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A Community Based Intervention Study on Public Awareness and Perception Towards Reporting of Adverse Drug Reaction in Dakshina Kannada

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Abstract: The present study was aimed to asses the knowledge, attitude and practice in handling ADR, to find the reason behind under-reporting of ADR, to educate community about importance of ADR reporting and also to analyse the impact of education on ADR reporting. A survey-based study was conducted for a period of 6 months among the general public of Dakshina Kannada. A total of 300 participants were completed the questionnaire and participate in the study. Based on knowledge participants were scored and score <6 (150) were grouped as intervention group further they were subcategorized as control and treatment 75 each. Intervention study was carried using PIL and video after the interval of 1 month re-administered same questionnaire to check the impact pharmacist intervention regarding ADR and its management.

Majority (68%) of the participants were unaware about the term ADR, 31% believe that all the drugs available in the market are safe, 28.6% were unsure where to report ADR. Although 79.66% of the participants believe that ADR is harmful but 95.3% of them have not reported the suspected ADR. When enquiring reasons for not reporting not sure about ADR (65.52%), not sure where to report (11.54%), thinking that ADR reporting is not necessary, legal liability issues and fear of consequences were expressed. After intervention majority 78.66% of the participants were willing to report ADR, there was a significant improvement in the knowledge among the participants regarding ADR and its management was observed.

The study concludes that there was a significant improvement in the knowledge among the participants after the intervention and majority of participants were in willing to report ADR but there is a requirement of public sensitization in this regard so the concern authorities need to impose more effort on increasing the public awareness towards the ADR handling through campaigns and public awareness programs, also a brief information about ADR can be included in text books in school level.

Keywords*: Adverse Drug Reaction, Public Awareness, Intervention, Patient Information Leaflet (PIL).*

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I. INTRODUCTION

Adverse Drug Reactions (ADRs) are a significant cause of morbidity and mortality worldwide.[1] Adverse Drug Reactions (ADRs) are responsible for 10% of Outpatient appointments and 3.5 - 10% of Hospital admissions and are the fifth leading cause of death in hospitalized patients, in addition to prolonging stays and presenting a high economic impact.[2-3]

The key to reducing the consequences of ADRs and strengthening Pharmacovigilance is to identify and promptly report ADRs.[4] Pharmacovigilance Programme of India (PVPI) was introduced in 2010 with the vision to improve patient safety and welfare of Indian population by monitoring the safety of medicines and thereby reducing the risk associated with their use.[5] Adverse Drug Reaction Monitoring Centres (AMC) were setup across various cities in India, in all the medical colleges approved by Medical Council of India (MCI) with the AIIMS, New Delhi as the

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National Coordination centre (NCC) for monitoring ADRs in the country for safeguarding public health. The causality assessment system proposed by the World Health Organization (WHO) collaborating centre for International Drug Monitoring, the Uppsala Monitoring Centre (WHO – UMC).[6-7]

Moreover, in many studies, the majority failed to correctly define ADR. Most patients are confused ADR, side-effects, and adverse events. Low knowledge of ADR may be the reason in patients/consumers for under-reporting. Consumers prefer to report ADR to HCPs over other reporting channels. Therefore, to increase the number of ADR reports from patients/consumers, the community should be educated more and improve reporting.[7] The present study were conducted in community to analyse the reasons for not participating in ADR reporting.

In India, especially due to the Adverse Drug Reaction (ADR), has been implicated as a leading cause of considerable morbidity and mortality. It has been suggested that annual rates of ADR related deaths ranged from 0.08/100,000 to 0.12/100,000 and rate increase significantly over time at a rate of 0.0058/year.[8]

Adverse drug reactions are more common especially in pediatrics, geriatrics, female gender, multiple and intercurrent disease and taking poly pharmacy and in impaired liver or kidney functions patients. ADR's not only increases morbidity and mortality even it can affect the quality of life of patient and leading to financial burden. Even Government and Pharmacovigilance Programme of India (PVPI) is taking initiation to generate awareness among public by organizing Continuous Medical Education (CME) programs in hospitals and to sensitize the public, National Pharmacovigilance Week is celebrated from 17th September - 23rd September every year which is under utilized , has come up with helpline number 18001803024 and own mobile application named 'ADR PvPI', but still improvement in ADR reporting is not achieved.[9]So, there is a need of identifying the reasons for non-participation of public in such drive, hence the present study was selected.

II. PRIMARY OBJECTIVE

This study mainly aims to analyse the reasons for under-reporting of ADR in Dakshina Kannada and its management.

➢ *Specific Objectives:*

- To assess knowledge, attitude and practice in handling ADR.
- To find the reasons behind under-reporting of ADR.
- To educate community about importance of ADR reporting.
- To analyse the impact of education on ADR reporting and channel.

III. METHODOLOGY

➢ *Materials and Methods:*

- *Study Design:*

A survey was conducted with the help of questionnaire to collect the data from the community to assess their knowledge, attitude and management of ADRs at Mangalore. Articles were collected from the online sources such as PUBMED and GOOGLE SCHOLAR and questionnaire were prepared by using these articles. The data obtained from this survey were analysed, assessed and interpreted.

- *Study Site:*

The present study was survey-based study which were conducted among the community.

- *Study Duration:*

The present study was survey-based study which were conducted among the community.

- *Sample Size:*

The study was enrolled people during the time schedule (from 24/07/2023 to 24/08/2023) allotted for the project including other circumstances. The sample size were 300.

- *Ethical Clearance:*

The study protocol was approved by the Institutional Ethics Committee (IEC) of Srinivas Institute of Medical Science, Mukka, Mangalore.

➢ *Study Criteria:*

- *Inclusion Criteria:*

Individuals willing to participate and voluntarily enrolled were included for the study. Subjects less than 18 years of age and not willing to participate were excluded from the study.

➢ *Source of Data:*

- *Pre-Test:*

Data[s] were collected using the pre-validated questionnaires [4,5,6,7,10] through direct interaction with the subjects in various locations of Dakshina Kannada. The current study included participants from a variety of socio-economic backgrounds.

- *Post-Test:*

Revisiting the study site after 1 month for post study. 50% of the participants were provided intervention with Patient Information Leaflet [PIL] and their responses were recorded and analysed for the impact of intervention on under-reporting ADR.

➢ *Study method:*

Preparation of subject information sheet: Subject information sheet was prepared in both Kannada and English language. Both were used in the study.

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Preparation of information consent form: Information consent form was prepared in Kannada and English and the same was used in the study.

Before the selection of subjects, the subject information sheet was explained orally. Later consent form was orally explained to the participants before filling it taking their signature. Only the willing participants were used for the study.

- *Study Data collection:*

Data was collected through surveys using structured questionnaires adapted from previous studies and modified to suit our purpose. Questionnaire were prepared in English and Kannada including all relevant variables based on the objectives of study.

The tools used have 4 sections designed to address:

- ✓ Socio-demographics characteristics
- ✓ Knowledge
- ✓ Attitude
- ✓ Practice of participants towards management of ADRs.

