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Original Research Article

Evaluation of drug use health related quality of life and pharmacoeconomics in autoimmune skin disorders: focus on blistering skin disorders-a prospective observational study

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ABSTRACT

Background: Autoimmune skin disorders (ASDs) are complex diseases triggered by autoantibodies action against epidermal antigens or the dermo epidermal junction. Although rare, they present high morbidity, affecting the quality of life (QoL) of patients and financial status of patient.
Methods: This prospective, observational study was carried out in department of dermatology for 2-3 months after ethical approval. Drug usage pattern, heath related QoL (HRQOL) by using DLQI (Dermatology life quality index) and cost were evaluated in patients with ASDs. Statistical analysis was done using Microsoft excel office 2019 and rechecked with SPSS (version 23.0). P<0.001 was considered as statistically significant.
Results: Out of 73 patients enrolled, 32 were male and 41 were female with the mean age was 48.27±14.93 years; 55% patients had autoimmune blistering skin disorders (AIBDs) and 45% having other ASDs (OADs). Pemphigus vulgaris (PV) (35%) being the most common among all ASDs. Systemic steroid (60.27%), topical steroid (79.45%), levocetirizine (63%) were most commonly prescribed drugs. Mean DLQI score at baseline and after treatment was 11.64±2.49 and 6.8±2.75 respectively. It was highly significant statistically (p<0.0001). Total cost of illness per month was 813.64±481.21 INR. Maximum percentage variation in cost was seen with prednisolone (1706.28%).
Conclusions: ASDs have a female bias and inflict severe impairment to the QoL of patients. Appropriate drug therapy with corticosteroids and other adjuvant drug lead to positive impact on QoL. There was very wide price variation of different brands of the same generic most commonly prednisolone and levocetirizine.

Keywords: ASDs, AIBDs, Percentage variation in cost, QoL, Steroids

INTRODUCTION

The autoimmune blistering skin disorders (AIBDs) are a group of skin disorders that result from autoimmunity against intercellular adhesion molecules or components of the basement membrane in the skin and mucosa.[1] Their clinical severity varies from atypical manifestation, with spontaneous remission, to lethal forms refractory to treatment. They are characterized by vesicles and cutaneous blisters which evolve with erosion areas and itching. The classification depends on the site of the blister in the epithelium, which may be subepidermal and intraepidermal, besides the pathological substrate.[2] ASDs are classified as blistering and other ADs. The main AIBDs are PV, pemphigus foliaceus (PF), bullous pemphigoid (BP) and dermatitis herpetiformis (DH).[3-5] OADs are psoriasis, lichen planus (LP), vitiligo, Darier's disease and alopecia areata.[6]

Pemphigus is a group of disorders that is characterised by blisters formation on the skin and inside the mouth, nose, throat, eyes, and genitals. BP characterised by itchy blisters to form on the arms, thighs, and belly. IgA mediated bullous dermatoses comes in two types: 1. DH causes clusters of itchy blisters to appear on the elbows, knees, scalp, and buttocks. 2. Linear IgA disease forms "cluster of jewels"; ring shaped new blisters around old ones on the skin. This is sometimes called a "cluster of jewels." Psoriasis is characterised by rashes or patches of red, inflamed skin, often covered with loose, silver-colored scales and Itchy, painful skin that can crack or bleed. LP generally appears as purplish, itchy, flat bumps that develop over several weeks. Vitiligo characterised by include patchy loss of skin color, which usually first appears on the hands, face, and areas around body openings and the genitals. Darier disease typically presents with scaly crusted papules in a seborrheic distribution and in skin folds. Alopecia areata characterised by hair falls out in small patches around the size of a quarter. [7]

Topical and systemic corticosteroids (CS) are the most effective treatment for the ASDs.[8] The most commonly used steroid-sparing immunosuppressive agents with steroids are azathioprine, mycophenolate mofetil (MMF), and cyclophosphamide to reduce maintenance dose of CS and reduce the side effects related to use of CS.[8-9] ASDs are low incidence entities (1.9-4.3 cases for every 100,000 adults) of high morbidity, which significantly compromise the QoL of patients.[10] DLQI developed by Finlay and Khan in 1994, was the first tool of HRQOL evaluation related to dermatological disorders. It consists of ten questionnaire, which approximate disease influence regarding: symptoms and feelings, daily activities, leisure, work, school, personal relationships and treatment. Previously there were few studies of impact on QoL of patients with ASDs, but none of these studies were on Indian population.[11]

Objectives

Objectives of the study were to evaluation of drug use in patients with ASDs, evaluation of QoL in patients with ASDs using DLQI questionnaire and evaluation of pharmacoeconomics i.e., total cost of illness considering Direct and indirect cost, percentage variability in cost of drugs prescribed.

