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Research Article

Evaluation of the effect of topical cefadroxil on bacterial load of pathogenic staphylococci in anterior nares in human volunteers, comparative study between oral vs. topical cefadroxil and evaluation of effect of combination of oral plus topical cefadroxil in patients with staphylococcal superficial skin infections

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ABSTRACT

Background: Cefadroxil has good tissue penetration & exerts more sustained action at the site of infection after oral absorption. Our aim of the study was to check topical cefadroxil has any efficacy over staphylococcal superficial skin infection or not.
Methods: Pre-treatment nasal swabs were obtained from 25 healthy human volunteers and bacterial load was recorded. After single application of topical cefadroxil 3% in left anterior nare and placebo (vehicle) in right anterior nare nasal swabs were obtained and results were compared. 150 patients with staphylococcal superficial skin infections were distributed in 4 groups: Group A - oral cefadroxil 500 mg twice daily for 5 days, Group B - topical cefadroxil (0.5 % to 5%) twice daily, Group C - cefadroxil 500 mg orally plus placebo (vehicle) topically twice daily and Group D -cefadroxil 500 mg orally plus cefadroxil preparation topically twice daily. Bacterial load was measured before treatment, on follow up &after clinical cure and results were compared.
Results: Topical cefadroxil significantly reduced bacterial load after single application in anterior nare. Topical cefadroxil cured and significantly reduced bacterial load in staphylococcal superficial skin infections within 3 days of treatment. Oral plus topical cefadroxil combination therapy significantly reduced bacterial load and cured infection within 3 days of treatment in patients with moderate to heavy bacterial growth. No any adverse effect was observed during entire study period in any of groups.
Conclusions: Topical preparation of cefadroxil is safe and effective in treating staphylococcal superficial skin infections. Combination of oral plus topical cefadroxil showed synergistic effect in infections with moderate to heavy growth. This study is registered at CTRI [REG ID: CTRI/2013/02/003433 REF: REF/2013/02/004576].

Keywords: Staphylococcal superficial skin infections, Cefadroxil

INTRODUCTION

Staphylococcal superficial skin infections are very common health problem. Though easily treatable, the conditions are known for their chronicity, recurrence & other complications. The nose is regarded as the major site of S. aureus carriage from where the organisms can spread to other parts of the body.[1] The proposed pathogenesis for a number of endogenous infections would be that from the nose the skin becomes colonized, causing subsequent infection in patients with impaired skin sites, e.g., in patients with open wounds, hemodialysis[2] and continuous ambulatory peritoneal dialysis[3] and intravascular catheters.[4] Reagan et al[5] have shown that elimination of nasal carriage by using topical mupirocin also eliminates hand carriage.

Successful antimicrobial therapy of an infection ultimately depends on the concentration of the antibiotic at the site of infection, which must be sufficient to inhibit growth of the offending micro organisms. The drug concentration at the site of infection must inhibit the

organism but also must remain below the level that is toxic to human cells.

Cefadroxil, the first generation cephalosporin acts by inhibiting bacterial cell wall synthesis. After oral absorption, it has good tissue penetration & exerts more sustained action at the site of infection.[6] Though its plasma half life is 1.5 hours; dose recommended for staphylococcal infections is 500 mg 12 hourly.

In our preclinical study[7], topical cefadroxil showed significant efficacy in experimental rat models of staphylococcal superficial skin infections.

Various studies have shown comparison between oral and topical antimicrobial agents for superficial skin infections and derived that topical antimicrobial are as effective as oral agents in treating the infections.[8-16]

Aim of the Study

On the basis of above mentioned data our aim of the study was to see whether its topical preparation has such efficacy or not.

Objectives of the study

(i) To evaluate the effect of topical cefadroxil on bacterial load of pathogenic staphylococci in anterior nares in healthy human volunteers.
(ii) To compare efficacy of oral & topical cefadroxil in patients with staphylococcal superficial skin infections.
(iii) To evaluate effect of combination of oral & topical cefadroxil in patients with moderate to heavy bacterial growth.

