

A cross sectional survey on the knowledge and attitude of Ayurvedic practitioners of Kerala towards Pharmacovigilance

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ABSTRACT

Background: The popular perception of Ayurvedic medicines of being devoid of any adverse drug reaction is at stake. Owing to the increased industrialization in this field, there is an alarming increase in the rate of adverse drug reactions. To tackle these issues, National Pharmacovigilance Programme for AYUSH drugs was introduced. An in-depth research was conducted to assess the knowledge and attitude of Ayurvedic Practitioners of Kerala towards Pharmacovigilance and the extent to which they report adverse drug reactions (ADRs) to the higher centres.

Methods: A validated web based questionnaire was designed and a cross sectional survey was conducted among 100 Ayurvedic clinical practitioners in different districts of Kerala (n=100). Inclusion criteria were Clinical practitioners and excluded Teaching faculties and PG Scholars. Statistical method employed was Descriptive statistics.

Results: Statistical analysis revealed that only 58% physicians are aware of the existence of National Pharmacovigilance Programme. 56% does not have the idea of the higher reporting centres. 80% are unaware of the existence of Peripheral Pharmacovigilance centre in Kerala. 60% are ignorant that ADRs should be reported and 77% are not familiar with the standard form for ADR reporting of Ayurvedic medicines.

Conclusion: The present study brought into light the lack of knowledge of National Pharmacovigilance Programme and ADR reporting of Ayurvedic medicines. This study has unveiled the urgent need for a regular training and reinforcement for the ADR reporting among the Ayurvedic Practitioners.

Key words: - Cross sectional survey, Pharmacovigilance for Ayurvedic medicines, ADR

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INTRODUCTION

The popular perception of Ayurvedic medicines of being devoid of any adverse drug reaction is at stake. The utilization of these drugs since thousands of years itself supports this notion. But in present scenario, increased industrialization of these practices raised concerns about their safety and efficacy which created doubts on Indian heritage. To tackle these issues, National Pharmacovigilance Programme for AYUSH drugs was introduced. Pharmacovigilance is defined as the science and activities relating to the detection, assessment and prevention of adverse events and all other problems related to medicine. The pharmacovigilance program may also applied in cases where medicines are unavailable, unaffordable, unsafe or improperly used or poorly monitored clinical trials. Moreover, it has an important role in therapeutic decision making either for an individual or national or global perspective. There is an ongoing problem with unexpected toxicity of herbal products due to quality issues including use of poor quality herbal material, incorrect or misidentified herbs, and incorrect processing methods, supply of adulterated or contaminated herbs. Hence poor quality is likely to remain a problem. Improper consumption of these herbal medicines may lead to Adverse drug reactions (ADRs). The purpose of pharmacovigilance program is to identify the Adverse drug reactions (ADRs) in large populations, record the frequency and to

implement measures for further prevention of these Adverse Drug Reactions (ADRs).

At present, Ministry of AYUSH has been remodelled new central sector scheme for promoting pharmacovigilance of ASU &H drugs. The scheme consists of a three tier network of National Pharmacovigilance Centre (NPvC) Intermediary Pharmacovigilance Centres (5) and peripheral Pharmacovigilance Centre (42). All India Institute of Ayurveda, New Delhi has been designated as NPvC for coordinating various activities of the initiative. With this background, the present study is to assess the knowledge and attitude of Ayurvedic Practitioners of Kerala towards Pharmacovigilance and the extent to which they report adverse drug reactions (ADRs) to the higher centres.

METHODS

A structured and validated web based questionnaire was designed and distributed among 100 Ayurvedic clinical practitioners from different districts of Kerala (n=100)

DESIGN: Cross sectional Survey

STUDY TOOL: Web based questionnaire

INCLUSION CRITERIA: Clinical practitioners

EXCLUSION CRITERIA: PG Scholars, Teaching faculties

STATISTICAL METHOD USED: Descriptive statistic

QUESTIONNAIRE:

Survey on the knowledge and attitude towards pharmacovigilance:

Name of the Practitioner:

Qualification :

Designation :

1. Have you heard about the term pharmacovigilance?

Yes No

2. Are you aware of existence of National Pharmacovigilance Program for AYUSH drugs in India?

Yes No

If yes, where is the National pharmacovigilance centre for AYUSH drugs situated?

