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Pharmacoeconomic Study of Topical Dermatological Products Available in Indian Market

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INTRODUCTION

Drug therapy is an integral part of health services [1]. Drug costs forms a considerable portion of treatment costs, varying from 30 to 40% in developing countries [2]. Adherence to treatment and outcome of therapy are clearly related to the cost of therapy. Increased cost of treatment decreases compliance and affect the outcome negatively. So every attempt should be made to decrease the cost of treatment without compromising efficacy [3]. Skin is the largest organ of human body. It is exposed to various external factors such as chemical, infectious, environmental as well as internal factors such as metabolic, immunological and genetic which contribute to different skin disorders. Many systemic diseases and adverse effects of drugs also manifest as dermatological signs and symptoms [4]. Skin disease is one of the most common human illnesses and causes a huge disease burden globally. It is seen in all cultures, occurs at all age groups, and affects 30% to 70% of population. Globally, it was 4th leading cause of nonfatal health burden in 2010 [5]. India being a tropical country, skin diseases like fungal infections, pyoderma, acne, scabies etc. are very common [6]. Skin disorders affect quality of life of the patients because

Abstract: India is a tropical country where skin diseases like fungal infections, pyoderma, acne, scabies etc. are very common. A large number of dermatological preparations are available in Indian market but studies on the price variation between commonly used topical brands are lacking. Hence the present study was carried out to obtain information on the price variation among different brands of anti-infective, anti-acne & analgesic topical preparations present in India. Information about dosage forms and prices of different brands of commonly used topical preparations was obtained from Current Index of Medical Specialties & Drug Update. Number of brands, percentage price variation, cost ratio etc for various drugs and combinations were calculated. There were total 206 brands manufactured by 52 different pharmaceutical companies of 35 drugs, out of which 24 showed more than 50% cost variation. Largest price variations were seen with mupirocin 2% cream (408.33 %), tazarotene 0.05% gel (183.8%) and diclofenac diethylammonium 1% gel (650 %) in single drug categories & gentamicin 0.1% + clobetasol 0.05% cream (308.82 %) among all fixed dose combinations. Least variation was observed for salicylic acid 2% foam (4.76 %) and terbinafine 1% + ofloxacin 0.75% + ornidazole 2% + clobetasol 0.05% cream (5.69 %). Cost of drugs play a crucial role in treatment outcome by directly influencing the patient compliance. Hence, it is essential to train physicians about cost variations among different brands available in the market so that they can reduce financial burden of patients without compromising the effectiveness of therapy.

Keywords: Skin diseases, Drug Brands, Price Variation, Cost of drugs, Compliance.

they are not only associated with increased physical, psychological, social suffering but also increase financial burden as many of the skin diseases require prolonged treatment [7]. Indian drug market has multiple branded formulations for dermatological treatment like antifungal drugs which gives rise to large price variations [8,9]. Because of large numbers of brands, doctors often find difficulty in prescribing the most suitable product [10]. Information on the price variation of commonly used topical preparations except for topical steroids & antiseptics was not available in the recent literatures. Hence we undertook this study to find the variation in costs of different brands of antiinfective, anti-acne & analgesic topical preparations and to also check the association between the price variation & number of brands, if any.

METHODS

Current Index of Medical Specialties (CIMS) & Drug Update (July-September 2016 edition, India) were used for obtaining the information about dosage forms and prices of the different brands of commonly prescribed topical preparations because they are readily available and frequently used as authentic sources of

commercial drug information [9,11]. The drugs were grouped into three broad therapeutic categories namely: anti-infective including anti-parasitic, anti-acne and analgesics. They were further subdivided into single drugs & combinations. Maximum and minimum costs of different brands of different drugs and their combinations were noted as per type of preparation & strength. Some of the dermatological preparations like creams, gels and ointments were available in different size of packages. In such cases, we took the amount with maximum brands as a standard (usually 15 g) for the preparation and recalculated the price corresponding to the standard amount.

