INAPPROPRIATE USE OF TOPICAL CORTICOSTEROIDES IN THE DERMATOLOGY OUTPATIENT

Ivona Lovrić¹, Ivan Tomić¹, Ivona Tomić², Ivan Zeljko¹, Mateo Bevanda¹, Marta Mandić², Sanjin Lovrić³ & Dubravka Šimić^{1,2,3}

¹Department of Dermatology and Venereology, Clinical Hospital Mostar, Mostar, Bosnia and Herzegovina ²Faculty of Pharmacy, University of Mostar, Mostar, Bosnia and Herzegovina ³School of Medicine, University of Mostar, Mostar, Bosnia and Herzegovina

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SUMMARY

Introduction: Topical corticosteroids are group of drugs which have anti-inflammatory, immuno-suppressive, anti-proliferative and vasoconstrictive effects and are among the most commonly prescribed medication, important and efficacious for management of various dermatological disorders. Strict implementation of the existing regulations is the need of the hour to prevent their widespread abuse. Aim of the study was to investigate the usage of topical corticosteroids therapy with the recipe of a doctor and without it.

Subjects and methods: The subjects were patients who visited Pharmacies in Mostar from April to July 2020 and were buying topical corticosteroids with or without a recipe or medical report from the doctor. 80 subjects completed a questionnaire themselves included: the way of buying a topical corticosteroids, the information about using topical corticosteroids earlier, the information about subject's visits to the doctor; the length of time using topical corticosteroids, the type of topical corticosteroids used, the part of body the topical corticosteroids was applied on.

Results: A total of 80 subjects were treated in the observed period, 58.8% were female. 72.5% subjects had already used local corticosteroids, 62.50% purchased the drug at the recommendation of the pharmacist, 66.30% had no recent diagnosis or no diagnosed disease at all, 21.25% used the drug for more than a month, the most often purchased one was moderate potent local corticosteroid Betamethasone diproprionate 0.05%. Most commonly subjects applied local corticosteroids on arms (50%).

Conclusion: Strict regulations regarding only prescription-based dispensing of local corticosteroids must be put into practice. This will hopefully bring down both the extremes of ever increasing cases of steroid-induced dermatoses in everyday dermatology practise on one hand and the irrational fears of using TCs in well justified indications on the other.

Key words: topical corticosteroids - outpatient dermatology - recipe, improper use of topical corticosteroids

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INTRODUCTION

Topical corticosteroids (TCs) are group of drugs which have anti-inflammatory, immuno-suppressive, anti-proliferative and vasoconstrictive effects (Uva et al. 2012). TCs are among the most commonly prescribed medication in an out-patient dermatology setting since they were first introduced (Tadicherla et al. 2009). TCs have greatly contributed to the dermatologist's ability to effectively treat several difficult dermatoses. However, the rapid rise in incidence of improper use of these drugs by dermatologists, general physicians, and patients threatens to bring disrepute to the entire group of these amazing drugs (Al-Dhalimi & Aljawahiri 2006). Benefits of rational and ethical use and the harm of overuse and misuse for nonmedical, specially for cosmetic purposes, should be clearly conveyed before penning a prescription involving TCs. This will hopefully bring down both the extremes of ever increasing cases of steroid-induced dermatoses on one hand and the irrational fears of using TCs in well justified indications on the other (Rathi & D'Souza 2012). Studies in patients presenting with steroid-related eruptions have shown that there are several nonmedical

advisers like friends, neighbors, beauticians, barbers, etc. telling them to use it as fairness/cosmetic creams, anti-acne, anti-fungal therapy and for that matter any skin eruptions (Rathi 2006). There is a tendency to reuse old prescription for a recurrent or new rash. Prescription sharing with relatives and friends on the presumption that similar looking skin problems can be self-treated by simple prescription copying is rampant. To compound this problem, there is easy availability of these drugs almost for the asking without a valid prescription at every chemist shop. Moreover, store pharmacists also double up as doctors doling out advice about which TCs to use. These instances are reported from many places worldwide (Kumar et al. 2011, 2016). Inappropriate or excessive use of topical corticosteroids can lead to cutaneous and systemic adverse effects which occur more commonly with the use of very potent steroids. Monitoring and analysis of the prescription practices of topical steroids can help to achieve rational prescription of these drugs (Suvarna Rathod et al. 2013). To minimize adverse cutaneous and systemic reactions, especially with prolonged use, the rational use of topical steroids should include careful consideration of the patient's age, total area of application, quantity to be

