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Original Research Article

Evaluation of drug utilization pattern, quality of life and pharmaco-economics in patients of contact dermatitis: a prospective observational study

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ABSTRACT

Background: Contact dermatitis (CD) is a common inflammatory skin condition due to T-cell mediated immune reaction on exposure to different allergens. The disease significantly affects Quality of Life (QoL) and all over impact can be seen in Pharmacoeconomics.
Methods: This is the prospective observational study done between October 2019 to February 2020 at Dermatology outpatient department (OPD) of a tertiary care teaching hospital. Patients diagnosed with CD aged eighteen years or older of either gender and willing to give written consent were included in study. The impact of CD on the QoL of affected persons was assessed using the Dermatology Life Quality Index (DLQI). Direct, indirect and total cost as well as percentage variation in cost of individual drugs was calculated for Pharmacoeconomics analysis.
Results: The study population consisted of 180 patients. The most commonly prescribed drugs were corticosteroids (47.44%). The average score of DLQI at baseline was 8.97±4.85. The DLQI score was significantly more impaired in women as compared to men (12.91versus 4.93) (p=0.0001). Average income per month was 11,611.11±230.34₹. The average direct, indirect and total cost was 131.55±70.55 ₹, 136.44±16.93 ₹ and 168.11±74.08₹ respectively. The percentage variation of cost was largest for prednisolone 5 mg tablet and least for clobetasol cream (0.05%).
Conclusions: The impact of CD on QoL and Pharmacoeconomic burden is significant and requires specific attention in health care facilities.

Keywords: Contact dermatitis, Drug utilization pattern, Pharmacoeconomics, Quality of life

INTRODUCTION

Contact dermatitis (CD) is a common inflammatory skin condition characterized by erythematous and pruritic skin lesions caused by T-cell-mediated immune reaction on exposure to various allergens.[1] CD is mainly divided into Allergic Contact Dermatitis and Irritant Contact Dermatitis. Allergic contact dermatitis (ACD) is an inflammatory skin disease that affects about 20% of the adult general population and that is also an important occupational skin disease.[2]

Many drugs like topical and systemic corticosteroids, antihistamines, antimicrobials, immunosuppressants and emollients are commonly used in the treatment of CD. However, they are the least studied drugs in terms of their prescribing patterns.[3]

CD has a huge impact on Quality of Life (QoL) of Patient. Though it is not a life-threatening disease it produces an invisible psychological burden on the patients as most people are very conscious and particular about their physical appearance. On the other hand, some patients

having minor degree of symptoms accept it as a part of life. The use of QoL measures provides patients an opportunity to express their concerns and assist clinicians in their evaluation of the overall effectiveness of management.[4]

CD is a long-term disease so along with QoL; pharmacoeconomic evaluation is also an important aspect of this condition. CD can cause considerable distress to patients and their caregivers, with significant social and financial cost to families.

However as relatively few studies have been published concerning the impact of CD on the QoL we decided to study it. Also, the financial burden of this disease has not been evaluated in our country so we wished to evaluate it along with drug utilization pattern in CD in our set up.

METHODS

This prospective, observational study began after obtaining approval from Institutional Review Board. It was carried out between October 2019 to February 2020 at a tertiary care teaching hospital.

Patients fulfilling the inclusion criteria such as those aged eighteen years or older; of either gender; attending Dermatology OPD and diagnosed with CD and willing to give their written informed consent were included in our study.

Indoor patients, pregnant and lactating females and those with severe co-morbid conditions were excluded from the study.

The data was analysed for age groups and gender distribution, type of dermatitis and prescription patterns. Patients having air born contact dermatitis, photo contact dermatitis and chronic eczema at the site of suspected contact allergen were included in allergic contact dermatitis. The prescription was evaluated in relation to the drugs prescribed, the dosage form, dosage used, frequency and the route of drug administration. The cost of drugs was also noted.

Effectiveness of treatment in terms of patient's quality of life was measured by using Dermatology Life Quality Index (DLQI) questionnaire. It is a ten-question tool which evaluates the impact of skin disease on the quality of life of an affected person. DLQI was filled at the time of first contact and then after 15 days to calculate the effectiveness as well as effects of treatment on patient's quality of life. Scores range from 0 to 30 and a higher score indicates an adverse effect on patients QoL.