MEHTODS

[a] Evaluation of the effect of topical cefadroxil on bacterial load of pathogenic staphylococci in anterior nares in healthy human volunteers.

Permission for study was taken from Institutional Ethics Committee. Twenty five healthy human volunteers who gave consent were included in the study. Pregnant or lactating women, persons having history of allergy to penicillin, renal diseases were not included for participation.

Informed consent was taken from all volunteers. Sample collection was done by obtaining two nasal swab specimens with sterile cotton-wool swabs. Each swab was applied to both anterior nares (vestibulum nasi) by non-interrupted rotating five times around the inside of each nostril with even pressure.[17]

Microbiological procedures: The swabs were applied on blood agar medium using streaking for isolation process[18] and incubated at 35°c for 18-20 hours in aerobic condition.

Confirmation was done by various microbiological tests like Gram stain (for identification of gram positive cocci) followed by catalase test (for differentiation from streptococci) and coagulase test (for confirmation of pathogenic staphylococci).

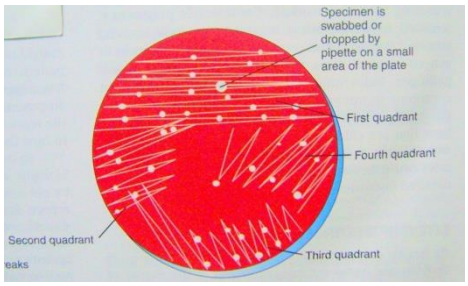

Figure 1: Streaking for isolation.[18]

Grading of bacterial colonies: No. of organisms present were graded as 4+ (many, heavy growth), 3+ (moderate growth), 2+ (few or light growth) & 1+ (rare).[18]

Antimicrobial agent: Cefadroxil powder was received as free sample by Torrent Pharmaceutical Ltd. Soft white paraffin was used as vehicle for cefadroxil topical preparation.

Application of placebo and test drug: Vehicle 1 FTU[19] (Finger Tip Unit) as placebo was applied in right anterior nare and topical preparation of cefadroxil (3% w/w) 1FTU was applied in left anterior nare.

After 12 hours nasal swabs were taken again from both anterior nares. Culture was prepared on blood agar. Gram stain, catalase test and coagulase test were done for confirmation and bacterial load was measured.

Outcome measures: Primary outcome-Decrease in bacterial load on the basis of grading of bacterial colonies after single application of the topical cefadroxil and placebo.

Statistical analysis: Pre-treatment and post-treatment bacterial load were compared by using student's paired t test ($p<0.05$, confidence interval 95%) for each nostril. The bacterial load after placebo and after topical cefadroxil were compared using paired t test ($p<0.05$, confidence interval 95%). For statistical analysis SPSS 17 version was used.

[b] Comparison between oral vs. topical cefadroxil & evaluation of effect of combination of oral & topical cefadroxil in patients with staphylococcal superficial skin infections.

Permission for study was taken from Institutional ethics committee.

Study design: The study was open label, prospective, randomised, comparative, controlled clinical trial,

conducted in 150 patients attending the OPD of dermatology department of C.U. Shah Medical College and Hospital from May 2009 to August 2009. The dermatologist diagnosed the patients of pyoderma, impetigo, sycosis barbae, folliculitis, furunculosis etc. The patients were approached with request to participate in trial. The patients who gave informed consent were included in the trial. Follow-up cases, pregnant or lactating women, patients having history of allergy to penicillin or any renal disease were not included in the study. The diagnosis was based on clinical history and clinical examination.

Sample collection: Before starting treatment, samples were taken with help of sterile swabs from sites of infection and applied on blood agar medium using streaking for isolation process[18] and incubated at 35°c for 18-20 hours in aerobic condition. For confirmation gram stain, catalase test and coagulase test were done. Grading of bacterial load was recorded as mentioned above.

Antimicrobial agents: Cefadroxil powder and tablets of cefadroxil (Droxyl) 500 mg were received as free samples by Torrent Pharmaceutical Ltd. Soft white paraffin was used as vehicle for cefadroxil topical preparation. Pilot study was done with 0.5% topical cefadroxil and concentration was increased in graded manner up to 5%; depending upon the response.

