The "International Journal of Pharma and Bio Sciences" (IJPBS) is an international journal in English published quarterly. The aim of IJPBS is to publish peer reviewed research and review articles rapidly without delay in the developing field of pharmaceutical and biological sciences.
COMPARATIVE STUDY OF 1% TERBINAFINE WITH 1% CLOTRIMAZOLE IN THE MANAGEMENT OF LOCALIZED Tinea CORPORIS AND Tinea CRURIS INFECTION

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ABSTRACT

The dermatophytosis constitutes a group of superficial fungal infections that infect only superficial keratinized tissues viz. stratum corneum of epidermis, hairs and nails. The infection is commonly designated as ringworm or Tinea. Tinea corporis and Tinea cruris are the clinical forms of dermatophytosis or ringworm infection or Tinea infection. Pruritis is the most common symptom. Typical lesion is usually annular or polycyclic and has a well marginated raised border, composed of multiple erythematous papulovesicles or scales with a clear center. Out of 30 patients of Terbinafine group 27 patients have effective treatment in terms of both clinical improvement and mycological cure (i.e., KOH negativity and culture negativity) at the end of 1st week. Out of 30 patients in Clotrimazole group 26 patients have effective treatment in terms of both clinical improvement and mycological cure. (i.e., KOH negativity and culture negativity) at the end of 4th week. The results of the present study suggest that 1 week of 1% Terbinafine applied twice daily is more effective than 4 weeks of 1% Clotrimazole cream applied twice daily. Thus 1% Terbinafine provides rapid relief of symptoms and short duration of therapy for tinea cruris and corporis infections.

KEY WORDS: Tinea cruris, Tinea corporis, dermatophytosis, Terbinafine, Clotrimazole.
INTRODUCTION

Fungal infections of the skin are the third commonest dermatophytosis after scabies and pyoderma. Tinea corporis and cruris are common superficial fungal infections. Dermatophytosis constitutes a group of superficial fungal infections that infect only superficial keratinized tissues viz. stratum corneum of epidermis, hairs and nails. Tinea corporis and T. cruris are the clinical forms of dermatophytosis. Tinea corporis (Ringworm of the body) is a type of dermatophytosis of skin with exclusion of certain specific locations (palms, soles, groin etc.). Tinea cruris (Groin ringworm.) is a type of dermatophytosis involving the groin area includes infections of genitalia, pubic area, perineal and perianal area. Pruritis is the most common symptom. Typical lesion is usually annular and has a well marginated raised border, composed of multiple erythematous papulovesicles or scales with a clear center.

COMPlications OF DERMATOPHYTOSIS

Secondary bacterial infection is the commonest complication, as the diseased skin is readily susceptible to infection.
1. Eczematization
2. Dissemination to other parts of body through auto inoculation.
3. Dermatophytid (‘id’ reaction) – Allergic manifestation to a focus of acute fungal infection.

MANAGEMENT

Treatment of fungal infection is now comparatively straight forward and cure rates for many forms of dermatophytosis is over 80%. In addition to treatment some other management measures are helpful.

Therapeutic Agents are classified as:
1. Antibiotics – Griseofulvin.
2. Azoles – Imidazoles – Topical – Clotrimazole, Miconazole, Econazole, Oxiconazole

The present study is to compare 1% Terbinafine with 1% Clotrimazole in management of localized tinea corporis and cruris infections.

CLOTRIMAZOLE

Clotrimazole is effective against a variety of human pathogenic dermatophytes. Although it is effective against many fungi, it is not so useful for systemic fungal infections. When given systemically it is more toxic.

Preparation: It is available as 1% cream, lotion, solution.

Therapeutic uses: It is used in the treatment of dermatophytosis and cutaneous candidiasis. It is also useful in vulvo vaginal candidiasis, oral and oropharyngeal candidiasis. Duration varies depending the site, usually 4 to 6 weeks. It is applied as 1% cream twice daily for ringworm infection.

TERBINAFINE

Terbinafine is an allylamine class of anti fungal drug with activity against dermatophytes and candida.

