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ASSESSMENT OF THE EFFECTIVENESS OF COMBINATION OF SYSTEMIC AND TOPICAL ANTIFUNGALS AGAINST MONOTHERAPY WITH EITHER ONE IN ONYCHOMYCOSIS; RISK FACTOR ASSESSMENT AND IMPACT OF PATIENT COUNSELLING ON QUALITY OF LIFE OF PATIENTS – A PILOT STUDY

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ABSTRACT

Background: Onychomycosis is one of the common infections which affect the daily activities and quality of life of patients. It will affect both the finger nails and toe nails. It has a major risk in the diabetic patients. **Aim:** To assess the effectiveness of monotherapy and combination of systemic and topical antifungals, to assess the risk factors associated with disease and to improve quality of life by patient counselling. **Objectives:** To assess the effectiveness of monotherapy and combination therapy, to evaluate the risk factors of disease and to evaluate the impact of patient counselling on quality of life by DLQI . **Materials and Methods:** A prospective observational study consisting of 20 patients with onychomycosis was conducted in the outpatient and inpatient Department of Dermatology at Cosmopolitan Hospital-Post Graduate Institute of Medical Science and Research, Thiruvananthapuram, Kerala. Patients were requested to sign the informed consent after knowing about our study using the patient information sheets. Patients who were having onychomycosis were analyzed using KOH method were included in the study. Also, the patient having onychomycosis and the history of diabetic, trauma, any nail infections were included. The age group was in between 20-80

years. Outpatients and Inpatients are selected for the study. The patients was divided into two groups, patients receiving monotherapy as Group I and patients receiving combination therapy as Group II and the KOH method was done on each individual. SCIO scoring was calculated and recorded. SCIO scoring from 1-30, the effectiveness of the treatment was obtained through this scoring method. Patient counseling was given to them using DLQI questionnaire, consisting of 10 questions and scoring range between 0-30, it was taken before and after treatment. Statistical analysis was performed using suitable computer programming. **Results:** The proportion of combination therapy from the paired t test was found to be $p< 0.001$ and the monotherapy $p= 0.343$. Onychomycosis was mostly affected on females (housewives), at the age group of 61-70 and DLSO type of onychomycosis was common. Most of the patients are diabetic and toe nails are affected more in such cases. **Conclusion:** Combination therapies are more effective than monotherapy and the quality of life of patient was improved after the patient counseling.

KEYWORDS: Onychomycosis, KOH method, monotherapy and combination therapy, DLQI, SCIO Index.

INTRODUCTION

Healthy-looking nails play an important role in an individual's body image and thus affect interpersonal relationships.[1] Onychomycosis is a fungal infection of nails caused by dermatophytes, yeasts, and non-dermatophytic molds where dermatophytes account for nearly 70% of the cases.[2] Although onychomycosis is not life threatening, the psychosocial and emotional effects due to the disease can be profound and it can have a significant negative impact on the quality of life of those affected.[3,4] Currently available routine laboratory methods are direct microscopy with potassium hydroxide mount (KOH) and mycological culture. The aging of population, increased use of immunosuppressive drugs, an increase in the prevalence of underling disease such as HIV and diabetes that suppress the immunostatus of patients, increased exposure to spas and public swimming pools, the use of tightly fitting shoes for fashions, and long-distance running in athletic games have been recognized as factor for the rise in the onychomycosis.[5,6] The different types of onychomycosis include DLSO, PSO, SWO, TDO, Candida onychomycosis, Endonyx. The most commonly given drugs for the treatmentof onychomycosis include Amorolfine, Ciclopirox, Luliconazole, Fluconazole and Itraconazole, it can be given either as monotherapy or as combination therapy. The main purposes of this study were to determine

the effectiveness of treatment of onychomycosis, the etiology, and associated risk factors and improvement in quality of life of patients through the patient counseling.

MATERIALS AND METHODS

Study Design: Prospective Observational Study.

Study Site: Department of Dermatology at Cosmopolitan Hospital-Post Graduate Institute of Medical Science and Research, Thiruvananthapuram, Kerala.

Study participants: The study participants were recruited from the outpatient and inpatient Department of Dermatology based on the inclusion, exclusion criteria.

Inclusion criteria

- Patients at age group of 20-80
- Patients having history of trauma, diabetic, nail infection.

Exclusion criteria

- Those who were unwilling to give informed consent form.
- Serious skin disorders/ allergies other than Onychomycosis.
- Psychiatric/ Psychological dysfunctions.
- Pregnant, Lactating women.
- Hypersensitive to Antifungal agents.