- *Data Analysis:*

Sample characteristics were computed in percentage/suitable and it is presented using tables and figures.

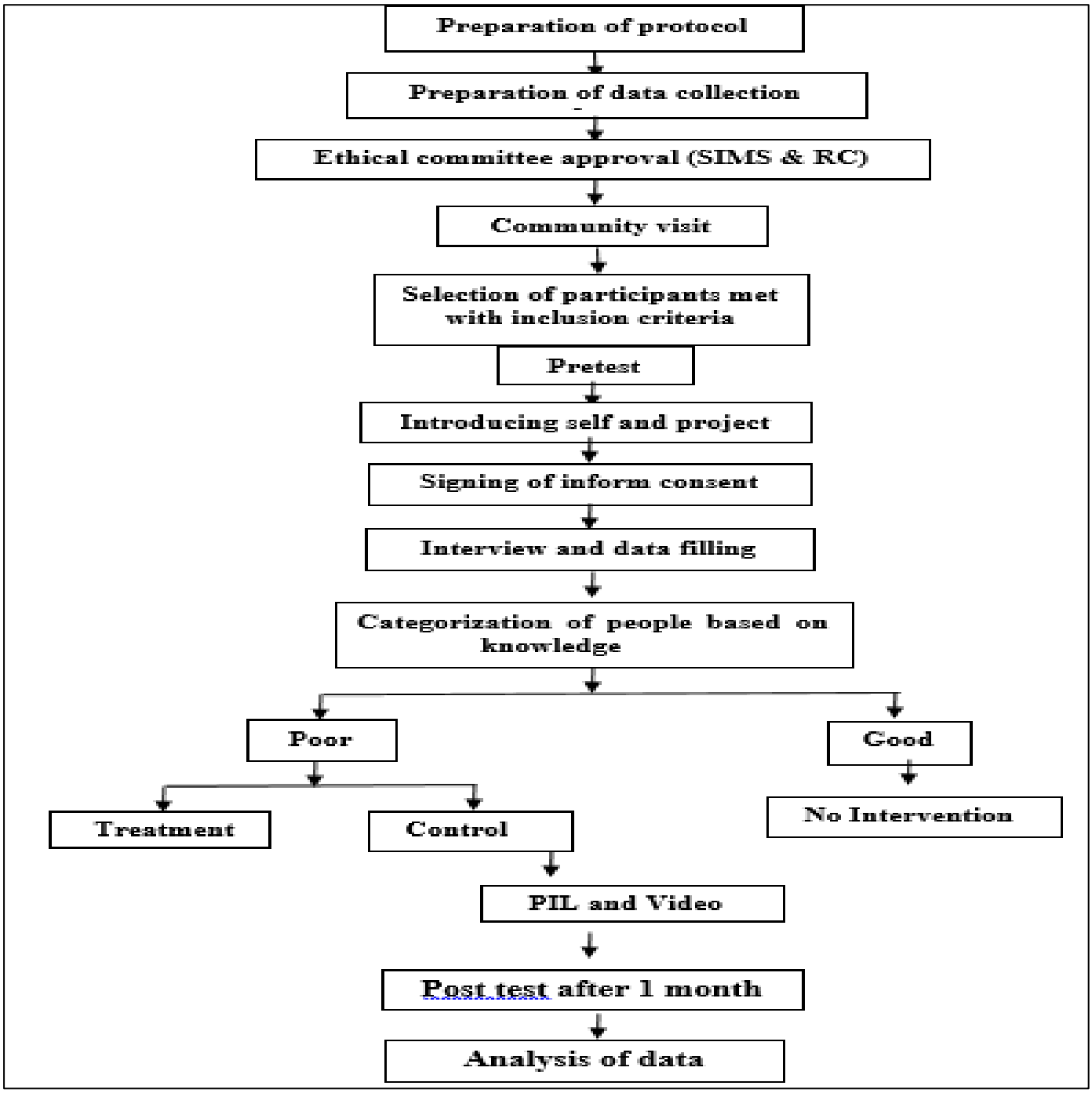

Fig 1 Operation Modality

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IV. RESULT

Out of 300 survey questionnaire distributed to the public, all the questionnaires were completed. The majority of participants were female (63%) and only 37% were male. Analysing occupation of study participants, it was found that majority were students (31%) followed by self-employed (20.33%), homemaker (21.33%),corporate worker(5%) and others(22.33%).The complete of the participant demographics can be found in Table 1.

- *Patient Socio-demographic:*

Table 1 Patients Demographic Characteristics (N=300)

Variables		N	Percentage
Gender	Male	111	37%
	Female	189	63%
Age in years	18-24	117	39%
	25-30	60	20%
	31-40	50	16.66%
	> 40	73	24.33%
Occupation	Corporate worker	15	5%
	Self-employed	61	20.33%
	Homemaker	64	21.33%
	Student	93	31%
	Others	67	22.33%

