


# BMJ Open Magnitude, characteristics and consequences of topical steroid misuse in rural North India: an observational study among dermatology outpatients

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## ABSTRACT

**Introduction** Current evidence indicates an alarming increase in topical steroid (TS) misuse in India. Data regarding the magnitude and characteristics of this problem in rural India, where 68% of the population resides, are insufficient. This study analyses the magnitude, causes, characteristics and consequences of TS misuse in rural India. It also examines the association between TS misuse and patients' perception of skin disease.

**Methods** A mixed-method observational study was conducted among the attendees of the dermatology outpatient department in a rural North Indian hospital. Those with a history of TS misuse were analysed for behaviour patterns and outcome.

**Results** Out of 723 patients, 213 (29.2%) misused TS. Clobetasol propionate (58.2%) was most commonly misused. Seventy brands of inappropriate fixed drug combination steroid creams were recovered from the patients. Pharmacists and local healers together contributed to 78% of the sources for steroid misuse. Almost 58% of participants perceived their skin conditions to be allergic reactions to food, when in fact 70.1% were tinea, 10% scabies and 9% acne. Eighty per cent of the respondents having tinea had tinea incognito and 97% had extensive lesions. Eighty-five per cent of the participants with scabies had atypical lesions and 80% with acne had steroid rosacea or aggravation of acne. The median expenditure incurred in purchasing these potentially harmful steroid creams was Rs 1000 (US\$14.1, equivalent to 3 days' wages of a labourer).

**Conclusion** Steroid misuse is a problem of epidemic proportion in rural India. This practice is changing the profile of many common and infective skin conditions, which portends diagnostic dilemmas and therapeutic challenges for clinicians. Misconceptions about skin disease drive the public to seek 'quick fixes' from non-allopathic providers who have unrestricted access to potent steroids. There is an urgent need to tighten regulatory controls over the manufacturing, sale and prescription of irrational TS combinations.

## INTRODUCTION

The usefulness of topical steroids (TS), the most widely used therapeutic agents in dermatology, has become a double-edged sword

## Strengths and limitations of this study

- This mixed-method study is one of the few studies that focuses on topical steroid (TS) misuse in rural India.
- A mixed method of structured questionnaire supplemented with qualitative interviews was used to assess TS misuse.
- The development of research objectives was informed by patients who had used topical steroids particularly those who had experienced side effects.
- The frequency of misuse may be underestimated due to the difficulty in identifying corticosteroids by respondents.
- Generalisability is limited by the sample being restricted to one outpatient department in one location.

with increasing prevalence of misuse, leading to disastrous consequences.<sup>1,2</sup> Of concern is the unprecedented increase in fungal infections as well as the emergence of resistant dermatophytosis in India, most likely due to unnecessary use of fixed drug combination (FDC) creams containing steroids.<sup>2</sup> Children are often victims of TS misuse as they are more vulnerable to the systemic effects of potent topical corticosteroids as well as to the spread of infections.<sup>2</sup> Non-medical use of TS in fairness creams has led to increasing occurrences of a condition that has been described as TS damaged face (TSDF).<sup>3-5</sup> Pharmacists and often qualified medical practitioners readily prescribe and dispense potent TS given that they provide dramatic symptomatic relief. The pharmaceutical industry also contributes to the problem as they manufacture and promote inappropriate FDC containing potent TS in combination with antifungals and antibacterials. This problem is further compounded by the unregulated over-the-counter supply and unrestricted sale of TS. Public and professional ignorance, legal ambiguity and government inaction



create a serious problem whereby FDC creams are used as a panacea for all skin problems.<sup>6</sup> In India, the unprecedented increase in sales of these ‘steroid cocktails’ by an alarming 26% in 2014–2015 is a reflection of the public appeal of these dangerous combinations.<sup>5,7</sup> This is especially unfortunate, given these medications are not only ineffective in curing but also cause more harm than good. In addition, this unnecessary expenditure can cause an economic drain impoverishing many who have scarce or no financial reserve. Though efforts are being made to draw attention to the multiple factors behind this problem in India,<sup>4,5,7,8</sup> it remains largely under researched in rural areas. Earlier studies were conducted in the urban setting of tertiary care hospitals with emphasis on TS usage on face.<sup>7–12</sup> However, no data are available to understand the impact of this epidemic in the rural areas where 68.84% of the Indian population dwells.<sup>13</sup>

This study analyses the magnitude, causes, characteristics, consequences and economic impact of TS misuse in a rural hospital in North India. We also seek to better understand the relation between TS misuse and patients’ perception of skin disease.

