



### Perspectives of *Pharmacovigilance* of AYUSH Drugs among Teaching faculty, Post graduate students and Interns of three different *Ayurvedic* Teaching Institute in Amravati District of Maharashtra state – A cross sectional survey.

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#### Abstract:

*Pharmacovigilance* helps to prove the system safe, more scientific in the terms of modern terminology. It is an absolute requirement to ensure public safety and to promote the AYUSH systems of medicine. *Pharmacovigilance* program launched in the India by Department of AYUSH, Ministry of health and family welfare, on 29/09/2008. Though it is helpful for development of system and government emphasized for implementation of it in root level, till date there is lack of awareness about this program among teaching faculties of AYUSH system. So to find out level of perspective of *Pharmacovigilance* in Teaching faculty, Post graduate students and Interns of Three different *Ayurvedic* Institutes in Amravati

districts present study was carried out in November 2020. Method: A structured and validated questionnaire with some minor modification used and distributed in the form of Hard copy among Teaching faculty, Residential medical officer and Interns of Three *Ayurvedic* colleges in Amravati District of Maharashtra state. Total of 50 teaching faculties with 62% of Lecturer cadre, 32% are of Reader and 2.50% of Professor Cadre responded to the questionnaires, with this one medical officer also responded to the questionnaire. Total 12 PG (Post graduate students) of different department take participation in the study while 88 Interns recorded their response in this study, so total participants in this study are 150 (n=150). Result: 52% (78) of

participants aware of *Pharmacovigilance* program for *Ayurvedic* drugs in India and 44% (66) of participants actually know exactly where the National *Pharmacovigilance* center for AYUSH Drugs is situated. Only 11.33% (17) of participants responded correct answer to question where the International *Pharmacovigilance* center for AYUSH drug is situated. In this study 58.66% (88) of participants accept that *Ayurvedic* drugs have adverse effect. Only 32.66% (49) participants responded that they are encountered with adverse event due to *Ayurvedic* drug in their clinical practice and out of which only 12% (18) of participants reported the adverse event. 18% of participants are familiar with standardized format for reporting ADR. Only 3.33% of participants give the example of *Ayurvedic* drugs banned due to ADR. Only 5.33% of participants attended the CME or training program about *Pharmacovigilance* of *Ayurvedic* drugs. Conclusion: Overall result shows the lack of awareness towards *Pharmacovigilance* program of AYUSH drugs in faculty and students of all *Ayurvedic* colleges in Amravati. Also *Blethonism* to point out adverse drug reaction (ADR) caused due to *Ayurvedic* drug and report it to the authorized center in standardized format. So to increase awareness about PV it should be included in Syllabus and more CME, Seminar and workshop should be organized for students, teaching faculty and private practitioner.

**Keywords:** *Pharmacovigilance*, AYUSH systems of medicine, Adverse drug reaction (ADR)

## Introduction:

Sometimes Drugs used in therapeutic doses may be liable to produce adverse drug reaction. Adverse drug reaction can be defined as an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment or alteration of the dosage regimen or withdrawal of the product.<sup>1</sup>

There is popular misconception that *ayurvedic* medicines are being devoid of any adverse drug reaction in society and also in AYUSH health workers too. This leads to self medication without prescription from Doctor and medication for long time. *Ayurvedic* medicine containing Metals, Nonmetals as main ingredients are consumed by patient for long time without proper consultation. Now days online purchasing of medicine is become very easy and all this leads to increase in number of reported cases of side effect caused by *Ayurvedic* medication in India and also in other countries. *Ayurvedic* classical texts explain the minute process of purification (*Shodhan* process) of metals and non metals before using in *Ayurvedic* Kulp. But due to increase demand and less supply of raw material there is increase tendency of adulteration of drugs with impure material. Sometimes herbal medicine may show hyper response on body.

To tackle these issues, National *Pharmacovigilance* program for AYUSH drug was introduced in India. *Pharmacovigilance* is defined as the science and activities relating to the detection,

assessment and prevention of Adverse event and all other problems related to medicine.<sup>2</sup>

The purpose of *Pharmacovigilance* program is to identify the ADR in large populations, records the frequency and implement measures for further prevention of these ADRs, with this motive ministry of AYUSH has been introduced New Central Sector Scheme, for promoting *Pharmacovigilance* of AYUSH drugs. All India Institute of Ayurveda, New Delhi has been designated as National *Pharmacovigilance* center. With this background to assess the perspective of Teaching faculty, Post Graduates students and Interns of three *ayurvedic* colleges in Amravati city of Maharashtra state present study was conducted.

#### Method

A structured and validated questionnaire with some minor modification

used<sup>3</sup> and distributed in the form of Hard copy among Teaching faculty, Residential medical officer and Interns of Three *ayurvedic* colleges in Amravati District of Maharashtra state. Total of 50 teaching faculties with 62% of Lecturer cadre, 32% are of Reader and 2.50% of Professor Cadre responded to the questionnaires, with this one medical officer also responded to the questionnaire.

Total 12 PG ( Post graduate students) of different department take participation in the study while 88 Interns recorded their response in this study, so total participants in this study are 150 (n=150).