applied, efficacy of the selected corticosteroid, and frequency of application (Saraswat et al. 2011). For successful treatment with TC, key factors to be considered are accurate diagnosis, selecting the correct drug, keeping in mind the potency, delivery vehicle, frequency of application, duration of treatment and adverse effects, and proper patient profiling (Ference & Last 2009). The potency of TCs is usually assessed by measurement of vaso-constrictive properties. This helps to classify TCs based on the extent to which the agent causes cutaneous vasoconstriction ('blanching effect') in a normal, healthy person. This is a useful but not perfect method for predicting the clinical effectiveness of steroids (Olsen 1991). Paradoxically, the same mechanisms which mediate their anti-inflammatory properties and underlie their usefulness are also responsible for their adverse effects (Hengge et al. 2006). TCs are divided into four groups according to their potency in keeping with the British National Formulary (BNF), while American system classifies them into seven classes, with class I being the super potent or ultra potent and class VII represent the least potent (Brazzini & Pimpinneli 2002).

As a general rule, low potency steroids are the safest agents for long-term use, on large surface areas, on the face, or on areas with thinner skin and for children. More potent TCs are helpful for severe disease and for thicker skin of palms and soles. High and ultra-high potency steroids should not be used on the face, groin, axillae, and under occlusion; except in rare situations and for short duration (Sheman 2006). They are encountered more frequently and have become more prevalent with the introduction of high potency TCs. These side effects depend on potency of steroid, duration of use (i.e. extended period), volume of the product applied (i.e. excessive amount), site of application, age of the patient and occlusion (if present) (Rathi & D'Souza 2012).

The aim of this study was to investigate the usage of topical corticosteroid therapy with the recipe of a doctor and without it.

SUBJECTS AND METHODS

This was a prospective study and the materials were taken in the period from April to July 2020 in the Mostar Pharmacies. The subjects were patients who visited Pharmacies in Mostar and were buying topical corticosteroids with or without a recipe or medical report from the doctor. The study included 80 subjects (33 men, 47 women). The subjects completed a questionnaire themselves, but if the subjects were children the questionnaire was completed by either of parents. The questionnaire consisted of 3 major group of questions with answers yes or no. Parameters like age and gender were included in the study and the questionnaire also included: the way of buying a topical corticosteroids (with or without the advice of a doctor, with a diagnose), the information about using topical corticosteroids earlier, the information about subject's visits to the doctor; the length of time using topical corticosteroids, the type of topical corticosteroids used, the part of body the topical corticosteroids was applied on.

Statistical analysis

All collected data were processed and stored in MS Excel 11.0 (Microsoft Corporation, Redmond WA, USA). SPSS 23.0 (SPSS, Chicago, IL, USA) was used for statistical analyses. Frequency distributions and percentages were used to describe categorical variables. Descriptive statistics were used for continuous variables (mean and standard deviation). Hi-square test was used for quantitative analysis.

RESULTS

Distribution by gender and age

A total of 80 (N=80) subjects were treated in the observed period. Out of the total number 33 (41.3%) were male and 47 (58.8%) female. There is no statistically significant difference between male and female gender, (χ^2 =2.450; df = 1; p=0.118) (Table 1).

The mean age of all subjects, expressed as arithmetic mean and standard deviation, was 44.66 years (SD = 2.741). In male, the average life expectancy was 42.55 (SD 23.517) and in female 46.15 (SD 20.532). The youngest male subjects was 2 years old and the oldest 77, while the youngest female was 3 years old, and the oldest one was 78 years (Table 1).