Preparations: It is available as 1% cream for topical use.

Therapeutic uses: It is used in fungal infections of the skin, hair and nails caused by dermatophytes. Topically it is applied once or twice daily as 1% cream in ringworm infection of skin.

PATIENTS AND METHODS

Male patients, in the age group of 16 to 60 years, with tinea corporis and cruris attending to the OPD Clinical Dermatology, Government General Hospital, Guntur were taken for this study.

Exclusion criteria: - Patients with
1. Recent history of treatment with any formulation
2. History of long standing disease
3. History of any systemic disease like diabetes
5. A history of tuberculosis was excluded from the study.

Inclusion Criteria: - Patients with
1. Localized infection with duration of symptoms within one month.
2. No past history of similar disease
3. No history of recent treatment
4. Positive KOH microscopy and culture were included in the study.

Pattern of study: - Patients were categorized into two groups.
1. Terbinafine group
2. Clotrimazole group.

1. Terbinafine Group: - This group of patients were given 1% Terbinafine cream applied twice daily for one week.
Each patient of this group was followed up at the end of one week of treatment with the following parameters.
i. Clinical improvement
ii. KOH microscopy
iii. Culture on sabouraud’s medium
iv. Adverse effects

2. Clotrimazole group: - This group of patients were given 1% Clotrimazole cream applied twice daily for 4 weeks.
Each patient of this group was followed up at the end of 1st, 2nd, 3rd and 4th week of treatment with the same parameters as above.

Direct microscopic examination
Skin scrapings are placed in a drop of 10% freshly prepared aqueous solution of KOH on a glass slide and examined under the microscope for hyphae and other fungal elements.

Culture on Sabouraud’s medium
Skin scrapings are inoculated into modified Sabouraud’s agar. The media is incubated at room temperature. They are examined for the appearance of growth. If no growth is found after 3 or 4 weeks, it is taken as that no fungi are grown.

RESULTS AND DISCUSSION

Terbinafine group (n=30 T. Cruris – 18, T. Corpis – 12)
At the end of first week
T. Cruris: - Out of 18 patients all have marked clinical improvement and 16 have KOH negativity and culture negativity.
T. Corpis:— Out of 12 patients, 11 patients have culture negativity.

Clotrimazole group (n=30 T. cruris – 18, T. corporis – 12)
At the end of first week
T. cruris: - Out of 18 patients 6 have mild clinical improvement. 8 have moderate clinical improvement and 4 have marked clinical improvement. Out of 18 patients, 6 have KOH negativity and 4 have culture negativity.

Table 1
Effectiveness of 1% Terbinafine at the end of 1st week

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Terbinafine group n=30</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tinea cruris n=18</td>
</tr>
<tr>
<td></td>
<td>Tinea corporis n=12</td>
</tr>
<tr>
<td>1.Clinical improvement</td>
<td>Marked in 18</td>
</tr>
<tr>
<td>2 KOH microscopy</td>
<td>Negative in 16</td>
</tr>
<tr>
<td>3. Culture</td>
<td>Negative in 16</td>
</tr>
<tr>
<td>4. Adverse effects</td>
<td>Nil</td>
</tr>
</tbody>
</table>

Clotrimazole group (n=30 T. cruris – 18, T. corporis – 12)

At the end of first week
T. cruris: - Out of 18 patients, 6 have mild clinical improvement. 8 have moderate clinical improvement and 4 have marked clinical improvement. Out of 18 patients, 6 have KOH negativity and 4 have culture negativity.
So, effective treatment in terms of both clinical improvement and mycological improvement is seen in 4 patients out of 18 patients at the end of first week.
T. corporis:— Out of 12 patients, 6 have mild clinical improvement. 1 has moderate clinical
improvement, 5 have marked clinical improvement. Out of 12 patients, 5 patients have KOH negativity. Out of 12 patients, 5 patients have culture negativity. So, effective treatment in terms of both clinical improvement and mycological improvement is seen in 5 patients out of 12 patients at the end of first week. Out of 30 patients in this group, 9 have effective treatment at the end of first week.

