| | DOI: 10.53945/2320-7094.1244 |

and Homoeopathy (ASU&H) drugs was launched as a central sector scheme under the Ministry of AYUSH, Government of India, keeping in view the increasing global concern regarding safety issues of ASU&H drugs.^[8,10] Under this programme, the designated Pv centres are reporting suspected ADRs and misleading advertisements for ASU&H drugs across India. The vision of PvPI is to improve patient safety and the well-being of individuals by monitoring drug safety and thereby reducing the risk associated with using medicines.^[6] Compared to the conventional system, reporting and documenting ADR in ASU&H are negligible.^[10] There is a widespread belief that Complementary and Alternative Medicine therapies such as homoeopathy is a mild and safe mode of treatment.^[11] This notion has led to large-scale self-medication using over-the-counter drugs (OTC) by the general population worldwide, inappropriate application of medicines is one of the challenges of the public health domain and may lead to serious ADRs that account for 3% to 23% of hospital admissions, prolong hospital stays and increase morbidity and mortality.^[12,13] Pv is essential for developing reliable information on the safety of drugs.^[14] Despite many efforts and the presence of a moderate number of Pv centres, Pv is still in its infancy.^[15] Lack of awareness and sensitisation towards Pv is one of the most important causes of under-reporting of ADRs, ADEs or any other misleading advertisement in homoeopathy by health-care professionals.^[15,16] There are very few evidences in defence when the safety of the drugs of AYUSH systems is being questioned.^[14] Health-care professionals need to be acquainted with how to report and where to report an ADR. The active participation of health-care providers in the Pv programme can improve ADR reporting,^[17] help to detect serious and unusual ADRs during the marketing of the drug and decrease the risk of ADRs by pharmaceutical products.^[15,16] To date, there are no such data available on the knowledge, awareness, attitude and practices (KAAPs) regarding the Pv aspect of homoeopathy.

This study aimed to explore the knowledge, awareness and attitude of the homoeopathic physician toward the Pv programme in homoeopathy as well as their practices in reporting the suspected ADRs or ADEs and misleading advertisements in homoeopathy.

MATERIALS AND METHODS

Study design

This cross-sectional study was conducted online survey of Indian homoeopathic physicians, from all the states of India, working in different capacities.

Study period

The period of data collection for the study was for 2 months, from August to October 2021. The online link of the form was active from the 18 August 2021 to the 20 October 2021 (approximately 2 months), following which further responses were denied.

Study settings

The study was carried out under the Clinical Research Unit for Homoeopathy, Siliguri, under the Central Council for Research in Homoeopathy, Ministry of AYUSH, Government of India. The survey was developed over an online platform (Google® forms) and the generated link was circulated publicly among different open social media platforms. When the interested individual would click the link, they would be directed to the online form. The form was a single-response form that could be accessed only after providing the email address of the participants.

Participants

A total of 274 participants attempted the survey online and 265 gave consent, all of whom were registered homoeopathic practitioners practicing in India. The participants were working under different capacities of teachers, private practitioners, practitioners at government institutions, researchers, interneers, house staff, postgraduate trainees and others. The participants included graduates and postgraduates in homoeopathy, urban, semi-urban and rural practitioners with varying years of clinical experience.

Eligibility criteria

Any registered homoeopathic practitioners including interns under training at homoeopathic institutions in India, with voluntary informed consent, were eligible to participate in the study.

Sampling methods

Convenience or pragmatic sampling methods were used for the selection of the participants of the study. The study form was shared with the participants by messaging them personally with the form link. The form link was also shared on different social media pages so that interested individuals could participate in the study.

Study tool

As previously no such study has been conducted to study the knowledge, attitude and practices of Pv in homoeopathy, the investigators themselves developed the questionnaire. Following the framing of questions, the questions were reviewed by a group of three experts for content, consistency, clarity and relevance. All the reviewers were coordinators of different Pv centres and had sufficient knowledge and experience in the field. Following the development of the questionnaire, it was pilot tested among 10 homoeopathic practitioners for their clarity, content, response time and the possibility to be conducted on an online platform. The results of the pilot testing are excluded from the analysis. Following the exercise, a total of 26 questions were selected under the headings, KAAP, in addition to general information of the participants.

Ethical statements

The ethical approval of the study was obtained from the Institutional Ethical Committee of the Clinical Research Unit for Homoeopathy, Siliguri (KAP-Pv/Survey/2021-23 dated 6

August 2021). The informed consent form from the participants was received online with the link, and before filling out the data collection form.