METHODS

This prospective, observational study began after obtaining approval from institutional review board. It was conducted from November 2019 to February 2020 at the department of dermatology of a Shardaben general hospital, affiliated with Smt. NHL municipal medical college, Ahmedabad.

The sample size was duration based. The data was collected on case record form and DLQI questionnaire.

All the patients confirming the inclusion criteria; those who attending dermatology OPD diagnosed with Autoimmune diseases of skin, whose age was more than or equal to 18 years and those willing to give their written informed consent and agreeing to answer questions related to their QoL were included in the study.

Patients not willing to give their written informed consent, indoor patients, pregnant and lactating females, those with severe co-morbid conditions were excluded from the study. Patients are divided into 2 groups: 1. AIBDs and 2. OADs and their data was analysed for age groups and gender distribution, drugs prescribed, patient's HRQOL using DLQI questionnaire, pharmacoeconomics and percentage variability in cost of drugs used for ASDs.

DLQI questionnaires contains 10 skin specific questions. The aim of this questionnaire is to measure how much your skin problem has affected your life over the last week. As with the parent instrument, scores vary from 0 (affect not at all) to 3 (affect very much).

Score 3 was interpreted as very much, 2 as a lot, 1 as a little and 0 as not at all and not relevant, in question 7, 'prevented work or studying' scored as 3. Maximum score is 30 and minimum score-0. The higher the score, the more QoL is impaired. Score fall between 0-1 was interpreted as no effect at all on patient's life, between 2-5 as small effect on patient's life, 6-10 as moderate effect on patient's life, 11-20 as very large effect on patient's life and 21-30 as extremely large effect on patient's life.[12,13] DLQI questionnaire was handed over to the patients who then filled the boxes and accordingly their scores were calculated before and after treatment. Patients were asked to come for a follow-up visit after 10-15 days in order to calculate the effectiveness as well as effects of treatment on patient's QoL. Out of 73 patients only 36 patients came for follow up and their data were analysed for DLQI score before and after therapy.

The statistical analysis was done using Microsoft excel office 365 and rechecked with IBM® SPSS version 25. Student's paired 't' test was used to calculate statical difference between the DLQI score of two groups and Unpaired t test was used calculate statical difference between direct cost, indirect cost and total cost of illness between the two groups. $P<0.001$ was considered as statistically significant.

Pharmacoeconomic analysis done by calculating direct cost, indirect cost and total cost of illness considering direct and indirect cost and percentage variability in cost of medicines. Direct costs were calculated that included medical cost (costs of treatment, cost of registration) and non-medical cost (cost of transportation and food). Indirect cost includes daily wage loss. The total cost was estimated by considering direct as well as indirect cost.

Drug today 2021 issues were reviewed for prices of drugs in terms of Indian rupees (INR) used in the management

of ASDs. The cost of medicines used for ASDs manufactured by different companies was estimated on the basis of medicines having the same strength and dosage form. The difference in the maximum price and minimum price of the medicine used for AIBSDs manufactured by different companies was calculated.

The formula for calculating variation in percentage of price was calculated by following formula.[14]

$$\frac{The\ price\ of\ most\ expensive\ brand - The\ price\ of\ least\ expensive\ brand}{\text{The price of least exensive brand}} \times 100$$

RESULTS

Demographic details

A total 73 patients of ASDs of either gender were enrolled in the study. Among them, 40 (55%) were of AIBDs and 33 (45%) of OADs. Demographic variables mentioned in Table 1.

Table 1: Demographic details.

Variables	ASDs, (n=73)	AIBDs, (n=40)	OADs, (n=33)
Mean age (years)	48.27± 14.93	53.37± 13.94	42.09± 13.89
F:M ratio	1.2	1.35	1.2

PV (65%) was the most common among the AIBDs and psoriasis (48%) was the most common among the OADs as shown in Figure 1 and 2 respectively.

