



*Lets scrape the opportunist*



*Comparison of the efficacy of  
Fluconazole mouthrinse and  
Clotrimazole mouthpaint in the  
treatment of Oral Candidiasis*

*Presented By*

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# *Introduction*



- ◆ Candidiasis occurs as an opportunistic infection in immunocompromised patients.
- ◆ Azoles – Ketoconazole, Itraconazole, Clotrimazole and Fluconazole have been the initial choice of antifungals for almost half a century.
- ◆ No study has evaluated the comparison of **clinical** and **mycological response** of Oral candidiasis to Fluconazole mouthrinse and Clotrimazole mouth paint.

# *Aim*

- ◆ To compare the efficacy of Fluconazole mouthrinse and Clotrimazole mouth paint in the treatment of oral candidiasis



# *Objectives*

- ◆ To compare the two test groups in terms of age, gender, severity of lesions prior to treatment.
- ◆ To compare the clinical efficacy of the two drugs.
- ◆ To compare the mycological cure achieved by the two drugs.
- ◆ To determine the side effects associated with the two drugs.

# *Subjects & Methods*

- ◆ The study group included 89 patients with a clinical diagnosis of oral candidiasis.
- ◆ A medical history was obtained and physical examination was conducted.
- ◆ Patients completed institution approved consent forms.

## INCLUSION CRITERIA

- ◆ Patients with signs and symptoms of Oral candidiasis like mucosal erythema, adherent white plaques, burning sensation and altered taste were included in the study.

# EXCLUSION CRITERIA

- ◆ If they were **pregnant or lactating**.
- ◆ If they had used any other **antifungal agent** during the past 10 days.
- ◆ If they were taking **barbiturates or anticoagulants**.
- ◆ If they had a known **sensitivity** to polyenes or the azole group of antifungals.
- ◆ If they had a history of **alcoholism, drug abuse, psychiatric disorder**.



- ◆ The first 43 patients - treated with fluconazole mouthrinse - **Group A.**
- ◆ 46 successive patients - treated with Clotrimazole mouthpaint - **Group B.**
- ◆ The **clinical diagnosis** - burning sensation / altered taste / mucosal erythema / adherent plaques.

- ◆ Signs and symptoms – **graded as** mild (+), moderate (++), and severe(+++)

Severity	Extent of lesion
<b>Mild(+)</b>	<2 localized areas
<b>Moderate(++)</b>	>2 localized areas
<b>Severe (+++)</b>	Generalized involvement

◆ Group A patients - **Fluconazole**  
2mg/ml in distilled water....

◆ Group B patients - 1% **Clotrimazole**  
mouthpaint....

- ◆ The mucosa of the patients was **swabbed** – laboratory.
- ◆ Patients
  - recalled after 2 weeks,
  - checked for clinical signs and symptoms
  - mycological assessment was carried out
- ◆ **Side effects** associated with both the mouthrinse and the mouthpaint were noted.

# Mycologic assessment:

- ◆ Candida colony counts were obtained using Sabouraud's dextrose agar.