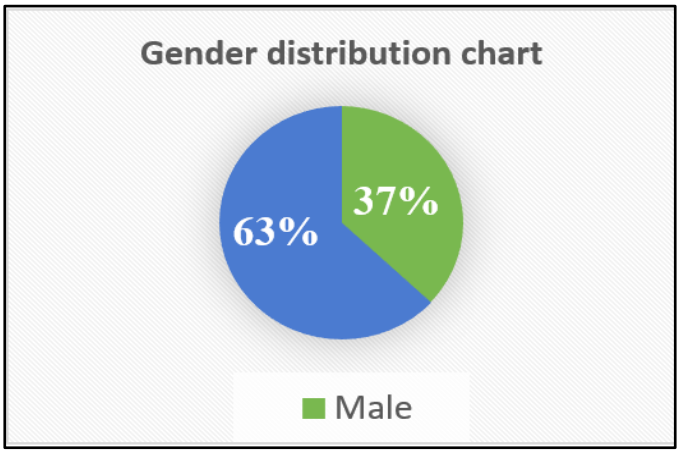

Fig 2 Gender Distribution of the Study Participants

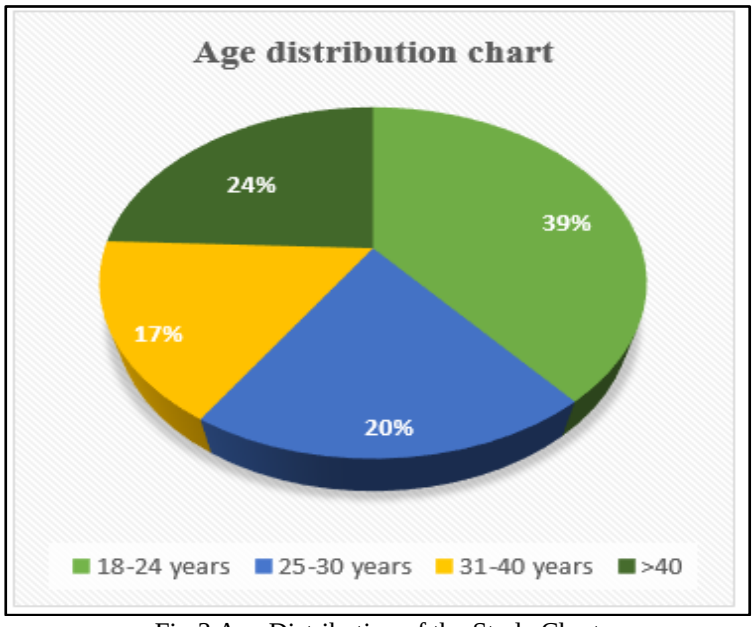

Fig 3 Age Distribution of the Study Chart

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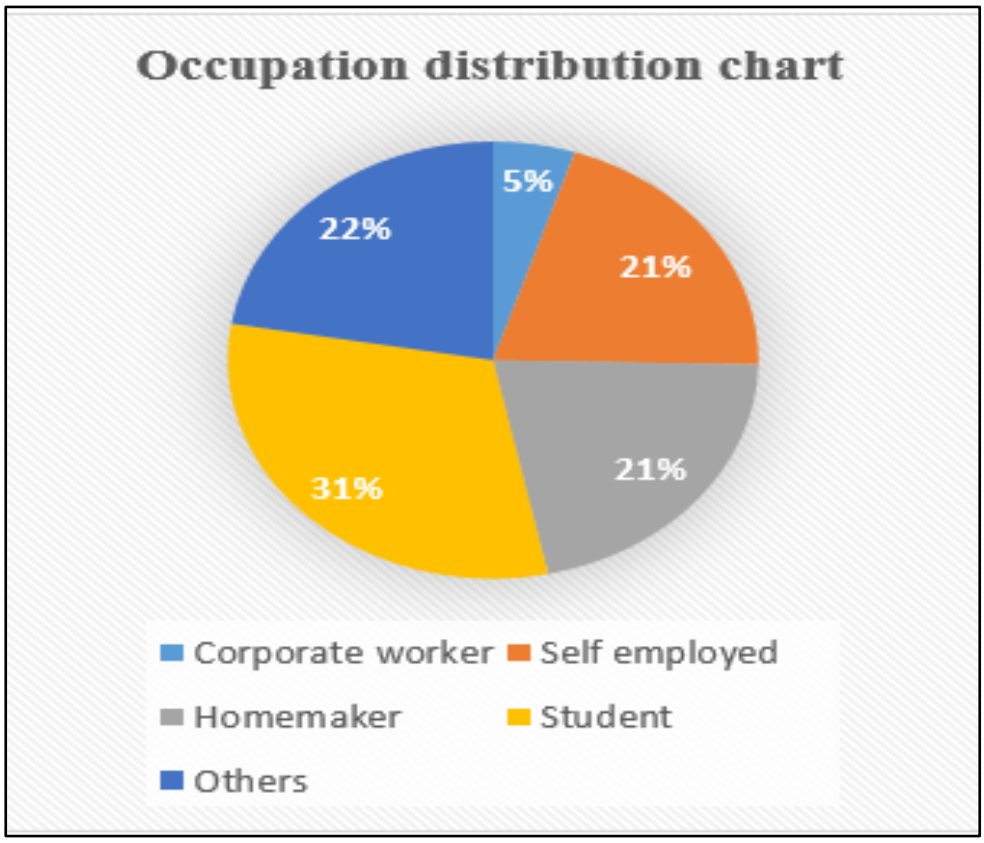

Fig 4 Occupation Distribution of the Chart

➢ *Awareness on Pharmacovigilance and Pharmacovigilance Programme of India (Pvpi):*

The participants were analysed for awareness about "Pharmacovigilance" to check their familiarity about the programme as the purpose of the PvPI is to collate data, analyze it and use the inferences to recommend informed regulatory interventions, besides communicating risks to healthcare professionals and the public, only 32% of responders were familiar with this terminology. When asked if they were aware of the Pharmacovigilance Programme of India, a mere 2.33% acknowledged previous knowledge of the centre (Table 2).

Table 2 Awareness On Pharmacovigilance And Pharmacovigilance Programme Of India (PvPI) (N=300)

SL.NO	QUESTION	OPTIONS	MALES N (%)	FEMALE N (%)
1	Are you aware of National Pharmacovigilance Program?	Yes	7(2.33%)	15(5%)
		No	104 (34.66%)	174 (58%)

➢ *Knowledge, Attitude And Practice Of Handling Adr:*

- *Knowledge towards ADRs:*

Table 3 Pre-Test Knowledge toward ADRs (N=300)

SL. NO	QUESTIONS	RESPONSE	PRE-TEST N (%)
1	Do you know about Adverse Drug reactions?	Yes	95 (32)
		No	205 (68)
2	Do you believe all drugs available in the market are safe?	Yes	31 (10.33)
		No	269 (89.66)
3	Do you know about the drugs which are banned in India?	Yes	85 (24)
		No	215 (76)
4	Do you know where to report adverse drug reaction?	Doctor	163 (54.33)
		Nurse	10 (3.33)
		Pharmacist	41 (13.66)
		Not Sure	86 (28.66)
5	Which age can be harmed from Adverse Drug Reaction?	Children	72 (24)
		Adult	8 (2.66)

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		Elderly	35 (11.66)
		All Ages	124 (41.33)
		Not Sure	61 (20.33)
6	Do you think that ADRs and side effects are same?	Yes	128 (34.66)
		No	172 (65.33)
7	Do you think ADR is harmful?	Yes	257 (79.66)
		No	43 (20.33)
8	Do you think it's important to report ADRs?	Yes	194 (52.33)
		No	106 (47.66)
9	Who should be notified about any serious ADR?	Physician	200 (66)
		Pharmacist	59 (31)
		Nurses	10 (1.33)
		Pharmacovigilance Centre	31 (3)
10	Who is responsible to report any possible ADR to PVC?	Medical Staff	162 (52.66)
		Consumer	138 (47.33)
11	What advantages the community can get from the ADR reporting system?	Increase the medication safety	107 (35.66)
		Increase the awareness of ADR among the community	125 (41.66)
		Improve our quality of life	54 (18)
		A solution for the low reporting issue	14 (4.66)

Knowledge of the study participants were analysed using a set of questions in term of general aspects covers difference between side effects and ADRs, safety ness of drugs available and banned in the Indian market, effect of ADR, responsibility and benefits of reporting ADR, resources to find ADR and reporting viz AMCs, PVPI.

It was found that majority (65.33%) of the study participants were believe that side effects and ADR are not same, also 10.33% of the responders believes that all drugs available in the market are safe, 76% of the participants did not have any information about banned medications in the Indian market. 79.66% of the participants believe that ADR is harmful but also majority of them (52.66%) believes that reporting ADR is the responsibility of medical staffs rather than themselves.78.66% of the study participants believe that ADR reporting was beneficial to the community, 35.66% of them responded that reporting ADR is important to increase medication safety.

