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Original Article

Evaluation of quality of life and awareness of adverse drug reaction reporting among patients with dermatological adverse drug reactions

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ABSTRACT

Adverse drug reactions (ADRs) are a common cause of morbidity and mortality worldwide and are only to rise in the future due to the increasing trend in self-medication, polypharmacy, marketing of new drugs and fixed combinations and increase in geriatric population. The dermatological ADRs not only out-number all other ADRs but are also unique in being significantly disturbing and adversely affecting the quality of life. So the current study focuses on these aspects along with awareness of ADR reporting. This is a cross-sectional study conducted on 74 participants within the study period and all the dermatological ADRs were recorded on the suspected ADR reporting form of PvPI (Pharmacovigilance Programme of India). ADRs were assessed for causality, severity and preventability using appropriate scales. The quality of life was assessed by using Dermatology Life Quality Index (DLQI) and the awareness of ADR reporting using appropriate questionnaire. The mean age of the study was 36.4 years and males were more commonly affected. Drug hypersensitivity reaction was the most common finding followed by fixed drug eruption. Antibiotics and non-steroidal anti-inflammatory drugs (NSAIDs) were the most common medication associated. Maximum ADRs were mild in nature, possibly due to the drug and were not preventable. The quality of life was extremely severely affected in maximum participants. Though the severe cases of dermatological ADRs are less, the quality of life hampered is far greater. The awareness of ADR among common people is quiet low.

KEYWORDS: adverse drug reaction, quality of life, dermatology life quality index.

INTRODUCTION

An adverse drug reaction (ADR) is defined as "any effect of a drug that is noxious and unintended and which occurs at doses used in humans for therapy, prevention or diagnosis of a disease" (WHO) [1]. They warrant reduction of dose or withdrawal of drug and precautions about future use of that drug. Majority of the ADRs occur either due to extension of the pharmacological action of the drug (Type A) or due to the genetic peculiarity of the individual or immunological property of the drug (Type B) [2]. The impact of ADRs on human life is huge. It may vary from mild inconvenience in daily living to a permanent disability, iatrogenic disease or even death. Apart from the physical impact it may cause significant emotional, social, financial harm to the patients [3]. The physical disfigurement, increased length of hospital stay, cost and death contribute to this. Hence ongoing monitoring and assessment of ADRs in all patients consuming marketed drugs in real life setting is mandatory through pharmacovigilance activities to register the new and rare adverse effects that were not possible in the setting of strict

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premarketing clinical trial phases [4]. Also awareness needs to be created among the patients and public about self-reporting of ADRs through available helplines [5]. Literature survey revealed that, the dermatological ADRs are one of the most common forms of ADR [6]. The dermatological ADRs not only out-number all other ADRs but are also unique in being significantly disturbing and adversely affecting the quality of life. The Health Related Quality of Life (HRQOL) is defined as "the physical, emotional and social aspects of quality of life influenced by an individual's disease and/or its treatment" [7]. There are only a few studies which ascertain the impact of ADR on Quality of Life but there is a lack of studies ascertaining the level of awareness and reporting of ADRs by the patients [8].

Hence this study was carried out to study various aspects of dermatological ADRs observed in our tertiary care hospital along with assessing its impact on the quality of life. Additionally the knowledge, perception and awareness of patients towards the ADR reporting were ascertained and analysed.

MATERIALS AND METHODS

This is a cross-sectional study, conducted from August 2017 to September 2019 in the department of Pharmacology in collaboration with department of Dermatology. Adult patients with diagnosed dermatological ADR were included and those cases with unknown drug were excluded. Data were collected on the Suspected ADR reporting form of IPC (Version 1.3) [9]. Causality, severity and preventability of the observed ADRs were determined using WHO-UMC causality assessment scale, Hartwig-Siegel's severity assessment score and Schumouch-Thornton's preventability criteria respectively [10-12]. Quality of life of the patients included in this study was assessed by using Dermatology Life Quality Index (DLQI) [13]. Appropriate questionnaire was designed which included major aspects of the patient's knowledge regarding ADR and its reporting. The above questionnaire was prior tested as a pilot study and was approved by two subject experts. The questionnaire was prepared in local language for proper understanding and response.

RESULTS

A total of 74 patients (male: 43, female: 31) were recruited for the study with the mean age of 36.4 ± 13.9 years.

Table 1 depict the spectrum of ADRs observed in our study which showed drug hypersensitivity reaction as the commonest.

Antibiotics followed by non-steroidal Anti-inflammatory drugs (NSAIDs) were the most common medications associated with the observed cases (Table 2).

Maximum of ADRs belonged to the possible category of causality assessment (Table 3).

Table 1. Spectrum of ADRs observed in study subjects (n = 74).

