Perspective

Sales, status, prescriptions and regulatory problems with topical steroids in India

Shyam B. Verma

Many members of the Indian Association of Dermatologists, Venereologists and Leprologists (IADVL) are increasingly discussing the abuse of topical steroids in India, their unregulated sale, the easy access to this group of drugs, and the damage caused, much of which goes unnoticed. There are Indian reports about the problem including a multi-centric study on topical steroid-damaged face conducted by the IADVL.[1-3] However, there is little information or discussion about the size of the dermatologic market, the size of the topical steroid market, the most popular topical steroids and their combinations, the number of prescriptions generated, who writes these prescriptions etc. This data is clearly important and will help us make a stronger case to the authorities for the curbing of this menace.

FIGURES ON SALES OF TOPICAL STEROIDS

IMS Health among other services provides data about over a million drug products in India and measures 75% of ethical drug sales (i.e., upon the prescription of a registered medical practitioner) which supports more than 3000 pharma manufacturers through 29,000 data suppliers and 225,000 chemists.[4] According to this agency, topical steroid sale for 2013 at the end of December stood at Rs. 1400 crores, (Approx. US$233 million**) showing an annual growth of 16%. The sale accounts for 82% of the topical dermatology market, a clear reflection of the popularity of topical steroids. There are a total of 1066 brands of topical steroids sold in the Indian market. The top selling combination preparations of topical steroids contain beclomethasone, neomycin and clotrimazole with a sale of Rs. 152 crores (approx. US$25 million**) in 2013. This is followed by combination products containing clobetasol, ofloxacin, ornidazole and terbinafine which sold Rs 110 crores (approx. $18 million**) [Table 1]. This means that the top two positions are enjoyed by 'broad spectrum' products despite the lack of scientific rationale or logic. According to IMS Health data, the top prescriber for topical steroid and combinations is the dermatologist followed by general practitioners, obstetrician and gynecologists, pediatricians and physicians [Tables 2 and 3].

Consultant Dermatologist, Chief Editor, Indian Dermatology Online Journal, Vadodara, India

Address for correspondence: Dr. Shyam B Verma, 18, Amee Society, Diwalipura, Vadodara - 390 015, Gujarat, India. E-mail: skindiaverma@gmail.com

Access this article online

Quick Response Code:

Website: www.ijdvl.com

DOI: 10.4103/0378-6323.132246

PMID: 24823396

GENERAL POPULATION AND PHYSICIAN POPULATION OF INDIA

The population of India today is 1.21 billion out of which about 70% live in villages.[5-7] The dermatologist population in India is currently approximately 7500. More than 80% of them practice in urban areas. This leads to a skewed ratio of very few dermatologists for a majority of Indian population who live in rural areas. The scenario is the same for all specialists in villages. The result is that the general practitioner/registered medical practitioners/AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy) doctor treats dermatoses which he is inadequately trained to do and that includes injudiciously prescribing steroids.

ERRANT CHEMISTS AND CONFUSING INTERPRETATION OF TOPICAL STEROIDS BY THE GOVERNMENT

There are approximately 700,000 chemists in India.

How to cite this article: Verma SB. Sales, status, prescriptions and regulatory problems with topical steroids in India. Indian J Dermatol Venereol Leprol 2014;80:201-3.

Received: January, 2014. **Accepted:** March, 2014. **Source of Support:** Nil. **Conflict of Interest:** None declared.

Table 1: Top three sellers of topical steroids combinations

Beclomethasone+Neomycin+Clotrimazole	152 crores
Clobetasol+Ofloxacin+Ornidazole+Terbinafine	110 crores
Steroids+salicylic acid	102 crores

Table 2: Top prescribers of topical steroids

	Projected prescriptions	Avg Drs	Rxs per doctor
Total	46,482,631	151,904	25
Dermatologist	15,784,101	5,505	239
G.P.(total)	14,988,671	69,469	18
Gynecologist	4,340,023	19,779	18
Pediatrician	4,312,653	14,807	24
Consulting Physician	2,449,534	13,459	15

Table 3: Top brands sold and their manufacturers

Surfaz-SN	Franco Indian
Quadriderm-RF	MSD pharmaceutical
Cloben-G	Indoco*
Panderm+	Macleods Pharma
Terbinaforce-plus	Mankind
Propysalic-NF	Hegde and Hegde
Dipsalic-F	MSD Pharmaceutical
Betnovate-N	GlaxoSmithKline*
Betnovate-C	GlaxoSmithKline*
Candid	Glenmark
Lobate-GM NEO	Abbott*
Betnovate-GM	GlaxoSmithKline*
Zole-F	Ranbaxy
Elocon	MSD pharmaceutical
Momate	Glenmark
Candid-B	Glenmark
Tenovate	GlaxoSmithKline*

*All topical steroid sales and volumes data have been accessed in the month of November 2013 and were made available through the help of a corporate annual subscription to IMS-Health data. This information is not readily available without a valid subscription, All INR to US$ conversions are calculated with an approximate conversion rate of INR. 60 to 1 US$

They are known to become ‘medical advisors’ who advise and sell topical steroids, most often potent topical steroids, and unscientific steroid combinations.[2,6] Many people self-treat their dermatoses with topical steroids and buy whatever brand they have heard about. There is often prescription sharing among family members and friends, too and chemists sell the drug to the client without a valid prescription and often in large numbers.