- *Adverse Drug Reactions (ADRs): Definition and Implications*

For the purposes of the survey, the researchers defined ADRs as "An unexpected and noxious reaction after taking the normal dose of a medication". Most participants (68%) were not sure about the definition of Adverse Drug Reaction. While only minimum of participants believed that all ages could be harmed from ADRs (41.33%), 79.66% think that ADRs are "somewhat serious". Although 93.33% believed that it is important to gather any information related to ADRs, 78.66% believed that reporting ADRs are for the benefit of the community, and that the major advantage of ADRs reporting system is to increase the awareness about ADRs among community (41.66%), and 50% stated that they would not report a non-serious ADR.

However, females were more motivated about the importance of gathering ADRs information, it might also observed because of higher participation of female responders. While analysing their knowledge about difference between ADR and side effect, majority (65.33%) does not believes that ADR and side effects are same.

- *Personal Responsibility:*

Analysing personal responsibility of study participants in handling ADR it was found that majority of the responders ask their healthcare providers about their medications' ADRs (61%) and the majority of them use their physicians (52%) or from books and magazines (22.33%) as resources to educate themselves about ADRs; however, 71% indicated that their physicians or pharmacists don't actively encourage them to report any ADRs that may occur during the treatment. In comparison with males, a significantly higher number of female participants indicated that healthcare providers failed to direct them to report any ADRs.

Table 4 Pre-Test on Personal Responsibility in Handling Adrs (N=300)

SL.NO	PERSONAL RESPONSIBILTY	RESPONSE	N(%)
1	Would you consult doctors or pharmacists for ADR information while purchasing drugs?	Yes	148(49.33)
		No	152(49.67)
2	Do you check the ADR section of the drug instructions in drug manual/monographs/packet information (PI)?	Every time	21(5)
		Most of the time	43(7)
		Sometimes	127(24.33)
		Never	109(63.33)

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➢ *ADRs reporting and evaluation:*

The participants were analysed about where to report the suspected ADRs, majority of the responders indicated towards physicians (66%) followed by pharmacists (31%) and pharmacovigilance centre (3%). However, the majority of responders (52.66%) believed that the medical staff, rather than consumers, should report ADRs.

Table 5 Pre-Test on ADR Reporting and Evaluation (N=300)

SL.NO	ADR Reproting and Evaluation	Responses	N(%)
1	What measures would you take when you have an ADR?	Stopping the medication	137(45.66)
		Inform health care professionals	118(39.33)
		Skipping the frequency	5(1.66)
		Changing the doctor	40(13.33)
2	Which of the following resources do you use to search about an ADR?	Asking prescribed physician	156(52)
		Asking the dispensed pharmacist	36(12)
		From books or magazines	66(22)
		From internet	38(12.66)
		From the leaflet that comes with the medication	54(18)

Majority (52%) of the responders mentioned that they prefer asking their consulting physician as a source for the information and majority (97.66%) of the participants were unaware of the ADR monitoring centre or pharmacovigilance centre. Most of the participants (61%) does not ask about their medication's ADR while purchasing. 41.33% of the participants have themselves experienced ADR and 27.66% of the participants have seen others experiencing ADR. 49.67% of the participants does not consult physician or pharmacist for the ADR information while purchasing the drugs. 63.33% of the study responders never check the ADR section of the drug instruction in drug manual or monographs. Majority (45.66%) of the participants prefer stopping the medication as a measure taken when ADR occurs.

➢ *Attitude (N=300):*

Table 6 Pre-Test on Attitude

SL.NO	QUESTIONS	Pre -Test	
		N (%)	
1	Do you think that our community will benefit from ADR reporting?	Yes	274(78.66)
		No	26(21.33)
2	Is it important to educate patients about ADRs and how to report one?	Yes	280(97.66)
		No	20(2.33)
3	Does your physician/pharmacist ask you to report any ADR that may happen to you?	Yes	88(12)
		No	212(88)

Attitude of the study participants were analysed regarding the importance of knowledge towards ADR management and it was found that 78.66% of the participants were indicated that our community will benefit from ADR reporting.97.66% of the study participants believes that it is important to educate patients regarding ADRs and how to report them. 88% of the participants informed that their physician or pharmacist does not ask them to report any ADR that may happen.

➢ *Practice (N=300):*

Table 7 Pre -Test On Practice

SL.NO	QUESTIONS	OPTIONS	Pre- Test
			N (%)
1	Do you ask about your medication's ADR?	Yes	43(39)
		No	257(61)
2	Have anyone you know experienced ADR?	Yes	79(27.66)
		No	221(72.33)
3	Are you familiar with nearest ADR Monitoring Centre/ pharmacovigilance centre?	Yes	11(2.33)
		No	289(97.66)
4	Have you ever experienced ADR?	Yes	70(41.33)
		No	230(58.66)
5	If you were suffered from a non-serious ADR, would you report that?	Yes	150(50)
		No	150(50)
6	Have anybody discussed with you about ADR?	Yes	80(24.33)
		No	220(75.66)

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7	Are you willing to report ADR?	Yes	251(78.66)
		No	49(21.33)
8	Have you ever experienced ignorance from any AMCs after reporting?	Yes	10(1)
		No	290(99)
9	If the ADR management is free, are you willing to report?	Yes	282(96.66)
		No	18(3.33)
10	Would you like to educate others about the ADRs?	Yes	291(87.66)
		No	9(12)

The practice of study participants were analysed and it was found that majority of the participants (69%) does not ask about their medication's ADR, 27.66% of participants have seen someone they know experienced ADR, 97.66% of the participants were unfamiliar with the nearest ADR monitoring centre/pharmacovigilance centre.41.33% of the participants were experienced ADR,50% of them would report non-serious ADR.75.66% of the participants were responded that no one discussed about the ADR. 78.66% are willing to report and if the management is free of cost, 96.66% were willing to report and 87.66% of them would like to educate others about the ADRs.

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- *Reasons Behind Under Reporting Of Adr:*

The participants were asked about why patients under report ADRs, 62.58% believed that patients do not know whether the reaction is from the medication or not, 11.54% stated that the reason was because patients don't know where to report ADRs, 10.48% stated that the reason for not reporting ADRs was lack of time, 8.74% responded that the participants thought that their reporting was not necessary, 3.84% stated the reason as avoiding the burden of possible follow-ups and procedures. This study highlighted the under-reporting of ADR by study participants

Table 8 Reasons behind under Reporting of ADR (N=300)

SL.NO	QUESTIONS	RESPONSE	N (%)
1	Have you ever reported about the suspected ADRs?	Yes	14(4.66)
		No	286(95.33)
	If No, what was the reason?	Lack of time	30(10.48)
		Not sure if it was ADRs	179(62.58)
		Not knowing where to report	33(11.54)
		Thought that my report was not necessary	25(8.74)
		Thinking that ADR reporting is not a duty of the community	5(1.74)
		Avoiding the burden of possible follow-ups and procedures	11(3.84)
		Legal liability issues	1(0.34)
		Fear of consequences	2(0.69)

- *Selection of Participants for Intervention study:*

Selection of participants for interventional study was done based on the scoring of the study participants on their knowledge about ADR and its handling. Participants were scored positively and negatively for their responses. Out of 11 if the participants gets less than 6 score, then the participants were considered having poor knowledge

Table 9 Selection of Participants for Intervention Study

SL.NO.	PARTICIPANTS	N(%)
1.	Having Poor knowledge	150(50)
2.	Having fair knowledge	150(50)

- *Post Intervention Study on Public Awareness and Perception Toward Adverse Drug Reaction Reporting:*

The participants with low knowledge in handling ADR were selected for intervention group (N=150) to study the impact of pharmacist intervention, they were further divided into control and treatment randomly consists of equal numbers (75).