Nature of ADR	Number of cases (%)
DHR	22 (30)
FDE	20 (28)
Rash	7 (9)
TEN	7 (9)
SJS	6 (8)
MPDR	5 (7)
EM	3 (4)
AGEP	3 (4)
DRESS	1 (1)

DHR: drug hypersensitivity reaction, FDE: fixed drug eruption, TEN: toxic epidermo necrosis, SJS: Steven John's syndrome, MPDR: maculo papular drug reaction, EM: erythema multiformi, AGEP: acute granulomatous exanthematous pustulosis, DRESS: drug rash with eosinophilia and systemic symptoms.

Table 2. Type of medications associated with ADRs.

Type of medication	Number of patients showing ADR (%)
Antibiotics	35 (47)
NSAIDs	25 (34)
Anti-epileptics	10 (14)
Anti-fungal	3 (4)
Anti-psychotics	2 (3)
Others	17 (23)

Mild severities of ADRs were observed in maximum number of cases (Table 4).

Most cases were not preventable when assessed (Figure 1).

The mean value of DLQI was 18.9 ± 6.5. The quality of life affected due to these ADRs was extremely severe in majority of cases when evaluated by DLQI (Table 5).

The responses of the study participants regarding the awareness and reporting of ADR showed that maximum cases were not aware or made aware of either ADRs or their reporting though it affected them physically, mentally and economically (Table 6).

DISCUSSION

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. Adverse cutaneous drug reactions vary in their patterns of morphology and distribution.

Table 3. WHO-UMC Causality Assessment of ADRs.

WHO-UMC scale	Cases (%)
Certain	9 (13%)
Probable	24 (32%)
Possible	41 (55%)

Table 4. Hartwig & Siegel's severity assessment of ADRs.

Modified Hartwig & Siegel's scale	Cases (%)
Mild	33(45%)
Moderate	26(35%)
Severe	15(20%)

The mean age of the ADR presentation was 36.4 ± 13.9, which was similar to the findings of Pudukadan *et al*. and Dimple *et al*. [14, 15]. Current study showed a male preponderance (58%) to female (42%), which was also seen in the studies of Shah *et al*., Sharma *et al*., Sushma *et al*. and Pudukadan *et al*. [15-18]. But the findings of Sudershan *et al*., Chatterjee *et al*., Suthar *et al*., Nandha *et al*. and Mbuagbaw *et al*. went in favour of female majority [19-23]. Some factors proposed for greater male predominance are more consciousness about their health, more independence, less social stigmata etc. But these factors are not conclusive.

Drug hypersensitivity reaction (DHR) was the most common presentation in our study comprising of 30% of the total followed by fixed drug eruption [FDE] (28%) and rash (9%) (Table1). In studies of Dimple *et al*., Ghosh *et al*., Sharma *et al*. and Noel *et al*., rash or maculopapular rash was found to be the most common dermatological ADR [14, 17, 18, 24]. Studies by Mbuagbaw *et al*. and Pudukadan *et al*. showed FDE to be the most common presentation, which was similar to this study [15, 23]. Many a times FDE appears and disappears with time as the patients don't take them seriously.

Among the medications, anti-microbial were used in maximum cases (47%) followed by NSAIDs (34%) (Table 2). Research work by Sharma *et al*.,

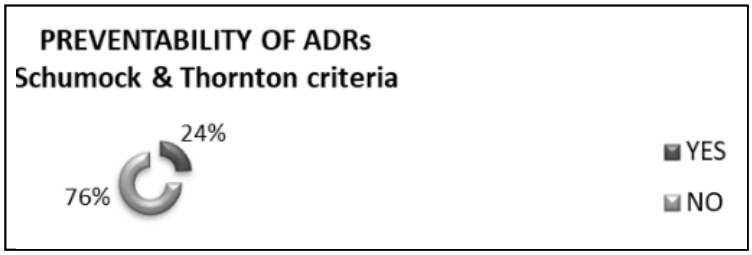


Figure 1. Preventability of ADRs.