Data analysis

The responses submitted on the Google® form were exported from the portal in Microsoft Excel®. The statistical analysis was conducted using the Statistical Package for the Social Science software® for Windows, version 25. The responses were coded and entered in the software. Descriptive statistics were used for reporting the data. Independent t-tests were conducted for the subgroup analysis.

RESULTS

Demographics

A total of 274 Indian homoeopathic doctors visited the link for the online questionnaire. Among them, 265 provided consent and proceeded for the survey, with a response rate of 96.7%. They alone were included in the analysis. Most of the study participants were 22–30 years of age ($n = 104$, 39.2%) and male participants ($n = 153$, 57.7%). Most of the participants had a master's degree in Homoeopathy ($n = 150$, 56.6%) as the highest qualification and practiced in urban settings ($n = 151$, 57%). Most participants were teaching faculty of different homoeopathic colleges ($n = 76$, 28.7%), followed by private practitioners ($n = 63$, 23.8%) and researchers ($n = 39$, 14.7%). Maximum participants had <5 years of clinical experience ($n = 137$, 51.7%). Among the study participants, only 24.2% ever attended any training on Pv in homoeopathy. Most of the knowledge regarding Pv was obtained from different institutional faculties ($n = 107$, 40.4%). The details are provided in Table 1.

Knowledge of Pv, ADR and misleading advertisements

The first section had nine questions that assessed Pv knowledge. The first question, which inquired about India's regulatory authority for homoeopathy Pv, was correctly answered by 43.8% of participants. The second question, which asked about the need for Pv in homoeopathy, was correctly answered by 69.4% of participants. The definition of an ADR was the next question, and 51.7% of participants responded appropriately. Only 13.2% of participants responded correctly to the next question regarding the statement that accurately defined an adverse drug event (ADE). The next question was on the precise definition of the term for any unfavourable medical occurrence at any dose that necessitates in-patient hospitalisation or prolongation of existing hospitalisation. Of the participants, 40.8% responded appropriately. The question on misleading advertising had 57.4% correct responses and the one on reporting any ADR, ADE or SAE that occurred during homoeopathic treatment had 45.7% accurate responses. When asked where to report an ADR, ADE or SAE during homoeopathic treatment, 34.3% responded appropriately. About 34.7% of participants correctly responded to the final knowledge question, which asked them where to report any misleading advertisements in homoeopathy. It was particularly

Table 1: Demographic details of the study participants

| Variable | Frequency | Percentage | P-value |
|--|-----------|------------|---------|
| Age groups (in years) | | | |
| 22–30 | 104 | 39.2 | <0.001 |
| 31–40 | 100 | 37.7 | |
| 41–50 | 47 | 17.7 | |
| 51–60 | 12 | 4.5 | |
| Above 60 years | 2 | 0.8 | |
| Gender | | | |
| Male | 153 | 57.7 | 0.014 |
| Female | 112 | 42.3 | |
| Nature of practice | | | |
| Urban | 151 | 57.0 | <0.001 |
| Semi-urban | 68 | 25.7 | |
| Rural | 46 | 17.4 | |
| Highest Education qualification | | | |
| Ph. D. | 3 | 1.1 | <0.001 |
| M.D. Homoeopathy | 150 | 56.6 | |
| BHMS/Graded BHMS | 109 | 41.1 | |
| Diploma (DMS/DHMS) | 3 | 1.1 | |
| Nature of employment | | | |
| Internee/House staff ship | 11 | 4.2 | <0.001 |
| Postgraduate Trainee | 31 | 11.7 | |
| Medical Officer in Centre/State Government | 37 | 14.0 | |
| Private practitioner | 63 | 23.8 | |
| Researcher | 39 | 14.7 | |
| Teaching faculty | 76 | 28.7 | |
| Others | 8 | 3.0 | |
| Years of clinical experience | | | |
| <5 years | 137 | 51.7 | <0.001 |
| 5–10 years | 56 | 21.1 | |
| 11–15 years | 23 | 8.7 | |
| 16–20 years | 21 | 7.9 | |
| 21–25 years | 18 | 6.8 | |
| 26–30 years | 5 | 1.9 | |
| More than 30 years | 5 | 1.9 | |
| Whether attended training in Pv or not? | | | |
| Yes | 64 | 24.2 | <0.001 |
| No | 201 | 75.8 | |
| Source of information on Pv | | | |
| Institutional faculty | 107 | 40.4 | <0.001 |
| Internet/Journal article | 77 | 29.1 | |
| Social media | 47 | 17.7 | |
| Newspaper | 7 | 2.6 | |
| Never heard of the term | 27 | 10.2 | |

Pv: Pharmacovigilance

noted that a range of 5.4–20.44% of participants answered 'can't say' to various knowledge section questions. The participants in the study received a mean score of 3.91 ± 2.603 . According to subgroup analyses, there was a significant difference between graduates and postgraduates (mean difference 0.864, 95% CI = 0.308, 1.420, $P = 0.002$), as well as between participants who had received prior training on Pv and those who did not (mean difference = 1.664, 95% CI = 1.044, 2.285, $P < 0.001$) [Tables 2, 3 and 4].

