

Abuse of Topical Glucocorticoids among Patients Visiting Community Pharmacy in Basrah-Iraq

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Abstract

Introduction: Topical glucocorticoids have been the mainstay for the treatment of many skin conditions since their introduction due to their anti-inflammatory, anti-proliferative vasoconstrictive and immunosuppressive properties. Availability of topical glucocorticoids in different potencies as over the counter medication in Iraq encourages their use for non-labeled indications, thus increasing the side effect of such drugs.

Objectives: The aim of this study was to evaluate the use, knowledge of the patients and patient education of topical glucocorticoids.

Methodology: A cross sectional community pharmacy based survey was conducted throughout Basrah city. Inclusion criteria were costumers visiting the community pharmacies asking for topical corticosteroids without prescription, aging 15 years and older and willing to participate in the study. 600 questionnaire forms for topical corticosteroids were distributed in the center and the districts of Basrah city. 254 forms out of 600 were returned out of which 212 were completed. Incomplete forms were excluded.

Result: 106 (50%) participants out of 212 misused topical glucocorticoids. As a single product, Betamethasone valerate and Clobetasol propionate was majorly used by the participants which are potent and ultra-high potent topical steroid respectively. The major source of topical steroid prescription was relatives. 49.8% participants didn't recognize any side effect of topical glucocorticoids while hypopigmentation was the most side effect identified by the participants (21.8%). Only 35% of the participants, whom topical steroid prescription source by physicians and pharmacists, was educated about the use of topical glucocorticoids.

Conclusion: Topical glucocorticoids are commonly abused in Basrah city and probably other cities of Iraq. Looking fair and improving face appearance is a common cultural believe in Iraq that push people to seek topical glucocorticoids from community pharmacies for skin lightening in addition to other unapproved indications without prescription.

Key words: topical corticosteroids, abuse of topical corticoids, misuse of topical corticoids.

Introduction

Topical glucocorticoids possess various properties which make them very effective to be used for different

non-infectious dermatological conditions⁽¹⁾. These properties are anti-inflammatory, anti-proliferative, vasoconstrictive and immunosuppressive properties⁽²⁾. Hydrocortisone was the first introduced then with various structural modifications others, such as betamethasone, mometasone, clobetasol, dexamethasone and triamcinolone, was produced⁽³⁾. Due to their usefulness and effectiveness they have been used widely for treating inflammatory dermatologic diseases which

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led to their abuse and emergence of their side effects such as hypopigmentation, telangiectasia, acne, hypertrichosis, suppression of hypothalamic–pituitary–adrenal (HPA) and rosacea⁽⁴⁾⁽⁵⁾. Topical glucocorticoids are classified according to their potency into 7 classes by WHO, Class 1 (most potent) to Class 7 (least potent). The individual topical glucocorticoids may exist in different classes depending on formulation (cream or ointment) and concentration.

For example, betamethasone valerate ointment 0.05% is in Class II (potent), while betamethasone valerate cream 0.05% is in Class III (upper mid-strength⁽⁶⁾).

Abuse of the drug is using drug for non-medical purposes while misuse is the wrong use of the drug for medical purposes⁽⁷⁾. In Iraq and other developing countries topical glucocorticoids are purchased as over the counter drug without medical supervision, from some community pharmacies, for different medical purposes which is not accepted legally. That may be due to different reasons such as low patient income and insufficient regulatory enforcement level⁽⁷⁾. Usually Iraqi patient keeps the prescription after being dispensed to refill it again with or without medical supervision which may encourage drug abuse or misuse⁽⁸⁾. Low level of patients counseling and education or insufficient knowledge of healthcare providers decrease patients adherence and awareness about the side effect of glucocorticoids⁽⁹⁾⁽¹⁰⁾.

Topical glucocorticoids misuse occurs at different levels starting from pharmaceutical companies, prescription, sales ending with the patients and layperson. Pharmaceutical companies make irrational combinations such adding moderate potent steroid with other combination for treatment of melasma⁽³⁾. Prescription misuse of Topical glucocorticoids occurs when prescription requirements are not taken into consideration that ranges from incomplete prescription (not writing the strength and vehicle of TC, dosing, site of application and length of treatment on the prescription) to erratic prescription of topical glucocorticoids for the treatment of skin disorders with undetermined

diagnoses⁽²⁾.

Sales misuse can occur from over-the-counter (OTC) availability of all strengths and formulations of Topical glucocorticoids. This does not allow for proper supervision of patients' using topical steroid resulting in indiscriminate purchase for self, family and friends. Salespersons play a critical role, as they often dispense these agents⁽²⁾.