All the patients were distributed in four groups. Group A was treated with tablet cefadroxil orally, 500mg twice daily for 5 days. Group B was treated with topical cefadroxil in the range of 0.5 % to 5% depending upon the grading and anatomical distribution of the wound, for the topical application 1 FTU twice daily. Group C was treated with tablet cefadroxil 500 mg. orally plus vehicle topically 1 FTU twice daily. Group D was treated with tablet cefadroxil 500 mg. orally plus topical cefadroxil preparation topically 1 FTU twice daily.

Follow Up*:* All the patients were called for the follow up on day 3 and day 5.

Outcome measures

1) *Primary outcome measure:* Clinical cure. Clinical evaluation was done by dermatologist on the basis of disappearance of erythema, pain, pus, crusting and no. of lesions and few systemic symptoms if present.

2) *Secondary outcome measure:* Decrease in bacterial load. Colonies were graded as described above. Culture samples were taken and gram stain, catalase test and coagulase test were done for further confirmation.

Statistical analysis: Student's paired t test was performed to compare pre-treatment and post-treatment bacterial load for each group ($p<0.05$, confidence interval 95%). Bacterial load after oral cefadroxil and topical cefadroxil were compared using unpaired t test ($p<0.05$, confidence interval 95%). Bacterial load after combination of oral cefadroxil plus topical placebo and after combination of oral plus topical cefadroxil were compared using unpaired t test ($p<0.05$, confidence interval 95%). For statistical analysis SPSS 17 version was used.

RESULTS

[a] Evaluation of the effect of topical cefadroxil on bacterial load of pathogenic staphylococci in anterior nares in healthy human volunteers.

There was reduction in bacterial load after single application of both placebo and topical cefadroxil (Image 1 & 2). There was statistically significant difference between mean grading of bacterial load after application of placebo as compared to topical cefadroxil (Table 1, Figure 1). This shows that topical cefadroxil has efficacy in reducing the bacterial load in healthy human volunteers.

Image 1: Pre-treatment bacterial load.

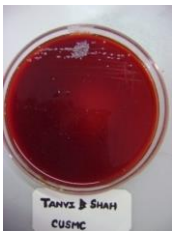

Image 2: Bacterial load in after application of topical cefadroxil.

Table 1: Mean grading for bacterial load before and after application of placebo and topical cefadroxil (3%) (n=25 per group).

	Grading for bacterial load (Mean ± S.E.M.)
Rt. anterior nare	
Pre-treatment	2.72 ± 0.19
Post-treatment (placebo)	2.2 ± 0.15*
Lt. anterior nare	
Pre-treatment	2.44 ± 0.23
Post-treatment (topical cefadroxil)	0.96 ± 0.07*#

*= significant at $p < 0.05$ as compared to before application in same anterior nare.
= significant at $p < 0.05$ as compared to after application of placebo.

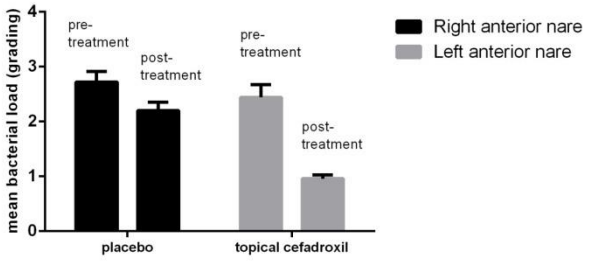

Figure 1: Mean grading for bacterial load before and after application of placebo and topical cefadroxil (3%) (n=25).

[b] Comparison between oral Vs topical cefadroxil & evaluation of effect of combination of oral & topical cefadroxil in patients with staphylococcal superficial skin infections.

Among 150 patients, 67 (44.67%) pts. were between 12-24 years; while 59 (39.33%) pts were of 25-48 years age group.18 (12%) and 6 (4%) pts were of age group 49-60 years and > 60 years respectively. Among all 150 pts 86 (57.33%) were males; while 64 (42.67%) were females (Table 2).