The group of patients was further followed up at the end of 2nd 3rd and 4th week.

Table 2
Effectiveness of 1% Clotrimazole at the end of 4th week

<table>
<thead>
<tr>
<th>Parameter</th>
<th>1st week</th>
<th>2nd Week</th>
<th>3rd Week</th>
<th>4th Week</th>
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</thead>
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<tr>
<td></td>
<td>Cru</td>
<td>Cor</td>
<td>Cru</td>
<td>Cor</td>
</tr>
<tr>
<td>1. clinical improvement</td>
<td>Mil-6</td>
<td>Mod-8</td>
<td>Mod-4</td>
<td>Mar-10</td>
</tr>
<tr>
<td></td>
<td>Mod-4</td>
<td>Mod-5</td>
<td>Mod-2</td>
<td>Mar-2</td>
</tr>
<tr>
<td></td>
<td>Mar-5</td>
<td>Mar-2</td>
<td>Mar-2</td>
<td>Mar-3</td>
</tr>
<tr>
<td>2. KOH microscopy</td>
<td>Neg-6</td>
<td>Neg-4</td>
<td>Neg-2</td>
<td>Neg-5</td>
</tr>
<tr>
<td></td>
<td>Neg-5</td>
<td>Neg-4</td>
<td>Neg-2</td>
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<tr>
<td></td>
<td>Neg-3</td>
<td>Neg-3</td>
<td>Neg-2</td>
<td>Neg-1</td>
</tr>
<tr>
<td>3. Culture</td>
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<td>Neg-2</td>
</tr>
<tr>
<td></td>
<td>Neg-5</td>
<td>Neg-2</td>
<td>Neg-3</td>
<td>Neg-2</td>
</tr>
<tr>
<td>4. Adverse effects</td>
<td>Nil</td>
<td>Nil</td>
<td>Nil</td>
<td>Nil</td>
</tr>
</tbody>
</table>

At the end of 4th week

T.cruris: Out of 18 patients all patients have marked clinical improvement. Out of 18 patients, all patients have KOH negativity. Out of 18 patients, 15 patients have culture negativity. So, effective treatment in terms of both clinical improvement and mycological improvement is seen in 15 patients out of 18 patients.

T. Corporis: Out of 12 patients all patients have marked clinical improvement. Out of 12 patients, 11 have KOH negativity and culture negativity. So effective treatment in terms of both clinical improvement and mycological improvement is seen in 11 patients of out 12 patients.

Out of 30 patients in this group 26 patients have effective treatment at the end of 4th week.

Comparision of Results at the end of 1st week of 1% Terbinafine and 1% Clotrimazole

Terbinafine group (n=30 T.cruris-18, T.corporis-12)

At the end of first week

T.cruris: Effective treatment in terms of both clinical improvement and mycological improvement (KOH negativity, culture negativity) is seen in 16 patients out of 18 patients.

T. Corporis: Effective treatment in terms of both clinical improvement and mycological improvement (KOH negativity, culture negativity) is seen in 11 patients out of 12 patients. Out of 30 patients in this group 27 patients have effective treatment at the end of first week.

Clotrimazole group (n=30 T.cruris – 18, T.corporis-12)

At the end of first week

T.cruris: Effective treatment in terms of both clinical improvement and mycological improvement (KOH negativity, culture negativity) is seen in 4 patients out of 18 patients at the end of first week.

T. Corporis: Effective treatment in terms of both clinical improvement and mycological improvement (KOH negativity, culture negativity) is seen in 5 patients out of 12 patients at the end of first week.