(Scores are categorized by: 0- 1 = no effect on the patient's QoL, 2-5 = low effect on the patient's QoL, 6-10 = moderate effect on the patient's QoL, 11-20 = significant effect on the patient's QoL, and 21-30 = extremely important effect on the patient's QoL.[5]

In relation to pharmacoeconomics; patient's income per month, direct cost and indirect cost of treatment was noted. Direct medical cost included OPD case charges. The medicines were provided free of cost to the patients from the hospital pharmacy. Non-medical direct cost included transportation expenses. In Indirect cost wage loss of patient or his/her accompanying person's wage loss was calculated.

As the medication provided to the patients was free of cost from the hospital pharmacy, we calculated the "Percentage variation in costs of the drugs prescribed" taking into account the most expensive and the least expensive brand of that particular drug. Current Index of Medical Specialties (CIMS) and Indian drug review (IDR) 2021 issues were used for evaluation of "Percentage variation in cost of drugs". The cost of medicines manufactured by different manufacturers was compared taking into account the same strength and dosage form.[6,7] The difference in the maximum price and minimum price of the drug used for contact dermatitis manufactured by different manufacturers was noted. We calculated the "percentage variation in cost" of different drugs used for management of CD by applying the following formula.[8]

$$\frac{The\ price\ of\ most\ expensive\ brand\ drug}{The\ price\ of\ least\ expensive\ brand\ drug} \times 100$$

The price of least expensive brand dug

All the costs calculated were in terms of Indian Rupees (INR). Analysis was done using Statistical package for social sciences (SPSS) version 23 software.

RESULTS

Socio-demographic profile

A total of 180 patients; 89 males and 91 females were included in the study. The age (mean±SD) of patients was 38.50±14.47 years. A majority of patients 96 (54.33%) were young adults in the age range of 20-39 years (Table 1).

Table 1: Age and gender distribution.

Age Group (years)	Gender Distribution		Total (n=180)
	Male	Female	
	N (%)	N (%)	N (%)
<20	3 (3.37)	6 (6.59)	9 (5)
20-39	41 (46.06)	55 (60.43)	96 (53.33)
40-59	32 (35.95)	22 (24.17)	54 (30)
60-80	13 (14.60)	8 (8.79)	21 (11.66)
Total	89 (49.44)	91 (50.55)	180 (100)
Mean ±S.D.	41.65±15.06	35.42±13.25	38.50±14.47

Drug utilization pattern

Out of 180 patients 133 (73.89%) were diagnosed with Allergic contact dermatitis and 47 (26.11%) were diagnosed with irritant contact dermatitis. The commonly prescribed drugs included corticosteroids, antihistaminic, antibiotics, antifungal and miscellaneous drugs.

Table 2: Drug utilization pattern.

Classification of drug groups	In the form of		Total (n= 586)	
	Topical	Systemic	N	%
Corticosteroids	219	59	278	47.44
Antihistaminic	0	209	209	35.67
Antibiotics	8	16	24	4.09
Antifungals	9	5	14	2.39
Vitamin E	12	11	23	3.92
Calamine lotion	28	0	28	4.77
Other Drugs	2	8	10	1.72
Total			586	

Among 180 prescriptions most common prescribed drugs were corticosteroids 47.44%. The corticosteroids prescribed were both topical and systemic. Among topical corticosteroids the most commonly prescribed topical corticosteroid was clobetasol (60%) and the most commonly prescribed systemic corticosteroid was prednisolone (17.98%). The second most commonly prescribed drugs were antihistamines followed by other drugs like antibiotics and antifungal drugs. Other Miscellaneous drugs were topical and systemic vitamin E, vitamin C, calamine lotion, liquid paraffin and Azathioprine. No injectable dosage form was prescribed. Only oral and topical dosage forms were used.

Average number of drugs per prescription were 3.25. 71.67% drugs were prescribed by generic name. (Table 2)

Analysis of QoL (DLQI) score of patients

The average DLQI score of 180 patients at baseline was 8.97±4.85 (mean±SD).

The DLQI score obtained at the time of first contact in females was 12.91±3.60 (mean±SD) and in males was 4.93±1.44 (mean±SD). The DLQI score was significantly more impaired in women as compared to men (12.91versus 4.93) (p=0.0001)

Out of 180 patients 28 patients turned up for follow up after 15 days. Only these 28 patients were analysed for improvement in QoL. (Table 3)

Baseline DLQI scores

Table 3 shows DLQI scores before and after treatment of the 28 patients who turned up for follow up. At baseline none of the patients were in the score category of 0-1. Patients in whom CD had a small effect on QoL (score category 2-5) were 4 in number. Patients with moderately affected QoL; score category 6-10 were 5. At baseline, in majority of patients (19/28); CD had a very large effect on QoL (score category 11-20). There were no patients in the category of extremely large effect on QoL (score category 21-30).