## MATERIALS AND METHODS

A mixed-method observational study of patients was conducted over a period of 3 months (March 2016 to May 2016) among all new patients attending the dermatology outpatient department of a secondary-level hospital, located in a rural part of Uttarakhand, North India.

Our data at Herbertpur Christian Hospital show an estimated figure of 16% for steroid abuse in ringworm (tinea) infections. Using this as an estimated prevalence of TS misuse and a margin of error of 5% and a 95%CI, the sample size required was approximately 160.

We undertook the study over a long enough time period (a quarter) in order to account for week-on-week variation and to smooth out any effects of unique events such as festivals, strikes and elections. Male and female patients of all ages who fulfilled the following criteria were recruited:

1. Having a skin condition for which TS is contraindicated, that is, acne, bacterial, viral, fungal or parasitic cutaneous infections such as tinea, furuncle, scabies, etc.
2. History of TS usage for that condition.

TS include either single-ingredient steroid products or a combination of TS molecule with antibiotics or antifungals. The patients were recruited following a clinical examination by the consultant dermatologist, after obtaining an informed written consent. Parents were interviewed for the purpose of gathering data regarding their children. Using a mixed method of structured questionnaire supplemented with qualitative interviews, patients were assessed for the misuse of TS. Taking this information into account, a trained clinician–researcher then made a decision as to what constituted misuse based on inappropriate indication, prolonged duration, unnecessary use of potent steroids, expense incurred and side

effects. All patients with tinea were subjected to direct microscopy and those who were tested negative were added only after positive response to antifungal therapy. The patients were also counselled regarding dangers of TS misuse and appropriate treatment was given for side effects, when present.

To minimise bias in reporting steroid use, we required patients to provide the actual tubes where available. Survey answers were also verified by a combination of clinical examination, interview and structured questionnaire.

## Patient and public involvement

The results of the study informed the production of a video and patient information handout to the communities from which the patients came. While patients were not involved in the recruitment and the conduct of the present study, the development of research objectives was informed by patients using TS, particularly those who had experienced side effects. The study was piloted to get feedback from patients on the formation of the questions.

## Data analysis

Data analysis was done using Stata V.14 (StataCorp, College Station, Texas, USA). Major variables of interest were dermatological conditions for which steroids were misused, types and quantities of steroids used, sources of prescriptions, adverse effects of misusing steroids, expenditure incurred and patients’ perception of the disease. All the original variables were categorical, except the number of tubes, duration of TS misuse and expenditure on TS, which were converted from numeric to categorical data for analysis. Data were presented as percentage with the exceptions of age and expenditure which were expressed in median (Q1–Q3). For multiple-response questions (side effects, types and sources of TS), we used MRTAB (Ben Jann and Hilde Schaeper, 2004)<sup>14</sup> to generate simple frequencies. To test the associations between major demographic variables and profile of misuse, we performed  $\chi^2$  test with the level of significance set at 0.05.

## RESULTS

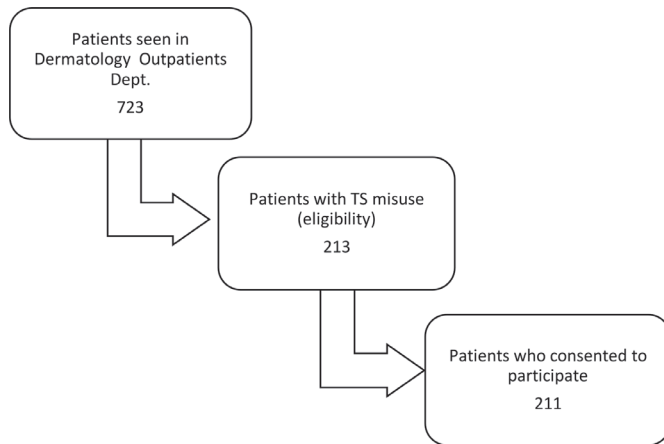
### Demographics

Of the 723 new patients seen in the dermatology outpatient department (OPD), 213 (29.5%, 95% CI 26 to 32.6) had a history of TS misuse and were eligible for the study (figure 1). Two did not give written consent to be involved leaving 211 patients. Nearly 60% were men and the median age was 30 years. Fifty-five per cent of the cases were in the 15–34 years age group. Those having only primary education seemed to be most affected by TS misuse (table 1).