The percentage price variation of all drugs for each dosage form and strength was calculated by using following formula: (Maximum cost - Minimum cost) $\times 100$ / Minimum cost. The cost ratio which shows how many times costliest brand costs more than the cheapest brand was calculated by dividing highest cost brand by lowest cost brand [11]. Average price variation was calculated for all therapeutic categories.

The total number of brands for a particular drug or combination was obtained by adding the number of individual brands for its various preparations & strength. We also studied whether there is any association between number of brands & price variation. We did not include drug preparation with a single brand or having more than one brand but with no price difference. To get overall idea, all drugs were divided into five groups, 0-25%, 25-50%, 50-75%, 75-100% and more than 100% depending on price variation.

RESULTS

A total of 206 brands of 35 different topical drugs and combinations manufactured by 52 different pharmaceutical companies were surveyed. We found that there was substantial variation in prices of different brands of topical preparations available in Indian market. Table 1 shows number of brands, cost ratio & cost variation of topical preparations according to type of preparation & strengths of drugs. Out of 35 drugs and their combinations studied, 11 showed up to 50% variation, 9 showed 50 to 100 % variation and 15 showed more than 100% variation. (Table 2)

Largest price variations was seen with mupirocin 2% cream (408.33 %), tazarotene 0.05% gel (183.8%) and diclofenac diethylammonium 1% gel (650 %) in anti-infective, anti-acne & analgesic categories respectively; while for their respective fixed dose combinations it was seen with gentamicin 0.1% + clobetasol 0.05% cream (308.82 %), clindamycin 1% + nicotinamide4% gel (156.41 %) & diclofenac 1% + methyl salicylate 10%+ menthol 5% gel (93.18 %).

Least variation was observed for salicylic acid 2% foam (4.76 %) and terbinafine 1% + ofloxacin 0.75% + ornidazole 2% + clobetasol 0.05% cream (5.69 %) among all single drug preparations & combinations respectively. Both of them had only couple of brands with same type of preparation & strength. (Table 1)

Among all therapeutic categories (single drugs), highest average variation (289.81 %) was seen in 31 brands of topical analgesics, followed by11 brands of anti-bacterials (148.02%). Although antifungal drugs had maximum number of brands (53), the price variation was lesser than above two (124.01%) and it was almost equal to mean variation for all the preparations studied (121.40 %). Minimum average variation was seen with anti-viral (47 %) which also had minimum number of brands (6). Surprisingly, among all combinations, anti-infective group had maximum number of brands (33) yet they showed the minimum variation (72.84 %) (Table 3). Drugs/ combinations having maximum number of brands for every class are shown in Table No 4. Among all preparations Clotrimazole (24) had maximum number of brands with Diclofenac being the next (18).

