



## Study of Cutaneous Adverse Drugs Reaction in Tertiary Care Hospital of Western Rajasthan

**Neha Meghwal<sup>1</sup>, Vinod Meghwal<sup>2</sup>, Gaurav Sharma<sup>3</sup>, R.P.Acharya<sup>4</sup>**

<sup>1</sup>Msc (Medicine) pharmacology department SPMC Bikaner, <sup>2</sup>Junior Resident General Medicine department RNT Medical College Udaipur, <sup>3</sup>Senior Resident DNB General Medicine, General Medicine department RNT Medical College Udaipur, <sup>4</sup>Senior Professor pharmacology department SPMC Bikaner Rajasthan

### **\*Corresponding Author:**

**Gaurav Sharma**

Senior Resident DNB General Medicine, General Medicine department RNT Medical College Udaipur Rajasthan

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### **ABSTRACT**

Background and Aims & objectives

With the advent of newer drugs by the day it has become absolutely essential to monitor the adverse drug reaction due to these drugs. Adverse drug reactions are the leading cause of morbidity and mortality in health care and have a significant impact on health care resources.<sup>1</sup>

Primary aim of the present study is to estimate the burden of adverse drug reactions, to study the prevalence of different ADR's occurring in our hospital, to study severity of ADRs, to study risk factors associated with occurrence of ADRs, to propose strategies to reduce occurrence of ADRs in patients visiting to dermatology department in a tertiary care hospital of Bikaner Rajasthan.

### **MATERIALS AND METHODS**

The present cross sectional observational study was conducted at Dermatology department in P.B.M. hospital, Bikaner. This study was done over a period from July 2019 to December 2019 after getting approval from institutional ethics committee. Written and informed consent from patients were taken. In this study 100 patients visited to outpatient department of dermatology department were included, and patients with drug reaction due to deliberate or unintentional over dosage, ADR after using alternate medicines like Ayurveda, Homeopathy, Unani, Drug reaction occurring due to prescribing and dispensing error, Mentally retarded, unconscious patients, already on other Antipsychotic agents and drug abuse, critically ill, Pregnant and lactating females were excluded.

### **Results**

In present study, according to Thornton-Schumock's preventability classification, maximum 61% were possibly preventable followed by 23% not preventable whereas 16 cases were preventable respectively, maximum 41% had their age between 31-40 years followed by 41-50 years (23%), while minimum 2% were found in >60 years, 65% cases were female while 35% cases were males. According to residential area, majority of cases were living in rural area (55%), maximum 51% had redness followed by 49% cases had itching and 15% cases had rash whereas minimum 1% had hair loss and Nail discolouration followed by hyper pigmentation (4%) and acne eruption (8%), maximum 22% taking oral antibiotics followed by topical betnovate (19%), whereas minimum 1% taking anticancer and iron drugs followed by 2% cases each taking anti TB and multivitamin. Maximum 61% were in possibly preventable group followed by 23% were not preventable whereas minimum 16% were in preventable group. Mean age in not preventable group cases was 41.52±8.64 years followed by in preventable group it was 41.06±9.6 whereas minimum 40.82±10.21 in possibly preventable group. In not preventable and possibly preventable had 2/3<sup>rd</sup> proportion of female whereas preventable group had 3/4<sup>th</sup> proportion of female and

rest were males. Equal distribution of residence in not preventable and possibly preventable. Maximum 75% were living in rural area and minimum 25% living in urban area in preventable group, distribution of cases according to adverse symptom in relation to Thornton-Schumock's Preventability Classification. Most common symptom was Redness (51%) followed by itching 49% whereas minimum 1.0% had hair loss and nail discolouration followed by hyper pigmentation (4%). Distribution of cases according to drugs in relation to Thornton-Schumock's Preventability Classification. Maximum 22% had taken Oral antibiotics in which maximum 26% in not preventable, followed by topical betnovate (19%) in which maximum 38% were in preventable group and NSAIDs (18%) in which maximum 39.1% cases belonged to not preventable whereas minimum 1% had taken anticancer and iron belonged to possibly preventable group, distribution of cases according to severity in relation to Thornton-Schumock's Preventability Classification. Maximum 69% had moderate severity (maximum 82.6% in not preventable group) whereas minimum 13% had severe severity (maximum 18% in possibly preventable group) followed by mild severity 18% (maximum 31.3% in preventable group).

## CONCLUSION

As CADR's are most common adverse drug reactions, drugs embroiled in past reaction should be avoided. A through history of previous allergies and drug hypersensitivity should be confirmed. Sensitivity testing like patch test should be done before administration of any injectable drug. In case of hyper sensitivity or allergy, alternate drug should be used.

**Keywords:** NIL

## INTRODUCTION

WHO defines Adverse drug reaction (ADR) as "Any reaction which is noxious and unintended and which occurs at doses normally used in man for the prevention, diagnosis & treatment of disease".<sup>2</sup>

A cutaneous adverse drug reaction (CADRs) caused by a drug is any undesirable change in the structure or function of the skin, its appendages or mucous membrane and it encompasses all adverse events related to drug eruption, regardless of etiology.<sup>3</sup> Although many of the skin reactions are not serious, some are life threatening such as Angioedema, Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis.<sup>4</sup>

ADR scales were assessed initially. Different scales included were, Naranjo's causality scale, WHO scale, Schumock and Thornton preventability scale, Hartwig and Siegel severity assessment scale to assess different parameters like causality, severity and preventability.