### Profile of steroid misuse

#### Dermatological conditions mismanaged with steroids

The most common condition for which steroids were misused was tinea (70.1%), followed by scabies (10%) and



**Figure 1** Patient recruitment flow chart.

acne (9%). A small number had two concomitant diseases such as tinea with scabies, tinea with acne or acne with scabies. Other conditions for which steroids were misused were vulval candidiasis, herpes genitalis, tinea versicolor, furuncle and melasma. In the case of melasma, for which mild potency steroids admixed with hydroquinone and retinoids are used, patient misuses consisted of inappropriate combinations of potent steroids with antifungal and antibacterial creams for extended periods.

#### Types of steroid formulations used

Fixed-dose combinations containing either a triple or quadruple combination of antifungal, antibacterial and steroid were the commonly used creams. Quadruple combinations are steroid creams which contain four ingredients, that is, two antibiotics ‘ofloxacin and ornidazole’ or others with four different ingredients. Such

**Table 1** Demographic details of patients who had a history of topical steroid misuse

	Observations (n)	Percentage
Age (years) Up to 14	11	5.2
15–24	56	26.5
25–34	61	28.9
35–44	44	20.9
45 and above	39	18.5
Gender		
Male	124	58.8
Female	87	41.2
Education		
Illiterate	37	17.5
Primary	66	31.3
High school*	50	23.7
College	10	4.7
Graduate	48	22.8

\*Included one imputed value based on father’s highest level of education, n=211.

**Table 2** Types of topical steroid misused

Steroid molecule	Observations (n)	Percentage
Clobetasol propionate	167	58.2
Beclomethasone/ betamethasone	91	31.7
Fluocinolone	17	5.9
Mometasone	11	3.8
Clobetasone	1	0.4

Multiple responses were allowed in this question. Percentages were based on total number of responses. Total number of responses=287. Total number of cases=211.

combinations have no clinical justification. Although most of the participants (66%) used only one class of TS, 32% used two classes and 3% used three classes. The most misused TS (table 2) was clobetasol propionate (58.2% of 287 responses). About 70 different creams (table 3), produced by a myriad of pharmaceutical companies, were recovered from the patients during the study. As shown in table 4, the 10 most misused combinations of creams have very similar compositions although packaged under different names and appearances. Patients often think they are prescribed a new cream at every visit while in fact they are using one with the same molecule, most often clobetasol propionate (class I potency), thereby perpetuating the side effects.

Twenty-five per cent of the respondents reported concomitant use of either oral steroids (OS) or injectable steroids or both along with TS. Of this, 39.6% had concomitant use of OS, 37.7% used both oral and injectable steroids and 22.7% used injectables along with TS. These patients reported that the OS were easily procured over the counter. Use of injectable steroid was found to be associated with the highest level of education (p=0.04) and was obtained from local healers.

#### Sources of steroid procurement or prescription and steroid usage patterns

More than half of the respondents (65.9%) indicated one single source for procurement of TS, most often being pharmacists (56.8%). Patients reported that pharmacists freely dispensed TS for any complaints of itching which provided a quick remedy and helped them avoid cumbersome procedures required in a hospital. There was statistically significant gender difference ( $\chi^2=7.1$ ; p=0.008) in relation to steroid procurement from non-allopathic providers, suggesting that women were less likely to approach medical practitioners for treating their skin infections.

#### Extent of use and cost of usage

There was a wide range in the number of tubes (mostly 15g, a few are 20g and some 25g) used by the respondents. Twenty-one per cent (44) used one tube while about 3% (7) used more than 100 tubes. The majority (63%) used TS combinations for less than 6 months.