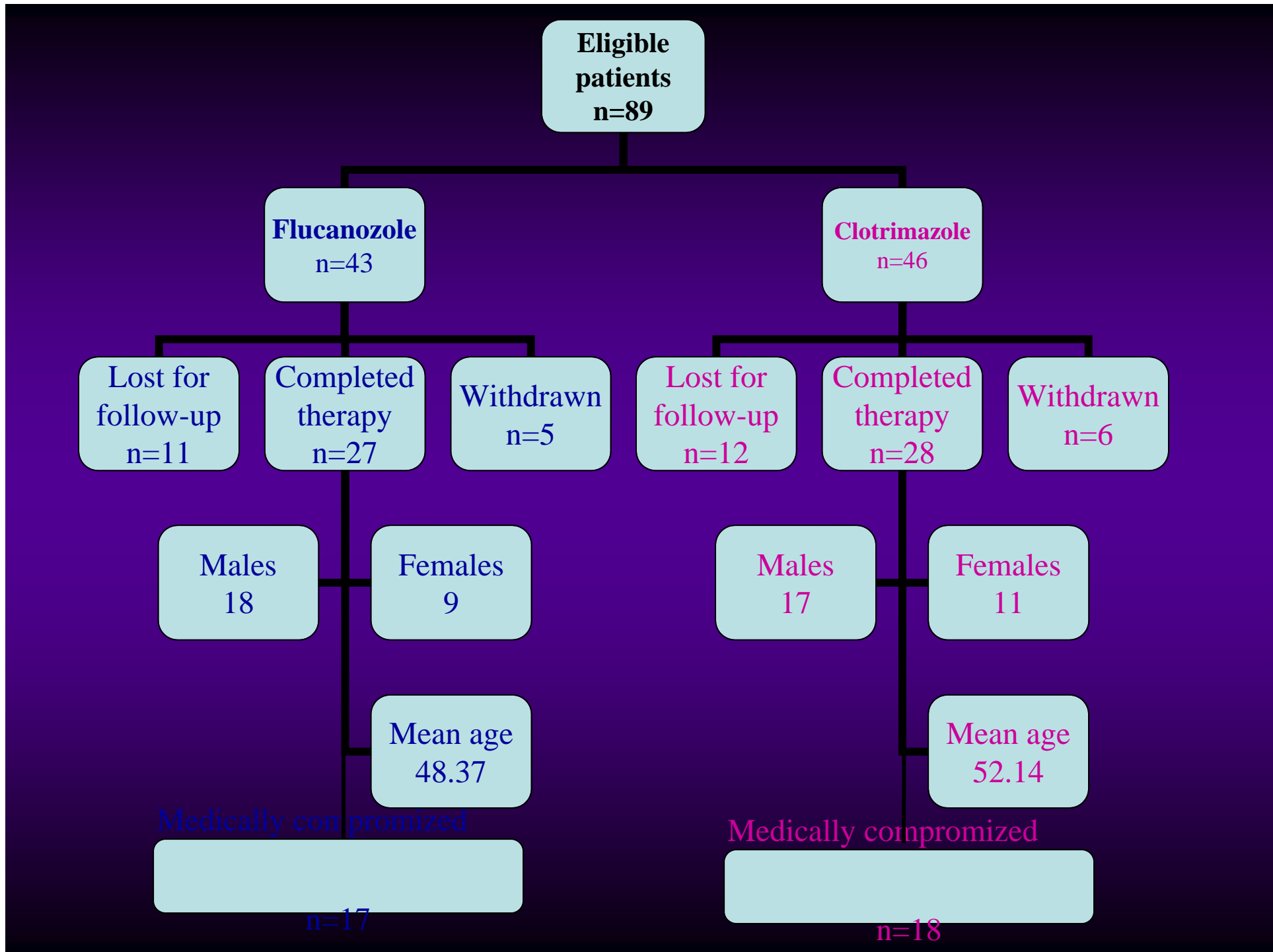


*Candida Colony counts*

# Statistical Methods

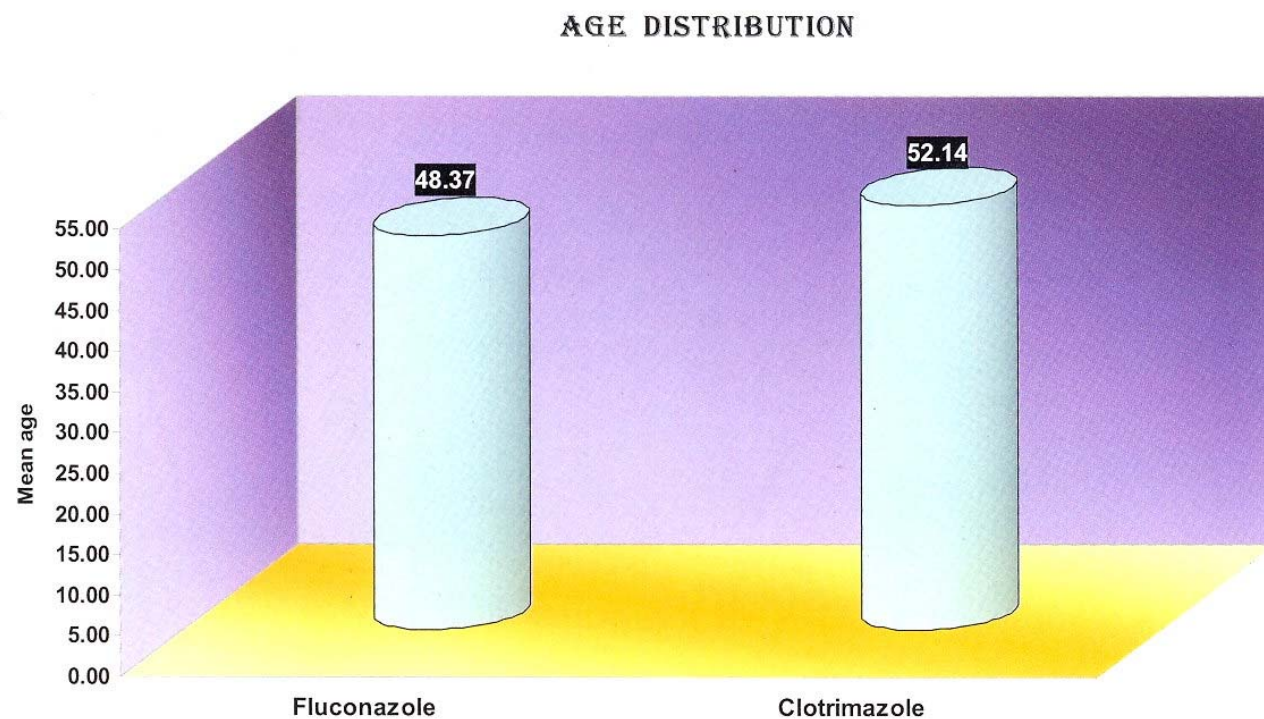
- ◆ Student's T test - comparison of age between two groups.
- ◆ Chi square test - comparison of the distribution of all the variables
- ◆ Fisher's exact test - comparison of side effects
- ◆ Mann Whitney U test - comparison of clinical cure between two groups.