Topical glucocorticoids are used for incorrect indications tinea, nonspecific pruritus and acne, etc. by general practitioners, homemade doctors (parents, siblings, neighbors) and chemists. Use of combination of antibacterial or antifungal with topical glucocorticoids for the treatment of bacterial or fungal infection randomly has led to emergence of resistant organism⁽¹¹⁾.

Brown and dark races with no skin disease abuse topical glucocorticoids, to look fair and hide their blemishes, due to their vasoconstrictive and hypopigmentation effect. Some of the reasons indicates why topical glucocorticoids are abused as cosmetic cream, are shown below⁽¹¹⁾:

- inexpensive.
- Easily available.
- careless about adverse effects.
- incomplete counseling by prescribers when prescribing topical glucocorticoids for appropriate indication.
- Social attitudes to skin color

Topical glucocorticoids have been used for the treatment of melasma either alone or in combination with tretinoin and hydroquinone, this triple combination is known as Kligman's formula. Majority of cases treated with this combination subjected to relapse once stopped the treatment forcing them to use the treatment again for months without medical advice leading to adverse effects on their face such as telangiectasia, hypertrichosis, acne, skin atrophy⁽¹²⁾.

Topical steroids are being misused by parents for diaper rash in their children where excess use of which lead to Cushing's syndrome⁽¹³⁾.

Methodology

This study was a community pharmacy-based survey. It was carried out in Basrah city only as other cities of Iraq where inaccessible because of COVID19 Lock down.

This forma was allocated for costumers visiting the community pharmacies asking for topical or oral corticosteroids without prescription, aging 15 years and older and willing to participate in the study.

The questionnaires form comprised of six parts where the first part was about the sociodemographic information such as age, sex, place of residence and chronic diseases. The second question was to investigate the most topical corticoid asked by the patients while the third part identified the source of topical corticosteroids prescription. The fourth part was to investigate if the patients was educated properly about the use of corticosteroids and the fifth part was to identify the reason for using topical steroids. The last part to evaluate the awareness of the patients about the side effect of both topical corticosteroids.

Community pharmacists was, after providing the topical corticosteroids, asking the patients for their agreement verbally about participation in the study. After their agreement, the community pharmacist introduces the questionnaire paper (who was previously trained on) of the topical corticosteroids and report the answers of the patients. The survey was completely voluntary and required about 10 minutes to complete.

In this study we define abuse of the drug is using drug for non-medical purposes without prescription⁽⁷⁾

Sample size

600 forma of questionnaire for topical corticosteroids were distributed in the center and the districts of Basrah city. 254 forma out of 600 were returned out of which 212 were completed. Incomplete questionnaires were excluded from the study.

Statistical Analysis

Data has been tested using specialized software for data analysis and Microsoft Excel 2019. The data of this study were analyzed using descriptive statistic and chi-square test. The level of significant was considered for p less than 0.05.

Result

Table 1 shows characteristics of participants answered the questionnaire related to topical glucocorticoids where the total number of participants where 212. 52% of them are female and 48% are male, $p=0.4922$.

There was non-significant ($p<0.05$) difference among the ages of the patients that participated in the study where 33.1% had an age of (15-20), 31.1 had an age of (25-35) and 35.8 had an age of (>40), $p=0.6$

There was non-significant ($p<0.05$) difference among the education level of the patients participated in the study (18.4% illiterate, primary school 24.1%, high school 28.1%, graduated 29.2%, $p=0.1011$).

There was significant ($p<0.05$) difference in the residency of participants where 37% in the center of the city versus 63% outskirts, $p=0.0001$.

Table 1 Characteristics of participants in Questionnaire about topical glucocorticoids, N=212

Parameters	N	%	P value
gender			
Male	111	52	0.4922
Female	101	48	
Age Distribution (years)			
15-25	70	33.1	0.6987
25-35	66	31.1	
>35	76	35.8	
Scientific degree			
Illiterate	39	18.4	0.1011
Primary school	51	24.1	
High school	60	28.3	
Graduated	62	29.2	
Residency of participants			
center	78	37	0.0001
outskirt	134	63	
Disease history			
Hypertension	36	17	< 0.0001
Diabetes	19	9	
seizure	3	1.4	
Others	35	16.5	
Non	119	56.1	
P value <0.05 considered significant			

A Comparison the frequency of prescriptions sources for common types of topical glucocorticoids used by the participants

AS shown in table 2, there was a significant ($p < 0.05$) difference in sources of topical steroid prescription (physicians 22.5%, 24.3% from pharmacist, 7.3% from nurses, 30.3% from relatives, 7.3% from internet and 8.3

% from other sources).