Among 150 patients 126 (84%) patients had clinical grading score I. While 21 (14%) patients had II, 3 (2%) patients had III. While none of the patients had clinical grading score IV (Table 3).

Before treatment, out of total 150 patients, 38 (25.3%) patients had grade 4 + (many, heavy growth); 64 (42.67%) patients had grade 3+ (moderate growth); 47 (31.33%) patients had grade 2+ (mild growth); 1 (0.67%) patient had grade 1+ (rare) and none had grade 0 (no growth) (Table 4).

After the treatment with different regimens, out of 150 patients, no patient had grade 4+; 1 (0.67%) patient had grade 3+; 15 (10%) patients had grade 2+; 30 (20%) patients had grade 1+ and 89 (59.33%) patients had no growth (Table 4).

Table 2: Distribution of patients according to age groups and gender.

Groups of patients	A (n=50)	B (n=50)	C (n=25)	D (n=25)	Total (n=150)
Age (years)	**No of pts.(%)**	**No of pts.(%)**	**No of pts.(%)**	**No of pts.(%)**	**No of pts.(%)**
12-24	14 (28)	17 (34)	19 (76)	17 (68)	67 (44.67)
25-48	22 (44)	25 (50)	6 (24)	6 (24)	59 (39.33)
49-60	10 (20)	6 (12)	0 (0)	2 (8)	18 (12)
>60	4 (8)	2 (4)	0 (0)	0 (0)	6 (4)
Gender					
M	25 (50)	29 (58)	16 (64)	16 (64)	86 (57.33)
F	25 (50)	21 (42)	9 (36)	9 (36)	64 (42.67)

Table 3: Distribution of patients according to clinical grading scores of lesions.

Groups of patients	A	B	C	D	Total
Clinical grading score of lesions	**No. of patients (%)**	**No. of patients (%)**	**No. of patients (%)**	**No. of patients (%)**	**No. of patients (%)**
I	37 (74)	47 (94)	22 (88)	20 (80)	126 (84)
II	12 (24)	3 (6)	2 (8)	4 (16)	21 (14)
III	1(2)	0 (0)	1 (4)	1 (4)	3 (2)
IV	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 4: Distributions of patients according to grading of bacterial load.

Groups of patients	A No. of pts. (%)		B No. of pts. (%)		C No. of pts. (%)		D No. of pts. (%)		Total No. of pts. (%)	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Grading										
4+	12 (24)	0 (0)	8(16))	0 (0)	10 (40)	0 (0)	8 (32)	0 (0)	38 (25.3)	0 (0)
3+	22 (44)	0 (0)	22 (44)	0 (0)	10 (40)	1 (4)	10 (40)	0 (0)	64 (42.67)	1 (0.67)
2+	15 (30)	4 (8)	20 (40)	3 (6)	5 (20)	6 (24)	7 (28)	2 (8)	47 (31.33)	15 (10)
1+	1 (2)	18 (36)	0 (0)	14 (28)	0 (0)	10 (40)	0 (0)	3 (12)	1 (0.67)	30 (20)
0	0 (0)	28 (56)	0 (0)	33 (66)	0 (0)	8 (32)	0 (0)	20 (80)	0 (0)	89 (59.33)
Total	50	50	50	50	25	25	25	25	150	150

GROUP A Vs. GROUP B: In group A, pre-treatment mean grading of bacterial load was 2.9 ± 0.12 while after treatment with oral cefadroxil for 5 days it was reduced to 0.52 ± 0.09. This was clinically as well as statistically significant. In Group B, pre-treatment mean grading of bacterial load was 2.76 ± 0.10; after application of topical cefadroxil for 3 days, it was reduced to 0.38 ± 0.09. This was clinically as well as statistically significant. This shows that topical cefadroxil has efficacy in reducing bacterial load in staphylococcal superficial skin infections. No any adverse effect was observed during entire study period in any group (Table 5).

Table 5: Mean grading of bacterial load before and after treatment.