- ◆ Wilcoxon's sign rank sum test - comparison of mycological cure between two groups.
- ◆ The test was considered
  - Significant**, if P value was  $\leq 0.05$
  - Highly significant** if P value was  $\leq 0.01$
  - Very Highly significant** if P value was  $\leq 0.001$

# *RESULTS AND ANALYSIS*





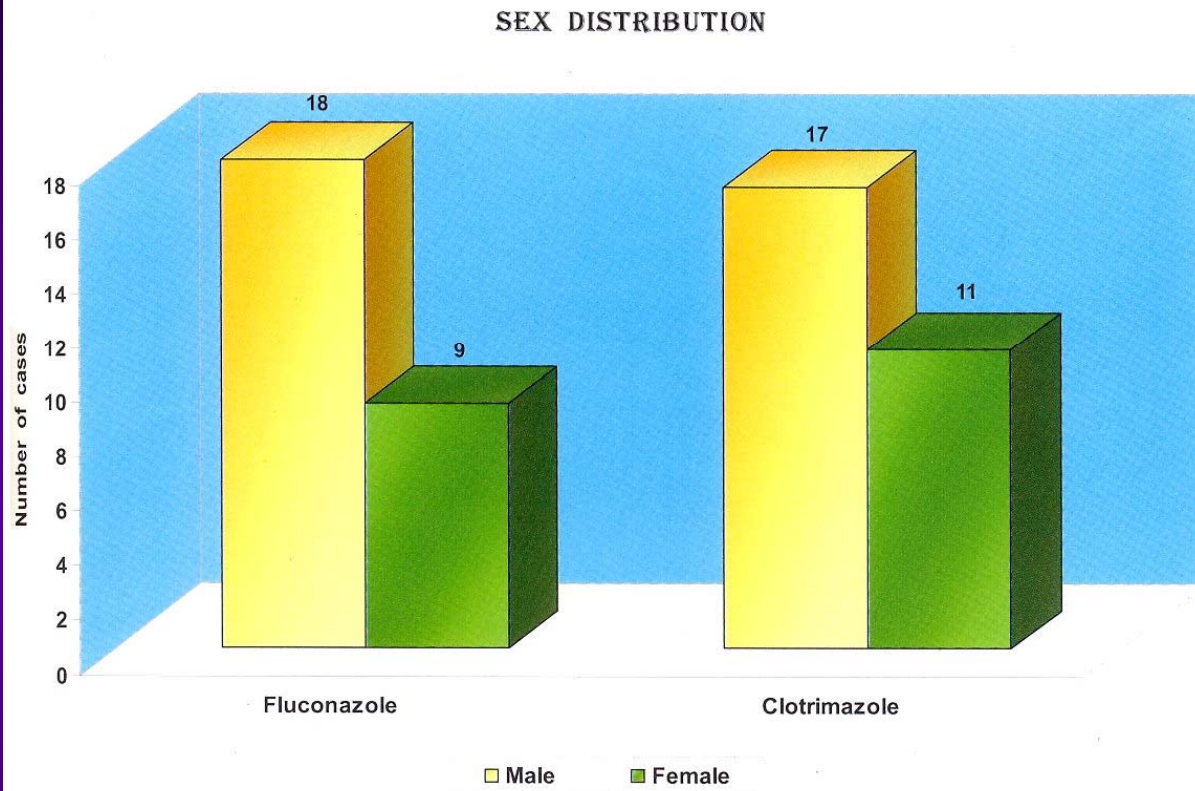
Graph 1 : Age distribution between Group A and Group B