- *Post Intervention Study On Knowledge, Attitude and Practice Towards Adr Handling Knowledge Toward Adrs:*

The participants with low knowledge on handling of ADR was further divided into control and treatment group with 75 participants each. Interventional study was conducted on the participants of treatment group to check the impact of pharmacist intervention on the knowledge regarding handling of ADR among the study participants.

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Table 10 Knowledge Toward ADRs (N=75+75=150)

SL.NO	KNOWLEDGE	RESPONE	CONTROL 75 N (%)	TREATMENT 75N (%)	P value
1	Do you know about Adverse Drug reactions?	Yes	0(0)	66 (88)	0.0001
		No	75(100)	9 (12)	
2	Do you believe all drugs available in the market are safe?	Yes	5(6.66)	2(2.66)	
		No	70(93.33)	73(97.33)	0.2614
3	Do you know about the drugs which are banned in India?	Yes	7(9.66)	44 (58.66)	
		No	68(90.33)	31 (41.33)	0.0001
4	Do you know where to report adverse drug reaction?	Doctor	38(50.66)	53 (70.66)	0.0001
		Nurse	2(2.66)	6 (8)	
		Pharmacist	19(25.33)	16(20.33)	
		Not Sure	16(20.33)	0(0.00)	
5	Which age can be harmed from Adverse Drug Reaction?	Children	19(25.33)	7 (9.33)	0.0001
		Adult	3(4)	0 (0)	
		Elderly	8(10.66)	12 (16)	
		All Ages	18(24)	56(74.66)	
		Not Sure	27(36)	0(0)	
6	Do you think that ADRs and side effects are same?	Yes	52(69.33)	4 (5.33)	0.0001
		No	23(30.66)	71 (94.66)	
7	Do you think ADR is harmful?	Yes	51(68)	74 (98.66)	0.0006
		No	24(32)	1 (1.33)	
8	Do you think it's important to report ADRs?	Yes	44(58.66)	73 (97.33)	0.0001
		No	31(41.33)	2 (2.66)	
9	Who should be notified about any serious ADR?	Physician	60(80)	28 (37.33)	0.0001
		Pharmacist	10(13.33)	17(22.66)	
		Nurses	3(4)	0 (0)	
		Pharmacovigilance Centre	2(2.66)	30 (40)	
10	Who is responsible to report any possible ADR to PVC?	Medical Staff	43(57.33)	21 (28)	0.0004
		Consumer	32(42.66)	54 (72)	
11	What advantages the community can get from the ADR reporting system?	Increase the medication safety	31(41.33)	47 (62.66)	0.0019
		Increase the awareness of ADR among the community	27(36)	8 (10.66)	
		Improve our quality of life	10(13.33)	15(20)	
		A solution for the low reporting issue	7(9.33)	5(6.66)	

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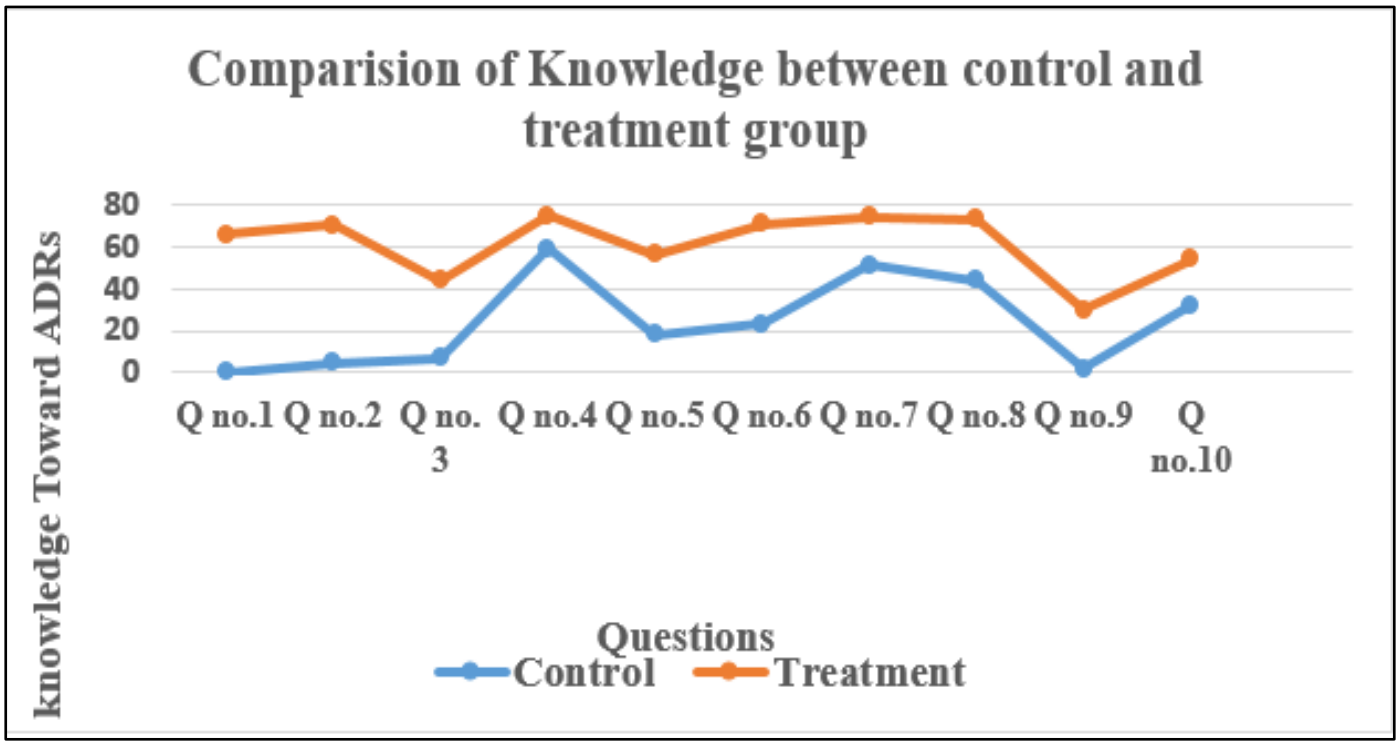

Fig 5 Comparison of Knowledge between Control and Treatment Group

➢ *Attitude Towards Adr Handling:*

Interventional study on attitude of the study participants towards handling of ADR shows a significant difference in the responses among the treatment group. Majority of the participants (97.33%) thinks that the community will benefit from ADR reporting.