After being informed about the study the informed consent was obtained from the out patient and in patient.

A total of 20 patients were included in the study who met the inclusion and exclusion criteria. Data's were collected using a suitably designed proforma.

Statistical Analysis

Statistical Analysis was performed using SPSS Software and the level of significance was assessed by using chi- square and paired t- test.

RESULTS

There were 20 patients diagnosed with Onychomycosis and receiving anti-fungal agents included, of which 10 patients are taking monotherapy of either oral or topical antifungals

(Group I) and other 10 patients are taking combination of oral and topical agents (Group II). In Group I, out of 10 patients 7 were females (70%) and 3 were males (30%) and in Group II, the number of females and males are 5 (50%). The gender is illustrated in fig.1 (P value is 0.361).

Table 1: Gender distribution.

Gender	Group I		Group II		Total		χ^2	Df	p
	n	%	n	%	n	%			
Female	7	70	5	50	12	60			
Male	3	30	5	50	8	40	0.833	1	0.361
Total	10	100	10	100	20	100			

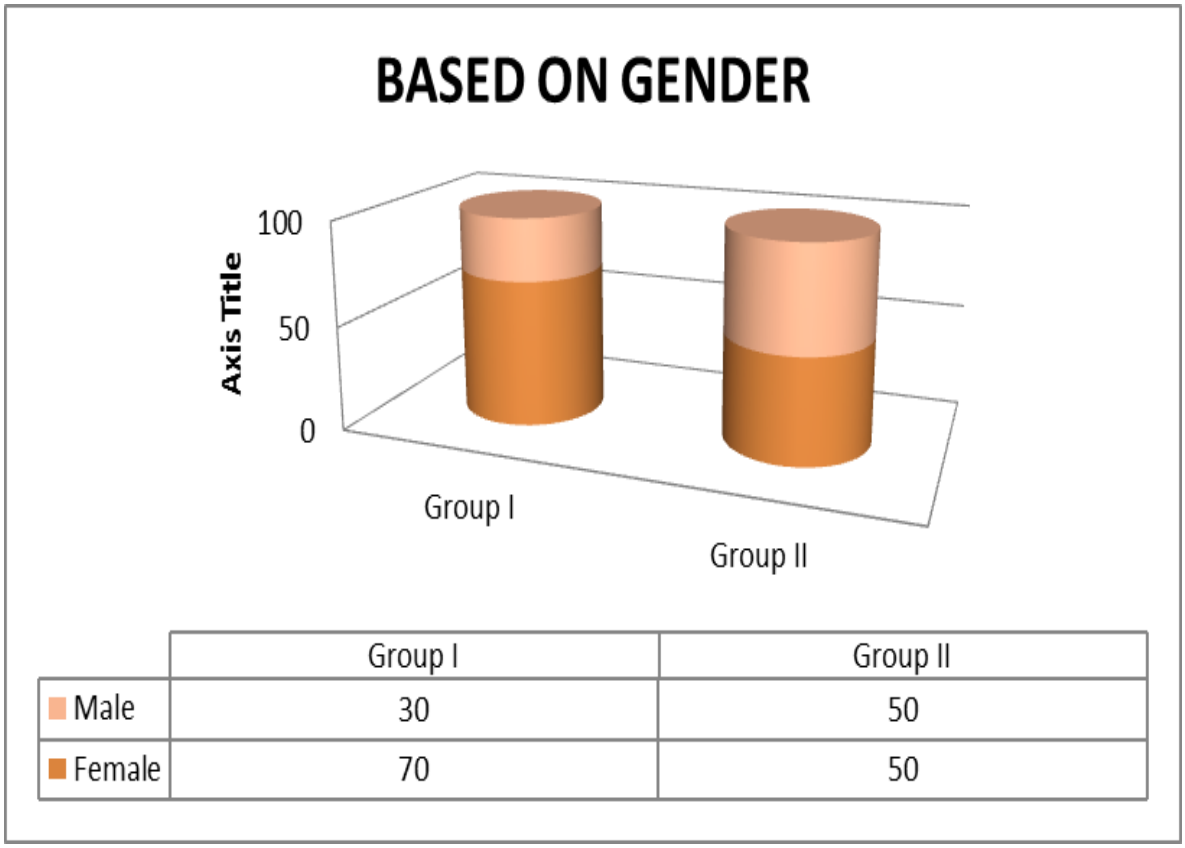

Figure 1: **Gender distribution in onychomycosis therapy, showing who are more involved in monotherapy and combination. In Group I (Monotherapy) females are more involved (70%) and in Group II, (Combination) males and females are equal in number (50%).**

Table 2: Age distribution.