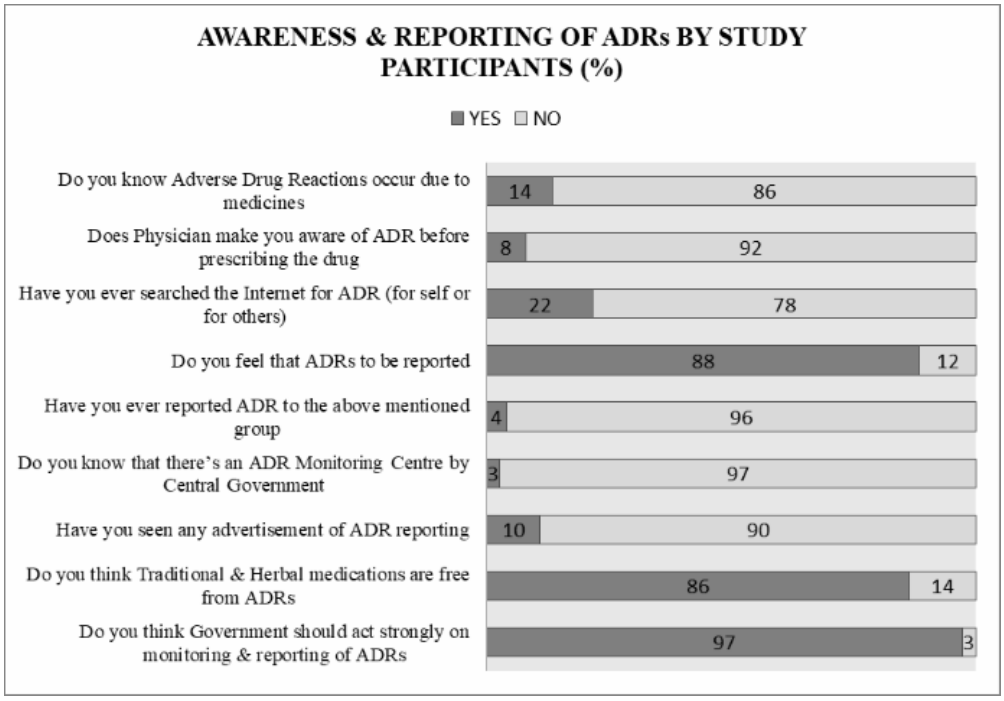
Nandha *et al*. and Sejal *et al*. showed that the two most common drug groups were anti-microbial and NSAIDs [17, 22, 25]. This may be related to the common prescribing pattern and self-medication habits among the local population likely to be using NSAIDs, fixed dose combinations of cough preparations, and antibiotics.

Table 5. Extent of quality of life affected in study subjects.

Extent of QOL affected	Cases (%)
Mild	2 (3%)
Moderate	7 (10%)
Severe	30 (40%)
Ext. severe	35 (47%)

In our study 13% ADRs were certainly caused due to the drugs, 32% were probably and 55% were possibly due to drugs according to WHO-UMC scale (Table 3). Our study showed a higher percentage of cases in certain group. This may be due to the fact that in our study the treating physicians conducted re-challenge test in a well-controlled manner, keeping the well-being of patients in mind. Similar results were observed in

Table 6. Awareness and reporting of ADRs by study participants.



Do you read the instructions written over the medicines/ package insert before taking the medication?	**Never**	**Seldom**	**Often**	**Always**
	73%	19%	5%	3%
How do you think ADRs affect patients?	**Physically/Mentally/Economically**		**All**	
	40%		60%	
What is your suggestion to strengthen ADR surveillance system?	**TO aware common people**	**To prevent OTC sell of drugs**	**To set more number of AMC**	**Other**
	60%	32%	6%	2%

the studies by Dimple *et al*., Sejal *et al*., and Ghosh *et al*. with respect to probable and possible causes [14, 24, 26]. Severity analysis showed that mild, moderate and severe form of cases occurred in 45%, 35% and 20% of participants (Table 4). Data from the present study co-related with the study of Ghosh *et al*. [24]. Current study showed that 76% of cases were not preventable and 24% were preventable (Figure 1). These findings co-related with the data of Manchanda Y. *et al*., Krishna *et al*. and Padmavathi *et al*. [27-29].

The dermatology life quality index (DLQI) is a unifying scoring system that has been described in at least 36 skin diseases and in more than 130 articles published in 21 languages [30]. So we used DLQI score for our study (Table 4). Some studies had revealed that the mean score of DLQI in some of the skin diseases were 7.2 and 12.9 [13, 31]. The higher value in our study in relation to other studies might be a matter of concern. As normally dermatological ADRs are overlooked as not so much physically affecting its psychological impact should not be omitted while treating the patients. Though the DLQI had not been often used in dermatological ADR, still it has got an important role to play in the assessment of quality of life, as dermatological adverse drug reaction can affect not only the external parts of the body but also diminish psychological wellbeing. Follow-up studies are needed to explore in which ways this information can best be provided and used for these stakeholders.

In our study we found that maximum numbers of cases were not aware about the ADR and their reporting. Also most cases were not being made aware of ADR by the treating physician. We also found that there are no significant efforts made to make them aware through any type of awareness or advertisement (Table 6).

CONCLUSION

The burden of dermatological ADRs is a significant health problem in the present scenario. Spectrum of these ADRs is wide and the medications associated are also ever changing with time. The overall quality of life is very severely affected, which cannot be ignored. The combined effort of awareness by government and by the treating physician might reduce these incidences.

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CONFLICT OF INTEREST STATEMENT

None to declare.

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