Awareness towards Pv

Six questions were included in the survey to gauge participants' awareness of Pv. On a 5-point Likert scale with the two extremes of 'not at all aware' and 'very much aware', the responses were gathered. Table 5 summarises the responses. According to the responses, participants have a high level of awareness of misleading advertisements in homoeopathy. Participants are less aware of the existing homoeopathic Pv centres, ADR reporting guidelines and online reporting portals. According to subgroup analyses [Tables 3 and 4], participants who have undergone Pv training have significantly higher awareness. Postgraduates' awareness of specific questions differs significantly, according to the analyses, but their awareness of existing homoeopathic Pv centres, ADR reporting guidelines and online reporting portals did not differ.

Attitude towards ADR, Pv and misleading advertisements

In the questionnaire, the participants were asked to rate six statements in the attitude section on a 5-point Likert scale ranging

from 'strongly disagree' to 'strongly agree'. The statements were broadly agreed upon by approximately 50–60% of participants. It is safe to conclude that homoeopathic professionals in India are generally supportive of Pv, that the participants concur on its significance to homoeopathic education and practice, and that it will, as a result, increase patient safety. The statement that pharmacovigilance must be included in the curriculum of homoeopathy was supported by a sizable majority (59.2%). Most participants concluded by saying that it was the duty of homoeopathic physicians to inform authorities of misleading advertisements. One more perspective concerning the OTC buying and utilisation of homoeopathic medications was asked, to which a greater part of members concurred (agreed = 43.8%, strongly agreed = 43.8%) and responded that such practices are liable for ADRs in homoeopathy [Table 6].

Practice of Pv

Participants were asked five questions in this section, and their responses were recorded on a 4-point scale from 'Never' to 'Frequently'. About 34.3% of participants responded that they had never read any literature on Pv. In addition, the participants indicated that they had either rarely (33.2%) or never (40%) experienced any ADR/ADE/SAE while receiving homoeopathic treatment. Nearly 70% of them never reported any ADR, ADE or SAE to the appropriate authority. In their responses, the participants stated that they have occasionally (51.3%), but rarely (66%) reported encountering deceptive advertisements in homoeopathy [Table 7].

State-wise analysis

Sub-group analysis was performed with respect to different states and union territories participating in the study. Data of only top 5 participating states are being demonstrated as the rest do not demonstrate meaningful data due to a small number of responses. West Bengal had the highest number of responses followed by Maharashtra, Gujarat, Tamil Nadu and Delhi. Maharashtra had the highest mean scores for the knowledge of Pv and the highest awareness of the Pv programme. Tamil Nadu showed the highest positive attitude, whereas Maharashtra demonstrated best practices for Pv [Table 8].

Table 2: Total knowledge scores in the study population

| S. No. | Details | Values |
|--------|---|--------|
| 1. | Sample size | 265 |
| 2. | Mean | 3.91 |
| 3. | Standard deviation | 2.306 |
| 4. | Median | 4 |
| 5. | Mode | 2 |
| 6. | Minimum score | 0 |
| 7. | Maximum score | 9 |
| 8. | Standard error of the mean | 0.142 |
| 9. | Variance | 5.318 |
| 10. | 25 th percentile | 2 |
| 11. | 50 th percentile | 4 |
| 12. | 75 th percentile | 6 |
| 13. | Skewness | 0.816 |
| 14. | Standard error of skewness | 0.150 |
| 15. | Kurtosis | -0.697 |
| 16. | Standard error of kurtosis | 0.298 |
| 17. | <i>P</i> -value (one-sample <i>t</i> -test) | 0.000 |

Table 3: Comparison of the scores among postgraduates and graduates

| S. No. | Graduation status | Frequency | Mean knowledge scores | Mean awareness scores (not at all aware: 1 point; highly aware: 5 points) | Mean attitude scores (strongly disagree: 1, strongly agree: 5) | Mean practice scores (never: 1, frequently 4) |
|--------|-------------------|-----------|-----------------------|---|--|---|
| 1. | Postgraduates | 153 | 4.27 | 18.65 | 24.51 | 9.74 |
| 2. | Graduates | 112 | 3.41 | 16.18 | 24.17 | 10.02 |