Age	Group I		Group II		Total		χ^2	Df	P
	n	%	n	%	n	%			
<50	2	20	2	20	4	20	0.476	3	0.924
51-60	3	30	3	30	6	30			
61-70	4	40	3	30	7	35			
>70	1	10	2	20	3	15			
Total	10	100	10	100	20	100			

The inclusion criteria for age group were between 20-80. On the basis of that 20 patients in each group were divided into 4 groups. Figure 2 represents the age group classification of onychomycosis patients. It suggests that majority of patients were in the age group of 61-70 in case of monotherapy, ie 4 (40%) and least were in the age group of above 70, ie 1 (10%).

In case of combination, majority are seen in the age group of 51-60 and 61-70, ie 3 (30%) and least is seen in the age group of less than 50 and above 70, ie 2 (20%). From both the age groups, it is specific that at the age of 61-70 are more prone to onychomycosis (P value is 0.924).

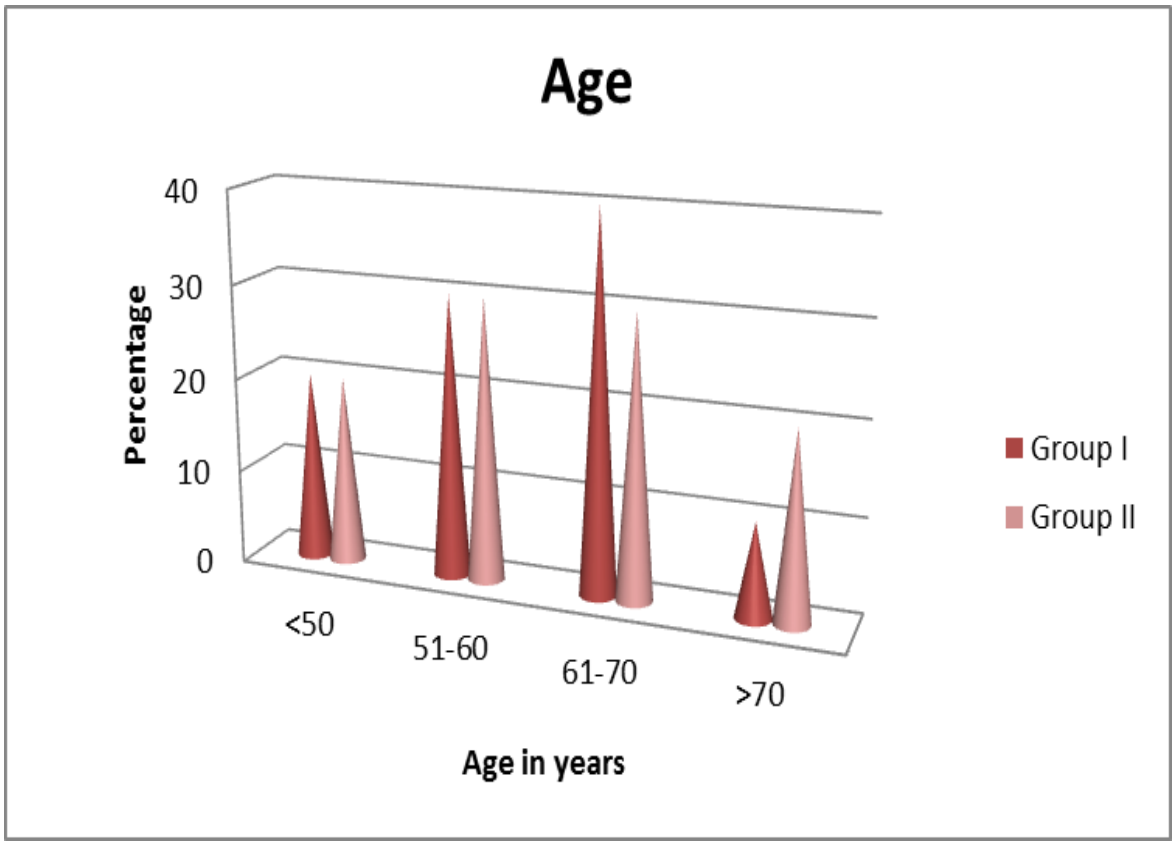

Figure 2: Percentage distribution of sample according to age in onychomycosis.