Table 11 Attitude towards ADR Handling (75+75=150)

SL.NO	QUESTIONS	CONTROL		TREATMENT	P value
1	Do you think that our community will benefit from ADR reporting?	Yes	68(90.66)	73(97.33)	0.1062
		No	7(9.33)	2(2.66)	
2	Is it important to educate patients about ADRs and how to report one?	Yes	70(100)	75(100)	1.0000
		No	5(0)	0(0)	

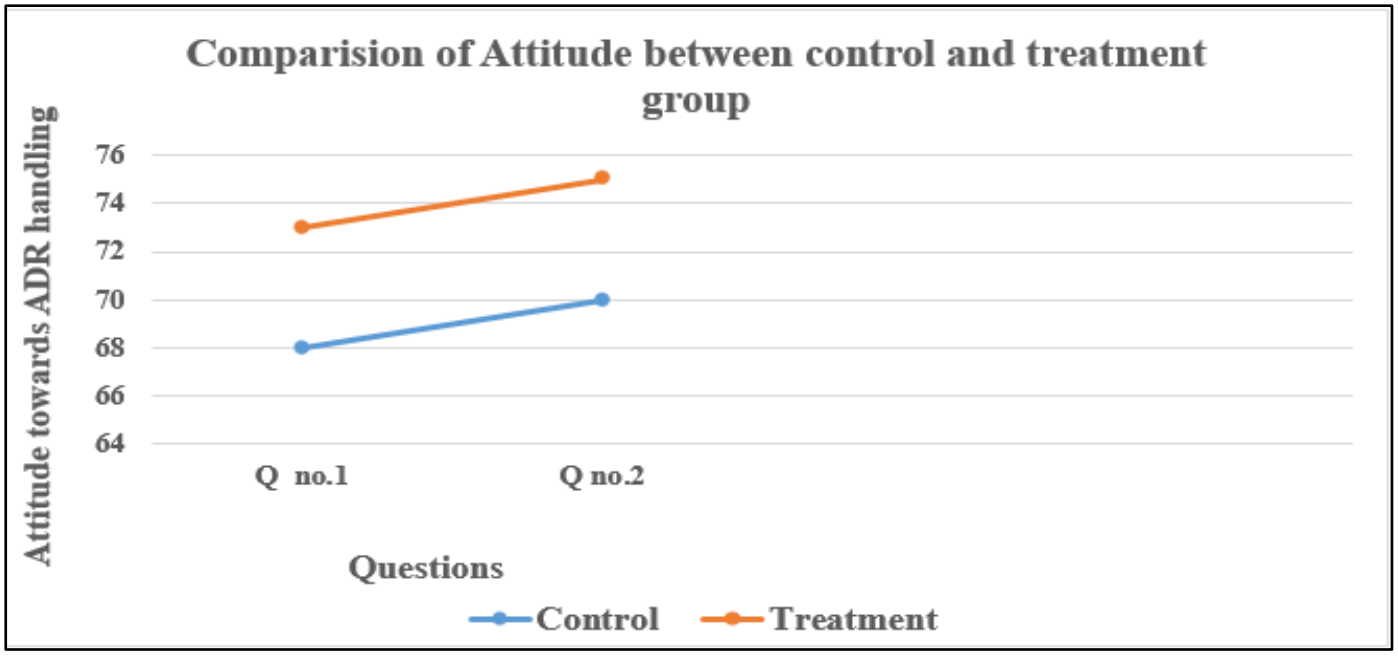

Fig 6 Comparison of Attitude between Control and Treatment Group

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➢ *Practice Towards Handling of Adr:*

Intervention study on practice of the study participants towards handling of ADR shows a significant difference in the responses among the treatment group. Majority of the participants (89.33%) are familiar with nearest ADR Monitoring Centre/ pharmacovigilance centre and like to educate others about the ADRs.

Table 12 Practice towards Handling of ADR (75+75 =150)

SL.NO	QUESTIONS	RESPONSE	CONTROL N (%)	TREATMENT N (%)	P value
1	Do you ask about your medication's ADR?	Yes	13(17.33)	59(78.66)	0.0001
		No	62(82.66)	16(21.33)	
2	Are you familiar with nearest ADR Monitoring Centre/ pharmacovigilance centre?	Yes	0(0)	67(89.33)	0.0001
		No	75(100)	8(10.66)	
3	If you were suffered from a non-serious ADR, would you report that?	Yes	52(69.33)	62(83.66)	0.0586
		No	23(30.66)	13(17.33)	
4	Have anybody discussed with you about ADR?	Yes	16(21.33)	70(93.33)	0.0001
		No	59(78.66)	5(6.66)	
5	Are you willing to report ADR?	Yes	64(85.33)	75(100)	0.0236
		No	11(14.66)	0(0)	
6	Would you like to educate others about the ADRs?	Yes	60(80)	67(89.33)	0.118
		No	15(20)	8(10.66)	

