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Efficacy of 1% metronidazole gel in facial seborrhic dermatitis: A double blind study.

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Abstract:

Background: Seborrhic dermatitis, also known as seborrhic eczema is a common inflammatory disease of the skin, occurring in 2-5% of the population. It is characterized by erythematous plaque that is covered with yellow greasy scale, which may or may not be associated with itching. Although few studies suggested use of topical metronidazole gel in the treatment of seborrhic dermatitis, there is no general consensus about it.

Aims: To evaluate and compare the efficacy of 1% metronidazole gel with its vehicle (placebo) in the treatment of facial seborrhic dermatitis.

Methods: This is a double blind prospective clinical trial. A total 50 patient were included in this study, 44 of them had completed the treatment course of 8 weeks. Patients of both the groups were evaluated with seborrhic dermatitis severity index during the time of entry in the study and at second, fourth, sixth and eighth week.

Results: there was statistically significant difference in the reduction of mean seborrhic dermatitis severity score between the two groups at second, fourth, sixth and eighth week ($p=<0.05$).

Conclusion: Metronidazole 1% gel topically is an effective treatment for facial seborrhic dermatitis.

Key ward: Metrogyl gel, face, seborrhic dermatitis

Running title: A double blind placebo control study was done to evaluate the effectiveness of topical metrogyl gel against placebo in treatment of facial seborrhic dermatitis and it is found to be effective.

Introduction:

Seborrheic dermatitis is a common chronic superficial inflammatory disease of the skin with predilection for scalp, eyebrow, eyelid, nasolabial crease, lips, ears, sternal area, axilla, submammary folds, groin, umbilicus etc.[1] The

disease is characterized by erythematous plaque studded with yellowish greasy scale.[2] The disease affects 2-5% of the general population.[1] It is the most common cutaneous manifestation in AIDS patients.[2] There were two peaks of ages of onset, one during first 3 months of life and second during third to seventh decade of life. It is more common in male than in female.[3] The aetiology of the disease is complex but may be related to presence of lipophilic yeast pityrosporum ovale.[4] The density of yeast are correlated with the severity of the disease. Other factors like nutritional disturbance, genetic predisposition, immune dysfunction, emotional stress etc. are contributing factors in causation of the disease. Seborrhic dermatitis can be treated with topical corticosteroid, topical or oral imidazole, calcipotriol, tacrolimus,[5] pimecrolimus,[6] ciclopirox olamine [7] etc. Terbenafine has also been used in the treatment of seborrhic dermatitis.[8]

Few previous studies suggested the role of topical metronidazole gel in the treatment of seborrhic dermatitis [9,10,11] but there is no general consensus about it particularly in the eastern part of India. Our objective was to evaluate the efficacy of 1% metronidazole gel with its vehicle (hydroxy propyl cellulose) in the treatment of facial seborrhic dermatitis

Aims: To evaluate and compare the efficacy of 1% metronidazole gel with its vehicle (placebo) in the treatment of facial seborrhic dermatitis.

Methods:

The study was a double blind randomized vehicle controlled clinical trial. It was done at Dermatology OPD of a tertiary care institute of west Bengal from December 2014 to March 2015. The objective population were the patients of seborrhic dermatitis who were older than 18 years, had not used topical zinc, salicylic acid, retinoids, systemic antifungal, antibiotic or immunosuppressive agents in last one month. Pregnant and lactating mother were excluded from the study. 50 patients of seborrhic dermatitis were randomly allocated by using random number table in metronidazole group and placebo (hydroxyl propyl cellulose) group. At the beginning of the trial a written consent was obtained from all patients and seborrhic dermatitis severity score

was evaluated by a dermatologist. The patients of one group were advised to apply 1% metronidazole gel in the involved area of face (including nasolabial folds, dorsal side of the nose, retro auricular area and eyebrows) and the other group were advised to apply placebo (Hydroxy propyl cellulose). The follow up was done at second, fourth, sixth and eighth week and seborrhic dermatitis severity score was evaluated by the same dermatologist.

For determining the severity of seborrhic dermatitis, the scoring system suggested by Koca et al [12] was used. In this system four different parts on the face like eyebrows, retro auricular area, dorsal side of the nose and the nasolabial folds were evaluated. The erythema, scaling, pruritus and papule were the parameters of the scoring system. They were scored from 0 to 3 (0= absent, 1= mild, 2= moderate, 3= severe). The sum of these values was considered as seborrhic dermatitis score of the face. The maximum score calculated to be 48, if all the areas were involved with maximum severity (4×4×3=48). After collection of data, the data were compiled and analyzed by using appropriate statistical tools.

