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Cost-Effectiveness Analysis of Luliconazole vs. Oxiconazole in Tinea Treatment in a Tertiary Care Hospital

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ABSTRACT

Background: To compare the efficacy and cost-effectiveness of luliconazole 1% cream and oxiconazole 1% cream in patients of tinea corporis and cruris receiving oral itraconazole.

Methods: This was an observational study conducted between November 2022 to October 2023. In the present study, 106 patients were matched for age, sex, and severity of the disease. They received one of the three treatment groups; topical luliconazole and oral itraconazole were in Group (A), topical oxiconazole and oral itraconazole were in Group (B) while those who received only oral itraconazole were in Group (C). Study groups also received levocetirizine 5 mg orally once daily. At the end of 2nd and 4th week change in clinical parameters was noted and pharmacoeconomic ratio was calculated at the end of 4th week.

Results: The change in mean composite scores of the three study groups were compared at the end of 2nd week (group A:50.7%;group;B:48.1%;group C: 46%) and 4th week (group A:89.4%;group B:85.1%;group C:88.4%) and were not statistically significant. ($p>0.05$) The pharmacoeconomic ratio was least for Group C patients irrespective of severity as compared to Group A and Group B.($p<0.05$).

Conclusion: The results of the present study suggests that topical luliconazole and oxiconazole are equally efficacious in patients of tinea corporis and cruris receiving oral itraconazole. Patients who received only oral itraconazole the treatment was more cost effective.

Keywords: Varicose veins, Venous leg ulcers, Great saphenous vein, saphenopopliteal junction, Phlebotonics, Intervention treatment

Introduction

Dermatophytosis is a cutaneous infection caused by keratinophilic fungi known as dermatophytes.(1) Trichophyton rubrum species is implicated as the most common causative agent of dermatophytosis in India.(2) The incidence of dermatophytosis is more common in countries like India due to environmental factors like heat, humidity and socio-economic conditions like overcrowding and poverty.(3) However in India, the most commonly occurring clinical type of dermatophytosis in adults is tinea corporis (36-59%) which affects trunk and the limb region followed by tinea cruris (12-27%) affecting the inguinal region.(4)

Tinea corporis and cruris of the skin presents clinically as well-demarcated, inflamed and scaling lesions, which are often accompanied by an itching or a burning sensation.(5) Presently, the most extensively used antifungal drugs for dermatophytosis are azoles.(6) The antifungal activity of azoles is by inhibiting fungal cytochrome P450 enzyme, lanosterol 14 demethylase, leading to inhibition of the ergosterol biosynthesis and thereby causing disruption of the fungal cell membrane.(7)

Topical antifungal therapy alone is often fraught with numerous clinical challenges including high relapse rates and recurrences. Patients of tinea corporis and cruris who fail to clear with repeated treatment using different topical agents should be considered for systemic therapy(8) Few comparative studies on the combination of systemic with topical antifungal agents have claimed that the preferred treatment of choice for superficial dermatophytosis was a combination of oral azole and topical azole (9,10).

The incidence of tinea corporis and cruris infections in Western rural Maharashtra has been increasing due to environmental factors like heat, humidity, and socioeconomic conditions like overcrowding and poverty.(11) Injudicious use of topical antifungals has resulted in an increased incidence of resistance.(12) Although, individually luliconazole and oxiconazole are efficacious in tinea infection.(13), (14) Reports of resistance to topical antifungal recommend adding of oral itraconazole to the topical antifungal therapy.(15) Very few studies comparing topical antifungals in combination with oral antifungal are present in the Indian population. Therefore, the present study was undertaken to compare the efficacy and cost-effectiveness of luliconazole cream with oxiconazole cream receiving oral itraconazole in patients of tinea corporis and cruris.

Aim & objectives

Aim: To compare the efficacy and cost-effectiveness of luliconazole 1% cream and oxiconazole 1% cream in patients of tinea corporis and cruris receiving oral itraconazole.

Primary Objectives: To compare the efficacy of luliconazole 1% cream and oxiconazole 1% cream in patients of tinea corporis and cruris receiving oral itraconazole.

Secondary Objectives: To compare the cost effectiveness of luliconazole 1% cream and oxiconazole 1% cream in patients of tinea corporis and cruris receiving oral itraconazole.

Study setting

The present study was conducted in the Dermatology, Venereology & Leprosy outpatient department of a Tertiary Care Teaching Hospital in Western rural Maharashtra.

Study design

This was an observational study which was conducted after obtaining Institutional Ethics Committee approval (IEC/2022/827).