Table 3: Occupation wise classification of sample.

Occupation	Group I		Group II		Total		χ^2	Df	P
	n	%	n	%	n	%			
Driver	0	0	1	10	1	5	5.111	8	0.746
Electrician	0	0	1	10	1	5			
Exservice	1	10	1	10	2	10			
Farmer	1	10	1	10	2	10			
House wife	5	50	4	40	9	45			
Security	1	10	0	0	1	5			
Shopkeeper	0	0	1	10	1	5			
Student	1	10	0	0	1	5			
Teacher	1	10	1	10	2	10			
Total	10	100	10	100	20	100			

While in case of occupation wise classification, majority of the patients are house wife in both the groups, ie 5(50%) in monotherapy and 4(40%) in combination therapy and least are seen in other occupations like driver, teacher, security, electrician, farmer, ex-service, student and shopkeeper. Figure 3 shows the percentage distribution of samples according to occupation.

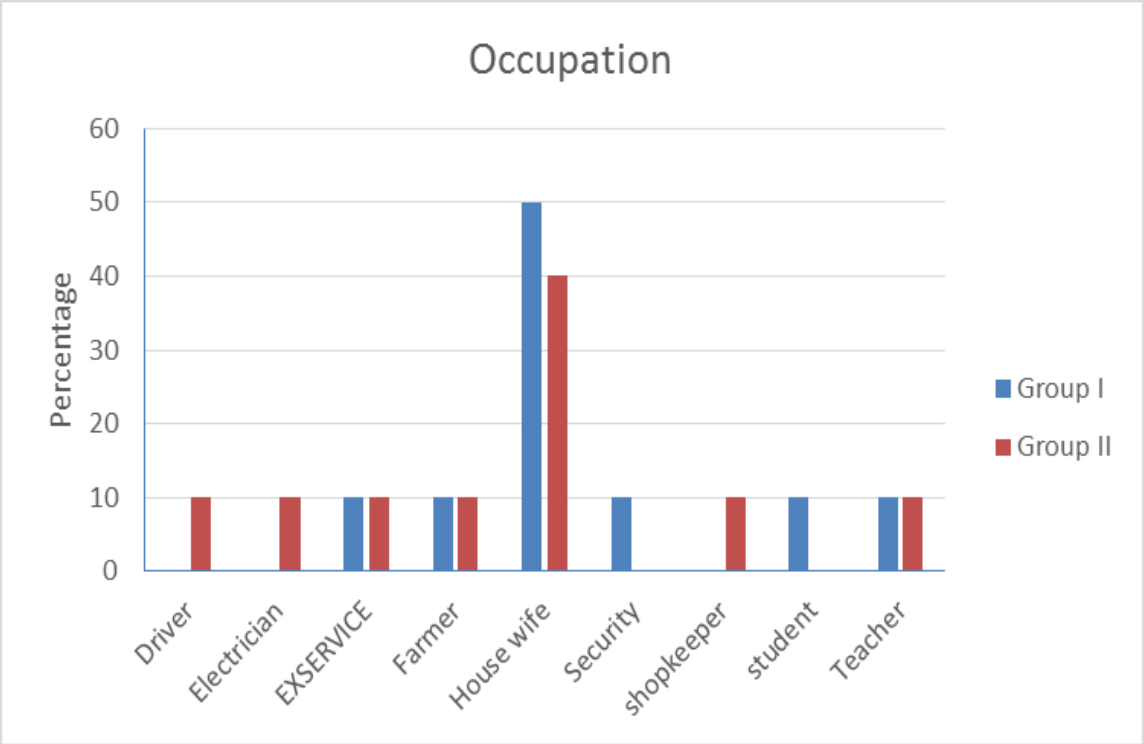

Figure 3: Percentage distribution of samples according to occupation.

From this graphical representation it is specific that house wife are more prone to the disease (P value is 0.746).

Table 4: Types of onychomycosis.

Type	Group I		Group II		Total		χ^2	Df	p
	n	%	n	%	n	%			
DLSO	2	20	9	90	11	55	10.121	2	0.006
PSO	5	50	1	10	6	30			
SWO	3	30	0	0	3	15			
Total	10	100	10	100	20	100			

Figure 4 and table 4 describe the different types of onychomycosis. The types of onychomycosis are DLSO, PSO and SWO.