IMS-Health data does not include over-the-counter sales. Therefore, the actual units of topical steroid creams may be much more than what is estimated by IMS Health since the company derives its data from extrapolation from top prescribers and top pharmacists. Perusal of the relevant section of the book “Law related to drugs and cosmetics” indicates that topical steroids are Schedule H drugs, meaning they need to be sold strictly upon the prescription of a registered medical practitioner.[8,9] Strangely only clobetasol propionate, clobetasone 17-butyrate, fluticasone propionate and mometasone furoate are included in the list of Schedule H drugs.[8,9] No other steroid molecules find a mention. The largest selling class of topical steroids in various combinations with antifungals and antibacterials are not in the list of Schedule H drugs! A note at the bottom of the list confuses matters more by stating that topically applied drugs do not come under the category of Schedule H which itself is a grey area waiting to be interpreted correctly.

MUCH NEEDED POLICIES RELATED TO TOPICAL STEROIDS: TOO SMALL A MATTER IN THE LARGER SCHEME OF THINGS?

In the Rs. 66000 crore (approx US$ 1.1 billion**) Indian pharmaceutical market, Rs. 1400 crores (approx. US$ 233 million**) topical steroid market is too insignificant to catch the attention of policy makers like the Central Drugs Standard Controls Office that houses the staff of the Drug Controller General of India. The voice of dermatology has never been loud enough in the offices of policy makers mentioned above or the Ministry of Health. Following are some glaring examples. The latest National List of Essential Medicines (NLEM) of 348 drugs, updated in 2011 (and to be revised in 2014) has included only one topical steroid and that is betamethasone dipropionate![10] The team of experts invited by the government to participate in preparing the NLEM of 2011 included only one dermatologist![10] From the analysis of the affidavit filed in the Supreme Court in November 2013 in a drug pricing case by All India Drug Action Network and others vs Union of India and others, 99.8% of topical steroids are out of price control, i.e., have escaped inclusion in Drug Price Control Order.[11] The understanding and importance of dermatology prescriptions in general seems quite low considering that there are only five dermatological drugs including one topical steroid listed in the NLEM.[10]

WHAT WOULD BE THE WAY FORWARD?

This is too complex an issue and is outside the scope of the article. IADVL needs to make necessary representations to the Health Ministry and the Drug

Controller General of India. The importance of dermatology and the potential hazards of topical steroid abuse need to be constantly discussed with policy makers to sensitize them to the problem. Repeatedly explaining the magnitude of the problem and following up are only ways of trying to effectively fight this scourge. Apart from taking up the issue with the government we need to, individually and collectively, educate the public about topical steroids, their advantages and their adverse reactions when abused and when bought without a medical practitioner's prescription. Irrational combinations need to be weeded out by dialogues with the industry and by drawing the attention of the DGCO. Public education regarding this issue is necessary at many levels and through many sources. For all this to happen we will need to earmark this problem, prioritize it and then act on it on a war footing. Only then will we be able to begin to shake the system out of its inertia.

REFERENCES

1. Verma S.Effect of alternative medicinal systems and general practice. Int J Dermatol 2007;46 Suppl 2:46-50.
2. Rathi SK, D'Souza P. Rational and ethical use of topical corticosteroids based on safety and efficacy. Indian J Dermatol 2012;57:251-9.
3. Saraswat A, Lahiri K, Chatterjee M, Barua S, Coondoo A, Mittal A, *et al*. Topical corticosteroid abuse on the face: A prospective, multicenter study of dermatology outpatients. Indian J Dermatol Venereol Leprol 2011;77:160-6.
4. Imshealth.DanburyCT.Available from: http://www.imshealth.com/. [Last accessed on 2014 January 2.
5. University College of Medical Sciences.NewDelhiUniversity College of Health Sciences. Selected Health Statistics of India. Available from: http://www.ucms.ac.in/Selected%20health%20statistics%20of%20India%20October%202012.pdf. [Last accessed on 2013 Jan 17].
6. Verma S. Nonclinical challenges of Indian dermatology-cities vs. villages, poverty and lack of awareness. Int J Dermatol2007;46 Suppl 2:42-5.
7. Yeravdekar R, Yeravdekar VR, Tutakne MA, Bhatia NP, Tambe M. Strengthening of primary health care: Key to deliver inclusive health care. Indian J Public Health 2013;57:59-64.
8. Laws Relatingto Drugs and Cosmetics. Malik V, editor. Lucknow: Eastern Book Company; 2010. p. 409-16.
9. Drug Control. Jaipur. Drugs and Cosmetics (2nd Amendment) Rules.Available from: http://www.drugscontrol.org/Schedule_H.pdf. [Last accessed on 2014 Jan 18].
10. World Health Organisation. National List of Essential Medicines of India. Available from: http://www.searo.who.int/entity/medicines/neml_ind_2011_govweb_ok.pdf. [Last accessed on 2014 Jan 18].
11. Government of India. Departmentof Pharmaceuticals. Available from: http://pharmaceuticals.gov.in/DPCO2013.pdf. [Last accessed on 2014 Jan 17].