Patients of tinea corporis and tinea cruris, clinically diagnosed by the dermatologists and confirmed by laboratory 10% KOH testing were selected for the study. Subject selection for the study was based on the following criteria.

Inclusion criteria:

1. Newly diagnosed patients of tinea corporis and tinea cruris infection. (Diagnosed by dermatology clinician and mycologically confirmed by 10 % KOH test)
2. 18-60 years of age of either gender.
3. Patients who had given written informed consent.

Exclusion criteria

1. Immunocompromised patients
2. Patients who had superadded bacterial infections.
3. Patients who had any other dermatological condition in addition to dermatophytosis. (psoriasis, scabies, atopic dermatitis, contact dermatitis, seborrheic dermatitis).

4. Pregnant or lactating women (Itraconazole contraindicated in pregnancy could cause congenital abnormalities.)
5. Patients who had a history of hypersensitivity to study drugs.

Methodology and Materials

• Patients who satisfied the above inclusion criteria were given the patient information sheet which provided the aim and detailed plan of the study.
• A written informed consents were obtained from the patients.
• Demographic data - age, sex, occupation of the patients was recorded in the case information sheet. Clinical parameter like (A) Pruritus, (B) Erythema, (C) Desquamation, and (D) Vesicles were assessed and graded at the baseline. The respective data was entered in the case information sheet.
• Mycological assessment was done by using KOH (10%) at baseline and was entered in the case information sheet.
• Dermatologists decided which treatment was the best for the patients and accordingly prescribed the study drugs.
• Patients who received topical luliconazole and oral itraconazole were in in Group (A), patients who received topical oxiconazole and oral itraconazole were in Group (B) while those who received only oral itraconazole were in Group (C). Patients were matched for age, sex, and severity of the disease.
• Following instructions were given to the patients
• Apply cream on the affected area and about 1 inch of the surrounding area(s)immediately after bath and before sleeping and consume oral itraconazole after meal twice daily. (16),(17)
• To keep the affected area dry and clean.
• To maintain personal hygiene.
• To refrain from wearing tight clothing near the lesions.
• Not to take any other medications.
• Clinical parameter like (A) Pruritus, (B) Erythema, (C) Desquamation, and (D) Vesicles were assessed and graded at the end of the 2nd and 4th week when the patients were called for follow-up. The respective data was entered in the case information sheet.
• KOH (10%) slide test was performed at the end of 4th week of treatment to observe the mycological cure rate of the study drugs.

All the patients received the same brands as to avoid change in pharmacokinetic parameters of different brands of same drug.
Itraconazole – Syntran capsule 100 mg.
Glenmark Pharmauticals Ltd.
100 mg BD.
Price per unit – 14.00 INR
Oxiconazole – Zoderm E 1% 50gms.
Glaxo Smith Kline Pharmaceuticals Ltd.
Price – 257.65 INR
Luliconazole – Lulibet 1% 50gms.
Intas Pharmaceuticals
Price - 480.00 INR
Note - Patients were told to buy the medication from any pharmacy store and were instructed to get the tubes of medication at each follow-up to ensure the use and compliance of medication.

Assessment of Efficacy

Pruritus:
For assessment of pruritus patient was given Visual Analogue Scale for subjective analysis. Patients had to mark on the Subjective Visual Analogue Scale and accordingly the Principal Investigator graded the pruritus, (18)

Table 1. Severity of pruritus

Points	Severity of pruritus
0	no pruritus
1 point	mild pruritus
2-3 points	moderate pruritus
4-7 points	severe pruritus
8-10 points	very severe pruritus

Pruritus:
For assessment of pruritus patient was given Visual Analogue Scale for subjective analysis. Patients had to mark on the Subjective Visual Analogue Scale and accordingly the Principal Investigator graded the pruritus, (18)
Analysis of Visual Analogue Scale,
Grading of Pruritus was done as per the following table (19),

Table 2. VAS points

Grade	VAS points
0	0 VAS points
1	1-3 VAS points
2	4-7 VAS points
3	8-10 VAS points

Erythema:

According to Scoring System for Physician Global Assessment (PGA), Erythema was graded based on its intensity as follows, (20)

Table 3. Clinical features of Erythema

Score	Grade	Clinical features of Erythema
0	None	No evidence of erythema although hyperpigmentation may be present
1	Mild	Light red coloration
2	Moderate	Red coloration
3	Severe	Dark to deep red coloration

Desquamation:

According to Scoring System for Physician Global Assessment (PGA), Desquamation was graded based on its intensity as follows, (20)