The percentage distribution of these classes showed that DLSO are more while comparing both the groups, ie 11 (55%) and least is SWO, 3(15%) (P value is 0.006). In case of monotherapy, majority is PSO, 5 (50%) and least is DLSO, 2(20%). In case of combination, majority are in the class of DLSO, 9(90%) and least in SWO.

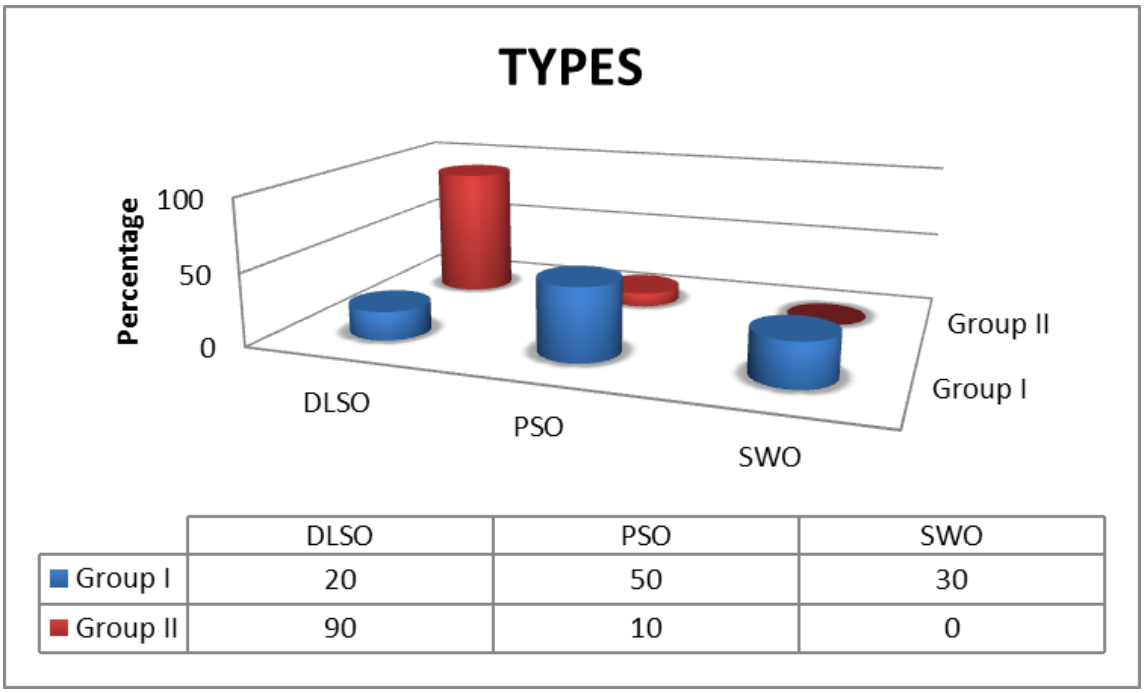

Figure 4: Percentage distribution of samples according to different types of onychomycosis.

Table 5: Percentage distribution of samples according to area of involvement.

Area	Group I		Group II		Total		χ^2	Df	p
	n	%	n	%	n	%			
finger nails	5	50	3	30	8	40	1.591	2	0.451
toe nails	5	50	6	60	11	55			
TOE,FINGER	0	0	1	10	1	5			
Total	10	100	10	100	20	100			

Onychomycosis can affect either finger nails/toe nails/both the nails. Figure 6 describes the area of involvement of nails. In case of monotherapy 5(50%) patients are reported for toe nail infection and 3(30%) for finger nails. While in combination, 5(50%) were having infected toe nails and 6(60%) patients having infected fingernails. By comparing both the groups, majority of cases are reported for toe nail infections, 11(55%) than finger nails, 8(40%). The P value is 0.451.