Results:

50 patients were enrolled in this study, 25 in the each group (15 male and 10 female in the each group). 44 patients completed the study (22 in the each group). In the metronidazole group, one patient opted out due to pruritus and other two patients opted out due to lack of improvement. In vehicle (placebo) group, patient discontinued because increased papular eruptions over nose. Age of the patient ranged from 18 to 64 years in both the groups. Most of the patients in both the groups were between 21-30 years. Mean age of the participants in metronidazole and placebo group were 28.2 and 25.4 respectively.

The mean severity score of and patients at time of presentation for the metronidazole and vehicle group were 12.81 and 10.45 respectively. The difference was not statistically significant (p=>0.05).

There were significant difference in the reduction in the Mean severity score between the two groups at the end of 2nd, 4th, 6th and 8th weeks (p=<0.05 in every occasions). At final visit the mean severity score for metronidazole and placebo group were 5.28 and 7.26 respectively. The results are depicted in **Table 1.** Response at the end of study is summarized in **Figure 1.**

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Tables and Figures –

Table-1: Comparison of mean seborrhic dermatitis severity score reduction in metronidazole and vehicle (placebo) group.

Visit	Group	Reduction in mean severity score	P value
2nd visit Vs 1st visit	Metronidazole	2.34	<0.05
	Vehicle (placebo)	0.15	
3rd visit Vs 1st visit	Metronidazole	4.29	<0.05
	Vehicle (placebo)	1.56	
4th visit Vs 1st visit	Metronidazole	5.76	<0.05
	Vehicle (placebo)	2.62	
5th visit Vs 1st visit	Metronidazole	7.53	<0.05
	Vehicle (placebo)	3.19	

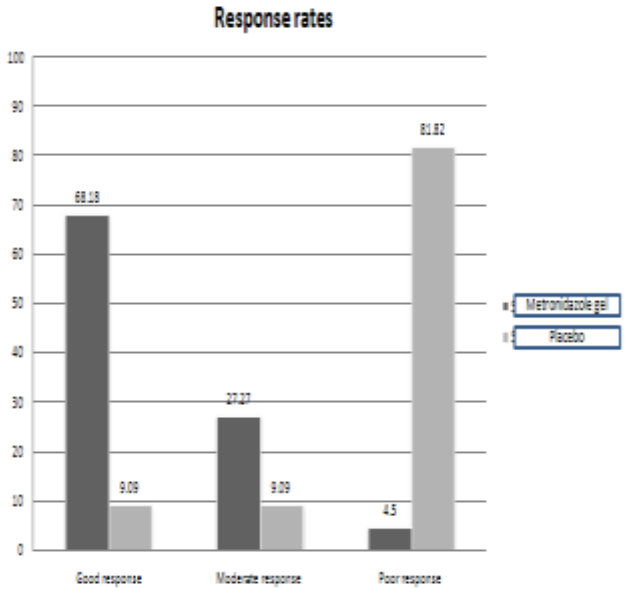

Figure 1 – Response rates with Metronidazole gel and placebo in facial **seborrheic dermatitis.**

Discussion:

Metronidazole is a synthetic nitroimidazole mainly effective against anaerobic organisms and amoeba. It acts through prevention of nucleic acid synthesis and DNA destruction. In addition to its antimicrobial effect, it has an anti inflammatory effect through inhibition of leucocytes chemotaxis. It also prevents release of inflammatory mediator from the neutrophils and decreases oxidative stress to the tissue. [11]

There are few previous reports of using topical metronidazole gel in seborrhic dermatitis. Prasad et al [10] evaluated the efficacy of topical 1% metronidazole gel in a double blind placebo control study which showed 66% of patients of metronidazole group had marked improvement of their facial seborrhic dermatitis while 12% of the

placebo group showed marked improvement. In our study around 68% of patient showed marked improvement and around 27% patient showed moderate improvement while in the placebo group around 18% patient showed good to moderate improvement. Plewig and Jensen in their literature concluded that topical metronidazole gel was effective in the treatment of facial seborrhic dermatitis [2] which confirms our observations. Koca et al [12] evaluated the efficacy of topical 0.75% metronidazole in double blind placebo control trial and concluded that there was no statistical significance in the mean severity score of seborrhic dermatitis between metronidazole and placebo group in the treatment of facial seborrhic dermatitis. In contrary the present study showed that there were significant statistical difference in reduction of mean severity index between metronidazole and vehicle group (p=<0.05).

According to the results obtained form the study it can be concluded that topical 1% metronidazole gel is more effective in the treatment of facial seborrhic dermatitis than its vehicle. So, it can be used as an effective treatment of facial seborrhic dermatitis.

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