Table-1: Cost ratio & percentage cost variation of commonly used topical preparations					
Drug name	Preparation	Strength	No of	Cost	% Cost
			Brands	ratio	variation
<u>A Anti-infective Drugs</u>					
1. Single Drugs					
a. Antibacterial					
Fusidic acid	Cream	2%	4	1.25	25
Gentamicin	Cream	0.1%	2	1.11	10.71
Mupirocin	Cream	2%	5	5.08	408.33
b. Antifunal					
Butenafine	Cream	1%	2	1.32	31.73
Clotrimazole	Powder	1%	10	2.51	150.61
	Lotion	1%	3	3.78	277.78
	Cream	1%	9	2.21	121.43
	Solution	1%	2	1.48	48.08
Ketoconazole	Cream	2%	4	2.74	174.29
	Solution	2%	3	1.32	31.66
Miconazole	Cream	2%	3	3.17	217.35
Sertaconazole	Cream	2%	3	1.79	78.57
Terbinafine	Cream	1%	15	2.09	108.57
c. Antiviral			-		
Acyclovir	Cream	5%	6	1.47	47
d. Anti-parasitic			-		
Permethrine	Lotion	5%	8	2.89	188.89
	Soan	1%	3	1 48	48.33
2 Combinations	Doup	170	5	1.10	10.55
Cotrimazole + Beclomethasone	Cream	1 % + 0 025 %	7	1.88	87 52
Fusidic acid + Beclomethasone	Cream	1% + 0.025%	3	1.00	35.06
Gentamicin + Miconazole +	Cream	$0.1\% \pm 2\% \pm 0.05\%$	2	1.55	55.00
Beclomethasone	Cream	0.1 /0 + 2 /0 + 0.05 /0	2	1.55	55.55
Gentamicin + Clobetasol	Cream	$0.1.\% \pm 0.05.\%$	5	4.00	308.82
Naomycin + Baclomathasona	Cream	$0.1 \ 70 \ \pm \ 0.05 \ 70$	3	1.03	00.84
Kataconazola - Zn pyrithion	Lotion	0.3 ± 0.03 70	4	1.91	90.84 46.64
Misepagela - Clobatasel	Cream	2% + 1%	2	1.47	40.04
Terbinafina + Oflowagin + Ornidazala +	Cream	2% + 0.05%	2	1.19	16.32
Clobatasol	Clean	1% + 0.75% + 2%	2	1.00	5.09
DUC - Catrimida	Lation	+0.03%	2	1.07	7 1 4
BHC + Ceutinide	Lotion	1 % + 0.1 %	3	1.07	/.14
<u>B Anti-acne Drugs</u>					
1. Single Drugs		0.10/		2.67	4 4 4 4 7
Adapalene	Gel	0.1%	6	2.67	166.67
Benzoyl peroxide	Gel	5%	2	1.77	77.22
Clindamycin	Gel	1%	9	2.77	177.19
	Solution	1%	2	2.82	181.86
Salicylic acid	Ointment	12%	3	1.24	23.64
	Ointment	6%	2	1.06	6.38
	Foam	2%	2	1.05	4.76
Tazarotene	Gel	0.05%	2	2.84	183.80
	Cream	0.1%	2	2.63	163.43
Tretinoin	Cream	0.05%	2	2.21	121
2. Combinations					
Adapalene + Clindamycin	Gel	0.1 + 1 %	5	2.43	143.04
Clindamycin + Nicotinamide	Gel	1 % + 4 %	3	2.56	156.41
Clindamycin + Adapalene	Gel	1% + 0.1%	2	1.44	44.44
Tretinoin + Hydroquinine +	Cream	0.025 % + 2 % + 0.1	8	1.78	77.78
Mometasone		%			
C. Analgesics					
1. Single Drugs					
	1				

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Diclofenac diethylammonium	Gel	1%	6	7.50	650
	Gel	1.16%	12	2.83	183.12
Nimesulide	Gel	10 mg/gm	8	1.53	52.52
Piroxicam	Gel	0.5%	5	3.74	273.58
2. Combinations					
Diclofenac + Methyl salicylate+	Gel	1 % + 10 % + 5%	4	1.93	93.18
Menthol					
Diclofenac + Methyl salicylate +	Gel	1.16 % + 10 % + 5 %	6	1.59	59.18
Menthol + Linseed oil		+ 3 %			

Table-2: Percentage price variation of topical dermatological drugs

Percentage Variation	No of Drugs/ combinations (%)
0-25	6 (17.14)
25-50	5 (14.29)
50-75	3 (8.57)
75-100	6 (17.14)
> 100	15 (42.86)

Table-3: Percentage price variation according to drug class

Class	Average percentage variation	No of Brands
1.Anti-infective		
Single drugs		
- Antibacterial	148.02	11
- Antifungal	124.01	53
- Antiviral	47	6
- Anti-parasitic	118.61	11
Combinations	72.84	33
2. Anti-acne		
Single Drugs	92.16	32
Combinations	105.42	18
3. Analgesic		
Single Drugs	289.81	31
Combinations	76.18	10

