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RESEARCH ARTICLE
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COMPARATIVE EFFICACY AND SAFETY OF TOPICAL 1% IVERMECTIN AND 5% PERMETHRIN CREAMS IN PEDIATRIC PATIENTS WITH UNCOMPLICATED SCABIES: A PROSPECTIVE CLINICAL STUDY

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ABSTRACT

Introduction: Scabies is a highly contagious skin condition caused by Sarcoptes scabiei var. hominis. Pediatric patients are particularly vulnerable due to close interpersonal interactions, necessitating effective and well-tolerated treatment options. Although topical 5% Permethrin is widely used, topical 1% Ivermectin cream is emerging as an alternative with potential advantages in efficacy and tolerability.

Methods and Material: A prospective, comparative clinical trial was conducted on 140 pediatric patients of age group 5 to 18 years diagnosed with uncomplicated scabies in a tertiary care hospital. Participants were randomly assigned to receive either topical 1% Ivermectin or topical 5% Permethrin cream, applied once at night and repeated after seven days.

Treatment efficacy was assessed at weeks 1, 2, and 4 based on pruritus severity (VAS scale), lesion count, treatment response, and adverse effects. Chi-square tests, t-tests, and Fischer's exact test were used to compare treatment outcomes.

Results: By week 4, the Ivermectin group demonstrated significantly superior improvement in pruritus severity (VAS score: 2.1 ± 0.9 vs. 2.8 ± 1.0, $p < 0.001$) and lesion count reduction. A significantly higher percentage of patients in the Ivermectin group achieved a good response (>75% improvement) compared to the Permethrin group (45.71% vs. 24.28%, $p = 0.049$). Adverse effects were less frequent in the Ivermectin group (17.1%) compared to the Permethrin group (41.4%).

Conclusions: Topical 1% Ivermectin cream demonstrated greater efficacy, faster symptom relief, and a better safety profile compared to 5% Permethrin in pediatric scabies. These findings suggest that

Ivermectin may be a preferred first-line treatment, especially in children. Future studies with larger cohorts are essential to confirm these results and assess resistance patterns.

Key words- Scabies, sarcoptes scabiei, pediatric dermatology, permethrin, ivermectin

INTRODUCTION

Scabies is a highly contagious parasitic skin disease caused by Sarcoptes scabiei var. hominis[1]. It manifests as severe itching, erythematous papules, and burrows, commonly affecting areas such as the interdigital spaces, wrists, axillae, periumbilical region, and buttocks. Scabies is a global health concern, affecting an estimated 300 million individuals worldwide at any given time[2]. Scabies disproportionately affects pediatric populations, especially in overcrowded settings with poor hygiene and limited healthcare access[3].

Traditional treatments for scabies include topical agents such as Permethrin, Lindane, Benzyl Benzoate, and Crotamiton. Among these, 5% Permethrin cream has been considered most effective. However, increasing resistance to Permethrin and its potential for skin irritation have led to the exploration of alternative treatment options[4,5]. Ivermectin, an antiparasitic agent with a broad spectrum of activity, has emerged as a promising alternative due to its ease of application, fewer adverse effects, and favorable pharmacokinetic properties[6].

This study aims to compare the efficacy, safety, and tolerability of topical 1% Ivermectin cream versus 5% Permethrin cream in pediatric patients with uncomplicated scabies. Given the high prevalence of scabies in children and the need for an effective, well-tolerated treatment option, this research seeks to determine whether topical Ivermectin can serve as a superior alternative to Permethrin.

MATERIALS AND METHODS

A prospective comparative study was conducted at the Dermatology OPD of a tertiary care hospital, Bareilly, over one year. A total of 155 pediatric patients with uncomplicated scabies were screened for eligibility. Of these, 22 patients were excluded due to not meeting the inclusion criteria (n=15), declining participation (n=7) and 3 due to other reasons.

The remaining 140 patients were randomly assigned to receive either 1% Ivermectin cream (n=70) or 5% Permethrin cream (n=70). A detailed flow of participant enrollment, exclusions, randomization, and follow-up is illustrated in Figure 1.