Table 4: Comparison of the scores among individuals with prior training and no prior training on Pv

| S. No. | Training status on Pv | Frequency | Mean knowledge scores | Mean awareness scores (not at all aware: 1 point; highly aware: 5 points) | Mean attitude scores (strongly disagree: 1, strongly agree: 5) | Mean practice scores (never: 1, frequently 4) |
|--------|-----------------------|-----------|-----------------------|---|--|---|
| 1. | Had prior training | 64 | 5.17 | 23.33 | 24.33 | 10.81 |
| 2. | Had no prior training | 201 | 3.51 | 15.78 | 24.38 | 9.55 |

Pv: Pharmacovigilance

Table 5: Frequency (percentage) of responses to awareness-related questions

| Question | Not at all aware, n (%) | Slightly aware, n (%) | Somewhat aware, n (%) | Moderately aware, n (%) | Very much aware, n (%) |
|--|-------------------------|-----------------------|-----------------------|-------------------------|------------------------|
| Are you aware of 'Pv in homoeopathy'? | 41 (15.5) | 70 (26.4) | 56 (21.1) | 56 (21.1) | 42 (15.8) |
| Are you aware of ADR, ADE and SAE in homoeopathy? | 30 (11.3) | 57 (21.5) | 49 (18.5) | 63 (23.8) | 66 (24.9) |
| Are you aware of the misleading advertisement in homoeopathy? | 15 (5.7) | 35 (13.2) | 35 (13.2) | 70 (26.4) | 110 (41.5) |
| Are you aware of the existing Peripheral/Intermediary/National centres of Pv for homoeopathic drugs? | 77 (29.1) | 57 (21.5) | 37 (14.0) | 51 (19.2) | 43 (16.2) |
| Are you aware of the reporting guideline of ADR/ADE/SAE or any Misleading advertisements? | 96 (36.2) | 51 (19.2) | 34 (12.8) | 44 (16.6) | 40 (15.1) |
| Are you aware of the online reporting system of Pv for homoeopathic drugs? | 125 (47.2) | 51 (19.2) | 21 (7.9) | 38 (14.3) | 30 (11.3) |

ADR: Adverse drug reaction, ADE: Adverse drug event, SAE: Serious adverse event, Pv: Pharmacovigilance

Table 6: Frequency of responses to attitude-related questions/statements

| Question | Strongly disagree, n (%) | Disagree, n (%) | Neither agree nor disagree, n (%) | Agree, n (%) | Strongly agree, n (%) |
|--|--------------------------|-----------------|-----------------------------------|--------------|-----------------------|
| Giving importance to Pv in homoeopathy is required | 2 (0.8) | 1 (0.4) | 12 (4.5) | 77 (29.1) | 173 (65.3) |
| Reporting adverse drug reactions is necessary for homoeopathic practice | 2 (0.8) | 4 (1.5) | 11 (4.2) | 94 (35.5) | 154 (58.1) |
| Reporting ADR will increase the patient's safety | 1 (0.4) | 8 (3.0) | 12 (4.5) | 88 (33.2) | 156 (58.9) |
| Pv should be taught in detail to all homoeopathic physicians | 1 (0.4) | 4 (1.5) | 13 (4.9) | 90 (34.0) | 157 (59.2) |
| Reporting misleading advertisements regarding homoeopathy is a professional responsibility for homoeopathic physicians | 1 (0.4) | 2 (0.8) | 17 (6.4) | 94 (35.5) | 151 (57.0) |
| Does an unethical prescription or OTC (over the counter) drug have any role in developing ADR/ADE? | 1 (0.4) | 3 (1.1) | 29 (10.9) | 116 (43.8) | 116 (43.8) |

ADR: Adverse drug reaction, ADE: Adverse drug event, Pv: Pharmacovigilance, OTC: Over-the-counter