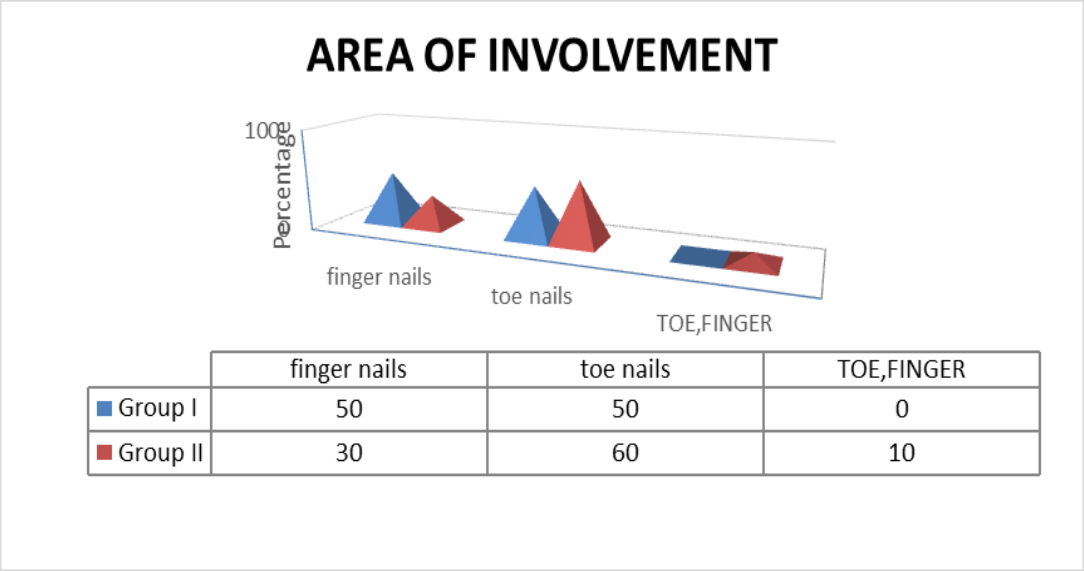

Figure 5: Percentage distribution of samples according to area of involvement.

Table 6: Percentage distribution of samples, about the risk factors.

Risk Factors	Group I		Group II		Total		χ^2	Df	p
	n	%	n	%	n	%			
Diabetes	3	30	6	60	9	45	1.818	1	0.177
Trauma	1	10	2	20	3	15	0.392	1	0.531
Water contact	3	30	2	20	5	25	0.267	1	0.606
Infection	2	20	1	10	3	15	0.392	1	0.531
Others	1	10	1	10	2	10	0	1	1
Total	10	100	10	100	20	100			

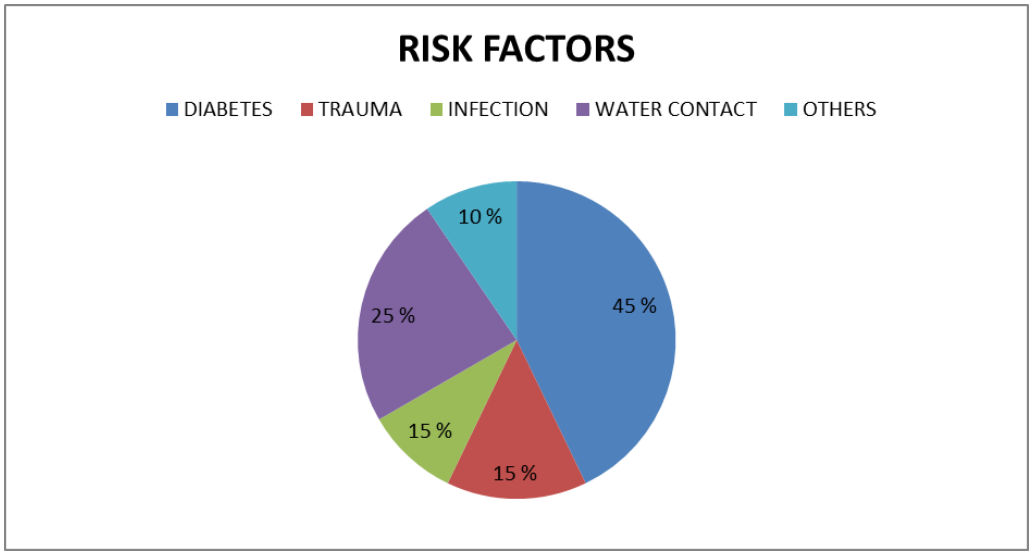

Figure 6: Percentage distribution of samples, according to various risk factors associated with the disease.

From figure 6, it is clear that there exist a strong correlation between various risk factors and the development of onychomycosis. 45% of patients was diabetic and its p value = 0.177, 15% of patients was trauma and its p value = 0.531, 25% of patients was in water contact and its p value = 0.606, 15% of patients was infectious and its p value = 0.531, 10% patients considered to be other risk factor and p value = 1. From these it was found to be diabetic is considered as the most risk factor among others.