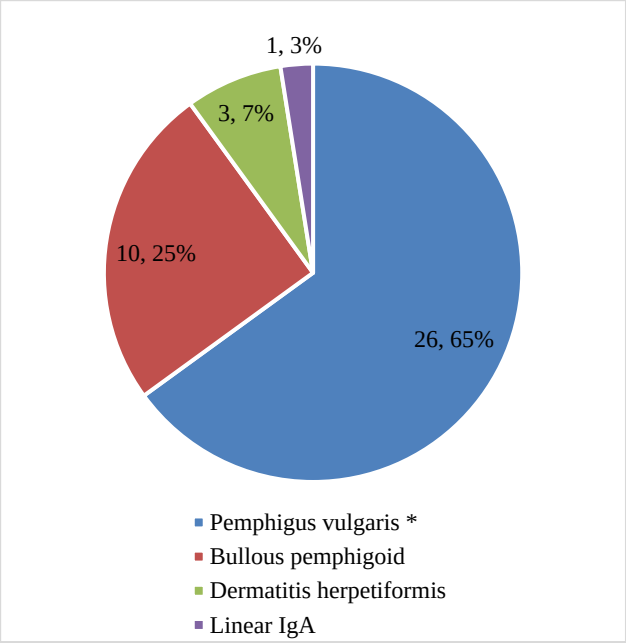

Figure 1: Subtypes of AIBDs.

*Out of 26 patients of PV, 17 (65%) were female and 9 (35%) were male.

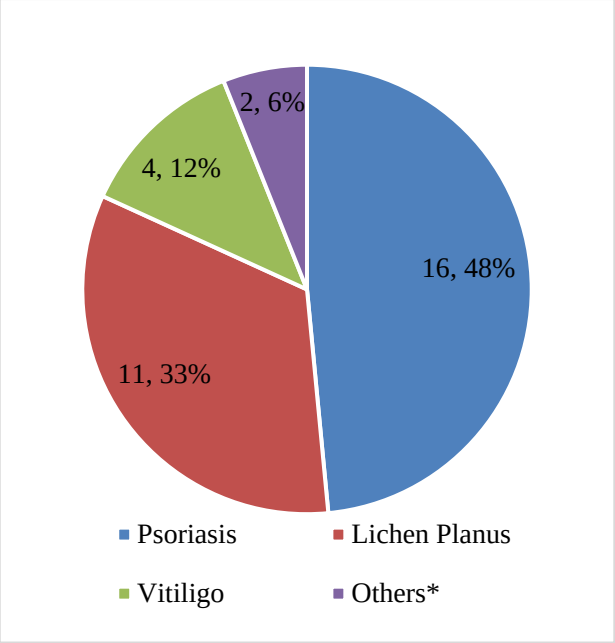

Figure 2: Subtypes of OADs.

*Others include Darrier's disease and Alopecia Areata

Overall, 35% (26) of patient had PV, 22% (16) had LP, 15% (11) had psoriasis, 13.7% (10) had BP followed by vitiligo (4; 5.5%), DH (3; 4.10%), linear IgA (1;1.3%), Darrier's disease (1;1.3%) and alopecia areata (1;1.3%).

Pattern of drug usage in patients with ASDs, (n=73)

Among 73 patients, topical steroids (58; 79.45%) were most commonly prescribed medication followed by anti-histaminic like levocetirizine (46; 63%) followed by prednisolone (44; 60.27%), topical salicylic acid (36; 49.31%), chlorpheniramine maleate (15; 21%). Other medication includes proton pump inhibitors (23; 32%) like pantoprazole or rabeprazole, iron and folic acid (23; 32%), multivitamins (22; 30%), endoxaban (9; 12%), dapsone (9; 12%), cefixime (7; 10%), azithromycin (5; 7%).

Among topical steroids (58; 79.45%), clobetasol propionate cream (42; 72.41%) was most commonly prescribed followed by betamethasone + fusidic acid combination (12%), fluocinolone lotion (9%), mometasone cream (3.4%) and beclomethasone dipropionate ointment (3.4%). Clobetasol was prescribed alone (14; 24.14%) or in combination with gentamicin (16; 28%) or salicylic acid (12; 21%).

Drug usage in AIBDs, (n=40)

Prednisolone (35; 87%) was most commonly given for the treatment of blistering skin disorder followed by topical steroids (30; 75%) like clobetasol, beclomethasone etc. In 5 (12.5%) patients they prescribed azathioprine + Prednisolone combination and in other 5 (12.5%) they prescribed cyclophosphamide + prednisolone combination.