Students t test

t	p
1.13	0.261
	ns

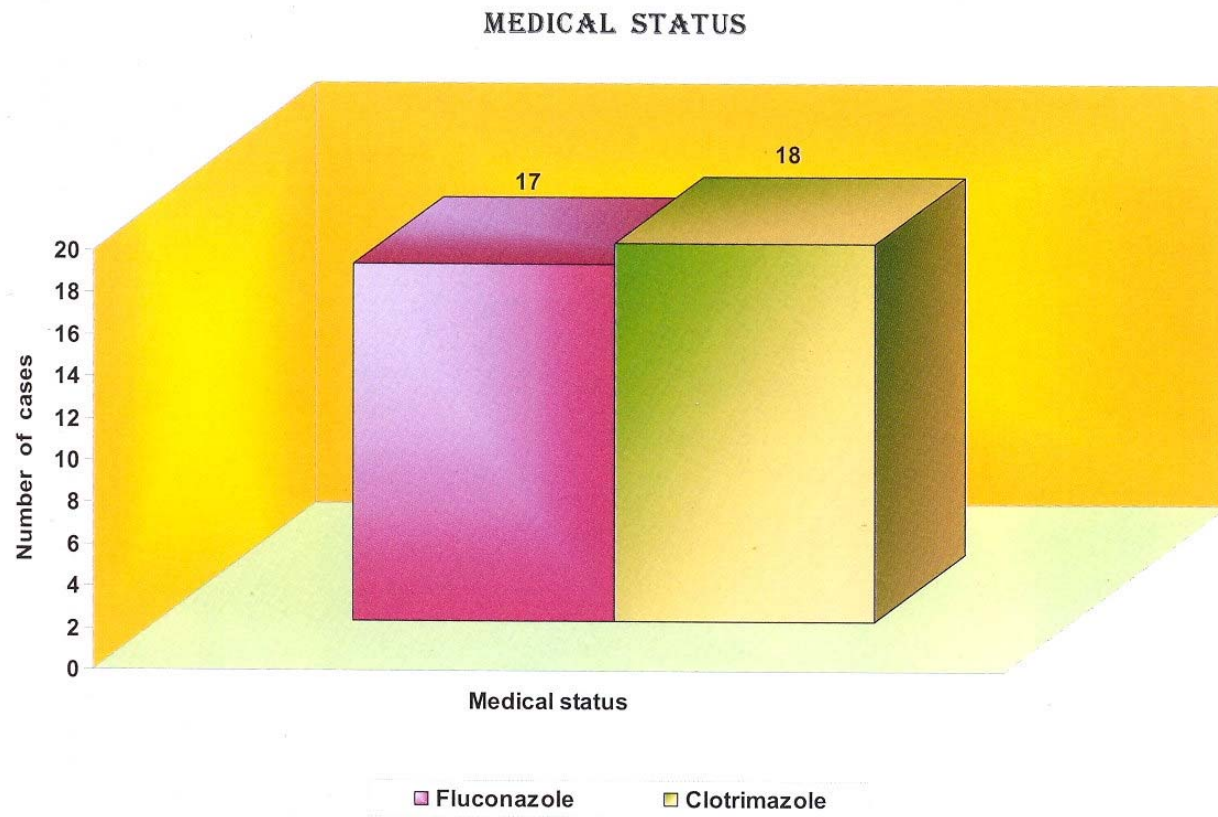
Graph 2 : Sex distribution between Group A and Group B