Table 4. Clinical features of Desquamation

Score	Grade	Clinical features of Desquamation
0	None	No evidence of scaling
1	Mild	Fine scale dominates
2	Moderate	Moderate: coarse scale predominates
3	Severe	Marked: thick, non-tenacious scale dominates

Vesicles

According to Dyshidrotic eczema area and severity index (DASI), the vesicles were graded based on number of vesicles present per cm2 of affected surface area.(21)

Table 5. Vesicles

Score	Grade	Vesicles(n/cm2)
0	None	0
1	Mild	>0-2
2	Moderate	2-8
3	Severe	>8

• Physician Global Assessment score was used to determine the severity of tinea corporis and cruris at baseline and it was obtained by dividing the composite score by 4. Patients were categorized as follows,(22)

Table 6. Physician Global Assessment score

Sr. No.	Disease Severity	Physician Global Assessment score
1	Mild	majority of lesions have individual scores that average 1.
2	Moderate	majority of lesions have individual scores that average 2.
3	Severe	majority of lesions have individual scores that average 3.

Composite score

• The score of pruritus, erythema, desquamation and vesicles were added to obtain the composite score at baseline, at the end of 2nd week and 4th week respectively.

• The change in composite score from the baseline to the end of 4th week indicated the efficacy of study drugs.

• Efficacy of the study drugs was also assessed in terms of mycological cure by 10% KOH mount at the end of 4th week.

Assessment of cost-effectiveness

• Cost effectiveness analysis for all three groups was calculated on basis of the following formula,

Cost-effectiveness = Cost of the treatment/outcome (23)

Cost effectiveness can be calculated by dividing the total cost of the treatment by difference in composite score.

For, cost-effectiveness = Total cost of the treatment in rupees / Difference in composite score

Methods

Data of patients suffering from tinea corporis and cruris receiving study drugs was collected from the Dermatology OPD and entered in Microsoft Excel 2019 and was analysed by using IBM SPSS Statistics(Chicago Illinois) version 27. Quantitative data were expressed as mean and standard deviation and comparison was done between the groups and within the groups by ANOVA. Qualitative data were expressed in frequency and percentage and comparison was done by using the Kruskal-Wallis test and Mann-Whitney test.

Result and Discussion

For the present study, 120 patients were recruited. 106 patients completed the study (37 from Group A, 35 from Group B, 34 from Group C). 4 patients from Group A, 3 patients from Group B & 5 patients from Group C were lost to follow-up due to nausea and vomiting. Also, 2 patients from Group A experienced redness of the skin as an adverse effect and were lost to follow as well. The percentage of male patients (47.2%) and female patients (52.8%) was comparable. At baseline, all the demographic parameters, disease severity, and PGA score were comparable between Group A, Group B & Group C.

Efficacy assessment

Composite Score

At the end of 2nd week and 4th week, all the three treatment groups showed statistically significant change in mean composite score. ($p<0.05$) The change in mean composite scores of the three study groups were compared at the end of 2nd week (group A:50.7%;group;B:48.1%;group C: 46%) and 4th week (group A:89.4%;group B:85.1%;group C:88.4%) and were not statistically significant. ($p>0.05$)

Table 7. Three treatment groups

Study Group	Composite score	Mean	Standard deviation (SD)	% change from baseline
Group A	Baseline	8.162	0.430	-
	2nd week	4.027	0.320	50.7
	4th week	0.865	0.162	89.4
Group B	Baseline	8.029	0.442	-
	2nd week	4.171	0.329	48.1
	4th week	1.200	0.166	85.1
Group C	Baseline	8.118	0.449	-
	2nd week	4.382	0.334	46
	4th week	0.941	0.169	88.4