Table-4: Drugs/ combinations with maximum brands of each class

Drug Class	Drug Name	Maximum Brands
1 Anti-infective		
Single drug		
- Antibacterial	Mupirocin	5
- Antifunal	Clotrimazole	24
- Antiviral	Acyclovir	6
- Anti-parastic	Permethrine	11
Combinations	Cotrimazole + Beclomethasone	7
2. Anti-acne		
Single drug	Clindamycin	11
Combinations	Tretinoin + hydroquinine + mometasone	8
3. Analgesic		
Single drug	Diclofenac diethylammonium	18
Combinations	Diclofenac + methyl salicylate + menthol + linseed oil	6

DISCUSSION

Increasing medical costs is concerning sign not only for patients but also for policy makers and service providers. Every year millions of Indian people are dragged into poverty due to direct and indirect medical cost. WHO's annual World Health Report 2010 states that health and medical service is a limited resource for an unlimited demand. Millions of people suffer and die due to lack of access to affordable medical treatment; others suffer by paying through borrowed debts and selling assets etc. According to the report, between 20%-40% of all health expenditures are wasted because of inefficiency. In some countries, costs of medicine are up to 67 times higher than the average international prices which result in gross over expenditure and demands review of health policies [12]. Providing cost effective healthcare management without hampering the quality of patient care has created a challenge for physicians [13]. There is lack of awareness among clinicians about the availability of cheaper yet effective drugs in the market. Such ignorance may inadvertently lead to increased overall healthcare cost to patients [14].

In our study, sixty percent drugs showed price variation of more than 75 %. Maximum cost variation was seen with mupirocin, tazarotene and diclofenac diethylammonium in a single drug category and combination of gentamicin & clobetasol among all FDCs. Topical analgesics & antibacterials showed wide variation in price. Presence of multiple brands is generally a contributing factor for giving rise to such a large variation. But we found that anti-infectives showed the minimum variation despite having maximum number of brands among all combinations.

A study investigating 40 drugs and combinations of topical dermatological products of India and Nepal found that 62.5% showed more than 75% variation. In the therapeutic categories, the maximum variation was observed among topical antiseptics, topical antivirals and corticosteroids. The combination of betamethasone, gentamicin and clotrimazole showed the maximum variation [11]. In another survey, it was seen that dermatologist especially resident doctors were most likely to underestimate the cost of medications commonly prescribed for dermatologic conditions but they were more accurate estimating the cost of procedures. It shows that there is a lack of proper training in this area [15].

To deal with the issue of affordability and availability of medicine, the Government of India introduced mechanisms such as drug price control order and the National Pharmaceutical Pricing Authority. Drug Price Control Orders (DPCOs) are issued by the government for enabling them the government to fix the maximum price for essential and lifesaving medicine [16]. The cost of drugs included in National list of essential medicines (NLEM) is regulated by Drug price control order. There are total 376 medicines included in the latest 2015 list while there were only 348 medicines in NLEM 2011 list. We observed few changes when we compared the two essential drug lists. Miconazole & was substituted by clotrimazole in the antifungal category. Acyclovir & benzyl benzoate were removed without any replacement in antiinfective and scabicides categories. For medicines affecting skin differentiation and proliferation, dithranol was replaced by benzoyl peroxide and podophyllin resin [17, 18].

Cost is considered as one of the important criteria for selecting the drug. As per the WHO, rational use of medicines requires that "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community" [19]. Prescribing generic rather than branded medications, including those used for topical purpose, can be used to decrease cost of treatment. In fact, the growth of cost of prescription has decreased in association with increased use of generic drugs [20]. Recently, medical council of India has issued a circular for doctors practicing medicine to prescribe drugs with generic names, legibly and preferably in capital letters apart from ensuring the rationality in prescription [21].

CONCLUSION

We found that there was a wide variation in the cost of topical dermatological products. Large number of brands may not be always responsible for such variation. Price of drugs play crucial role in treatment outcome by influencing the patient compliance. Many of the skin disorders need prolonged treatment, so it is essential to train physicians about cost variations among different brands of topical drugs available in the market. It will help in reducing the financial burden of patients without compromising the effectiveness of therapy.

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