## Chi sq test

$\chi^2$	p
0.21	0.646
	ns

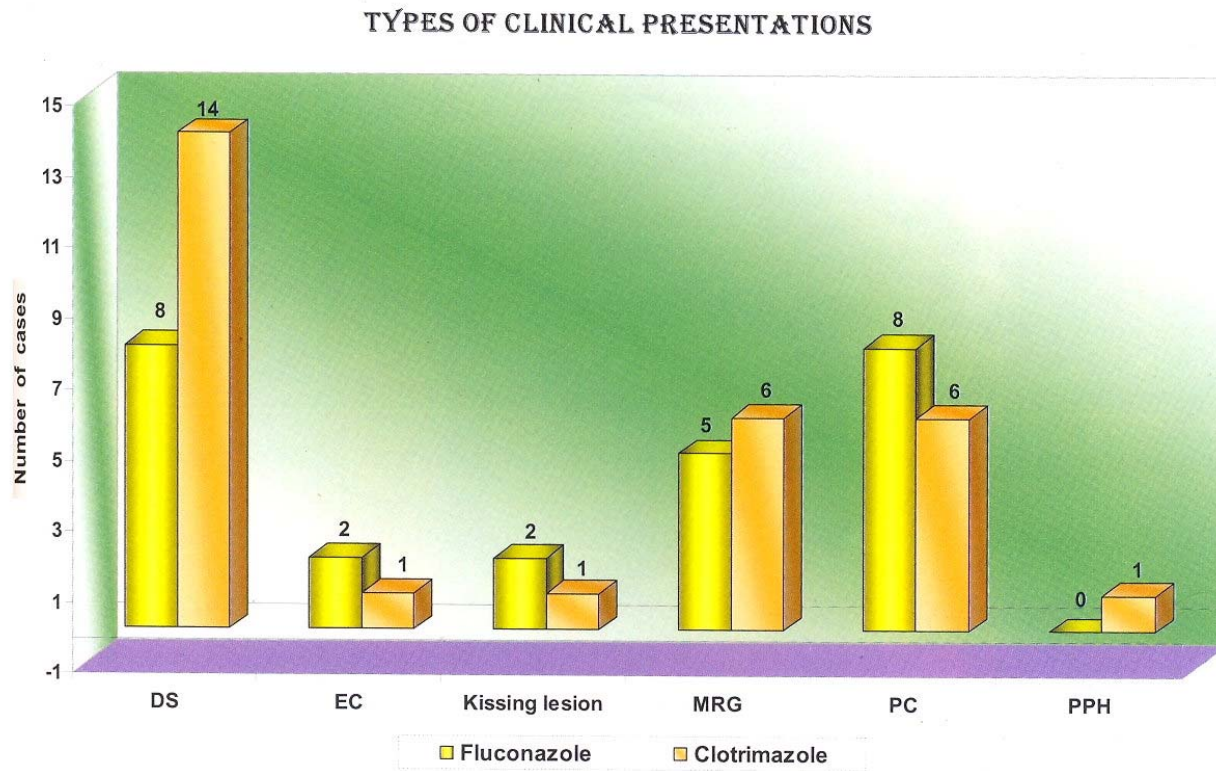
Graph 3 : Comparison of Medical Status between Group A and Group B