**Table 3** List of 70 different brand creams, many having the same composition of steroid, antibiotic and antifungal molecules, recovered from patients during the study

Brand name	Steroid	Antibiotic	Antifungal
Panderm+, Terderm+, Orniderm, Nikderm+, Oltef-NF, Laboderm-oc, Terbinaforce+, Terbicad, Fourderm, DermikemOC, Pardum+, Castor-NF, Totalderm+, Terogood, Orkid4, Sarvocin-CT, Orkaderm, Soltex, Bifine-plus, Dermek-TC, Turgoder-oc, Tocoder-oc, Onflox-TC,	Clobetasol propionate	Ofloxacin, ornidazole	Terbinafine hydrochloride
Dermacin-k5, Amitone-5, Clotebate-GM, Clobezine-CM, Tecderm-KT, Dermiford, Dermifrench-KT, Dermiford-K5	Clobetasol propionate	Iodochlorhydroxyquinoline, gentamicin	Ketoconazole, tolnaftate
Clostar-GM, Ring-out+, Clobriv-MG, Clobeta GM, Adoder-oc-MN, Zincodem-GM, Candid 3D, lobate, Neo Clobenate-GM, Clobenate-GM, Lucobet-GM, Cosvate-GM	Clobetasol, propionate	Neomycin sulphate	Clotrimazole
Medisalic, Clorap-s, Lozivate-MF, Lozivate	Clobetasol propionate and salicylic acid		
Lobate GM	Clobetasol propionate	Neomycin sulphate	Miconazole
Unikderm	Clobetasol propionate	Gentamicin	Ketoconazole
EVzole	Beclomethasone dipropionate	Neomycin sulphate	Clotrimazole
Betnovate-C	Betamethasone valerate	Clioquinol	Chlorocresol
Betnovate-N,	Betamethasone valerate	Neomycin sulphate	Chlorocresol
Nuforce-GM, Betamil, Quadri-oc-derm RF, Canditas-BG, Lupiderm-GM, Onabet-B, Quadri-oc-derm, Surfaz-SN, Zenoder-oc, CBN,	Beclomethasone dipropionate	Neomycin sulphate	Clotrimazole
Sertamide-B	Beclomethasone dipropionate		Sertaconazole
Candid -B	Beclomethasone		Clotrimazole
Cipro-CF, Ceflox-CF,	Fluocinolone acetonide	Ciprofloxacin, neomycin sulphate	Clotrimazole
Zole-F	Fluocinolone acetonide		Miconazole
Flucort-H	Fluocinolone acetonide		
Sure-KT	Clobetasone	Gentamicin	Ketoconazole
Aluderm	Clobetasol propionate	Ofloxacin	Ornidazole

Approximately 16% of the respondents used TS for over a year. The pattern of steroid usage was erratic, varying from using either one tube intermittently over a few months or most often in combination with oral and/or injectable steroids, or using more than 100 tubes continuously.

The total amount of money spent to date on TS ranged from US\$0.5 to more than US\$2500. The median expenditure was US\$20 (Q1:US\$4; Q3:US\$80), equivalent to 3 days' wages of a daily labourer. These FDC creams are available at lower cost than single-ingredient antifungal creams. The plain antifungal creams (available as 30 g tubes) are three times more costly than the FDC creams containing potent steroid and antifungal combinations available in smaller sizes. Due to the low cost, the pharmacists stock the FDC creams as they have quick turn over while plain antifungal tubes are not stocked and are

hence hard to procure. It would benefit the community significantly if the government could supply plain antifungal creams at an affordable price.

#### Adverse effects of topical and systemic steroid misuse

Table 5 shows the adverse effects reported by 204 respondents.

A. Effect on dermatological conditions—97% of patients with steroid-modified tinea had extension of tinea to non-flexural areas of body, that is, face, ears, wrists, entire trunk, dorsum of hands and genitalia in men. Eighty per cent had tinea incognita, a term used when appearance of tinea is varied or modified from the normal as a result of steroid misuse. This presented with atypical clinical signs like lichenification, eczematization, large geographic patterns, pseudoimbricata,