Groups of Patients	Grading of Bacterial Load Pre-Treatment (Mean ± S.E.M)	Grading of Bacterial Load Post-Treatment (Mean ± S.E.M)
Group A	2.9 ± 0.12	0.52 ± 0.09*
Group B	2.76 ± 0.10	0.38 ± 0.09*
Group C	3.2 ± 0.15	1.0 ± 0.17*
Group D	3.04 ± 0.16	0.28 ± 0.12*#

*= significant as compared to before treatment in same group ($p < 0.05$).
#= significant as compared to group C ($p< 0.05$).

The difference between these two treatment regimens was statistically not significant. But clinically, the reduction in bacterial load with oral cefadroxil was after 5 days while with topical cefadroxil, the reduction was after 3 days treatment. Topical cefadroxil reduced bacterial load faster than oral cefadroxil.

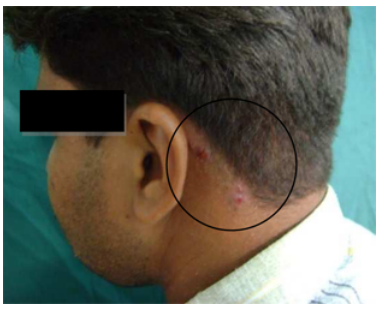

Image 3: Folliculitis (before treatment).

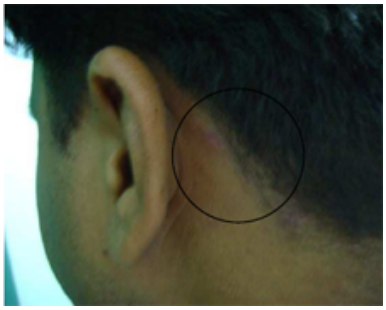

Image 4: After treatment with topical cefadroxil (3%).

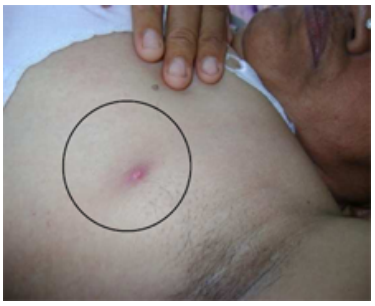

Image 5: Pustular lesion in left axillary region (before treatment).

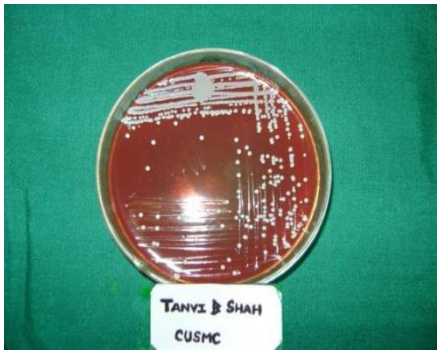

Image 6: Bacterial load (4+) (before treatment).

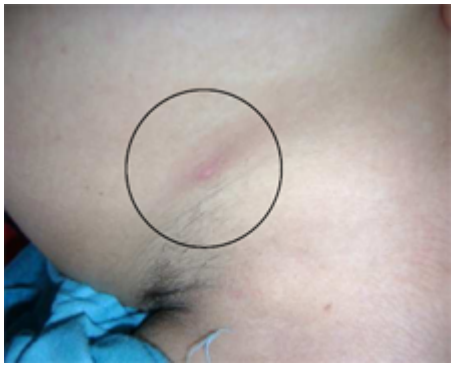

Image 7: After 3 Days (after treatment with 5% topical cefadroxil).

Image 8: Bacterial load (1+) (after treatment with 5% topical cefadroxil).

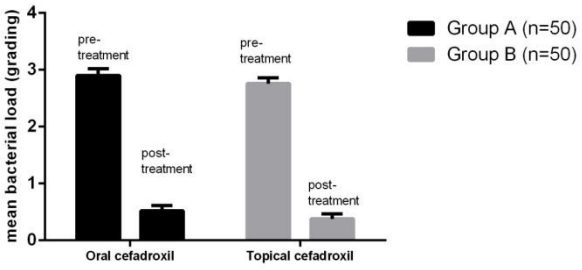

Figure 2: Comparison of mean grading of bacterial load before and after treatment with oral cefadroxil and topical cefadroxil (n = 50).