Table 2 also represents the frequency of dispensed topical steroids; there was a significant difference ($p < 0.05$) among the dispensed steroids (betamethasone valerate 20.2%, Clobetasol propionate 15.1%, mometasone furoate 7.1%, hydrocortisone acetate 4.7% and others or combinations 52.8%, $p < 0.0001$).

Table 2 A Comparison the frequency of prescriptions sources for common types of topical glucocorticoids used by the participants in the questionnaire

Source of prescription	Beta-methasone valerate	Clobetasol propionate	Mometasone furoate	Hydro-cortisone acetate	Others*	Total N(%)	P value
physicians	7	4	10	5	23	49(22.5)	^ 0.0001
pharmacists	9	9	2	4	27	51(24.3)	
nurses	3	0	0	0	13	16(7.3)	
relatives	20	14	3	0	28	65(30.3)	
internet	0	2	0	1	10	13(7.3)	
others	4	3	0	0	11	18(8.3)	
Total (%)	43(20.2)	32(15.1)	15(7.1)	10(4.7)	112(52.8)	212(100)	

*P value <0.05 considered significant
 *others are products containing topical steroids with other products

A Comparison the frequency of reasons led to use topical glucocorticoids by participants

Table 3 shows the reasons for using topical glucocorticoids by the participants; where there was a significant difference (p<0.05) for the causes of using topical glucocorticoids among the patients (Eczema

7.5%, Allergic dermatitis 38.7%, Psoriasis 1.9%, Melasma 16.5%, Vaginal infection 3.3%, Acne 2.4%, Skin lighting 16%, Diaper rash 4.3%, Skin ulcer 0.5%, Wound healing 0.9%, Skin fungal infection 6.1%, p<0.0001

Table 3 Frequency of Reasons for using topical glucocorticoids mentioned by participants in the questionnaire. data expressed as N(%)

Reason of use	N(%)	P value
Eczema	16(7.5)	< 0.0001
Dermatitis	86(38.7)	
Psoriasis	4(1.9)	
Melasma	35(16.5)	
Vaginal infection	7(3.3)	
Acne	5(2.4)	
Skin lighting	34(16)	
Diaper rash	9(4.3)	
Skin ulcer	1(0.5)	
Wound healing	2(0.9)	
Skin fungal infection	13(6.1)	
Total	212(100)	

P value <0.05 considered significant
 Bold is irrational use(14)(15).

A Comparison the frequency of known adverse effects of topical glucocorticoids mentioned by the participants in the questionnaire

Table 4 shows a significant(p<0.05) difference in the knowledge of the patients about the side effects of steroids, (Delayed wound healing 6.3%, Striae 11.7%, Hypo/hyperpigmentation 21.8, Hirsutism 4.1, and the patients who didn't know were 49.8%, p<0.0001).

Table 4 Frequency of adverse effects of topical glucocorticoids described or known by the participants. Data expressed as N(%)

Side effects of glucocorticoids(16)	N(%)	P value
Delayed wound healing	15(6.3)	< 0.0001
Striae	28(11.7)	
Acne	15(6.3)	
hypopigmentation	52(21.8)	
Hirsutism	10(4.1)	
Don't know	126(49.8)	
Total	246(100)	

P value <0.05 considered significant
 Some participants indicated > 1 side effect

A Comparison the frequency of education of participants by pharmacists and physicians about the use and adverse effects of topical glucocorticoids

In Table 5 there is significant ($p < 0.05$) difference between number of the patients that have been educated by physician and pharmacists and those who have not been (65% versus 35%, $p = 0.0027$).

Table 5: A comparison between the source (physicians a pharmacists) of prescription and if the patient has been educated about the topical glucocorticoids or not. data expressed as N(%)

Source of prescription	Physicians	Pharmacists	Total N(%)	P value
Patients who have been educated	20	15	35(35)	0.0027
Patients who haven't been educated	29	36	65(65)	
Total	49	51	100	
P value < 0.05 considered significant				

Discussion

Table 2 demonstrates the frequency of prescriptions sources for common types of topical glucocorticoids used by the participants in the questionnaire. This study found that relative personnel are considered the main source of topical glucocorticoid prescription (p value < 0.0001) followed by pharmacists and physicians respectively. Meena S et al. found that pharmacists were the main source of prescription⁽¹⁷⁾.

That is may be due to most participants where from outskirt (63% versus 78%) or due low level of education (about 30% graduated versus 70% non-graduated). Other reasons are patients may have trust in their relative personnel that tried same product for same indication without getting advice from healthcare provider, this due to low economic conditions made the patients seek free of charge advice from the pharmacists rather than visiting the physicians.

A firm regulations about dispensing topical glucocorticoids by prescriptions from qualified

healthcare advisers should be made.