The issue of drug-related harm is currently one of the most important public health problems all over the world, although public and scientific attention has focused on adverse drug reactions (ADRs) since the thalidomide tragedy in the early 1960s.<sup>5</sup>

Studies have found the overall incidence of adverse drug reactions in skin in developed countries as 1-3 % and in the developing countries it is higher between 2-5%. 5- 10% of hospital admissions are due to drug related problems, in which 50% are avoidable.<sup>6</sup>

In India epidemiological studies estimated that ADRs are fourth to sixth leading cause of death.<sup>7</sup> ADRs are one of the leading causes of morbidity and mortality, adding to overall healthcare cost. It is estimated that approximately 2.9– 5.6% of all hospital admissions are caused by ADRs and as many as 35% of hospitalized patients experience an ADR during their hospital stay.<sup>8</sup>

Almost any medicine can induce skin reactions, and certain drug classes, such as non-steroidal anti-inflammatory drugs (NSAIDs), antibiotics and antiepileptic drugs, have drug eruption rates approaching 1– 5%.<sup>9</sup> Most of the Cutaneous drug reactions are not serious but some are severe and potentially life-threatening. Serious reactions include Angioedema, Erythroderma, Stevens-Johnson syndrome (SJS) and Toxic epidermal necrolysis (TEN). Drug eruptions can also occur as a result of multi-organ involvement, as in Drug-induced Systemic lupus erythematosus. Drug reactions can be

classified into immunologic and nonimmunologic etiologies. Skin reactions as a result of non-immunological causes are more common and include cumulative toxicity, overdose, photosensitivity, drug interactions, and metabolic alterations.<sup>10</sup>

Adverse drug reactions (ADRs) are a major cause of morbidity, hospital admission, and even death. Hence it is essential to recognize ADRs and to establish a causal relationship between the drug and the adverse event. It is desirable that ADRs should be objectively assessed and presented. Majority of Cutaneous adverse drugs reactions (CADRs) are diagnosed clinically. These reactions may differ with different classes of drugs. Generating data is essential to understand the pattern of CADRs of different classes and generating information regarding offending drugs. Adverse reactions are recognized hazards of drug therapy. Early detection, evaluation and monitoring of adverse drug reactions are essential to reduce harm to patients and thus improve public health. With the increase in the production of various pharmaceutical products, newer drugs are being introduced every year.<sup>11</sup> Hence it has become essential to monitor the

effects and adverse drug reactions pertaining to these drugs.

We undertook this study to detect and analyse ADRs in the outpatient department of Dermatology. Developing awareness in patients and healthcare professionals will help in reducing the adverse drug reactions, the suffering due to the adverse drug reaction and socio- economic impact.

## MATERIALS AND METHODS

The present cross sectional observational study was conducted at Dermatology department in P.B.M. hospital, Bikaner. This study was done over a period from July 2019 to December 2019 after getting approval from institutional ethics committee. Written and informed consent from patients were taken. In this study 100 patients visited to outpatient department of dermatology department were included, and patients with drug reaction due to deliberate or unintentional over dosage, ADR after using alternate medicines like Ayurveda, Homeopathy, Unani, Drug reaction occurring due to prescribing and dispensing error, Mentally retarded, unconscious patients, already on other Antipsychotic agents and drug abuse, critically ill, Pregnant and lactating females were excluded.

## OBSERVATIONS

**Table 1 Distribution of study population according to Thornton-Schumock's Preventability Classification**

Thornton-Schumock's Preventability Classification	No.	%
Not Preventable	23	23.0
Possibly Preventable	61	61.0
Preventable	16	16.0
Total	100	100

In present study, according to Thornton-Schumock's preventability classification, maximum 61% were possibly preventable followed by 23% not preventable whereas 16 cases were preventable respectively.

**Table 2 Distribution of cases according to age group**

Age Group	No of patients	%
21-30	13	13.0
31-40	41	41.0
41-50	23	23.0
51-60	21	21.0
>60	2	2.0

In our study, maximum 41% had their age between 31-40 years followed by 41-50years (23%), while minimum 2% were found in >60 years.

**Table 3 Distribution of cases according to gender**

Gender	No.	%
Female	65	65.0
Male	35	35.0
Total	100	100

In our study 65% cases were female while 35% cases were males.