After treatment DLQI scores

After treatment (Table 3) 4 patients continued in the category of little effect on QoL. A major shift was seen in patients who had a very large effect on QoL (19/28), where after treatment only 1 patient remained in this category and 18 patients improved and shifted to the category of moderate effect on QoL. The number of patients in the category of moderate effect on QoL increased from 5 to 23.

Table 2: Analysis of DLQI score of patients.

DLQI		Total no. of patients (n=28)			
Effects on Patient's QoL	**DLQI Score**	**At baseline**		**After treatment***	
		n (%)	**DLQI Score (mean ± SD)**	**n (%)**	**DLQI Score (mean ± SD)**
No effect at all	0-1	0 (0)	0	0(0)	0
Small effect	2-5	4 (14.29)	4.25 ± 0.96	4 (14.29)	3 ±0.82
Moderate effect	6-10	5 (17.86)	8.6 ± 0.89	23 (82.14)	7.43 ± 2.18
Very large effect	11-20	19 (67.86)	13.10 ± 5.07	1 (3.57)	12
Extremely large effect	21-30	0 (0)	0	0 (0)	0

DLQI = Dermatology Life Quality Index, QoL = Quality of Life, *p<0.0001.

Table 4: Percentage variability in cost of contact dermatitis medications.

Contact dermatitis medication	Strength and dosage form	Minimum cost in ₹	Maximum cost in ₹	Difference in cost in ₹	Percentage variability in cost (%)
Clobetasol cream	0.05% cream	55	99	50	80
Prednisolone	5 mg tablet	3.82	69	65.18	1706.28
Cefixime	100 mg tablet	45	134	89	197.78
Chlorpheniramine maleate	5 mg tablet	12.4	25.5	13.1	105.64
Fluconazole	150 mg tablet	6.85	31.2	24.35	355.47
Levocetirizine	5 mg tablet	7	57.65	50.65	723.57
Calamine Lotion	100 ml lotion	125	525	400	320
Vitamin E (oral)	200mg tablet	8.88	40	31.12	350.45
Vitamin E (Topical)	60 gm cream	119.25	275	155.75	130.60

There was an overall improvement in QoL scores from 10.89±3.73 at baseline to 6.96±2.06 after treatment which was statistically significant. Statically significance was calculated using student's paired 't' test ($p<0.0001$).

Pharmacoeconomic analysis

Out of 180 patients 49 patients dependent on family members. 2 patients had income <5000₹ per month. 84 patients had income between 5000-15,000₹ per month. 36 patients had income between 16,000-30,000₹ per month. and 9 patients had income >30,000 ₹ per month. Majority of patients 46.67% (84/180) have income between 5000-15,000₹ per month.

Average income per month was 11,611.11±230.34₹ (mean±SD). The patients paid ₹10 for getting the OPD case made. The medications were provided free of cost from the hospital pharmacy. The difference in direct cost within patients was due to differences in transportation costs. The difference in indirect costs were due to different wages of patients and the accompanying person. The average Direct cost observed was 131.55±70.55 ₹ (mean±SD) and the observed indirect cost was 136.44±16.93 ₹ (mean±SD) respectively. The average total cost was 168.11±74.08₹ (mean±SD).

Table 4 shows the percentage variation of cost of the most commonly used drugs in the treatment of contact dermatitis. Highest percentage variability was seen in tablet prednisolone 5 mg (1706.28%) followed by tablet levocetirizine (723.57%). The lowest percentage variation in cost was seen with 0.05% clobetasol cream (80%)

DISCUSSION

In our literature search we found that very few studies had been carried out in our country evaluating the impact of Contact dermatitis on Quality of life as well as Pharmacoeconomics of this condition. This prompted us to take up this study. Contact Dermatitis is associated with not only a cosmetic problem but also with a significant psychosocial impact and pharmacoeconomic burden.[9,10]

This prospective observational follow up study was carried out in 180 consenting patients visiting the Dermatology Outpatient Department of a tertiary care teaching hospital.

Socio-demographic analysis

Analysis of socio-demographic characteristics showed that a large number of patients were young adults with a preponderance in women. This is comparable with the study done by Bylappa et al.[11] This is probably because young adults are more conscious about their physical appearance. Gender distribution was also almost similar in the present study.