Chi sq test

$\chi^2$	p
3.6	0.825
	ns

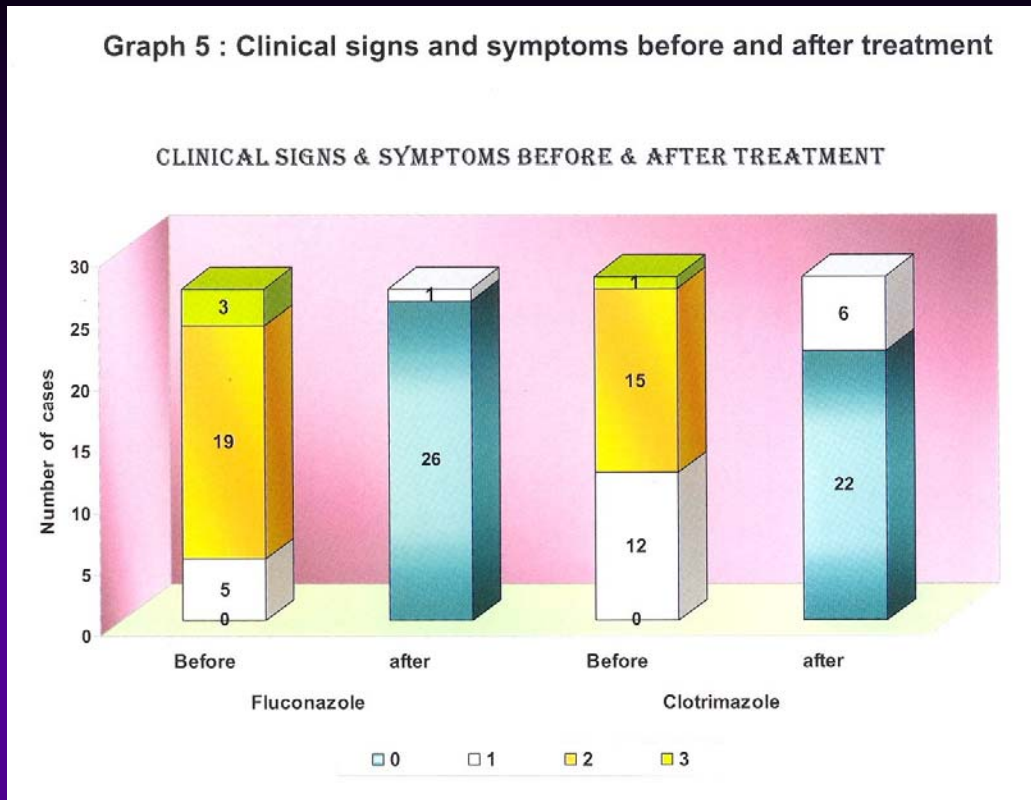
Graph 4 : Types of clinical presentation in Group A and Group B