**Table 4** Ten most commonly used fixed drug combination creams containing steroid

Brand name	Composition	Responses, n (%)
Neoclobenate GM	Clobetasol propionate, miconazole, neomycin	55 (17.7)
Castor NF	Clobetasol propionate, ofloxacin, ornidazole, terbinafine hydrochloride	43 (13.8)
Quadri-derm	Beclomethasone dipropionate, clotrimazole, neomycin	32 (10.3)
Betnovate-N	Betamethasone valerate, neomycin	30 (9.7)
Dermiford	Ketoconazole, iodochlorhydroquinoline, tolnaftate, genatamicin and clobetasol propionate	30 (9.7)
Betnovate-C	Betamethasone valerate, clioquinol	26 (8.4)
Dermikem OC	Clobetasol propionate, ofloxacin, ornidazole, terbinafine hydrochloride	25 (8.0)
Lobate GM	Clobetasol propionate, miconazole nitrate, neomycin sulphate	25 (8.0)
CBN	Beclomethasone dipropionate, clotrimazole, neomycin sulphate, chlorocresol	25 (8.0)
Terbinaforce plus	Clobetasol propionate, ofloxacin, ornidazole, terbinafine hydrochloride	20 (6.4)

arciform, pustular and polycyclic lesions as well as lesions mimicking other diseases like psoriasis, pityriasis rosea, lichen planus and seborrheic dermatitis. Three per cent of tinea infection had localised exacerbation with pustulations. Fifty-eight per cent of patients with acne developed features of either steroid rosacea, pustular or nodulocystic acne. Ninety-five per cent of patients with scabies had generalised papules instead of the characteristic areas making it difficult to recognise (scabies incognito).

#### B. Other effects

**Table 5** Adverse effects reported by participants

	Frequency	Per cent of responses	Per cent of cases
Tinea extension	145	60.17	71.08
Tinea exacerbation	5	2.07	2.45
Scabies extension	20	8.30	9.8
Scabies exacerbation	1	0.41	0.49
Acne extension	11	4.56	5.39
Acne exacerbation	9	3.73	4.41
Cushingoid*	11	4.56	5.39
Hypertension*	8	3.32	3.92
Striae*	6	2.49	2.94
Weight gain*	6	2.49	2.94
Diabetes*	5	2.07	2.45
Other exacerbation †	5	2.07	2.45
Other complications ‡	9	3.73	4.41

Multiple responses were allowed in this question. Percentages were based on total number of responses. Total number of responses=241. Total number of cases=204.

\*Patients used systemic steroids in addition to topical steroids.

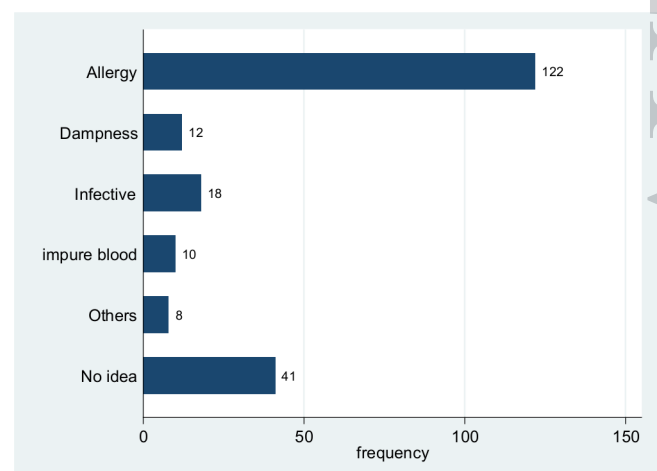
†These include lichenification in tinea and chronicity in herpes genitalis

‡These include local cellulitis, topical steroid damaged face (TSDF), telangiectasia, peri oral dermatitis and scabietic nodules

1. Striae—six patients (2.5%) had striae and these were very extensive over the groins, inner thighs, lateral sides of abdomen and axillae. Three of these patients concomitantly used oral and/or injectable steroids.
2. Cushingoid facies—11 patients (4.6%) showed Cushingoid features mainly characterised by facial puffiness. Seven of them concomitantly used oral and/or injectable steroids.
3. Hypertension—eight respondents (3.3%) had new-onset hypertension. Three of these patients concomitantly used oral and/or injectable steroids.
4. Diabetes—five individuals (2.1%) had new-onset diabetes. Four of them concomitantly used oral and/or injectable steroids.

#### Patients' perception of the disease

The majority (57.8%) considered their itchy skin condition or eruptions to be an allergic response to some food or drink which heats up the body (figure 2). About 9% thought it was infective and approximately 6% related


**Figure 2** Patients' perception of causes of their skin conditions. Total number of cases: 211.

to dampness. Nineteen per cent did not know the cause. Five per cent believed that their skin condition was due to impure blood. Some resorted to tonics such as 'Koon safi' (blood purifier) and even 'blood purification'. One respondent regularly withdrew a small quantity of his blood, mixed it with triamcinolone and injected the mixture back into his body. Other explanations (3.8%) for their skin conditions were bowel irregularities, heredity, unclean water and a few even considered it to be due to evil spirits.