Table 7: Frequency of responses to practice-related questions

| Question | Never, n (%) | Rarely, n (%) | Sometimes, n (%) | Frequently, n (%) |
|--|--------------|---------------|------------------|-------------------|
| Have you ever read any of the articles on ADR/ADE/SAE in homoeopathy? | 91 (34.3) | 82 (30.9) | 71 (26.8) | 21 (7.9) |
| Have you ever experienced any ADR in your patient during your clinical practice? | 106 (40.0) | 88 (33.2) | 64 (24.2) | 7 (2.6) |
| Have you ever reported any ADR/ADE/SAE regarding homoeopathic medicine? | 200 (75.5) | 28 (10.6) | 30 (11.3) | 7 (2.6) |
| Have you ever noticed any misleading advertisements regarding homoeopathy? | 31 (11.7) | 40 (15.1) | 136 (51.3) | 58 (21.9) |
| Have you ever reported any misleading advertisement regarding homoeopathy? | 175 (66.0) | 32 (12.1) | 38 (14.3) | 20 (7.5) |

ADR: Adverse drug reaction, ADE: Adverse drug event, SAE: Serious adverse event

Table 8: State-wise scores displaying knowledge, awareness, attitude and practice scores (of top 5 respondent states)

| S. No. | State | Frequency | Mean knowledge scores | Percentage of participants with the highest awareness levels (very much aware) | Percentage of participants with the lowest awareness levels (not at all aware) | Percentage of participants with the highest positive attitude (strongly agree) | Percentage of participants with the highest practice scores (frequently) | Percentage of participants with the poorest practice scores (never) |
|--------|-------------|-----------|-----------------------|--|--|--|--|---|
| 1. | West Bengal | 125 | 3.68 | 19.87 | 26.8 | 57.20 | 9.6 | 44.8 |
| 2. | Maharashtra | 24 | 4.33 | 23.6 | 14.58 | 57.65 | 13.32 | 44.16 |
| 3. | Gujarat | 23 | 3.35 | 12.32 | 28.75 | 59.43 | 2.58 | 60 |
| 4. | Tamil Nadu | 15 | 3.87 | 10.55 | 21.12 | 63.35 | 10.66 | 49.32 |
| 5. | Delhi | 12 | 4 | 17.45 | 27.78 | 51.40 | 8.34 | 43.34 |

DISCUSSION

The study aimed to assess the KAAP of Pv among homoeopathic professionals in India to determine the major barriers to the implementation of the programme in the

homoeopathic community of India. Being an online study, the actual response rate was very difficult to determine but the number of participants consenting to the survey was quite high. Participation in this study was observed from all states of the

country, and homoeopaths working in different capacities with different years of experience, and therefore, the results can be somewhat generalised to the actual picture of Pv in the country.

The results of the study show that the overall knowledge and awareness of Pv are relatively low among homoeopathic physicians. However, it may also be considered that the programme was only initiated in Homoeopathy in 2018 and is still in its infancy. The number of awareness programmes conducted since the initiation by the different Pv centres have not covered the bulk of homoeopathic practitioners. This study confirms the same as only 24.2% of individuals had ever attended any training/awareness programmes in Pv, and the knowledge and awareness scores of such participants are significantly different from the others. Another significant difference in knowledge scores has been observed in postgraduate students which may be attributed to better knowledge of research methodology and homoeopathic subjects as taught in the postgraduate coursework. However, the awareness of ADR reporting of postgraduate physicians is not significant in comparison to graduates. Sound awareness and knowledge were observed mainly in the questions related to misleading advertisements due to the increasing number of such advertisements encountered on different social media platforms. The knowledge and awareness of the three most important aspects of the Pv programme, 'who can report?', 'how to report' and 'where to report?' was poor among the majority of participants.

The attitude of the participants in the study was very positive towards Pv and a majority of the participants felt that the implementation of a Pv programme shall improve homoeopathic practice and the safety of the participants. The participants also felt that it is the professional responsibility of the physicians to report ADR/ADE/SAE and misleading advertisements. The majority of the participants also agreed that the topic of Pv must be taught in detail and included in the coursework of homoeopathic students. The statement in the survey regarding the OTC purchase of homoeopathic drugs without the prescription of a registered practitioner led to ADRs in homoeopathy, to which most of the participants agreed has been the leading cause for ADRs in Homoeopathy. This had earlier been mentioned in a study by *Dantas and Rampes* that medicines prescribed by trained homoeopathic professionals are less likely to provoke ADR and the same stands true within the Indian scenario.^[18] The practice of physicians toward Pv has been very disappointing and rarely it has been observed that any ADR reporting has been done by homoeopathic physicians. The major issue for this rare practice is mainly due to deficient knowledge and awareness of the three aspects earlier pointed out. Homoeopathy has always been promoted as a 'safe' and 'without side-effects' mode of treatment and therefore, the physician's mindset prompts them to overlook any such ADRs. The Homoeopathy curriculum in India includes teaching about the prognosis following treatment, as Kent's 12 observations and often the physicians consider homoeopathic aggravations as a part of the course of homoeopathic treatment.^[19]