Table 1. Total number of subjects and the average life time by gender, expressed as arithmetic mean (M) and standard deviation (SD).

Gender	N	М	SD
Male	33	42.55	23.517
Female	47	46.15	20.532

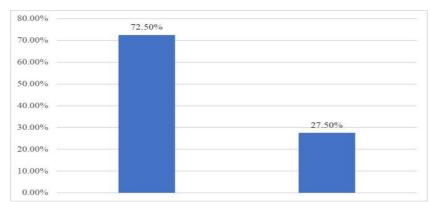
T-test for independent samples was used to test the significance of differences between male and female. There were no statistically significant differences, i.e. that male and female were aproximately the same age (t-test =-0.728; df = 78; p=0.469).

Survey results

The survey sample included a total of 80 subjects.

58 subjects (72.5%) had already used local corticosteroids, while less than 22 (27.5%) subjects used them for the first time (Figure 1).

Out of the total number of subjects, 30 (37.5%) bought a local corticosteroid with prescription of the physician while 50 subjects (62.50%) purchased the drug at the recommendation of the pharmacist (Figure 2).





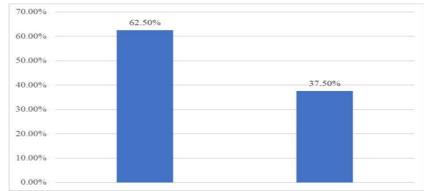


Figure 2. The frequency of subjects who purchased a local corticosteroid at a physician's recommendation and the recommendation of a pharmacist

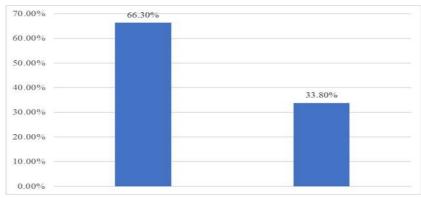


Figure 3. Frequency of subjects with and without diagnosed disease

Out of the total number of subjects using the local corticosteroid, 27 (33.80%) had a diagnosed disease, while the other 66.30% had no recent diagnosis or no diagnosed disease at all (Figure 3).

17 patients (21.25%) used the drug for more than a month, while only 2 subjects (2.5%) used the formulation for more than 6 months.

As for frequency of the purchased local corticosteroids the most often purchased one was moderate potent local corticosteroid Betamethasone diproprionate 0.05%, (in 33 cases or 41.3%) followed by low-potency Hydrocortisone sodium phospate, mild (21 cases or 26.3%) and moderate potent 0.5 mg betamethasone diproprionate + 30 mg acidum salicilyci in 11 cases (13.8%). The other local corticosteroids were purchased at a lower percentage (Figure 4). There was a statistically significant difference between the age of subjects and potency of three most common types of local corticosteroids purchased ($\chi^{2}=177.081$; df = 3; p<0.01).

According to the potency of the purchased local corticosteroids there was no statistically significant difference in relation to the gender of the subjects (χ^2 =11.040; df = 5; p=0.051) Fisher's exact test.

Frequencies of use of local corticosteroids on certain parts of the body: according to the results of the survey subjects were using the local corticosteroids on several different parts of the body. They were most commonly applied on arms (50%), then trunk (41.30%), legs (31.30%) face (13.80%), the genital area (6.30%) and the scalp (1.3%) (Figure 5).

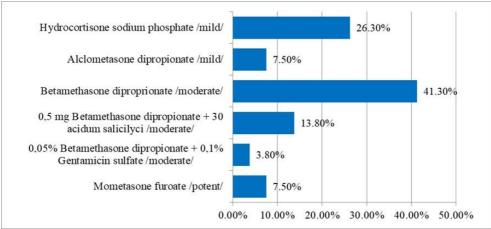


Figure 4. Frequency of purchased local corticosteroids by potency

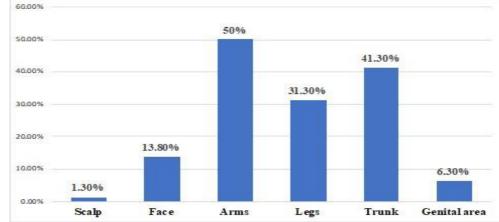


Figure 5. Frequency of use of local corticosteroids on individual parts of the body