**Table 4 Distribution of cases according to residential area**

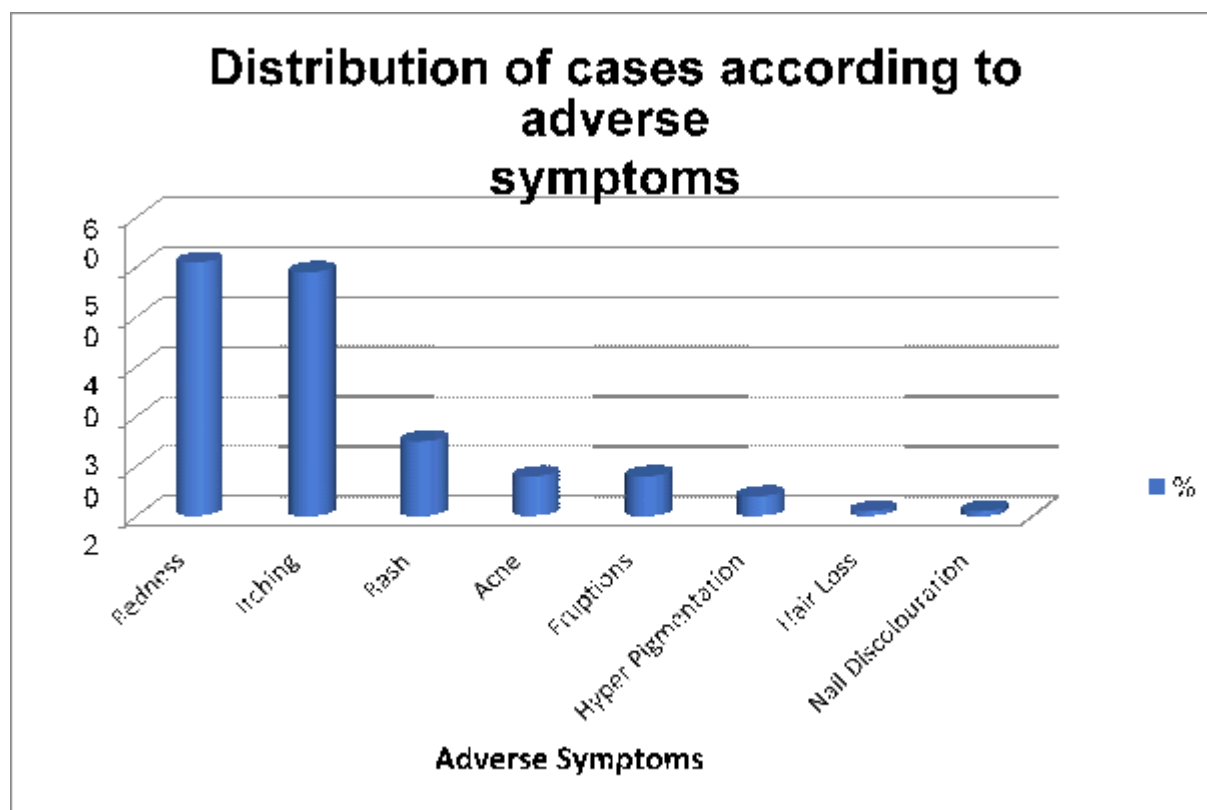
Residential area	No.	%
Rural	55	55.0
Urban	45	45.0
Total	100	100

According to residential area, majority of cases were living in rural area (55%).

**Table 5 Distribution of cases according to adverse symptoms**

Adverse Symptoms	No.	%
Redness	51	51.0
Itching	49	49.0
Rash	15	15.0
Acne	8	8.0
Eruptions	8	8.0
Hyper Pigmentation	4	4.0
Hair Loss	1	1.0
Nail Discolouration	1	1.0

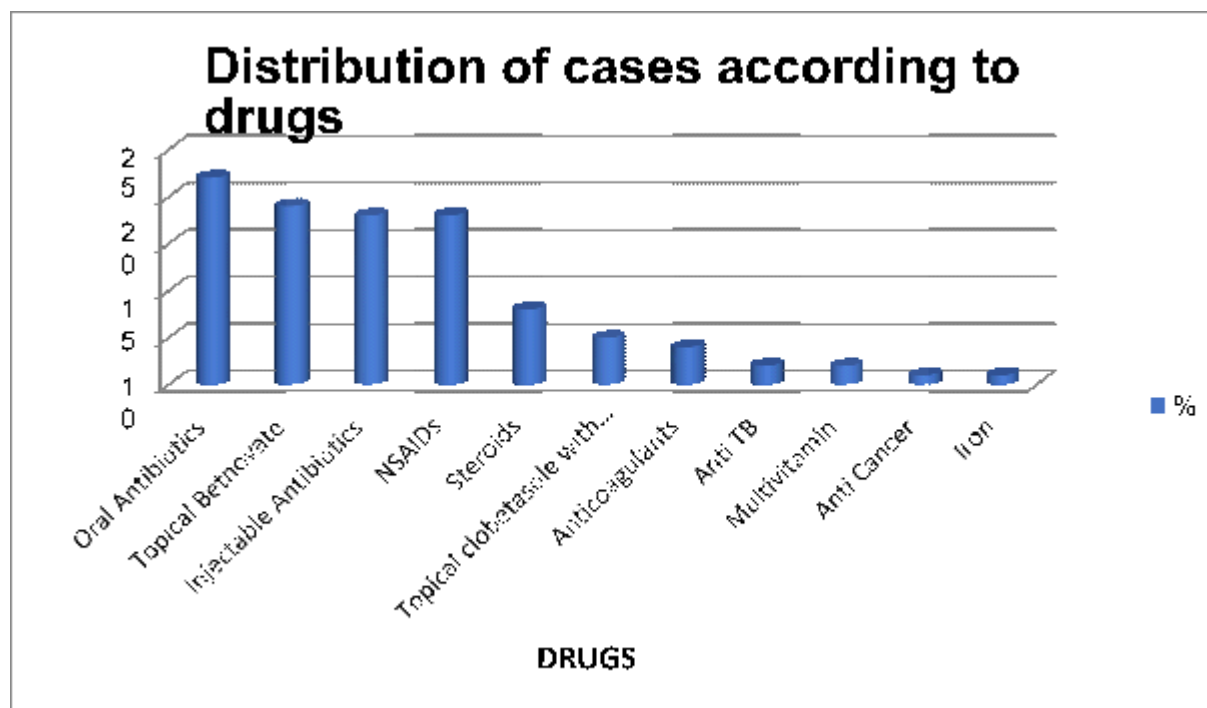
According to above table, maximum 51% had redness followed by 49% cases had itching and 15% cases had rash whereas minimum 1% had hair loss and Nail discolouration followed by hyper pigmentation (4%) and acne ,eruption (8%).