The reported study aimed to identify the different barriers to the implementation of the Pv programme in homoeopathy. It seems the existing strategy of awareness programmes is not having an adequate outreach to the homoeopathic physicians. Inclusion of the topics of ADR, reporting guidelines and awareness of misleading advertisements within the coursework of graduation and postgraduation in homoeopathy can create a difference in the current parameters as demonstrated within the study. The attitude of the physicians is a positive one but guidance for proper practices is essential. A majority of participants were from the teaching faculty and postgraduates, yet awareness and practices were very poor. As an immediate measure, the authorities must ensure hands-on training for ADR reporting for the teachers and postgraduates at the institute level. The study had the limitation that it was only a pragmatic sample, based on the outreach efforts of the authors, which somewhat shows an apparent picture of the parameters observed in the study. The parameters and the attrition rate could also differ if the study could have been conducted on a randomised cluster population of homoeopathic physicians.

Based on this study, the authorities can strategise future plans for interventional programmes for homoeopathic physicians within the country. The results have hinted at the lacunae in the knowledge and awareness of ADR and their reporting. Regulatory authorities must try to create awareness regarding the professional obligation of homoeopathic physicians to report ADRs and misleading advertisements. An open collaboration between policymakers, academia, researchers and physicians shall ensure the execution of such a process.

CONCLUSION

The participants have a positive attitude towards Pv. Policymakers must cultivate this attitude with care, ensuring adequate awareness of every homoeopathic physician towards ADR reporting. A study based on a similar data collection format, but with greater rigour, may be conducted in the future to observe the changes in the scenario in near future.

Acknowledgements

The authors acknowledge Dr. Ghalib, National Pharmacovigilance Centre, Dr. Swapan Paul, Intermediary Pharmacovigilance Centre, National Institute of Homoeopathy, Kolkata, and Dr. Vivek Shaktidharan, Peripheral Pharmacovigilance Centre, Father Mueller Homoeopathic Medical College and Hospital for their expertise in developing the questionnaire of the study.

Financial support

No costs were incurred in the study.

Conflicts of interests

None to declare.

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Connaissance, sensibilisation, attitude et pratique des médecins homéopathes indiens concernant la pharmacovigilance en homéopathie : une étude transversale en ligne

Contexte: La pharmacovigilance (Pv) est la science et les activités liées à la détection, l'évaluation, la compréhension et la prévention des effets indésirables ou de tout autre problème lié aux médicaments. Le sujet est essentiel pour développer une information fiable sur la sécurité des médicaments AYUSH. **Objectif:** Cette étude a exploré les connaissances, la sensibilisation, l'attitude et la pratique (KAAP) des médecins homéopathes envers le programme Pv en homéopathie. **Méthodes:** Une enquête transversale en ligne a été menée auprès de 274 praticiens homéopathes en Inde pendant 2 mois. L'équipe a élaboré le questionnaire en consultation avec trois experts en la matière, et celui-ci a été diffusé sous forme de lien généré entre différentes poignées de médias sociaux. Les participants intéressés consentant à l'étude ont été dirigés vers le format de collecte de données via un portail en ligne. Les données ont été recueillies dans 4 domaines : connaissances, sensibilisation, attitude et pratique. Des statistiques descriptives ont été utilisées dans l'analyse des données et des tests t indépendants pour l'analyse des sous-groupes. **Résultats:** Au total, 274 praticiens homéopathes ont été approchés, dont 265 ont accepté de remplir le questionnaire, soit un taux de réponse de 96,7 %. La plupart des participants à l'étude avaient obtenu de faibles scores en matière de connaissance et de sensibilisation au programme. Des différences statistiquement significatives ont été observées entre les diplômés et ceux ayant une formation préalable en pharmacovigilance. L'attitude envers l'acceptation du programme était relativement élevée parmi les participants, mais la faible sensibilisation a conduit à une diminution des observations et des rapports sur les effets indésirables en homéopathie. **Conclusion:** Malgré la bonne attitude des praticiens homéopathes envers le programme Pv, une formation pratique suffisante est nécessaire pour identifier et signaler les effets indésirables en homéopathie.