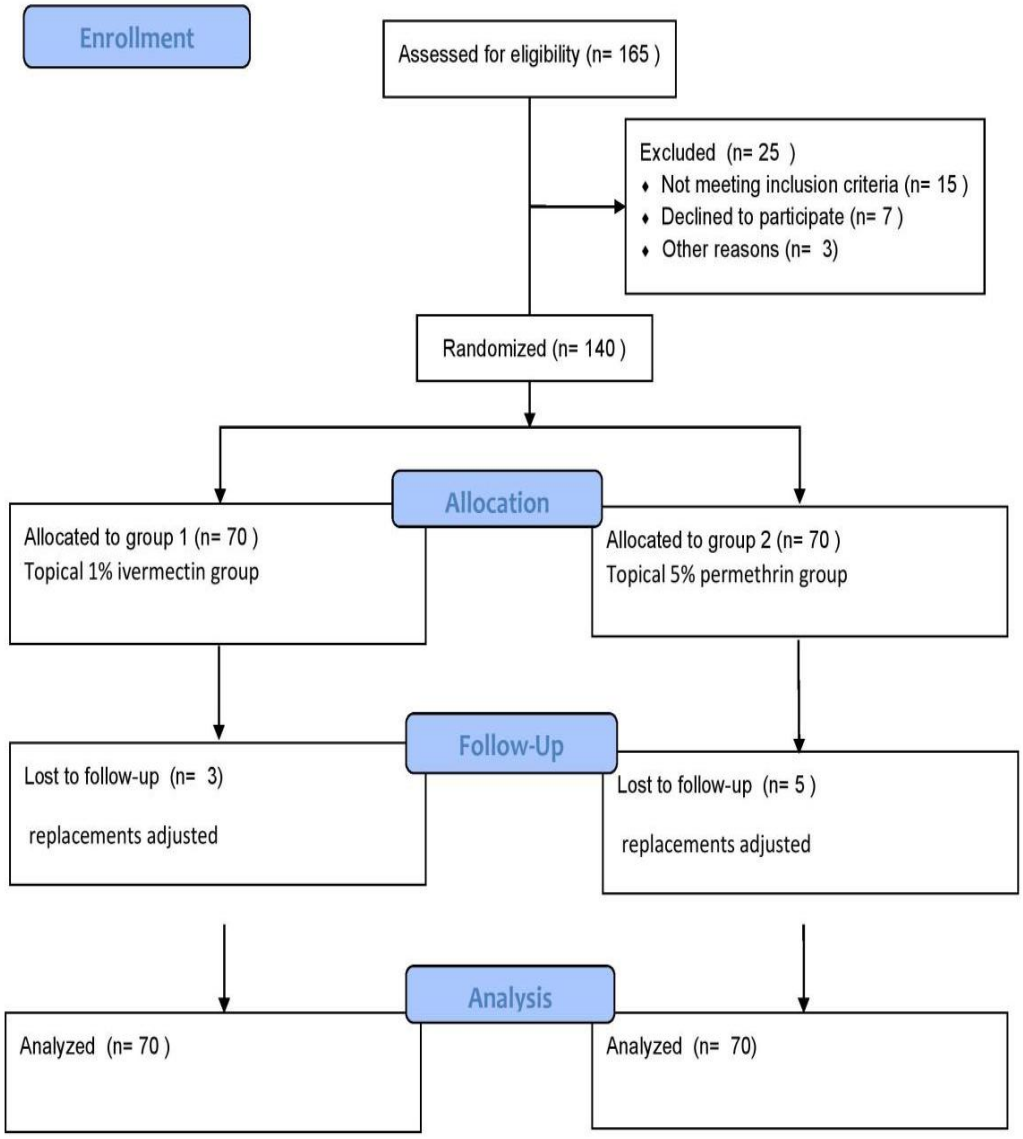
Inclusion Criteria:

Pediatric patients (5-18 years) with clinically diagnosed uncomplicated scabies.
Patients who consented to adhere to the study protocol and attend all follow-up visits.

Exclusion Criteria:

Patients with prior use of systemic or topical scabicidal agents within the previous four weeks, history of hypersensitivity to Permethrin or Ivermectin, atypical scabies presentations such as crusted scabies, patients with secondary bacterial infections.