**Table 6 Distribution of cases according to drugs**

Drugs	No.	%
Oral Antibiotics	22	22.0
Topical Betnovate	19	19.0
Injectable Antibiotics	18	18.0
NSAIDs	18	18.0
Steroids	8	8.0
Topical clobetasole with gentamicin	5	5.0
Anticoagulants	4	4.0
Anti TB	2	2.0
Multivitamin	2	2.0
Anticancer	1	1.0
Iron	1	1.0
Total	100	100

According to drugs, maximum 22% taking oral antibiotics followed by topical betnovate (19%), whereas minimum 1% taking anticancer and iron drugs followed by 2% cases each taking anti TB and multivitamin.



**Table 7 Distribution of cases according to age group in relation to Thornton-Schumock's Preventability Classification**

Age Group	Thornton-Schumock’s Preventability Classification						Total	
	Not Preventable		Possibly Preventable		Preventable			
	No.	%	No.	%	No.	%	No.	%
0-20	0	-	0	-	0	-	0	-
21-30	0	-	11	18.0	2	12.5	13	13.0
31-40	14	60.9	20	32.8	7	43.8	41	41.0
41-50	3	13.0	16	26.2	4	25.0	23	23.0
51-60	6	26.1	13	21.3	2	12.5	21	21.0
>60	0	-	1	1.6	1	6.3	2	2.0
Total	23	100%	61	100%	16	100%	100	100%
Mean Age	41.52±8.64		40.82±10.21		41.06±9.60			
F	0.043							
P	0.958							

Maximum 61% were in possibly preventable group followed by 23% were not preventable whereas minimum 16% were in preventable group. Mean age in not preventable group cases was  $41.52 \pm 8.64$  years followed by in preventable group it was  $41.06 \pm 9.6$  whereas minimum  $40.82 \pm 10.21$  in possibly preventable group. On applying ANOVA test, the difference was found statistically insignificant ( $p > 0.05$ ).

**Table 8 Distribution of cases according to gender in relation to Thornton-Schumock's Preventability Classification**

Gender	Thornton-Schumock’s Preventability Classification						Total	
	Not Preventable		Possibly Preventable		Preventable			
	No.	%	No.	%	No.	%	No.	%

Female	15	65.2	38	62.3	12	75.0	65	65.0
Male	8	34.8	23	37.7	4	25.0	35	35.0
Total	23	100	61	100	16	100	100	100
$\chi^2$	0.900							
P	0.638NS							

In not preventable and possibly preventable had 2/3<sup>rd</sup> proportion of female whereas preventable group had 3/4<sup>th</sup> proportion of female and rest were males. On applying chi square test, the difference was found statistically insignificant ( $p>0.05$ ).

**Table 9 Distribution of cases according to residential area in relation to Thornton-Schumock's Preventability Classification**

Residential Area	Thornton-Schumock's Preventability Classification						Total	
	Not Preventable		Possibly Preventable		Preventable			
	No.	%	No.	%	No.	%	No.	%
Rural	12	52.2	31	50.8	12	75.0	55	55.0
Urban	11	47.8	30	49.2	4	25.0	45	45.0
Total	23	100	61	100	16	100	100	100
$\chi^2$	3.091							
P	0.213NS							