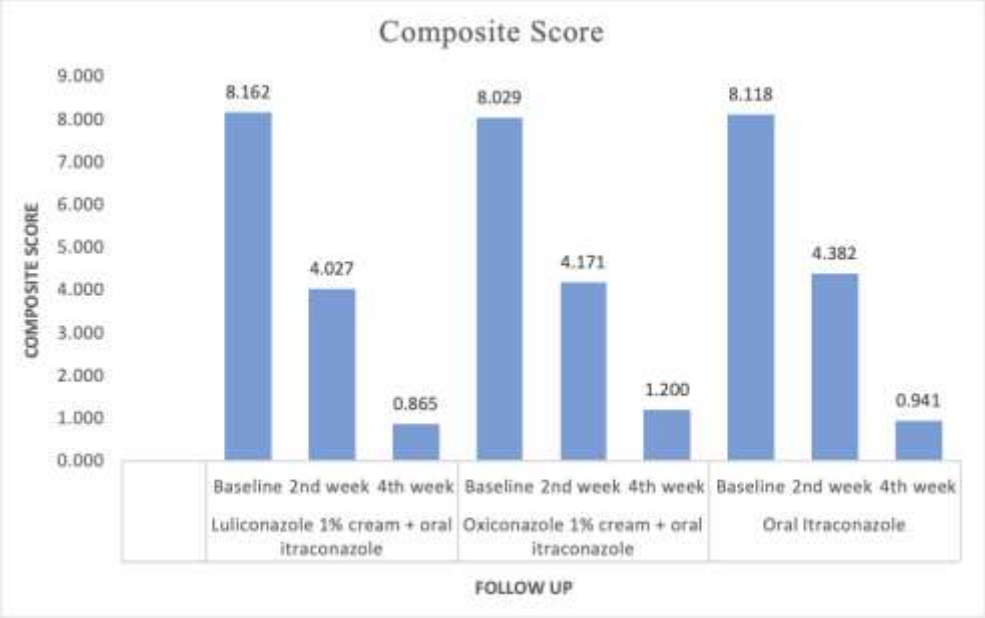

Figure 1. Composite Score

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Treatment efficacy and age group

Composite Score

When three study groups were compared in terms of age there was no statistically significant change in mean composite score. (p>0.05)

Treatment Efficacy and occupation

Composite Score

Manual labourers in Group A showed statistically significant change in mean composite score (95.2%) (p<0.05) when compared to manual labourers in Group B (76.1%) and Group C (77.8%).

Treatment Efficacy and severity

Composite Score

When three study groups were compared in terms of severity there was no statistically significant change in mean composite score. (p>0.05).

Table 8. Composite Score

Study Group	Occupation	Composite Score	Mean	Standard deviation (SD)	% change from baseline
Group A	Homemaker	Baseline	7.429	0.864	-
		2nd week	3.392	0.727	54.3
		4th week	0.714	0.354	90.4
	Working Professional	Baseline	7.867	0.658	-
		2nd week	3.867	0.497	50.8
		4th week	0.733	0.242	90.7
	Manual Labourer	Baseline	9.727	0.769	-
		2nd week	4.000	0.580	58.9
		4th week	0.464	0.282	95.2
	Student	Baseline	8.412	1.275	-
		2nd week	3.690	0.962	56.1
		4th week	1.368	0.468	83.7
Group B	Homemaker	Baseline	7.818	0.769	-
		2nd week	3.378	0.580	56.8
		4th week	0.680	0.282	91.3
	Working Professional	Baseline	7.824	0.618	-
		2nd week	3.765	0.467	51.8
		4th week	0.833	0.227	89.4
	Manual Labourer	Baseline	9.000	0.772	-
		2nd week	5.000	0.541	44.4
		4th week	2.147	0.201	76.1
	Student	Baseline	8.750	1.275	-
		2nd week	4.000	0.962	54.2
		4th week	1.500	0.468	82.9
Group C	Homemaker	Baseline	7.723	0.736	-
		2nd week	3.367	0.555	56.4
		4th week	0.500	0.270	93.5
	Working Professional	Baseline	8.213	0.707	-
		2nd week	3.615	0.534	55.9
		4th week	1.130	0.260	86.2
	Manual Labourer	Baseline	8.871	0.864	-
		2nd week	4.857	0.627	45.2
		4th week	2.013	0.354	77.8
	Student	Baseline	8.240	1.303	-
		2nd week	3.821	0.862	53.6
		4th week	1.822	0.662	77.9