Out of 30 patients in this group 9 patients have effective treatment at the end of first week.
Table 3

Comparison of results at the end of 1st week of 1% Terbinafine & 1% Clotrimazole

<table>
<thead>
<tr>
<th>Parameter</th>
<th>1 week Terbinafine</th>
<th>1 week Clotrimazole</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T. Cruris n=18</td>
<td>T. Cruris n=18</td>
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<tr>
<td></td>
<td>T. corporis n=12</td>
<td>T. corporis n=12</td>
</tr>
<tr>
<td>1. clinical improvement</td>
<td>Mar-18 Mil-6 Mod-8 Mar-4</td>
<td>Mar-12 Mil-6 Mod-1 Mar-5</td>
</tr>
<tr>
<td>2 KOH microscopy</td>
<td>Neg-16 Neg-6 Neg-4</td>
<td>Neg-11 Neg-5</td>
</tr>
<tr>
<td>3 culture</td>
<td>Neg-16 Neg-11 Neg-4</td>
<td>Neg-12 Neg-5</td>
</tr>
<tr>
<td>4. adverse effects</td>
<td>Nil Nil Nil</td>
<td>Nil Nil</td>
</tr>
</tbody>
</table>

(mil=mild; mod=moderate; mar=marked; neg=negative; KOH=Potassium Hydroxide)

Out of 30 patients in Terbinafine group 27 patients have effective treatment at the end of first week. Out of 30 patients in Clotrimazole group 9 patients have effective treatment at the end of first week.

**COMPARISON OF RESULTS AT THE END OF 1st WEEK TERBINAFINE AND 4th WEEK OF CLOTRIMAZOLE**

Terbinafine group (n=30 T.cruris – 18, T. corporis-12)

**T. Cruris:** Effective treatment in terms of both clinical improvement and mycological improvement is seen in 16 patients out of 18 patients.

**T. Corporis:** Effective treatment in terms of both clinical improvement and mycological improvement is seen in 11 patients out of 12 patients.

Out of 30 patients in this group 27 patients have effective treatment at the end of first week.

**At the end of 4th week Clotrimazole**

**T.cruris:**- Effective treatment in terms of both clinical improvement and mycological improvement is seen in 15 patients out of 18 patients.

**T.corporis:**- Effective treatment in terms of both clinical improvement and mycological improvement is seen in 11 patients out of 12 patients.

Out of 30 patients in this group 26 patients have effective treatment at the end of 4th week.
Table 4
comparision of results at the end of 1st week of 1%terbinafine and 4th week of 1%clotrimazole

<table>
<thead>
<tr>
<th>Parameter</th>
<th>1st week of Terbinafine</th>
<th>4th week of Clotrimazole</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T. Cruris n=18</td>
<td>T. Cruris n=18</td>
</tr>
<tr>
<td></td>
<td>T.corporis n=12</td>
<td>T.corporis n=12</td>
</tr>
<tr>
<td>1. clinical improvement</td>
<td>Mar-18</td>
<td>Mar-12</td>
</tr>
<tr>
<td>2 KOH microscopy</td>
<td>Neg-16</td>
<td>Neg-11</td>
</tr>
<tr>
<td>3 culture</td>
<td>Neg-15</td>
<td>Neg-11</td>
</tr>
<tr>
<td>4. adverse effects</td>
<td>Nil</td>
<td>Nil</td>
</tr>
</tbody>
</table>

(mil=mild; mod=moderate; mar=marked; neg=negative; KOH=Potassium Hydroxide)

No adverse effects are seen in both groups.

CONCLUSION

Tinea corporis and cruris are most common superficial fungal infections. Terbinafine group of patients receive 1 week of 1% Terbinafine applied twice daily. This group of patients was followed up at the end of 1st week with parameters like clinical improvement, KOH microscopy, culture and adverse effects. Clotrimazole group of patients receives 4 weeks of 1% Clotrimazole applied twice daily. This group of patients was followed up at the end of 1st, 2nd, 3rd and 4th week with parameters like clinical improvement KOH microscopy culture and adverse effects. The results indicate that one week of 1%Terbinafine is sufficient in treating tinea corporis and cruris infection than 4 weeks of treatment with 1%cotrimazole.
REFERENCES

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7. Evans EG et al – Dermatology 1997; 194 suppl 136