Descriptive statistics of scio index

Table 7: The statistical values of SCIO index of samples in Group I & II before and after treatment.

Group I	**n**	**SCIO score**		**Paired t test**	
		Mean	**sd**	**t**	**p**
Before treatment	10	4.6	3.3	1	0.343
After treatment	10	4.0	2.2		
Group II	n	SCIO score		Paired t test	
		Mean	sd	t	p
Before treatment	10	18.1	1.7	16.38	<0.001
After treatment	10	6.9	1.9		

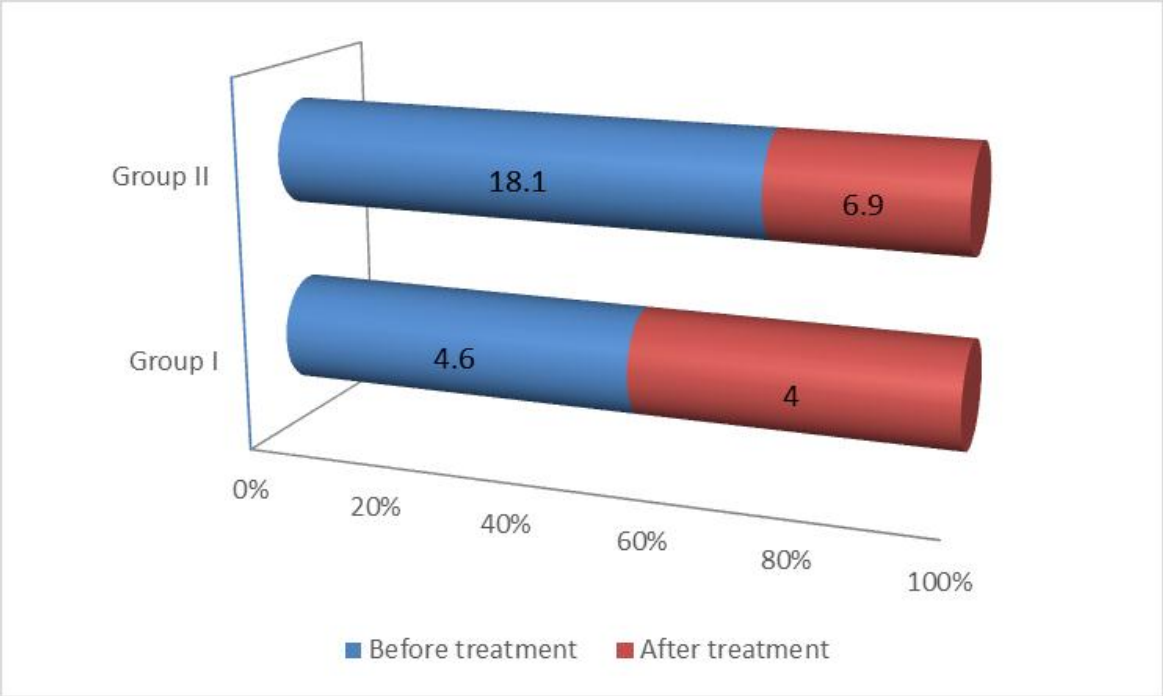

Figure 7: The mean of SCIO Index in samples before and after treatment.

From the figure it is clear about the clinical response of the patients towards the therapy. SCIO give an index of the overall severity of onychomycosis and it may be possible to better compare the clinical response to therapy. The higher score (range is 1 -30) suggests that the condition is more severe and may require more prolonged treatment. In case of group II, there is a mean difference of 11.2 between before and after treatment and in group I, the mean difference is 0.6, showing minor variation in the score. From the data it is clear that combination therapy is more effective than monotherapy.

Descripive statistics of dlqi

Table 8: The statistical values of DLQI of samples in Group I & Group II before and after counselling.