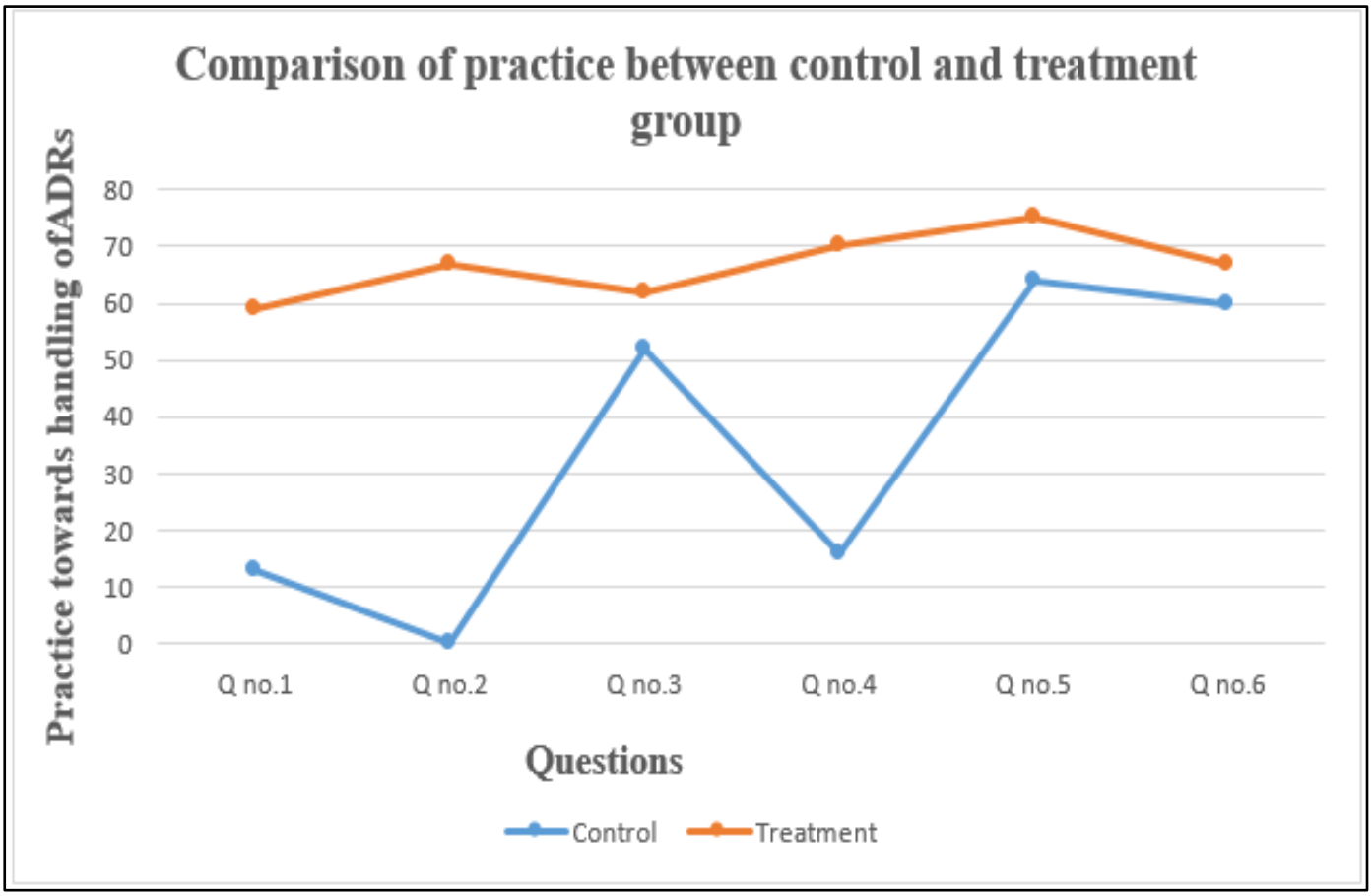

Fig 7 Comparison of Practice between Control and Treatment Group

➢ *Post Intervention Study Public Participation And Education:*

While the majority of responders believed that it is important to educate patients about ADRs and how to report them (93.33%). The participants were asked "if there was a policy that makes it easier for patients to report ADRs, would they take initiation" 88.33% were willing to take the initiation. Similarly, 94% of participants were willing to report suspected ADRs if the management of ADRs is free of cost.

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Table 13 Public Perception and Education

SL. NO	PUBLIC PERCEPTION AND PARTICIPATION	RESPONSE	CONTROL N(%)	TEATMENTS N(%)	P value
1	Has anybody educated you regarding the importance of ADR reporting?	Yes	15(20)	70(93.33)	0.0001
		No	60(80)	5(6.66)	
	If yes, who educated you?	Doctor	11(14.66)	11(14.66)	0.0001
		Nurse	4(5.33)	0	
		Pharmacist	0(0)	59(78.66)	
2	Have you followed the provided information?	Yes	15(20)	36(48)	0.0004
		No	60(80)	39(52)	
	If yes, do you think it was useful?	Yes	15(20)	36(100)	0.6720
		No	0(0)	0(0)	
3	If there is a policy that makes it easier for patients to report ADRs, would you take the initiation?	Yes	70(93.33)	72(96)	0.4720
		No	5(6.66)	3(4)	

- *Post Intervention Study on Awareness on Pharmacovigilance and Pharmacovigilance Programme of India (Pvpi)***:**

Table 14 Awareness on Pharmacovigilance and Pharmacovigilance Programme of India

Sl. No	AWARENESS ON PHARMACOVIGILANE	RESPONSE	CONTROL N(%)	TREATMENT N(%)	P Value
1	Are you aware of National Pharmacovigilance Program?	Yes	0(0)	73(97.33)	0.0001
		No	75 (100)	2 (2.66)	

- *Personal Responsibility:*

Majority of the responders ask their healthcare providers about their medications' ADRs (61%) and the majority of them use their physicians (52%) or from books and magazines (22.33%) as resources to educate themselves about ADRs; however, 71% indicated that their physicians or pharmacists don't actively encourage them to report any ADRs that may occur during the treatment. In comparison with males, a significantly higher number of female participants indicated that healthcare providers failed to direct them to report any ADRs. If the participants decided to report an ADR, they prefer to report by phone (54%), by using the internet (22%), fill a specific form and send manually (18%) or using a specific application on smartphone (7%).

Table 15 Personal Responsibility

Sl.NO	PERSONAL RESPONSIBILITY	RESPONSE	CONTROL N(%)	TREATMENT N(%)	P value
1	Would you consult doctors or pharmacists for ADR information while purchasing drugs?	Yes	27(36)	49(65.33)	0.0004
		No	48(64)	26(34.66)	
2	Do you check the ADR section of the drug instructions in drug manual/monographs/packet information (PI)?	Every time	2(2.66)	3(4)	0.0050
		Most of the time	3(4)	7(9.33)	
		Sometimes	39(52)	18(24)	
		Never	31(41.33)	47(62.66)	

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➢ *Adrs Reporting and Evaluation:*

The participants were analysed about where to report the suspected ADRs, majority of the responders indicated towards physicians (66%) followed by pharmacists (31%) and pharmacovigilance centre (3%). However, the majority of responders (52.66%) believed that the medical staff, rather than consumers, should report ADRs.

Table 16 ADR Reporting and Evaluation

Sl.NO	REPORTING AND EVALUATION	RESPONSE	CONTROL N(%)	TREATMENT N(%)	P value
1	What measures would you take when you have an ADR?	Stopping the medication	18(24)	39(52)	0.0006
		Inform health care professionals	41(54.66)	22(29.33)	
		Skipping the frequency	7(9.33)	3(4)	
		Changing the doctor	9(12)	17(22.66)	
2	Which of the following resources do you use to search about an ADR?	Asking prescribed physician	46(61.33)	55(73.33)	0.0005
		Asking the dispensed pharmacist	7(9.33)	17(22.66)	
		From books or magazines	0(0)	0(0)	
		From internet	22(29.33)	5(6.66)	
		From the leaflet that comes with the medication	0(0)	2(2.66)	

V. DISCUSSION

The knowledge of participants were analysed using a set of questions about Adverse drug reactions (ADRs), most of the participants were unaware of the term ADR. The healthcare professionals should hold campaigns and program regarding educating public about Adverse drug reactions and also the benefits of reporting suspected ADRs. Adverse drug reactions are the third main reason causing death in India. Reporting of ADRs in India is less than 1% and lack of knowledge among public is one of the reason for under-reporting.