Figure 1: CONSORT Flow Diagram



The flowchart represents the enrollment, randomization, follow-up, and analysis of study participants. A total of 155 pediatric patients were assessed for eligibility, out of which 22 were excluded due to not meeting inclusion criteria (n=15) or declining participation (n=7) and 3 due to other reasons. The remaining 140 patients were randomized into two groups: 1% Ivermectin cream (n=70) and 5% Permethrin cream (n=70). After treatment, a small number of patients were lost to follow-up (n=3 in group 1 and n=5 in group 2), but adjustments ensured 70 patients were analyzed per group.

Parents and guardians of all patients were informed about the disease, the advantages of the treatment, and any possible adverse effects. Ethical committee approval (IRB No. 52/2023) and Informed consent was taken from all patient's Parents/Guardian before initiation of treatment. Diagnosis was made clinically and patients were assigned into two treatment groups by simple randomization; Group 1: Received 1% topical Ivermectin and Group 2: Received 5% topical Permethrin.
Both treatments were applied to the entire body and reapplied after seven days. Clinical improvement was assessed at weeks 1, 2, and 4 using the Visual Analog Scale (VAS) for pruritus severity and lesion count.

ASSESSMENT OF PARAMETERS[7]:

Pruritus severity was assessed using the Visual Analog Scale (VAS), a 10 cm line where 0 represents no itching and 10 represents the most intense itching. Based on VAS scores, pruritus severity was categorized as mild (1-3), moderate (4-6), and intense (7-10).

Disease severity was determined by the total number of lesions and classified into three categories: mild (≤10 lesions), moderate (11-49 lesions), and severe (≥50 lesions).

Based on treatment response, patients were further classified into four response categories:

Good Responders: >75% improvement in both pruritus severity and disease severity scores.

Moderate Responders: 51-75% improvement in both pruritus severity and disease severity scores.

Mild Responders: 26-50% improvement in both pruritus severity and disease severity scores.

Poor Responders: ≤25% improvement in both pruritus severity and disease severity scores.

Standardized Statistical Analysis

Statistical analysis was conducted using SPSS v26. Baseline data were summarized as mean ± SD and percentages. Chi-square, t-test, and Fisher's exact test were used for comparisons. Logistic regression adjusted for confounders. Statistical significance was set at $p < 0.05$, with 95% CI reported.

RESULTS

The study included 140 pediatric patients diagnosed with uncomplicated scabies, with 70 patients each in the Ivermectin and Permethrin groups. Baseline characteristics were comparable across groups.[table *1*, *2*]

Table 1: Demographic Characteristics among study population

Groups	Mean Age (years) ± SD	Male/Female	Rural/Urban	Lower SES / Upper SES (%)	Test Statistic (χ^2 / t)	p-value
Group 1 (Topical 1% Ivermectin)	11.2±3.5	39 / 31	54 / 16	97.16/2.84	t = 0.32 χ^2= 1.40, 0.04,1.91	0.747 0.237, 0.837, 0.167
Group 2 (Topical 5% Permethrin)	11.0±3.8	31 / 39	56 / 14	90.0 /10.0		

Table 2: Clinical Characteristics among study population

Groups	Close Contacts Affected (%)	Complaint Duration (weeks) ± SD	p-value	Test Statistic (χ^2 / t)
Group 1 (Topical 1% Ivermectin)	87.14	6.2 ± 2.5	0.262	χ^2 = 1.26 t = -0.74
Group 2 (Topical 5% Permethrin)	78.57	6.5 ± 2.3	0.461	

By week 4, the Ivermectin group demonstrated significantly better improvement in pruritus severity (VAS score : 2.1 ± 0.9 vs. 2.8 ± 1.0, $p<0.001$) and lesion count reduction. A higher percentage of patients in the Ivermectin group achieved a good response (>75% improvement) compared to the Permethrin group (32 out of 70 patients (45.71%) vs. 17 out of 70 patients (24.28%), p=0.049).[table 3, 4 and figure 2, 3]

Table 3: Comparison at 1st week, 2nd week and 4th week by visual analogue scale for itching

Week	Group 1 (Mean ± SD)	Group 2 (Mean ± SD)	Test Statistic (t)	p-value
1st	6.5 ± 1.2	6.8 ± 1.3	t = -1.42	0.45
2nd	4.4 ± 1.1	4.7 ± 1.2	t = -1.54	0.31
4th	2.1 ± 0.9	2.8 ± 1.0	t = -4.35	<0.001