GROUP C Vs. GROUP D: In Group C, pre-treatment mean grading of bacterial load was 3.2 ± 0.15. After three days of treatment with oral cefadroxil plus topical placebo mean grading was 1.0 ± 0.17. This was statistically significant. In Group D pre-treatment mean grading of bacterial load was 3.04 ± 0.16; after treatment with oral plus topical cefadroxil combination for 3 days, it was reduced to 0.28 ± 0.12. This was clinically as well as statistically significant (Table 5).

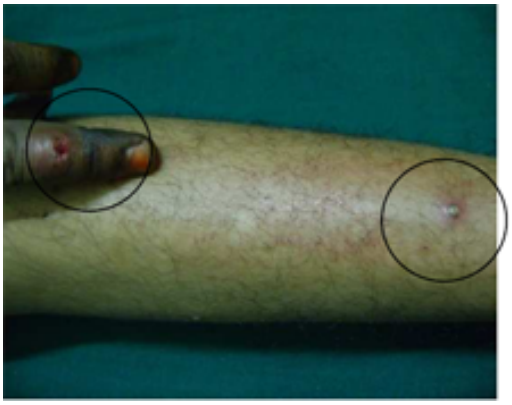

Image 9: Exudating lesion in right middle finger and pustular lesion on left lower leg (pre-treatment).

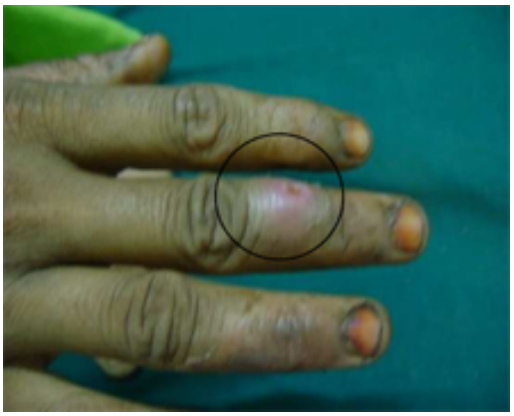

Image 10: Right middle finger after 3 days (after treatment with oral plus topical cefadroxil).

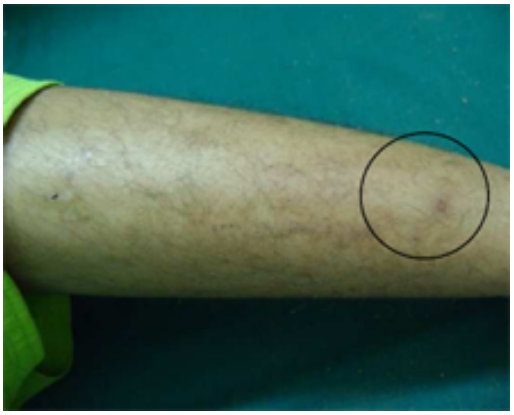

Image 11: Left lower leg after 3 days (after treatment with oral plus topical cefadroxil).

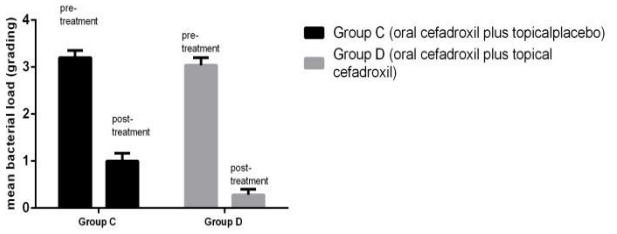

Figure 3: Comparison of mean grading of bacterial load after treatment with oral cefadroxil plus topical placebo and oral cefadroxil plus topical cefadroxil after 3 days (n=25).

The difference between group C vs group D was statistically as well as clinically significant (Table 5). No any adverse effect was observed during entire study period in any group.