Wissen, Bewusstsein, Einstellung und Praxis indischer homöopathischer Ärzte zur Pharmakovigilanz in der Homöopathie: Eine webbasierte Querschnittsstudie

Hintergrund: Pharmakovigilanz (Pv) ist die Wissenschaft und die Aktivitäten, die sich mit der Erkennung, der Bewertung, dem Verständnis und der Vorbeugung von unerwünschten Wirkungen oder anderen arzneimittelbezogenen Problemen befassen. Dieses Thema ist für die Entwicklung zuverlässiger Informationen über die Sicherheit von AYUSH-Arzneimitteln von wesentlicher Bedeutung. **Zielsetzung:** Diese Studie untersuchte die Kenntnisse, das Bewusstsein, die Einstellung und die Praxis (KAAP) der homöopathischen Ärzte in Bezug auf das Pv-Programm in der Homöopathie. **Methoden:** Eine Online-Querschnittsumfrage wurde unter 274 homöopathischen Ärzten in Indien über einen Zeitraum von 2 Monaten durchgeführt. Das Team entwickelte den Fragebogen in Absprache mit drei Fachexperten, und der Fragebogen wurde als generierter Link über verschiedene soziale Medien in Umlauf gebracht. Die interessierten Teilnehmer, die der Studie zustimmten, wurden über ein Online-Portal zum Datenerfassungsformat geleitet. Die Daten wurden in 4 Bereichen erhoben: Wissen, Bewusstsein, Einstellung und Praxis. Für die Datenanalyse wurden deskriptive Statistiken und unabhängige t-Tests für die Untergruppenanalyse verwendet. **Ergebnisse:** Insgesamt wurden 274 homöopathische Praktiker angeschrieben, von denen 265 dem Ausfüllen des Fragebogens zustimmten, was eine Rücklaufquote von 96,7 % ergab. Die meisten Studienteilnehmer hatten niedrige Werte bei Wissen und Bekanntheit des Programms erzielt. Statistisch signifikante Unterschiede wurden bei den Postgraduierten und denjenigen mit einer vorherigen Ausbildung in Pharmakovigilanz festgestellt. Die Einstellung zur Akzeptanz des Programms war bei den Teilnehmern relativ hoch, aber das geringe Bewusstsein führte zu einer geringeren Beobachtung und Meldung von UAW in der Homöopathie. **Schlussfolgerung:** Trotz der guten Einstellung der homöopathischen Praktiker zum Pv-Programm ist eine ausreichende praktische Ausbildung erforderlich, um UAW in der Homöopathie zu erkennen und zu melden.

होम्योपैथी में फार्माकोविजिलेंस से संबंधित भारतीय होम्योपैथिक चिकित्सकों का ज्ञान, जागरूकता, दृष्टिकोण और अभ्यास: एक वेब आधारित क्रॉस-सेक्शनल अध्ययन

पृष्ठभूमि: दवा से संबंधित विपरीत प्रभावों या किसी अन्य समस्याओं की पहचान करने, मूल्यांकन करने, उन्हें समझने और उनसे बचने से संबंधित विज्ञान और गतिविधियाँ फार्माकोविजिलेंस (Pv) कहलाता है। आयुष दवाओं की सुरक्षा से संबंधित विश्वसनीय जानकारी का विकास करने के लिए यह विषय अत्यंत महत्वपूर्ण है। **उद्देश्य:** इस अध्ययन में होम्योपैथी में Pv कार्यक्रम के प्रति होम्योपैथिक चिकित्सकों के ज्ञान, जागरूकता, दृष्टिकोण और प्रथाओं (केएएपी) का पता लगाया गया है। **विधि:** 274 भारतीय होम्योपैथिक चिकित्सकों का एक ऑनलाइन क्रॉस-सेक्शनल सर्वेक्षण 2 महीनों तक किया गया। तीन विषय-विशेषज्ञों के परामर्श से प्रश्नावली तैयार की गयी, और इसे उत्पन्न लिंक के माध्यम से विभिन्न सोशल मीडिया हैंडल द्वारा प्रसारित किया गया। अध्ययन के लिए सहमत प्रतिभागियों को एक ऑनलाइन पोर्टल के माध्यम से डाटा संग्रह प्रारूप के लिए निर्देशित किया गया। 4 डोमेनों से संबंधित डाटा को एकत्र किया गया : ज्ञान, जागरूकता, दृष्टिकोण और प्रथाएँ। उपसमूह विश्लेषण के लिए डाटा विश्लेषण और स्वतंत्र टी-परीक्षणों में वर्णनात्मक आंकड़ों का उपयोग किया गया। **परिणाम:** इस संबंध में कुल 274 होम्योपैथिक चिकित्सकों से संपर्क किया गया, जिनमें से 265 प्रतिभागी प्रश्नावली भरने के लिए सहमत हुए, जिस से प्रतिक्रिया दर 96.7% रही। अध्ययन में भाग लेने वाले अधिकांश प्रतिभागियों ने कार्यक्रम के ज्ञान और जागरूकता में कम अंक प्राप्त किये। स्नातकोत्तर और पहले से फार्माकोविजिलेंस में प्रशिक्षित प्रतिभागियों के बीच सांख्यिकीय रूप से महत्वपूर्ण अंतर देखा गया। प्रतिभागियों में