The most common type of contact dermatitis observed in our study was allergic contact dermatitis (59/180 patients) and most cases were due to occupation related allergens like chemicals, dye, paints, cement, dust etc. The best way to prevent recurrence of CD is avoiding skin contact with substances to which the patient is allergic.[12]

Drug utilization evaluation

Drug utilization evaluation studies help in corelating drug use with optimal benefit in health care.[13] In patients in whom a possible causative substance is known, the first step is to see if the problem resolves with avoidance of the substance. Localized acute allergic contact dermatitis lesions are successfully treated with mid- or high-potency topical steroids, such as triamcinolone 0.1% or clobetasol 0.05%.[14] In our study, we found that corticosteroids both topical and systemic were the most commonly prescribed drugs (47.44%) followed by antihistamines (35.67%), antibiotics (4.09%) and antifungals (2.39%).

A study done in South India by Divyashanthi et al, Pathak et al analyzed the WHO core prescribing indicators in patients with allergic contact dermatitis.[15,16] The similarity observed in this study as compared to our study was that in this study also corticosteroids both topical and systemic were the most commonly prescribed drugs (45.54%) followed by antihistamines (30.69%) and antimicrobials (13.86%).

The prescription patterns in this study differed from ours in some respects. In this study carried out in a total of 81 patients of CD from the Outpatient department of dermatology, 10% patients received parenteral drugs while no patient in our study was given a parenteral dosage form. The most frequently prescribed topical steroid in this study was Desonide whereas in our study it was Clobetasol. Desonide is a low potency steroid that is preferred in areas with thinner skin such as flexural surfaces, eyelids, face, anogenital region because it reduces the risk of skin atrophy. Clobetasol is a high potency steroid that is preferred in skin of other parts of the body.[14] The systemic steroid most frequently prescribed in both studies was prednisolone.

In our study, average number of drugs per prescription is 3.25 which was found to be lower compared to the above-mentioned study where the average number of drugs prescribed were 6.8. In our study 71.67% drugs were prescribed by generic name; this is also higher compared to 22.77% drugs being prescribed by generic name in the above-mentioned study. No injectable dosage form was prescribed. Only oral and topical dosage forms were used. Less than 1% patients received Azathioprine an immunosuppressant showing that they had a severe form of the disease.

Analysis of QoL

Evaluation of QoL parameters was done using the DLQI Questionnaire. In the analysis of QoL, the baseline scores of female patients were significantly higher than the baseline scores of male patients (12.91±3.60 (mean±SD) in females versus 4.93±1.44 (mean±SD) in males). This indicates that the QoL of female patients was more affected as compared to the male patients. One probable reason could be that female patients are more conscious cosmetically. Other reasons for the difference need to be further evaluated.

Out of 180 patients only 28 patients reported for follow up so only these 28 could be evaluated for the improvement in QoL scores. That is a limitation of this study. Major improvement in QoL was seen in the category of patients where CD had a very large effect on QoL (19/28). This number was reduced to 1 after treatment as 18 patients shifted to the category of moderate effect. There was an overall improvement in QoL scores that was statistically significant.

Kalboussi et al studied the impact of CD on QoL and work productivity. This was a single point contact study where QoL scores were calculated by using the same DLQI questionnaire. The average scores in this study were 6.5±2.7(Mean±SD) and 53% male patients were affected. The QoL scores of patients with allergic CD in this study were better than our baseline scores for CD (10.89±3.73) (Mean±SD). In our study there was a preponderance in females which is in contrast to this study.[17] We did not analyse work productivity loss in our study.

Pharmacoeconomic analysis

In our literature search we did not find any Indian study that analysed Pharmacoeconomics of CD hence a direct head-to-head comparison could not be done. Patients in our study belonged to a lower socioeconomic group. Majority of patients had income less than 15,000₹ or were dependent on their spouse or family members. As the patients were provided medication free of cost they were saved of considerable expenses as compared to purchasing them from the market. The direct medical costs included a trivial ₹10 charge for issue of OPD case book. The nonmedical direct cost included transport cost which was responsible for the differences in direct cost of individual patients. Indirect cost included loss of wages of the patient or his accompanying relative.

In our analysis of percentage variation in cost of the drugs used in the treatment for CD we found the maximum variation in cost in relation to tablet prednisolone 5 mg (1706.28%) followed by tablet levocetirizine (723.57%). The lowest percentage variation in cost was seen with 0.05% Clobetasol cream (80%). The cause was this wide variation in cost of tablet prednisolone and Tablet Levocetirizine needs to be looked into.

Limitations

This was a short duration single centre study, and a large number of patients were lost to follow up so for assessment of improvement in DLQI scores we could only enroll 15.55% (28/180) patients out of total sample size.

CONCLUSION

The impact of severe CD is considerable, with substantial financial costs to sufferers and their families. With the increasing prevalence of dermatitis in developed countries, the burden of CD on the health system is becoming an issue.

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