**Design-** Cross sectional survey

**Study tool-** Questionnaire

**Inclusion criteria-** Teaching faculty, PG and Intern students

**Exclusion criteria-** UG student and non Teaching faculty

#### Questionnaire

##### Questionnaire about Perspective of *Pharmacovigilance*

Name (Optional):

Designation-

College Name-

Age-

Sex-Male/Female

UG College- Govt/Govt-aided/Private; PG College- Govt/Govt-aided/Private

Working department -

Experience (in Years only)-

#### Please answer the followings

1. Are you aware of *Pharmacovigilance* Program for *Ayurvedic* drugs in India?

Yes

☐

No

☐

2. Where is the National *Pharmacovigilance* Center for AYUSH drugs situated?

Ghaziabad

☐

Kolkata

☐

New Delhi

☐

Pune

☐

Not Known

☐

3. Where is the International *Pharmacovigilance* Center for AYUSH drugs situated?

USA ☐ UK ☐ Sweden ☐ Australia ☐ Not Known ☐

4. Do you think that *Ayurvedic* drugs have any adverse effect on body?

Yes ☐ No ☐

5. Have you ever encountered any adverse event with *Ayurvedic* drugs?

Yes ☐ No ☐

6. Have you ever reported any ADR? If Yes,

How many? \_\_\_\_\_ If not, what is the reason?

\_\_\_\_\_

7. Are you familiar with standardized form for Reporting ADRs of *Ayurvedic* drugs?

Yes ☐ No ☐

8. Do you know the commonly used scale to establish the causality of an ADR?

Yes ☐ No ☐ (If Yes, Can you name it? \_\_\_\_\_)

9. Can you give an example(s) of any *Ayurvedic* drug(s) banned due to ADRs?

*Ayurvedic* drug name-adverse event –

10. Have you attended any CME or training program about *Pharmacovigilance* of *Ayurvedic* drugs?

Yes ☐ No ☐ (If Yes, Can you name it? \_\_\_\_\_)

11. What are your suggestions for improving ADR reporting of *Ayurvedic* drugs?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## Results and Discussion:-

After completion of study statistical analysis revealed that 52% (78) of participants aware of *Pharmacovigilance* program for *Ayurvedic* drugs in India and 48% (72) of participants don't know about program. 44% (66) of participants actually know exactly where the National *Pharmacovigilance* center for AYUSH Drugs is situated while 36.66 % (55) participants responded not known and all remaining participants responded wrong answer.

Only 11.33% (17) of participants responded correct answer to question where the International *Pharmacovigilance* center for AYUSH drug is situated. While 72.66% (109) participants unaware of that.

At current scenario, increased in number of reported cases of adverse effect caused due to *Ayurvedic* drugs, there is increased tendency to accept *Ayurvedic* drugs have adverse effect on body. In this study also 58.66% (88) of participants accept that *Ayurvedic* drugs have adverse effect and 41.33% (62) participants still think that *Ayurvedic* drugs don't have adverse effect. Though there is increase in acceptance regarding adverse drugs effect of *ayurvedic* drugs but in reality only 32.66% (49) participants responded that they are encountered with adverse event due to *ayurvedic* drug in there clinical practice and out of which only 12% (18) of participants reported the adverse event. That suggests very large ignorance towards the reporting of ADR and with this one of the causes of not reporting ADR is that most of the health worker don't know about format of reporting ADR. In this study also that truth is again

proved because 82% (123) of participants are responded that they are not familiar with standardized format for reporting ADR and only 18% (27) of participant's familiar with standardized format for reporting ADR.

In this study about 98% (147) participants don't know the commonly used scale to establish the causality of an ADR, only 2% (3) knows about causality scale. Only 3.33% (5) of participants give the example of *Ayurvedic* drugs banned due to ADR. Only 5.33% (8) of participants attended the CME or training program about *Pharmacovigilance* of *Ayurvedic* drugs.

More than 72% (108) participants did not give any suggestion for improvement of ADR reporting of *Ayurvedic* drugs, 9.33% (14) participants suggested that more CME, Seminar or workshops should be organized on *Pharmacovigilance*, and 8.00% (12) participants thinks that *Pharmacovigilance* should be part of syllabus for Under graduate and Post graduate studies. 4% (6) participants focused on increase in number of center for reporting ADR.

## Conclusion:

Over all result shows the lack of awareness towards *Pharmacovigilance* program of AYUSH drugs in faculty and students of all *ayurvedic* colleges in *Amravati*. Also *Bletonism* to point out ADR caused due to *Ayurvedic* drug and report it to the authorized center in standardized format. So to increase awareness about PV it should be include in Syllabus and more CME, Seminar and workshop should organized for students, teaching faculty and private practitioner.

## References:

- 1) Edwards IR, Aronson J K, Adverse drug reaction: definitions, diagnosis & management. Lancet 2000;7(356); 1255-9
- 2) Arora D. *Pharmacovigilance obligations of the pharmaceuticals companies*. Indian J Pharmacol 2008; 40:S13-6.
- 3) Rajanandh MG, Dr.Chamundeeswari, Duraipandian. (2016). Perspectives of *Pharmacovigilance* of AYUSH Drugs among Health Care Professionals - A Cross-Sectional Survey. Sri Ramachandra Journal of Medicine. 9.

*Conflict of Interest: Non*

*Source of funding: Nil*

## *Cite this article:*

Paymalle, D. L., Amaley, D., & Joshi, D. (2021). Perspectives of Pharmacovigilance of AYUSH Drugs among Teaching faculty, Post graduate students and Interns of three different Ayurvedic Teaching Institute in Amravati District of Maharashtra state – A cross sectional survey. *Ayurlog: National Journal of Research in Ayurved Science*, 9(02).

<https://doi.org/10.52482/ayurlog.v9i02.806>

**Ayurlog: National Journal of Research in Ayurved Science- 2021; (09) (02):01-06**