Response	Group 1 (n=70)	Group 2 (n=70)	Test Statistic	p-value
Poor	0	0	Fisher's Exact Test	0.049
Mild	8	18		
Moderate	30	35		
Good	32	17		

1. **Table 4: Treatment Response among study population**

Figure 2: Hand images of a Group 1 patient treated with topical ivermectin 1% cream at week 0 (a) and after week 4 of treatment (b)

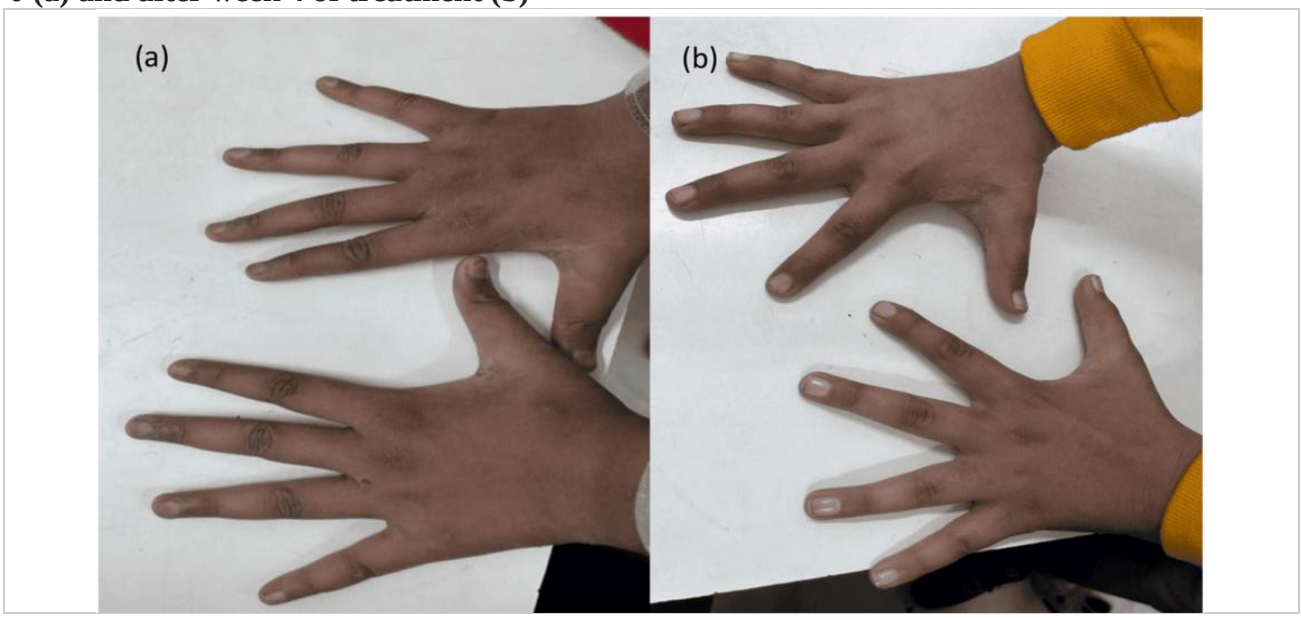


Figure 2: (a) Baseline presentation at week 0 before treatment initiation.
(b) Follow-up at week 4, showing improvements after the application of topical ivermectin 1% cream.

Figure 3: Hand images of a Group 2 patient treated with topical permethrin 5% cream at week 0 (a) and after week 4 of treatment (b)