DISCUSSION

Topical corticosteroids (TCs) are readily available and widely used in some part of Bosnia and Herzegovina as over the counter drugs. Generally, the problem of drug abuse is more present in Eastern countries. TCs are commonly used in all age groups regardless of their potency but their use must be indicated and prescribed by physician. However, already reported cases of 'steroid withdrawal syndrome' indicate that TCs overuse exists. Many studies have observed excessive and inappropriate use of potent TCs. In the study carried out in India, the prescription and use of TCs were observed in 200 patients attending a dermatology outpatient clinic. Potent TCs were commonly used in 86 (43%) patients. The quantity of TC was mentioned in only 4%, frequency of application was mentioned in 77%, the site of application in 69%, and duration of treatment in 55% of the total prescriptions (Rathi & D'Souza 2012, Uppal et al. 1991). Another study conducted on the prescription of TCs in north Palestine showed that TC are commonly prescribed for outpatients attending dermatology clinics there (51.6%). The quantity of the corticosteroid to be applied was not mentioned in 87.7% of the prescriptions and duration of use not mentioned in 71.6% (Sweileh

prescribing information about TCs was inadequate in majority of the prescriptions. The diagnosis and main complaints were not mentioned in about 85% of the prescriptions in which steroids were prescribed. In these 85% prescriptions, the basis of prescribing TCs could not be established. There may be a possibility of prescribing these drugs for the conditions where they are not indicated which suggests irrational use. The practice of inadequate prescription writing may mislead the patient about usage of medications which may be responsible for overutilization or underutilization of steroids resulting in potential side effects or subtherapeutic response to a drug, respectively (Saraswat et al. 2011). The result of this study has revealed that most TCs were being utilized without a prescription. In a study by Tsegaye et al more than two third (68.5%) of the participants utilized TCs as over the counter (OTC) and majority (60%) used the TCs for beautification purpose. Most of the participants (44.1%) in the study area selected the TCs by consulting a health professional while about one third of the participants selected TCs by asking a friend or pharmacist (similar with our results). Many of the participants (73.4%) claimed to read information that is

2006). TCs were prescribed in 28.4% of all the

prescriptions. Analysis of the prescriptions showed that

written on the container and 138 (48.3%) have reported that they read this information always when purchasing cosmetics (Tsegaye et al. 2018). In the study by Motghare et al. 94.36% among the topical steroids prescribed belonged to very potent groups (fluocinolone, clobetasol) which shows a trend toward prescribing potent steroids. The prescription of very potent steroids should be limited when possible (Motghare et al. 1995). Long and excessive use may carry the risk of suppression of the hypothalamic-pituitary-adrenal axis as well as local adverse effects (Walsh et al. 1993).

CONCLUSION

This study showed a trend of prescribing more mild and moderate potent steroids. This could be explained by availability of these medications as over the counter drugs in pharmacies, but the prescription of these drugs by physician cannot be overlooked. Strict regulations regarding only prescription-based dispensing of TCs must be put into practice. This will hopefully bring down both the extremes of ever increasing cases of steroid-induced dermatoses in everyday dermatology practise on one hand and the irrational fears of using TCs in well justified indications on the other. However, this may not be possible without simultaneous efforts of all legal institutions.

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Contribution of individual authors:

- Ivona Lovrić, Ivona Tomić & Dubravka Šimić conception and design of the manuscript and interpretation of data, literature searches and analyses, evaluations, manuscript preparation and writing the paper.
- Marta Mandić, Sanjin Lovrić & Dubravka Šimić made substantial contributions to conception and design, participated in revising the article and gave final approval of the version to be submitted.

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Correspondence:

Professor Dubravka Šimić MD, PhD School of Medicine, University of Mostar Bijeli Brijeg bb., 88 000 Mostar, Bosnia and Herzegovina E-mail: dubravka.simic@mef.sum.ba

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