DISCUSSION

In healthy human volunteers, pre-treatment mean grading for bacterial load was 2.72 ± 0.19 in rt. anterior nare and 2.44 ± 0.23 in left anterior nare. This shows normal carriage pattern of pathogenic strains in healthy population. Williams et al[20] produced evidence that the nose is the source of staphylococcal skin infections. Nagmoti MN et al[21] has shown that prolonged staphylococcal carriage in anterior nares could also be one of the causative factors for primary pyoderma. Tulloch et al[22] provided the strains of staphylococci isolated from a skin infection and from the anterior nares of the same patient were identical. This proved that nose is the primary source of infecting organisms in most cases of chronic staphylococcal skin infections. He also stressed on the importance of adequate sterilization of the anterior nares in the treatment of staphylococcal skin infections and methods for doing that. In our study, in both nares the decrease in bacterial load was statistically significant. While in comparison of placebo and topical cefadroxil, later decreases the bacterial load more significantly. This shows that topical cefadroxil has efficacy against pathogenic strains of staphylococci and preparation was safe for healthy human volunteers.

Pooled results of ten studies which compared mupirocin with oral erythromycin showed significantly better cure rates or more improvement with mupirocin (OR 1.76, 95% CI 1.05 to 2.97). However no significant differences were seen between mupirocin and cephalexin (Bass 1997)[16] or ampicillin (Welsh 1987).[23] Fusidic acid was significantly better than erythromycin in one study (Park 1993)[24], but no difference was seen between fusidic acid and cefuroxime in another arm of the same study. Bacitracin was significantly worse than oral cephalexin in one small study (Bass 1997)[16], but no difference was seen between bacitracin and erythromycin (Koranyi 1976)[25,] or penicillin (Ruby 1973).[26] A sensitivity analysis on the influence of the quality score on the comparison of mupirocin versus erythromycin (ten studies) revealed that there was no clear relation between the quality score of the study and the outcome. In meta-analysis, the three studies of good quality (Britton 1990; Dagan 1992; McLinn 1988)[9,12,13] revealed a better cure rate of mupirocin compared to erythromycin (OR 3.73 95% CI 1.35 to 10.34). The odds ratio for the overall analysis of ten studies also shows benefit for mupirocin. Another study (Moraes Barbosa 1986)[27] showed that oral erythromycin was significantly more effective than both neomycin/bacitracin (OR 0.06, 95% CI 0.01 to 0.68) and chloramphenicol (OR 0.14, 95% CI 0.02 to 0.96). There was no significant difference between fusidic acid and erythromycin (OR 3.57, 95% CI 0.53 to 23.95).

In our study there was no statistical significant difference between oral and topical therapy with cefadroxil. But results obtained with oral cefadroxil were after 5 days treatment, while results obtained with topical cefadroxil were after 3 days treatment. So, clinically topical cefadroxil provided faster results in mild to moderate infections. The combination of oral plus topical cefadroxil has shown synergistic results in terms of cure of the infection. The groups of patients with mean grading of bacterial load 3.2 ± 0.15 and 3.04 ± 0.16 had been given combination therapy i.e. oral cefadroxil plus placebo and oral cefadroxil plus topical cefadroxil respectively. With oral plus topical cefadroxil grading of bacterial load decreased to 0.28 ± 0.12, while with oral cefadroxil plus placebo it decreased to 1 ± 0.17. So in moderate to severe infection combination of oral plus topical cefadroxil achieved faster cure than oral or topical treatment alone.

CONCLUSION

Overall, the data from our study show that topical preparation of cefadroxil is safe and significantly effective in decreasing the bacterial load of pathogenic staphylococci present in anterior nares. There is no statistically significant difference between treatment with oral and topical cefadroxil, but on the grounds of efficacy and improved patient compliance, topical cefadroxil has a significant role in treatment of staphylococcal superficial skin infections. 3% preparation is safe and efficacious for infections viz., impetigo, boils, sycosis barbae, folliculitis etc. 5% preparation is proved better for the infections in areas like axillae, gluteal region, thigh, etc. where chances of friction with cloths are more. The combination of oral plus topical cefadroxil is synergistic especially in moderate to heavy bacterial growth. Limitation of this study was that topical cefadroxil was freshly prepared and given to patients for 2-3 days. Further research is needed to prepare topical formulation with stability and long shelf life and to confirm the efficacy on large number of patients.

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Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

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