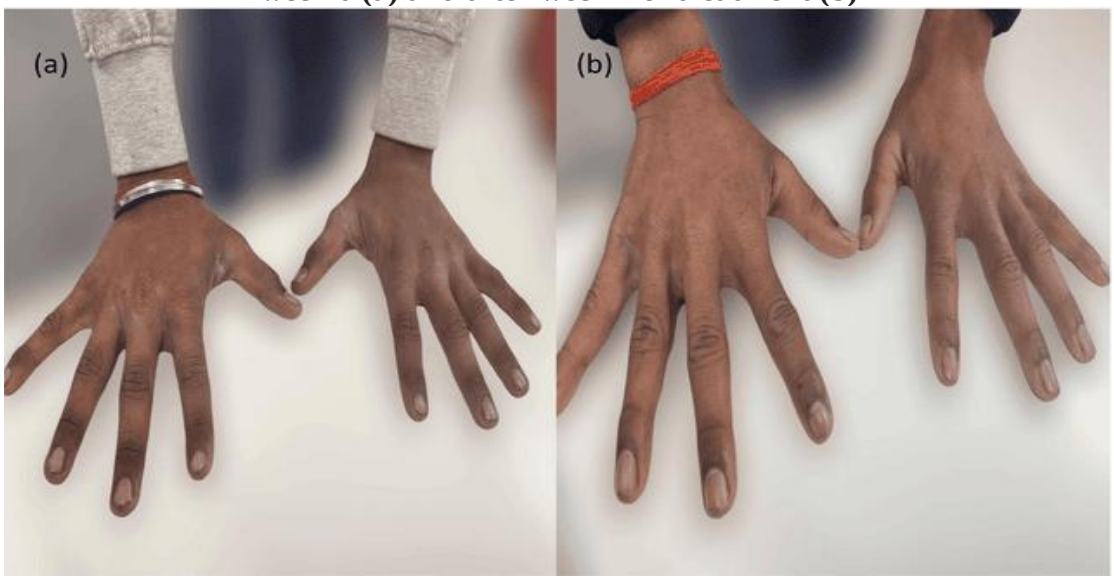


Figure 3: (a) Hand appearance at week 0, before treatment initiation.
(b) Follow-up at week 4, showing improvements after treatment with topical permethrin 5% cream.

Adverse effects occurred more frequently in the Permethrin group in 29 out of 70 patients (41.4%) than in the Ivermectin group in 12 out of 70 patients (17.1%), with increased itching, erythema, and burning/stinging sensations being the most reported symptoms. Only one patient in the Permethrin group experienced a relapse at the end of the 4th week, whereas no relapses were reported in the Ivermectin group. [table *5*]

Table 5: Adverse Effects of topical ivermectin and permethrin group

Side Effects	Group 1 (n=70)	Group 2 (n=70)
Increased Itching	3	9
Redness/erythema	2	7
Burning/Stinging	2	5
Dryness & Peeling	3	4
Dizziness/Headache	1	2
Secondary Infection	1	2
Total Patients with Side Effects	12	29

Discussion

Scabies remains a significant public health concern, particularly among pediatric populations in overcrowded settings. Effective treatment is crucial for reducing transmission and preventing complications such as secondary bacterial infections. This study compared the efficacy and safety of topical 1% Ivermectin and 5% Permethrin creams, demonstrating Ivermectin's superior clinical outcomes.

Demographic and Clinical Observations

The demographic characteristics of the study population were comparable across both treatment groups, ensuring homogeneity. The majority of patients were in the 10-15 years age group, with no significant differences in age or gender distribution. Our findings diverge from those of Hasan et al. who reported a higher prevalence of scabies in males than in females among children aged 3 to 18 years[8].

Rural residency was predominant in both groups, consistent with the findings of Romani et al. who noted a higher prevalence of scabies in rural areas compared to urban regions[9]. Socioeconomic status also showed no significant variation between the groups, further confirming the uniformity of baseline characteristics. In line with our findings, Heukelbach et al. reported significantly higher rates of scabies in low-income communities compared to high-income populations[10]. Similarly, Feldmeier et al. observed that crowded living conditions and poor personal hygiene contribute to higher scabies transmission rates, particularly in low-income populations[11].

Close contact with infected individuals was a major risk factor in both groups, with a slightly higher percentage in the ivermectin group in 61 out of 70 patients (87.14%) compared to the permethrin group 55 out of 70 patients (78.57%). This observation aligns with Barot et al. who found that prolonged contact between children and affected individuals is a common mode of scabies transmission in pediatric populations, highlighting the role of household and school environments[12]. The mean duration of symptoms prior to treatment initiation was similar between both groups, suggesting comparable disease progression at baseline.

Treatment Efficacy and Response

The Visual Analogue Scale (VAS) scores for itching demonstrated a steady decline in both treatment groups over the four-week period. No statistically significant difference in VAS scores was observed between the groups during the first and second weeks. However, by the fourth week, the ivermectin group exhibited a significantly greater reduction in symptoms ($p < 0.001$), indicating superior efficacy of topical 1% ivermectin in alleviating pruritus and lesion severity.