कार्यक्रम के प्रति स्वीकृति का दृष्टिकोण था, लेकिन कम जागरूकता के कारण होम्योपैथी में एडीआर के अवलोकन और रिपोर्टिंग में कमी पाई गई। **निष्कर्ष:** Pv कार्यक्रम के प्रति होम्योपैथिक चिकित्सकों का अच्छा दृष्टिकोण होने के बावजूद, होम्योपैथी में एडीआर की पहचान करने और रिपोर्ट करने के लिए पर्याप्त व्यावहारिक प्रशिक्षण की आवश्यकता है।

Conocimiento, conciencia, actitud y práctica de los médicos homeópatas indios sobre la Farmacovigilancia en homeopatía: un estudio transversal basado en la web

Fondo: La farmacovigilancia (Pv) es la ciencia y las actividades relacionadas con la detección, evaluación, comprensión y prevención de efectos adversos o cualquier otro problema relacionado con las drogas. El tema es esencial para desarrollar información confiable sobre la seguridad de los medicamentos AYUSH. **Objetivo:** Este estudio exploró el conocimiento, la conciencia, la actitud y la práctica (KAAP) de los médicos homeópatas hacia el programa Pv en homeopatía. **Métodos:** Se realizó una encuesta transversal en línea entre 274 médicos homeopáticos en la India durante 2 meses. El equipo desarrolló el cuestionario en consulta con tres expertos en la materia, y el mismo se distribuyó como un enlace generado entre diferentes redes sociales. Los participantes interesados que consintieron el estudio fueron dirigidos al formato de recolección de datos a través de un portal en línea. Los datos fueron recolectados en 4 dominios: conocimiento, conciencia, actitud y práctica. Se utilizó estadística descriptiva en el análisis de los datos y pruebas t independientes para el análisis de subgrupos. **Resultados:** Se contactó a un total de 274 médicos homeopáticos, de los cuales 265 consintieron en rellenar el cuestionario, arrojando una tasa de respuesta del 96,7%. La mayoría de los participantes del estudio habían obtenido puntajes bajos en conocimiento y conocimiento del programa. Se observaron diferencias estadísticamente significativas entre los postgraduados y aquellos con formación previa en Farmacovigilancia. La actitud hacia la aceptación del programa fue relativamente alta entre los participantes, pero la baja conciencia condujo a una reducción de las observaciones y la notificación de las ADRs en homeopatía. **Conclusión:** A pesar de la buena actitud de los médicos homeopáticos hacia el programa Pv, se requiere suficiente capacitación práctica para identificar e informar las ADRs en homeopatía.

印度顺势疗法医生关于顺势疗法药物警戒的知识、意识、态度和实践：一项基于网络的横断面研究。

背景: 药物警戒 (Pv) 是与检测、评估、理解和预防不良反应或任何其他药物相关问题相关的科学和活动。该主题对于开发有关AYUSH药物安全性的可靠信息至关重要。 **目的:** 本研究探讨顺势疗法医师对顺势疗法Pv项目的知识、意识、态度和实践 (KAAP)。 **方法:** 在印度274名顺势疗法从业者中进行了为期2个月的在线横断面调查。该团队与三位主题专家协商制定了问卷, 并将其作为不同社交媒体处理方式之间生成的链接分发。同意该研究的感兴趣的参与者通过在线门户网站被引导到数据收集格式。数据收集于4个领域: 知识、意识、态度和实践。描述性统计用于数据分析和分组分析的独立t检验。 **结果:** 共接触了274名顺势疗法从业者, 其中265人同意填写问卷, 回复率为96.7%。大多数研究参与者在该项目的知识和意识方面得分较低。研究生与之前接受药物警戒训练的研究生之间存在统计学显著差异。参与者对该项目的接受态度相对较高, 但低意识导致对顺势疗法不良反应的观察和报告减少。 **结论:** 尽管顺势疗法从业者对Pv项目的态度很好, 但需要进行充分的实践培训来识别和报告顺势疗法中的不良反应。