In contrast to this study, Hon et al 2006 in china found that physicians are the main source of topical glucocorticoids prescriptions followed by newspaper⁽¹⁸⁾. Also a different results were found by Lee et al 2015 in Korea where internet was the main source of prescriptions followed by media or TV⁽¹⁹⁾.

As a single product betamethasone was the most prescribed topical glucocorticoids followed by clobetasol. Deena et al. 2014 in Mosul-Iraq found the same result while different results was found by Al-Dhalim et al 2006 in Najaf-Iraq where clobetasol was the most prescribed followed by betamethasone⁽²⁰⁾⁽²¹⁾ In Meena S et al. Clobetasol was the most prescribed topical glucocorticoids⁽¹⁷⁾.

These are highly potent topical glucocorticoids and only physicians have the right to prescribe them while other sources are considered unofficial sources which includes pharmacists also as these products are non-OTC products. In this study relatives of the patients are more

familiar with betamethasone and clobetasol than other single products, therefore, they are the most prescribed and misused because relatives are unofficial source of prescription.

Majority of mometasone prescriptions has been prescribed by its official source (physicians) because relatives of the patients, main source of prescription in this study, are not familiar with mometasone or due to its high cost. Hydrocortisone is the other topical products prescribed by its official sources as relatives may not be familiar with it.

In Charman et al 2000 in UK; hydrocortisone was the most prescribed topical glucocorticoids followed by betamethasone which is not matched with this study(22). Also different results were found in.

Table 3 expresses what topical glucocorticoids was used for by the patients. 50% of the participants used topical glucocorticoids for unapproved indications where skin lightening and melasma were the most reason of use. Also same result were found by Deena et al. 2014 in Mosul-Iraq⁽²⁰⁾. In Al-Dhalim et al 2006 in ALNAJAF-IRAQ skin lightening and acne were the most reason of use⁽²¹⁾. Fungal infection and acne were the most reasons of use while skin lightening was the third most reason of use in Meena S et al.⁽¹⁷⁾.

Table 4 expresses the knowledge of the patients about the side effect of topical glucocorticoids. About 50 % of the patients didn't know any side effects of topical glucocorticoids. Hypopigmentation is the most side effect known by the patients and this clarifies the use topical steroids for skin fairness.

Table 5 demonstrate the level of education for patients whose source of prescription was physicians and pharmacists only as its their duty to ensure safety and a suitable use of the medication(23). A significantly higher percent (p value 0.0027) of patients was not educated by either physicians and pharmacists indicating inadequate level of patient's education practiced by them.

A similar result were found by Wing Man Lau et al. where pharmacists were less likely to advice the patients

about topical glucocorticoids(24). Ammar Abdulrahman Jairoun et al. found that deficiency in curriculum of pharmacy courses also affects the practice and advising process regarding topical glucocorticoids(25).

low level of patients counseling may be due to lack of information or time, the patients feel negatively about topical glucocorticoids or/and the physicians feel negatively about the counseling for topical glucocorticoids by the pharmacists. Min Jung Kang et al. found that bad feeling and physicians attitude was the most barrier for counseling⁽⁹⁾.

This study finds that topical glucocorticoids are abused commonly in Basra city and probably in other cities of Iraq also where Al-Dhalim et al 2006 in Najaf (another city in Iraq) and Deena et al. 2014 in Mosul(another city in Iraq) found the same results. In this study the major responsibility of misuse was put on the relatives of the patients. Pharmacists also bear a part of the responsibility as they were dispensing a potent topical glucocorticoids as OTC, or with prescription but with inadequate level of education. On other hand potent topical glucocorticoids relive the symptoms of the patients and after stopping the medication the symptoms recur leading the patients to reuse the potent topical glucocorticoids again without seeking medical advice.

Physicians and pharmacists should develop an intense relationship, reduce the inter-professional practice gap and improve communication lead to delivering a unified clear message about drug use and safety for the patients(26)⁽⁹⁾.

Conclusion

In Basrah-Iraq, topical glucocorticoids are used without prescription for unapproved indication such as skin lightening and melasma in addition to other unapproved indication. Having culturally accepted skin color represents the dominant incentive that urges people to abuse topical glucocorticoids. Betamethasone valerate is the predominant abused or misused topical glucocorticoids as a single product. Half of the participants who abuse topical glucocorticoids are

unaware of their adverse effect.

Community pharmacists can enhance people knowledge about the adverse effects of topical glucocorticoids through counseling before dispensing. Finally, Iraqi health officials need to promote people awareness about the risks of misusing topical glucocorticoids without medical supervision through education programs and advertisements in public health settings, media, and social networks.

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