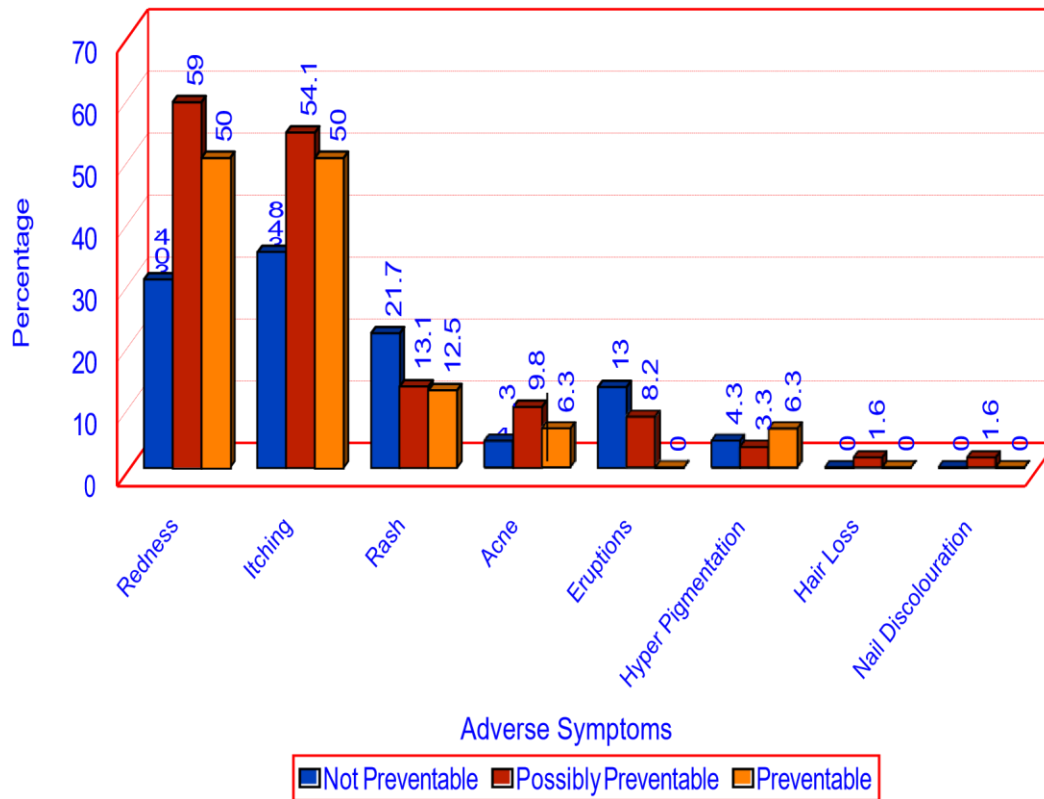
Equal distribution of residence in not preventable and possibly preventable. Maximum 75% were living in rural area and minimum 25% living in urban area in preventable group. On applying chi square test, the difference was found statistically insignificant ( $p>0.05$ ).



**Table 10 Distribution of cases according to adverse symptom in relation to Thornton-Schumock's Preventability Classification**

Adverse Symptoms		Thornton-Schumock’s Preventability Classification						Total		χ <sup>2</sup>	p
		Not Preventable		Possibly Preventable		Preventable					
		No.	%	No.	%	No.	%	No.	%		
Redness	Absent	16	69.6	25	41.0	8	50.0	49	49.0	5.468	0.065
	Present	7	30.4	36	59.0	8	50.0	51	51.0		
Itching	Absent	15	65.2	28	45.9	8	50.0	51	51.0	2.501	0.286
	Present	8	34.8	33	54.1	8	50.0	49	49.0		
Rash	Absent	18	78.3	5	86.9	14	87.5	85	85.0	1.068	0.586
	Present	5	21.7	8	13.1	2	12.5	15	15.0		
Acne	Absent	22	95.7	55	90.2	15	93.8	92	92.0	0.763	0.683
	Present	1	4.3	6	9.8	1	6.3	8	8.0		
Eruptions	Absent	20	87.0	56	91.8	16	100.	9	92.0	2.189	0.335
	Present	3	13.0	5	8.2	0	-	8	8.0		
Hyper Pigmentation	Absent	22	95.7	59	96.7	15	93.8	96	96.0	0.301	0.860
	Present	1	4.3	2	3.3	1	6.3	4	4.0		
Hair Loss	Absent	23	100	60	98.4	16	100	99	99.0	0.646	0.724
	Present	0	-	1	1.6	0	-	1	1.0		
Nail Discolouration	Absent	23	100	60	98.4	16	100.0	99	99.0	0.646	0.724
	Present	0	-	1	1.6	0	-	1	1.0		

Above table shows distribution of cases according to adverse symptom in relation to Thornton-Schumock's Preventability Classification. Most common symptom was Redness (51%) followed by itching 49% whereas minimum 1.0% had hair loss and nail discolouration followed by hyper pigmentation (4%). On applying chi square test, all the parameters had a insignificant correlation ( $p>0.05$  in all).