## DISCUSSION

Our study found that nearly one-third of new dermatology outpatients had misused TS and clobetasol propionate was the most common steroid misused. Tinea incognito and extension of lesions were seen in majority of patients with dermatophytosis. Most of the TS misusers in our study did not know the real cause of their skin disease. Nearly 80% of the patients received their TS from pharmacists or local healers.

This study demonstrates that TS misuse is a significant public health issue in rural India, with 3 out of 10 new dermatology outpatients using TS inappropriately. This result is much higher than those found in urban studies in India where prevalence of misuse was 11.8% in Delhi<sup>8</sup> and 15% in a Pan Indian urban study.<sup>4</sup> Our study demonstrated a male preponderance in contrast to the Pan Indian study which showed a female preponderance.<sup>4</sup> This is likely because the study was restricted to facial steroid usage. The average age of usage in our study was 32 years, which was similar to findings from the studies in urban areas of India.<sup>4,8</sup>

Tinea was by far the most common indication for steroid misuse in our study followed by acne and scabies. This concurs with some recent studies<sup>7,8</sup> but other studies in India showed the greatest TS use for acne<sup>9</sup> and skin lightening.<sup>12</sup> In another study by Saraswat *et al*, TS were most commonly used for both skin lightening and acne.<sup>4</sup> This difference in usage patterns could be due to infections like tinea being more prevalent in rural areas and skin colour being of more concern in urban areas.<sup>15</sup> This disparity could also be due to the recent spurt in dermatophytosis in India as a whole with its burden being felt in rural India as well.<sup>16</sup> The florid signs and symptoms caused by *Trichophyton mentagrophyes*, an inflammatory zoophilic species, which has emerged as a major causative organism for this epidemic, could be a reason for the rural poor to seek quick relief with cheap and easily accessible options like FDC-containing TS.<sup>17</sup>

For healthcare providers, TS abuse can make tinea difficult to distinguish from other common diseases like eczema, contact dermatitis and psoriasis and therefore increases misdiagnosis, mistreatment and even increased morbidity.<sup>2</sup> Tinea incognito and extension of lesions were seen in majority of patients with dermatophytosis because steroids tend to alter the characteristic 'ring or annular' lesion.<sup>2,10</sup> These cases can range from vague erythematous

plaques to lesions with oozing, prominent scaling, pustulation to large geographic lesions mimicking diseases like psoriasis. As seen in our study, it can be difficult for even dermatologists to accurately recognise steroid modified tinea. We also observed an increased occurrence in genital tinea, which was once rare. There is a need to educate the medical professionals about the wide variation in clinical presentation of steroid-modified tinea to enable proper diagnosis.

TS abuse in scabies, second after tinea in our study, can cause scaly and widespread lesions that are unrecognisable as scabies. Scabies incognito or steroid modified scabies can be a serious public health problem since it is very contagious, and diagnostic difficulty can increase the prevalence of scabies. Acne, the third most prevalent reason for steroid misuse, also leads to increased possibilities for TSDF and disfiguring sequelae of acne.

In our study, nearly half of the patients received their TS from pharmacists who had variable training. Likewise, in studies from other parts of the subcontinent, pharmacists were the most common source of inappropriate steroid use.<sup>4,10,18</sup> They often function as doctors, especially where the local health services are underdeveloped or unavailable. Many people also seek treatment from charlatans and Ayurvedic, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) practitioners, given the rarity of dermatologists and MBBS trained doctors in rural areas. AYUSH account for 31% of the TS misuse in our study. This is of great concern since it is illegal for a practitioner of complementary medicine to prescribe modern medicines like TS. Nevertheless, salespersons are still able to market TS to AYUSH practitioners.<sup>10</sup> Unfortunately, general physicians and even some dermatologists are also responsible for prescribing TS unnecessarily. This indicates the need for training of medical/paramedical personnel about the judicious use of topical corticosteroids and their potentially serious side effects. Saraswat's study on facial steroid use found that poor availability of physicians in rural areas was associated with non-physicians being likely to prescribe TS.<sup>4</sup>

Our study found that clobetasol propionate—the most potent TS—was the most common steroid misused. Beta-methasone valerate was the most widely misused steroid in urban studies.<sup>4,8,9</sup> This is consistent with Saraswat *et al* who noted that patients from rural areas tended to use potent TS.<sup>4</sup> Use of injectable steroids in our study was found to be associated with the highest education level ( $p=0.04$ ). Most of those who used oral and injectable steroids concomitantly with TS had either no education or only primary schooling. This could reflect their unwavering trust in the local healers.