Chi sq test

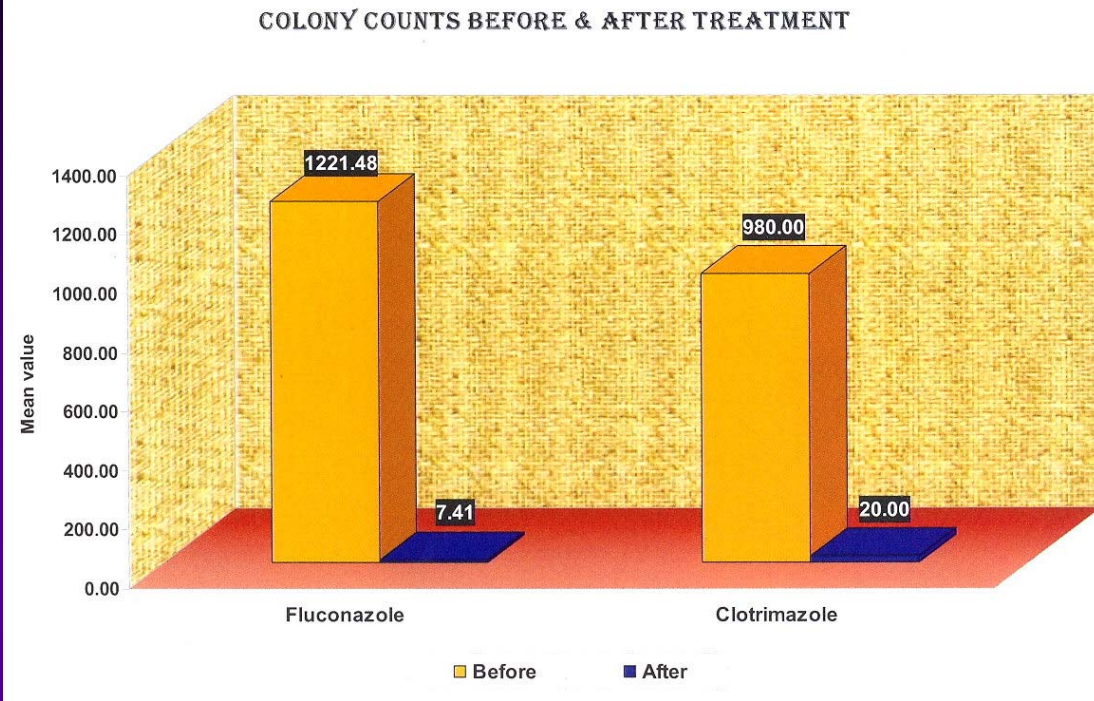
$\chi^2$	p
4.663	0.588
	ns

Graph 5 : Clinical signs and symptoms before and after treatment



	Group A (n=27)	Group B (n=28)	$\chi^2$	p
<b>Clinical signs before treatment</b>				
+ (mild)	5	12	4.336	0.114 ns
++(moderate)	19	15		
+++ (severe)	3	1		
<b>Clinical signs after treatment</b>				
+ (mild)	1	6	3.888	0.049 sig

Graph 6 : Colony counts before and after treatment



Wilcoxon sign rank sum test

	Z	p
Colony counts before treatment	0.48	0.63 ns
Colony counts after treatment	0.45	0.65 ns

## ◆ SIDE EFFECTS

Both treatment regimens were well tolerated.