The present study was conducted in 2 phases of 1 month interval. First phase involved assessing knowledge and categoring participants. In phase 2, only participants with poor knowledge were selected and made it to two groups control and treatment. Only treatment group were provided intervention using PIL and video, and control group is used to compare.

In the present study participants were asked whether they believe all drugs available in the market are safe, majority of the participants believe that all the drugs available in the market are safe, lack in knowledge generates confusion in understanding and reporting ADR. Adverse drug reactions can be minimized if more precautions are taken by Healthcare professionals.[11]

Most of the study participants were unaware of the drugs that are banned in India, which is also one of the major indicator for lack of knowledge. Numerous studies have shown life threatening ADRs with drugs such as hepatotoxicity, renal toxicity severe skin reactions, GI toxicity, and coronary artery.[12] Drugs like Numesulide was withdrawn from the Indian market because of the potential hazards of the drug [13,14,15], but still in use.

The participants were analysed whether they have any knowledge about where to report adverse drug reaction, majority of them were confused about where to report, similarly was observed with a study conducted by Sales I *et.al.* There is a greater need to create and enhance awareness in community and healthcare professionals about the importance of close monitoring of drug outcomes especially newer ones.[16]

Majority of the participants were believed that ADRs and side-effects are same. Adverse drug reactions (ADRs) and side effects are both unintended responses to a medication but scientific evidence suggest that ADRs are similar to side effects, but they're always harmful or negative.[17]

The participants were questioned about their knowledge regarding which age group is more susceptible to the ADRs and only small number of people were able to answer the correct option that is all ages. But, ADRs can be difficult to recognize in older people as they often present with nonspecific symptoms, for example falls, fatigue, cognitive decline or constipation, all of which have several etiologies.[18]

In current study, all 300 participants of the study were unaware of National Pharmacovigilance program, shows failure of Health Ministry to promote/reach National Pharmacovigilance Week Program to public. The pharmacists and healthcare professionals should provide information about the differences between ADRs and side effects to the public.

The current study analysed the practice of participants whether they ask about medication's ADR while purchasing drugs, minority of participants does not ask about ADR, more percentage of them does not consult doctor or pharmacist about ADR while purchasing the medicines, similarly was observed in a study conducted by Sales I *et.al.* It is important for the public to report ADRs to the healthcare professionals or ADR monitoring center during or after the treatment. So, pharmacist or other healthcare professionals should educate community about nearest pharmacovigilance centres through educational programs, information leaflets and advertisement by posters, mobile, television.

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Most of the participants never checked ADR section of the drug instructions in drug manuals or monographs. So it is important to instruct the patients to check the drug instructions present in drug manual or monographs. It is also the duty of healthcare professionals to inform patients to check the monographs.

In presence study large number of the participants responded that they would not consult health care professionals when ADR is suspected, similarly was observed in study conducted by Wang N *et.al*. Among them less than half of the participants suggested that they would stop the medication. When patients suspect the ADRs should inform the health care professionals immediately and should not abruptly stop the medications.

Not many people have experienced ADR themselves and few of the participants have seen others experienced ADR but majority of them could not report ADR because of lack of time, not sure if it was ADRs, not knowing where to report, avoiding the burden of possible follow ups and procedures. The community should be educated that there is no such risk or complications related to reporting ADR like any legal issues, fear of consequences and the process of ADR reporting is not as complicated. Advantages of reporting ADR is to increase the medication safety, batch withdrawal if applicable, updating OTC drugs to prescription only drugs, updating of pharmaceuticals packet inserts, to increase the awareness of ADR among the community, to improve the quality of life, a solution for the low reporting issue.

Most of the responders are willing to report ADR, but does not have any knowledge regarding ADR and its management. Large number of the participants suggested that if there is a policy which makes the ADR reporting easier, they would take the initiation.

- *Suggestion:*

There is a requirement of public sensitization so the concern authorities need to impose more effort on increasing the public awareness towards the ADR handling through campaigns and public awareness programs, also a brief information about ADR can be included in text books in school level. The pharmacist and other healthcare professionals should hold public information campaigns and educate consumers and thus play an important role in eliminating the market for banned drugs.[12]

- *Future Prospectives:*

Educate the community regarding ADR related information through ,

- Advertisement in social media and film theatre.
- Awareness program by concerned authority via National Pharmacovigilance Program.
- Including brief information about ADR in general knowledge books at school level.

VI. SUMMARY

The present study was planned to analyse KAP about handling ADR. It was a community-based study 300 people met inclusion criteria were selected for the study. The study period was divided into 2 phases, phase 1 was pre-intervention study where the knowledge was assessed and only participants with poor knowledge were selected for intervention study, further they were categorised as control and treatment. Only treatment group was provided with intervention using PIL after 1 month interview was conducted and once again knowledge was checked and compared with control group.

In this study the knowledge, attitude and practice regarding the handling of ADR was assessed among the general public in Dakshina kannada. The majority of the study population had lack of knowledge and understanding regarding the ADR reporting. The study participants had no knowledge about ADR monitoring centres and also had no knowledge about the National Pharmacovigilance Program. An intervention study was done on half of the study participant who had poor knowledge about handling of ADR. There was a significant difference in the knowledge and attitude before and after the intervention among the study participants.

The study participants were analysed regarding the reason behind under-reporting of ADR. Majority of the responders were unaware about the term ADR itself. Most of them did not know where to report the suspected ADR. Thinking that ADR reporting is not a duty of the community is also one of the reasons for under – reporting. The participants also indicated that fear of consequences and legal liability issues as the reason for not reporting ADR. An intervention study conducted to aware the public regarding benefits of reporting of ADR.

Intervention study was conducted to educate community about importance of ADR reporting through patient information leaflets (PIL) and also through media (video). The intervention included definition of ADR, various types of ADR, difference between side effects and ADR, details regarding ADR reporting (what to, when to, where to and how to report ADR), benefits of ADR reporting and information about the National Pharmacovigilance program.

After the intervention the study participants were analysed about the impact of education on ADR reporting and channel. The questionnaires were administered same as the pre-study to analyse the impact of the interventional study on the participants. There was a significant improvement in awareness and knowledge regarding ADR and its management among the study participants. In conclusion pre-intervention group had poor knowledge and practice in handling ADR, after intervention a significant improvement in KAP in management of ADR was observed.

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VII. CONCLUSION

The present study concludes that, majority of the study population had lack of knowledge and understanding regarding the ADR reporting, ADR monitoring centres and also National Pharmacovigilance Program but after intervention there was a significant improvement in the knowledge and attitude practice the study participants.

The reason behind the under-reporting of ADR was found to be unaware about ADR, where to report, thinking that ADR reporting is not a duty of the community, fear of consequences and legal liability issues.

The intervention of ADR through PIL and video, shown a significant increase in awareness and knowledge regarding ADR and its management among study participants. So form the study it is evident that pharmacist can play a major role in bringing awareness and to motivate community in ADR reporting.

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