This study also explored patient perception of their skin disease. Eighty-six per cent of respondents either misunderstood or did not know the cause of their skin disease. All pruritic symptoms or eruptions were perceived as allergic responses to hot, spicy food or impure blood. This wrong perception shifts the attention from common hygienic measures necessary to respond to infective

conditions like tinea and scabies, to unrelated factors like abstinence from certain food, unwarranted blood investigations and blood purification. An important reason for patients seeking primary recourse from nonmedical personnel could be lack of proper understanding regarding aetiology of their illness and lack of access to quality allopathy.<sup>19</sup>

Our study is consistent with the observations that factors leading to misuse of TS may occur at various stages during its journey from the factory to the skin.<sup>20</sup> The plethora of TS combinations recovered from the patients clearly indicates the ease of purchase and the unsubstantiated claims of TS combinations promoted by pharmaceutical companies. Despite the serious adverse effects, these drugs are manufactured and sold without appropriate regulatory control in India. Existing regulations pertinent to the prescriptions of these drugs are far from comprehensive. Although steroids have been included under Schedule H drugs, which requires proper prescription, inappropriate FDCs containing potent TS in combinations with antifungals and antibacterials are not on the same list.<sup>21</sup> Furthermore, the enforcement of the regulation regarding prescriptions of steroids at the ground level is rare.<sup>2</sup> For pharmacists and local healers, FDC creams are prescribed as one-stop answer to all skin conditions, regardless of the aetiology of the disease (whether it is a bacterial or fungal infection or inflammation). Unfortunately, many clinicians and occasionally even dermatologists also promote these multidrug combinations. At the consumer level, we found little awareness about the adverse effects. To address this, stringent regulations on the manufacture, sale and marketing of steroid cocktail creams are urgently required.

### Limitations

It was difficult for many patients to understand what TS were until they were shown samples. However, flooding of the market with innumerable brands containing TS made it difficult to show a sample of all brands. This could have led to underestimation of the frequency of the malpractice in our study.

Recollection of duration and quantity of use was difficult for patients who have used TS over a long period. This may also have led to under or overestimation of the total expenditure on TS. However, since the majority of participants used TS for less than 6 months, such potential inaccuracies were likely to be minimal.

Generalisability of our study is limited by the sample being restricted to one outpatient department in one location. To capture the true magnitude of the multifaceted problem of TS misuse in rural areas, a multicentric community study across the country is recommended.

### CONCLUSIONS

The epidemic of steroid-modified dermatoses in rural India due to injudicious use of TS is caused by multifaceted factors. Concerted, multipronged actions are

needed to address professional and public ignorance, political apathy and profit incentives for drug companies and pharmacists. Continuous education of clinicians and traditional practitioners to recognise the current altered and 'unrecognisable' steroid-modified dermatoses as well as the potentially harmful effects of TS is also required. Furthermore, there is a pressing need to increase the availability of family physicians, or equivalent, in rural areas where people go to whoever is local and affordable. In addition, drug control agencies should ensure strict regulation of TS sale and prohibit manufacturing of steroid cocktails. The Ministry of Health and Welfare could helpfully create awareness through social media and advertisements to warn people about the danger of TS misuse.

**Contributors** MT: principal investigator, contributed to the study design and methods, interpreted the data and drafted the manuscript. NG: developed concept of research, interpreted the data, reviewed, edited and approved the final manuscript. CW: contributed to the study design and methods, reviewed, edited and approved the final manuscript. PA: conducted statistical analysis, summarised and interpreted findings, reviewed, edited and approved the final manuscript.

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**Patient consent for publication** Not required.

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**Data availability statement** Data are available upon reasonable request. Data are available upon reasonable request by emailing to corresponding author (Dr Molly Thomas: vijuanmolly@gmail.com). No additional data are available for this study.

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