Group I	**n**	**DLQI score**		**Paired t test**	
		mean	**sd**	**t**	**p**
Before treatment	10	7.4	3.5	4.396	0.002
After treatment	10	3.1	0.9		
Group II	**n**	**DLQI score**		**Paired t test**	
		mean	**sd**	**t**	**p**
Before treatment	10	14.5	2.7	7.927	<0.001
After treatment	10	5.5	2.5		

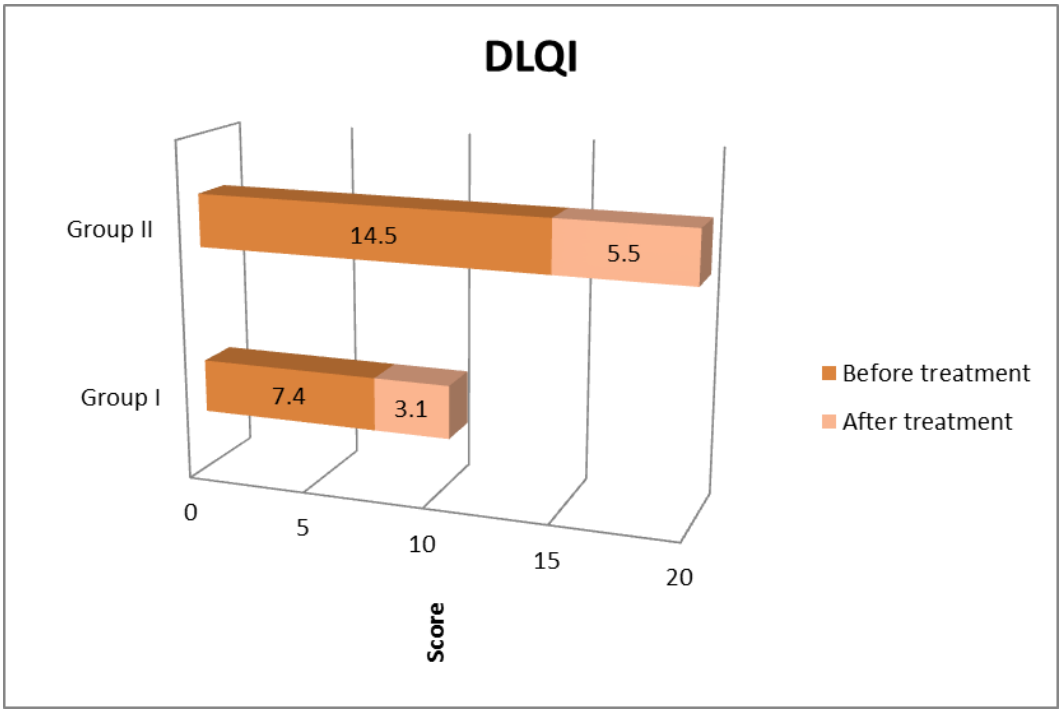

Figure 8: The mean of DLQI in samples before and after counseling.

DLQI is calculated by adding the score of each question, resulting in a maximum of 30 and a minimum of 0. The higher the score, the more quality of life is impaired.

From the figure it is clear that the QOL is largely affected, the symptoms are making greatly bad effects on patient's health. After giving proper patient counseling about disease, drugs and life style modifications the above mentioned score is obtained. The lowest score indicates better quality of lifeie, less than 10 (range 0-30). Majority of the patient's health status were improved after counseling. The p value is <0.001.

DISCUSSION

Onychomycosis is a common condition which may affect majority of the population of world wide. In our study female patients are more common, under the age group of above 50 years and this result was supported by a study done by Charussri Leeyaphan et al. In that study the disease was more commonly seen in female patients at the age group of above 60 years.

The most commonly affected occupational group were housewives comprising 50% patients in group 1 and 40% patients in group 2 because of the wetting of hands among housewives and frequent micro trauma during household work which increases the chance of onychomycosis. DLSO type of onychomycosis was the most common clinical pattern in our study in agreement with previous reports.[7,8]

Toenailsare more likely to be infected than finger nails because ofthe causative molds like fungi seen in soil, water, and decaying vegetation's. In our study, the patients having risk factors like diabetic, trauma, infections, water contact and others wereincluded; from these risk factors we concluded that diabetic patients(45%) are more prone to onychomycosis. The prevalence of onychomycosis has been shown to be significantlyhigher in diabetic patients than normal individuals was supported by a study done by Sarma .S et al.[8] Similar to our study, there was an increase in onychomycosis in diabetic patients.

In our study we conducted SCIO index scoring, before and after the treatment, in both the groups including monotherapy (p value – 0.343) and combination therapy (p value - <0.001), by this we concluded that combination therapy is most effective than monotherapy from paired t test. By conducting patient counseling using DLQI questionnaire before and after treatment, a drastic change was noticed in the quality of life of patients.

CONCLUSION

From this study we concluded that the combination therapy is most effective than the monotherapy through the SCIO index scoring method. So there is a need to give more medical attention to onychomycosis and all other onychopathies, otherwise it may leads to severe other conditions.

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