Drug usage in OADs, (n=33)

Topical steroids (28;85%) >levocetirizine (22;66%) >salicylic acid topical application (17; 52%)>prednisolone (9; 27%) >proton pump inhibitors (8; 24%)>chlorpheniramine (6; 18%)> azithromycin (5; 15%) >dapsone (3; 9%).

Analysis of HRQOL

Average DLQI score among the patient of all autoimmune skin disorder was 11.87±2.63; 75.34% had very large effect, 21.92% had moderate effect and 2.74% had very small effect on their lives.

Average DLQI score in patients with AIBDs was 13.05±2.16; 36 (90%) of patient had very large effects on their QoL and 4 (10%) of patient had moderate effects on their QoL

Average DLQI score in patients with OADs was 10.4±2.47, (19)57.6% of patient had very large effect, (12) 36.4% had moderate effect and (2) 6% had small effect on their QoL.

Out of 73 patients only 36 patients came for follow up and their data were analysed for DLQI score before and after therapy as shown in Figure 3.

Pharmacoeconomic analysis

Total direct cost

It is was a sum of direct cost of both groups (ABDs and OADs). The mean ± SD was 707.47±443.38 INR

Total direct cost

It is was a sum of indirect cost of both groups (ABDs and OADs). The mean ± SD of total indirect cost was 106.16±135.61 INR.

Total cost of illness

It is a sum of direct and indirect cost of therapy. The mean ± SD was 813.64±481.21 INR.

There is a no statistical difference between the direct cost (p=0.104), indirect cost (p=0.185) and total cost of illness (p=0.485) between two (AIBDs and OADs) groups (p>0.001).

As shown in Table 3, in our study, the maximum variation in percentage was for prednisolone (1706.28%) followed by levocetirizine (723.57) followed by chlorpheniramine maleate (105.64%) followed by azathioprine (100%). The lowest percentage variation was seen with clobetasol and salicylic acid combination cream (22.22%).

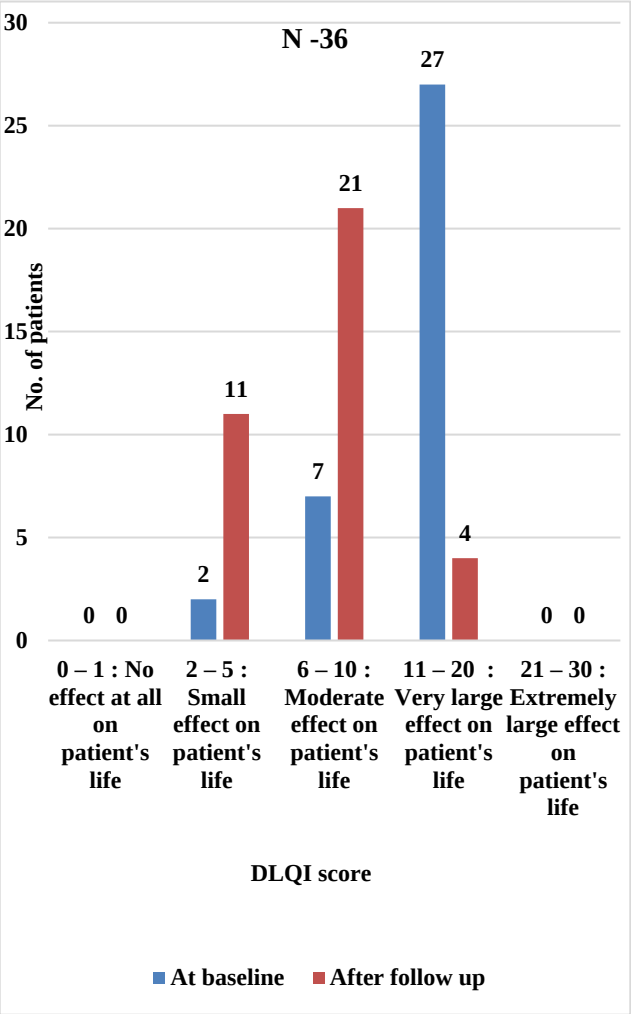

Figure 3: Analysis of DLQI score of patients at baseline and after follow up.