	Group A (n=27)	Group B (n=28)
Side effects	1	0

n = .491 ns

*Results of treatment with  
Fluconazole mouthrinse*



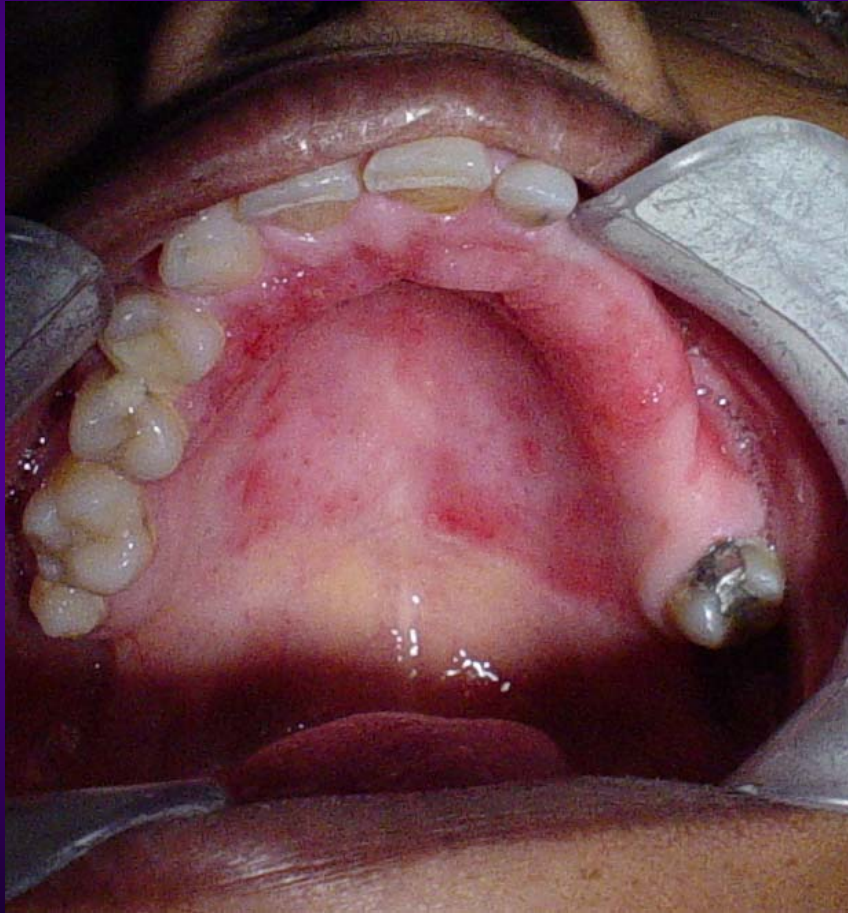
Pretreatment



Post-treatment



Pretreatment



Post-treatment



*Results of treatment with  
Clotrimazole mouthpaint*

Pretreatment



Post-treatment



Pretreatment



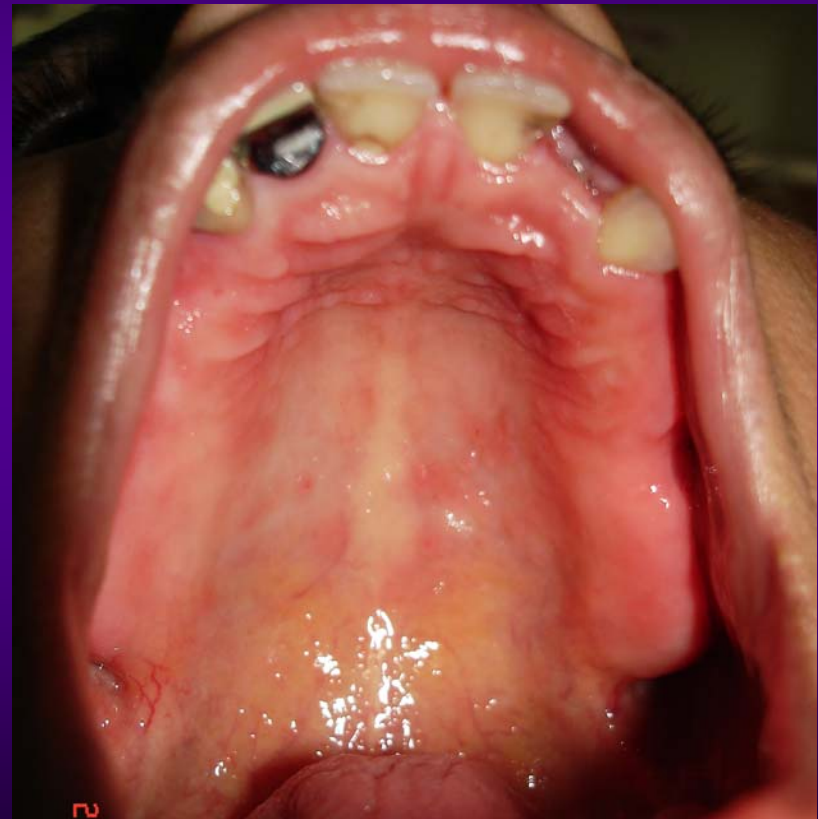
Post-treatment



Pretreatment



Post-treatment



Pretreatment



Post-treatment



# *Discussion*

- ◆ Candida - common and **harmless dimorphic yeast** that lives without producing disease in the oral cavities of upto 68% of normal individuals.
- ◆ This microorganism is typically **opportunistic** and lacks the pathogenic features necessary to produce a fungal infection.



- ◆ Thus local or general predisposing factors are necessary for candida to establish an infection.
- ◆ Accordingly, management of the candida infections should be directed towards eradicating these predisposing factors or antifungal agents are warranted.

# Limitations in this study

- ◆ It was **not double blinded** which could have lead to some bias among patients/clinician.
- ◆ Secondly, patients were not followed up after 2 weeks for any possibility of **recurrence**.
- ◆ Thirdly, patients were only asked about side effects but were **not assessed objectively** for any liver damage.

- ◆ However, although the sample size was small, the outcome was promising, the dose of Fluconazole used per day was only 30mg which is less than 1/3rd of the standard dose of Fluconazole.

# Conclusion



- ◆ The results of this study can be used as a basis for further studies with **larger sample** of patients with Oral candidiasis to compare the efficacy of fluconazole aqueous mouthrinse with Clotrimazole mouth paint.

# *Acknowledgements*

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