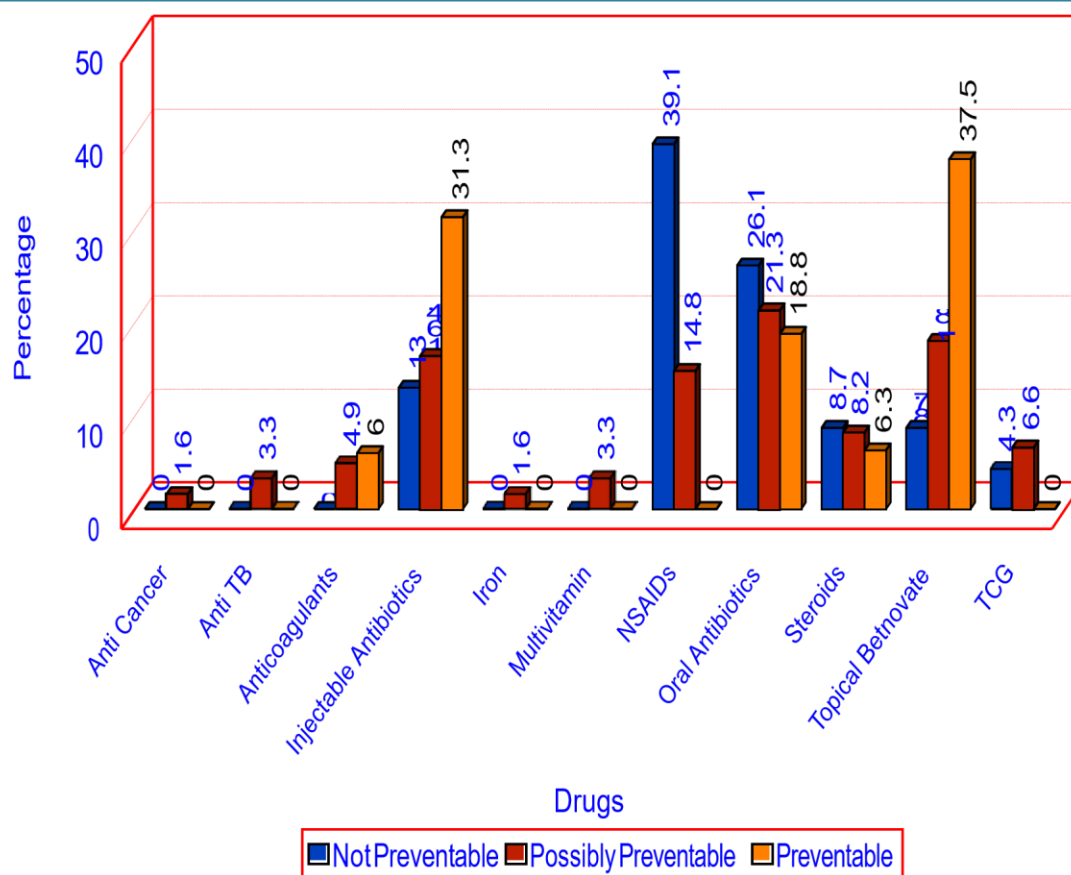


**Table 11 Distribution of cases according to drugs in relation to Thornton-Schumock's Preventability Classification**

Drugs	Thornton-Schumock's Preventability Classification						Total	
	Not Preventable		Possibly Preventable		Preventable			
	No.	%	No.	%	No.	%	No.	%
Anticancer	0	-	1	1.6	0	-	1	1.0
Anti TB	0	-	2	3.3	0	-	2	2.0
Anticoagulants	0	-	3	4.9	1	6.	4	4.0

Injectable	3	13.0	10	16.4	5	31.3	18	18.0
Antibiotics								
Iron	0	-	1	1.6	0	-	1	1.0
Multivitamin	0	-	2	3.3	0	-	2	2.0
NSAIDs	9	39.1	9	14.8	0	-	18	18.0
Oral Antibiotics	6	26.1	13	21.3	3	18.8	22	22.0
Steroids	2	8.7	5	8.2	1	6.3	8	8.0
Topical Betnovate	2	8.7	11	18.0	6	37.5	19	19.0
Topical clobetasole	1	4.3	4	6.6	0	-	5	5.0
with gentamicin								
Total	23	100	61	100	16	100	100	100
χ <sup>2</sup>	21.647							
p	0.360NS							

Above table shows Distribution of cases according to drugs in relation to Thornton-Schumock's Preventability Classification. Maximum 22% had taken Oral antibiotics in which maximum 26% in not preventable, followed by topical betnovate (19%) in which maximum 38% were in preventable group and NSAIDs (18%) in which maximum 39.1% cases belonged to not preventable whereas minimum 1% had taken anticancer and iron belonged to possibly preventable group. On applying chi square test, the difference was found statistically insignificant ( $p > 0.05$ ).