Figure shows analysis of DLQI score before and after giving treatment. At baseline, majority patients (27/40) had very large effects on their QoL whereas after treatment, majority i.e., 21/40 had moderate effects on their QoL.

Table 2: Overall mean of patient's DLQI score at baseline and after treatment.

DLQI score	Mean	Standard deviation	Standard error of mean	T value	Degree of freedom	P value
ABDs, (n=40)	13.05	2.16	0.34	4.8	71	<0.0001
OADs, (n=33)	10.45	2.47	0.43	4.72	64.07	
At baseline, (n=36)	11.64	2.49	0.41	11.16	35	<0.0001
After treatment, (n=36)	6.8	2.75	0.45			

Table 3: Percentage variability in cost of autoimmune skin disorder medications.

Autoimmune skin disorder medications	Strength and dosage form	Minimum cost (₹)	Maximum cost (₹)	Difference in cost (₹)	Variability in cost (%)
Clobetasol cream	0.05% cream	55	99	50	80
Clobetasol and gentamicin cream	0.05% and 0.1% (10 gm)	7.56	10.56	3	39.68
Clobetasol and salicylic acid cream	0.05% and 6% (15 gm)	45	55	10	22.22
Prednisolone	5 mg tablet	3.82	69	65.18	1706.28
Levocetirizine	5 mg tablet	7	57.65	50.65	723.57
Chlorpheniramine maleate	5 mg tablet	12.4	25.5	13.1	105.64
Cyclophosphamide	50 mg tablet	22.6	38	15.4	68.14
Azathioprine	50 mg tablet	60	120	60	100
Azithromycin	500 mg tablet	197	280	83	42.13

DISCUSSION

ASDs are chronic disorder that leads to great impairment of patients' QoL. The symptoms, clinical forms and the effects of treatment contribute to a greater morbidity. AIBDs present several clinical presentations with mucosal involvement, and/or a great extension of the tegument. Even though it presents a dropping rate of mortality due to the development of adjuvant treatments of the disease, all AIBD subtypes have a restricted prognosis, PV being the worst of them.[15]

Present study with 73 patients was undertaken in order to evaluate the drug usage, QoL and pharmacoeconomics. PV is the most common ASD; it preferentially affects women, and most of the patients are 50-60 years of age at disease onset that is comparable with the study by Kasperkiewicz et al.[16]

Analysis of demographic variables showed that females are more pretentious than male for developing ASDs. This is comparable with the study by Zhao et al.[17] Hormonal, immunological, microbiological and epigenetic theories can explain sex-specific autoimmunity. In females, sex hormones play a major role in increasing the vulnerability to autoimmune diseases. Sex hormone fluctuations during the menstrual cycle, pregnancy and menopause correlating to higher incidences of autoimmune diseases in females. Studies have shown that testosterone has a defensive action against immune system and estrogen stimulate the immune system.[18] These effects are due to sex hormone-dependent alteration of plasmacytoid dendritic cells' function, evident by in vivo mice models. Another theories are that estrogen can augment the immune response by stimulating the macrophages through Erα receptor and higher number of natural killer T cell in women than in men, with the effects of androgen and ERα exposure on its functioning elucidated by mice models.[19]

As per world health organization QoL assessment, QoL is a broad social concept that can be defined as an "individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns".[20] Dermatological disorders can affect the patients' daily lives and negatively affect their QoL.[21] Few studies have explored and quantified the effect of AIBDs on QoL.[22] When drug therapy for the ASDs is taken in an appropriate and continuous manner, then QoL of patients may show a positive impact. During the present study, DLQI questionnaire tool helped to understand the impact of ASDs on patient's QoL at baseline and after therapy. Here also, the limitation was 36 patients turning up for follow-up and in them mean DLQI scores were calculated before and after treatment. Results showed that before treatment, disease had very large effects on QoL and after treatment moved to moderate effects in a majority, thus showing benefits of treatment. Sung et al had analysed QoL in pemphigus patients and he found that DLQI score reduced during the disease remission phase because of treatment with steroids.[23] In our study using student's paired 't' test, it was also found that the mean difference between the two was highly significant ($p<0.0001$). This indicated the effectiveness of treatment with corticosteroids in those patients indirectly.