3. Are you aware of the existence of peripheral pharmacovigilance centre in Kerala?

Yes No

If yes, where?.....

4. Have you encountered any adverse event with Ayurvedic drugs?

Yes No

5. Are you aware that any sort of adverse drug reactions should be reported?

Yes No

6. Have you ever reported any Adverse drug reactions(ADR)

Yes No

If yes, how many?.....

If not, what is the reason?.....

7. Are you familiar with standardised form for reporting ADRs of Ayurvedic drugs?

Yes No

8. Have you ever advised patient to report adverse drug reactions (ADRs) to any health care professional?

Yes No

9. Have you attended any seminar or training program about pharmacovigilance of Ayurvedic drugs?

Yes No

10. What are your suggestions for improving ADR reporting and pharmacovigilance program of Ayurvedic drugs?

2 Are you aware of existence of National Pharmacovigilance Program for AYUSH drugs in India?

Yes 58
No 42

If yes, where is the National pharmacovigilance centre for AYUSH drugs situated?

New Delhi 19
Jamnagar 25
Don't know 56

3 Are you aware of the existence of peripheral pharmacovigilance centre in Kerala?

Yes 22
No 78

If yes, where

Kottakkal 6
Trivandrum 14
Don't know 80

ADR Familiarity

4 Have you encountered any adverse event with Ayurvedic drugs?

Yes 47
No 53

5 Are you aware that any sort of adverse drug reactions should be reported?

Yes 40
No 60

6 Have you ever reported any Adverse drug reactions(ADR)

Yes 8
No 92

7 Are you familiar with standardised form for reporting ADRs of Ayurvedic drugs?

Yes 23
No 77

8 Have you ever advised patient to report adverse drug reactions (ADRs) to any health care professional?

Yes 44
No 56

9 Have you attended any seminar or training program about pharmacovigilance of Ayurvedic drugs?

Yes 10
No 90

RESULTS

Statistical analysis revealed that only 58% physicians are aware of the existence of National Pharmacovigilance Programme. 56% does not have the idea of the higher reporting centres. 25% still believes that the National pharmacovigilance centre is at IPGT& RA, Jamnagar. 80% are unaware of the existence of Peripheral Pharmacovigilance centre in Kerala. 60% are ignorant that ADRs should be reported. A total of only 47% encountered adverse events and merely 8% reported adverse drug reactions (ADRs). 77% are not familiar with the standard form for ADR reporting of Ayurvedic medicines (Table 1). It was found that there is a huge gap between ADR experienced and ADR reported. Also, there is a lack of knowledge about pharmacovigilance and ADR reporting system of AYUSH drugs among the Ayurvedic practitioners.

Table 1: Knowledge of pharmacovigilance towards Ayurvedic drugs and ADR Familiarity

QUESTIONS	%
Knowledge of pharmacovigilance towards Ayurvedic drugs	
1 Have you heard about the term pharmacovigilance?	
Yes	58
No	42

SUGGESTIONS

1. More centres should be established to report the ADRs and strengthen the awareness among the Ayurvedic practitioners about pharmacovigilance and ADR reporting through social media and other sources
2. Conduct training programmes and the importance of pharmacovigilance and ADR reporting should be taught from BAMS level
3. Informations regarding the updations in pharmacovigilance and ADR reporting should be conveyed among all the practitioners.
4. Online submission of the ADR report forms should be initiated

CONCLUSION

The present study brought into light the lack of knowledge of National Pharmacovigilance Programme and ADR reporting of Ayurvedic medicines. This study has unveiled the urgent need for a regular training and reinforcement for the ADR reporting among the Ayurvedic Practitioners.

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