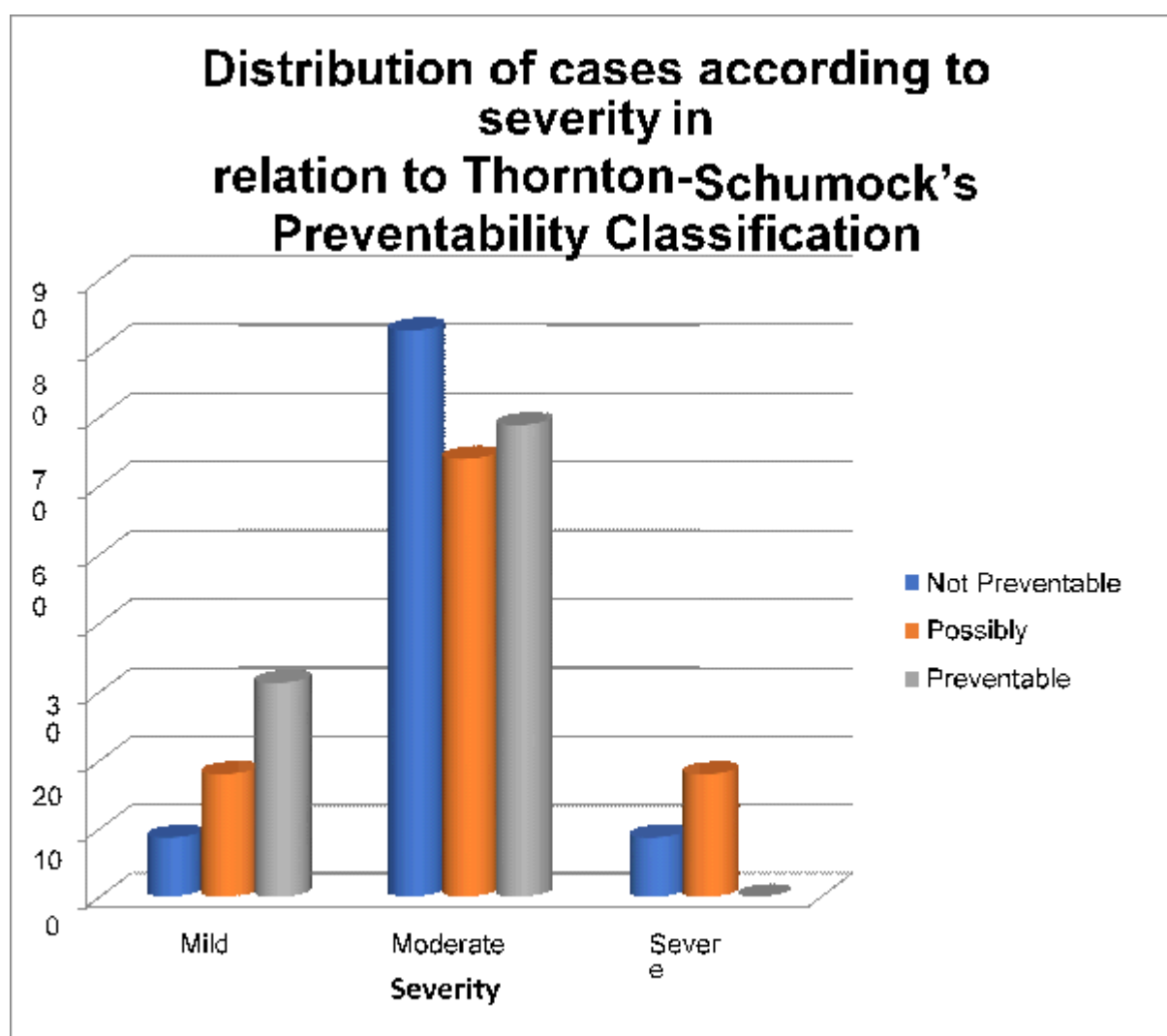


**Table 12 Distribution of cases according to severity in relation to Thornton-Schumock's Preventability Classification**

Severity	Thornton-Schumock’s Preventability Classification						Total	
	Not		Possibly		Preventable			
	Preventable		Preventable					
	No.	%	No.	%	No.	%	No.	%
Mild	2	8.7	11	18.0	5	31.3	18	18.0
Moderate	19	82.6	39	63.9	11	68.8	69	69.0
Severe	2	8.7	11	18.0	0	-	13	13.0

Total	23		61		16			
<input type="checkbox"/> 2	7.107							
P	0.130NS							

Above table shows distribution of cases according to severity in relation to Thornton-Schumock's Preventability Classification. Maximum 69% had moderate severity (maximum 82.6% in not preventable group) whereas minimum 13% had severe severity (maximum 18% in possibly preventable group) followed by mild severity 18% (maximum 31.3% in preventable group). On applying chi square test, the difference was found statistically insignificant ( $p>0.05$ ).



## DISCUSSION

Drugs are used for treatment and prophylaxis of various disease conditions and are considered as safer

drugs when used rationally. Drugs show some Adverse Drug Reactions in various patient conditions.

Adverse Drug Reaction monitoring is an essential aspect of therapeutics. However most of the time it is overlooked and not considered important.

Even when observed, many would not document and report voluntarily. Establishing pharmacovigilance units in the hospitals has facilitated this activity to a great extent.

This study focused on the pattern of dermatological Adverse Drug Reactions of drug class in the post marketing surveillance studies to find out the effects in a large and diverse population. In our study maximum 61% were possibly preventable followed by 23% not preventable whereas 16% cases were preventable respectively according to Thornton-Schumock's preventability classification. In other studies, such as the one carried out by Harsha R the majority of the ADRs were in the probable category. Also Tejas K Patel et al (2014) found "Definitely preventable", "probably preventable" and "not preventable" categories CADR's were 15.64%, 63.14%, and 34.64%, respectively according to Thornton-Schumock's preventability classification. In our study, maximum number of cases had their age between 31-40 years (41%) followed by 41-50Yrs had 23% cases, while least common age group in our study was >60 years where only 2% cases were found. Pudukadan D et al (2004), Sushma M et al (2005), SDI et al (2012), Rohini Sharma et al (2015), *Tejashwani et al (2018)*, Jagruti G. Dhanani et al (2017) found Most of cases were in the same age group. Whereas Patel Raksha M et al (2008) Maximum patients belonged to the age group 41-50. The maximum patients were in the age group of 31-40 years in our study, which is in accordance with another study that also reported similar observations. Majority 65% cases were female while 35% cases were male in our study whereas similar results were found by Pudukadan D et al (2004), SDI et al (2012) in their studies. Whereas male preponderance was found in Sushma M et al (2005), Rohini Sharma et al (2015), Jagruti G. Dhanani et al (2017) studies. There is no big difference in the numbers of male and female. The reason of higher incidence in present study could be that females are more conscious about any dermatological reaction and treatment of ADR before it gets severe. Majority of cases in study were living in rural area (55%). According to cutaneous symptom-wise analysis, maximum number cases (51%) had redness, 49% cases had itching problem, 15% cases had rash while