The first aim of treatment is to prompt disease remission. It should be followed by a period of maintenance treatment using the minimum drug doses required for disease control in order to minimize their side-effects.[24] Most patients are treated with CS, which are effective. Adjuvant drugs are commonly used in combination with the aims of increasing efficacy and of having a steroid-sparing action, thereby allowing reduced maintenance CS doses and reduced CS related side-effects. The most commonly used steroid-sparing immunosuppressive agents with steroids are azathioprine, mycophenolate mofetil (MMF) and cyclophosphamide to reduce maintenance dose of CS and reduce the side effects of CS. Although mortality and complete remission rates have improved since the introduction of adjuvant drugs, Ioannides et al found that cyclosporin as an adjuvant to corticosteroids was ineffective in patients with Pemphigus.[25] In our study corticosteroids were most commonly prescribed

medication, topical followed by solid dosage form. Among the topical corticosteroids, clobetasol propionate (72.41%) was most commonly prescribed followed by betamethasone + fusidic acid combination (12%). These findings were comparable with the study done by, Jena et al, Bylappa et al and Manju et al where clobetasol was the most common topical corticosteroid prescribed.[26-28] Manju et al stated that topical formulations of CSs were used extensively in many studies in dermatology because it had minimum side effects, unless systemic administration was inevitable.[28]

Other medicines include anti histaminic like levocetirizine, chlorpheniramine maleate to reduce the itching, proton pump inhibitors like rabeprazole and pantoprazole, multivitamins, iron and folic acid, dapsone, endoxaban, cefixime and azithromycin. Dapsone was the mainstay of treatment DH and linear IgA disease it also used in some cases of BP. In vitiligo different therapeutic approaches have been used, including the traditional therapy using corticosteroids, calcineurin inhibitors like tacrolimus ointment and narrow-band UVB or UBA radiation combined with the administration of oral photosensitizing molecules such as psoralen.

In our study pharmacoeconomic analysis was done by calculating direct cost, indirect cost and total cost of illness considering direct and indirect cost and percentage variability in cost of medicines. Direct costs were calculated that included medical cost (costs of treatment, cost of registration) and non-medical cost (cost of transportation and food). Indirect cost includes daily wage loss. The total cost was estimated by considering direct as well as indirect cost. The mean ± SD of total direct cost, total indirect cost and total cost of illness per month was 707.47±443.38 INR ,106.16±135.61 INR and 813.64±481.21 INR. There is a no statistically significant difference between the direct cost (p=0.104), indirect cost (p=0.185) and total cost of illness (p=0.485) between two groups (p>0.001). In developing country like India, drug prices play a pivotal role in healthcare. With adding growth of the Indian pharmaceuticals, the national market is full of branded generics manufactured with a lot of variations in the cost of different brands of the same formulation. There has been a worrying lack of consideration of the difference in the cost of various brands of drugs among the clinicians. This has resulted in an increase in the overall healthcare expenditures and has affected the financial status of the patients extremely. Our study showed highest cost variation seen with prednisolone (1706.28%) followed by levocetirizine (723.57%) which was most commonly used in ASDs. The lowest percentage variation was seen with clobetasol and salicylic acid combination cream (22.22%). Previously few studies of percentage variability of drugs commonly used in obstetrics and gynaecology and drugs for the thromboembolic disorders but there is no study on percentage variability in cost of medicines used in ASDs till now.[29]

Limitations

The study was carried out only in one tertiary care teaching hospital and conclusion of single focal study can't be extrapolated because of relatively small sample size as well as shorter duration of study.

CONCLUSION

ASDs have a female bias and are associated with higher disease incidence of AIBDs (55%) than OADs (45%). Corticosteroids were beneficial to a large no. of patients with ASDs. ASDs inflict severe impairment to the QoL of patients from a public outpatient clinic. Early precise diagnosis and therapeutic intervention aim to reduce the impact of QOL inflicted by ASDs. Work productivity remains evident as an important aspect of life that requires further research in adult patients with ASDs. We do not understand which aspects of ASDs have such a large impact on work productivity. Appropriate drug therapy with corticosteroids and other adjuvant drug lead to positive impact on QoL. In this study, there was very wide price variation of different brands of the same generic most commonly prednisolone and levocetirizine. For long term adherence to the treatment, cost of a drug plays an important role for successful drug therapy. This can be done by changes in the government policies and regulations, integrating pharmacoeconomics as part of medical education curriculum, and creating awareness among treating physicians for switching to cost effective therapy.

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