These findings were further supported by the response to treatment. A higher proportion of patients in the ivermectin group 32 out of 70 patients (45.71%) achieved a "good response" compared to those in the permethrin group 17 out of 70 patients (24.28%). In contrast, a greater percentage of patients in the permethrin group exhibited a "mild response," suggesting a slower rate of symptom resolution. This difference was statistically significant ($p = 0.049$), highlighting that ivermectin leads to a more rapid and effective resolution of scabies symptoms compared to permethrin.

Adverse Effects and Safety Profile

The safety and tolerability of treatment are crucial factors in selecting medications, especially for pediatric patients. In this study, adverse effects were more frequently reported in the permethrin group in 29 out of 70 patients (41.42%) compared to the ivermectin group in 12 out of 70 patients (17.14%). The most commonly reported side effects included increased itching, erythema, and burning or stinging sensations, with a higher incidence in the permethrin group. The difference in side-effect profile between the two treatments was statistically significant ($p < 0.05$).

The lower incidence of adverse effects in the ivermectin group suggests better patient tolerance, which may contribute to improved compliance and overall treatment success. These findings underscore the importance of considering both efficacy and safety when choosing a treatment regimen for pediatric scabies.

Comparison with Previous Studies

The findings of this study are consistent with previous research comparing topical ivermectin and permethrin for scabies treatment. Studies by Chhaiya et al. and Goldust et al. reported similar efficacy rates for both treatments but emphasized faster symptom resolution with ivermectin[2,13]. Our study further supports this by demonstrating that ivermectin is more effective in symptom relief and treatment response.

In contrast, studies by Usman et al. and Saeed et al. found no significant difference between the two treatments at the four-week mark[14,15]. The discrepancies between their findings and ours could be attributed to differences in study populations. Specifically, previous studies primarily focused on adult patients, whereas our study exclusively involved pediatric patients. This distinction may be significant, as pediatric patients may have different treatment responses due to factors such as immune system differences, skin physiology, or drug metabolism. Additionally, variations in study design, sample size, or duration of follow-up could also contribute to the observed differences in results.

Limitations of the study

Single-Center Study: Conducting the research in a single tertiary care hospital may not reflect variations in different demographic and geographic settings.

Short Follow-Up Duration: The study followed patients for only four weeks; longer follow-up could provide insights into recurrence rates and long-term efficacy.

Self-Reported Symptoms: Pruritus severity and treatment adherence were based on patient/guardian reports, which may introduce recall bias.

CONCLUSIONS

Topical 1% Ivermectin cream demonstrated greater efficacy, faster symptom relief, and a better safety profile compared to 5% Permethrin in pediatric scabies. These findings suggest that Ivermectin may be a preferred first-line treatment, especially in children. Future studies with larger cohorts are essential to confirm these results and assess resistance patterns.

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CONFLICTS OF INTEREST no conflict of interest to disclose

ETHICS STATEMENT We have taken Ethical committee approval (IRB No. 52/2023) and Informed consent from all patient's Parents/Guardian before initiation of treatment.

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LEGENDS

Table 1: SD- standard deviation
SES- socioeconomic status
%- percentage
x^2- chi-square test was used for categorical variables (Male/Female, Rural/Urban, Lower SES/Upper SES)
x^2 - 1.40 (Male/Female), 0.04 (Rural/Urban), 1.91 (Lower SES/Upper SES)
t- independent t test used for mean age
p value (< 0.05) - indicate statistical significance
p- 0.747 (mean age), 0.237 (Male/Female), 0.837 (Rural/Urban), 0.167 (Lower SES/Upper SES)
Table 2: %- percentage
SD- standard deviation
x^2- chi-square test used for close contacts affected
t- independent t test used for complaint duration
p value (< 0.05) - indicate statistical significance
Table 3: mean± SD - mean± standard deviation
Independent t-test(t) was used to compare VAS scores between the two groups.
p value (< 0.05) - indicate statistical significance
Table 4: n- total number of patients
p value (< 0.05) - indicate statistical significance
Table 5: n- total number of patients