8% cases each had acne and eruptions and 4% cases had hyper pigmentation while least common adverse symptoms were hair loss and Nail discolouration where only 1% cases were found. similarly studies conducted by Shah S.P. et al, V.M. Motaghare, Sharma VK et al (2001), Pudukadan D et al (2004), Sushma M et al (2005), and *Tejashwani et al (2018)* found that most common suspected ADR was maculopapular rash followed by urticaria and/or FDE which are were also observed in the present study. Whereas Sowmyanarayan S et al was observed that the most common cutaneous ADR observed was acne vulgaris (22.86%) and generalized skin rash (22.86%) followed by fixed drug eruption (11.43%). The other cutaneous ADRs seen included Tinea cruris (8.57%), melasma (5.71%), chronic urticarial (2.9%), tinea incognita (2.9%), contact dermatitis (2.9%), toxic epidermal necrolysis (2.9%), pruritic (2.9%), atopic dermatitis (2.9%), vasculitis (2.9%), cushingoid features (2.9%) and topical atrophy (2.9%). Also Babu L. N et al (2017) found among the skin reactions urticaria/ angioedema was the most common 109(37.2%) followed by generalised pruritus 57(19.5%) and fixed drug eruption 37(12.6%). According to drugs, 22% cases taking oral antibiotics, while 19% cases taking topical betnovate, 18% cases each were taking injectable antibiotics and NSAIDS while 8% cases taking steroids, Tropical clobetasole with gentamicin were taking 5% of cases while 4% cases taking anticoagulants, 2% cases each taking anti TB and multivitamin type Drugs while 1% each cases taking anticancer and iron drugs. In our study Mean age in not preventable group cases was 41.52±8.64 years followed by in preventable group it was 41.06±9.6 whereas minimum 40.82±10.21 in possibly preventable group of Thornton-Schumock's Preventability Classification. Lesser mean age were observed by SDI et al (2012) that the patients with cutaneous drug reactions had 30.5 years. Also Rohini Sharma et al (2015) found the mean age of the patients with CADR's was 33.26 years. Not preventable and possibly preventable had 2/3<sup>rd</sup> proportion of female whereas preventable group had 3/4<sup>th</sup> proportion of female and rest were males in Thornton-Schumock's Preventability Classification. Distribution of cases regarding their residence in Thornton-Schumock's Preventability Classification not preventable and possibly preventable had equal distribution.

Maximum 75% were living in rural area and minimum 25% living in urban area in preventable group. Regarding ADR, on applying Thornton-Schumock's Preventability Classification Most common symptom was Redness (51%) and association was found to be insignificant correlation. In our study the drugs used on applying Thornton-Schumock's Preventability Classification scale maximum 26% in not preventable had taken oral antibiotics, followed by topical betnovate 38% were in preventable group. This is quite consistent with present study that most offended drug class was antimicrobials followed by topical betnovate (steroid). Similar finding for most common cause of ADRs was antibiotics in other studies also but for 2<sup>nd</sup> most common cause they had different results as unknown medicines (Shah S.P. et al), NSAIDs by **Nandha et al**, V.M. Motaghare, Patel Raksha M et al (2008), Tejas K Patel et al (2014), Babu L. N et al (2017) anticonvulsants by Sharma VK et al (2001), antiepileptics by Sushma M et al (2005). On contrary Pudukadan D et al (2004) found the most common causes were co-trimoxazole (22.2%) and dapsone (17.7%). Also Patel Raksha M et al (2008) found cotrimoxazole was the commonest drug. Also SDI et al (2012) found most common drugs which caused the reactions were Nonsteroidal antiInflammatory Drugs (NSAIDs) (39.1%), Quinolones (22.1%). Also Jagruti G. Dhanani et al (2017) found Paracetamol was the most common offending drug followed by cotrimoxazole. Also *Tejashwani et al (2018)* found NSAIDs were the most common offending drugs (16.66%). According to severity, on applying Thornton-Schumock's Preventability Classification maximum 82.6% in not preventable group had moderate severity, 18% in possibly preventable group had severe severity, 31.3% in preventable group had mild severity. On contrary a study done by V.M. Motaghare et al had different results as, Severity assessment by modified Hartwig and Siegel's scale in the study showed that out of 18 ADRs, 8(44.44%) were mild, 8 (44.44%) were moderate and 2 (11.11%) were severe in nature. Acharya T et al had reported that the severity of adverse cutaneous drug reactions assessment to be 83% moderate and 15% mild in nature using a Hartwig and Siegel's scale.

## CONCLUSION

As CADR are most common adverse drug reactions, drugs embroiled in past reaction should be avoided. A through history of previous allergies and drug

hypersensitivity should be confirmed. Sensitivity testing like patch test should be done before administration of any injectable drug. In case of hyper sensitivity or allergy, alternate drug should be used.

Thus effective ADR monitoring plays a role in safety of medicines. So awareness regarding early diagnosis and prompt treatment should be spread in community and health care professionals. Reporting of CADR should be regularly practiced by all health care providers.

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