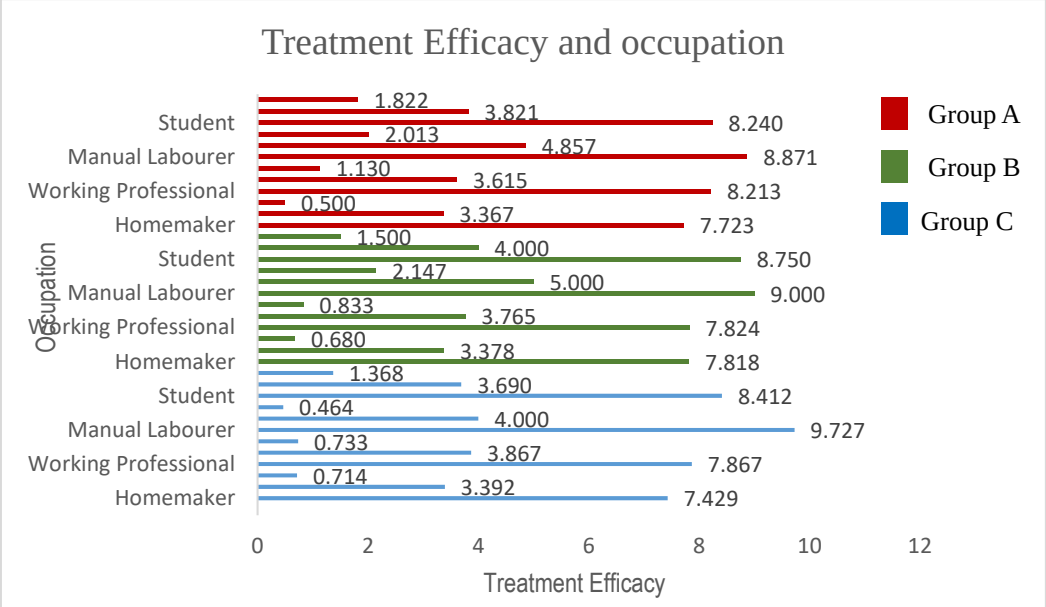

Figure 2. Treatment Efficacy

Cost-effective analysis

Direct health cost of drug treatment was taken into consideration for the cost-effectiveness analysis of the present study. The cost of 30 gm cream of luliconazole (1%) was Rs. 350, for 50 gm cream oxiconazole (1%), it was Rs. 258, and overall, 60 capsules of 100mg itraconazole were dispensed in the treatment duration of 4 weeks which accounted for 840 rupees. Tablet levocetrizine 5mg was also given in all three groups which resulted in additional cost of 29 rupees in all three groups.

In Group A patients receiving luliconazole 1% cream and oral itraconazole, for 37 patients the cost of the treatment ranged between 1207 and 1569 for 4 weeks depending on the severity of their clinical features. In Group B patients receiving oxiconazole 1% cream and oral itraconazole, for all the 35 patients the cost of the treatment for 4 weeks was 1127 rupees irrespective of their severity of clinical features at baseline. In Group C patients receiving only oral itraconazole, for all the 34 patients the cost of the treatment for 4 weeks was 869 rupees irrespective of their severity of clinical features at baseline.

Table 9. Pharmacoeconomic ratio

Sr. No.	Baseline clinical features	Change in composite score	Pharmacoeconomic ratio
Group A			
1	Mild	4-5	241-392
2	Moderate	5-8	196-314
3	Severe	9-11	157-174
Group B			
4	Mild	4-5	225-282
5	Moderate	5-8	141-287
6	Severe	8-10	113-141
Group C			
7	Mild	5	174
8	Moderate	7-8	109-124
9	Severe	9-10	87-145

The pharmacoeconomic ratio was least for Group C patients irrespective of severity as compared to Group A and Group B.($p<0.05$).

In rural India dermatophytosis is the second most common skin disease.(24) Tinea corporis (32.4%) and tinea cruris (19.7%) are considered the most prominent types of dermatophytosis in India.(25) Pruritus, erythema, vesicles, and desquamation are the common presenting clinical features of tinea corporis and tinea cruris which severely affect patients' quality of life.(26) According to various clinical trials, both luliconazole and oxiconazole, when taken with oral itraconazole or oral terbinafine have been proven to be efficacious in treating tinea corporis and cruris. (27) However, fewer studies have been conducted to compare the efficacy, safety, and cost-effectiveness of the topical luliconazole and topical oxiconazole in patients of tinea corporis and cruris receiving oral itraconazole. Therefore, the present study was undertaken in western rural Maharashtra to provide a more effective, safe, and affordable treatment for patients of tinea corporis and cruris owing to its long duration of treatment.

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In the present study, all three study groups namely, luliconazole 1% and oral itraconazole (Group A), oxiconazole 1% and oral itraconazole (Group B), and oral itraconazole (Group C) showed statistically significant change in the mean composite score of tinea corporis and cruris ($p<0.05$) after 4 weeks of treatment. A study done by Rana D et al compared the efficacy of combination of topical luliconazole with oral itraconazole and topical bland emollient with oral itraconazole in the management of dermatophytosis.(28) The study reported that both the treatment groups showed statistically significant change in the mean composite score ($p<0.05$) which was similar to the results of the present study. (Table 7) In a non-comparative multicentre study by Tawhidul et al,was reported that that the mean composite score for patients treated with oxiconazole 1% cream showed statistically significant improvement ($p<0.05$).(29) The findings of the present study were similar but patients receiving oxiconazole 1% cream were also receiving oral itraconazole. (Table 7) A study by Khurana et al reported that oral itraconazole alone showed statistically significant change in the mean composite score in patients of tinea corporis and cruris. (30) This was also similar to the results of the present study. (Table 7)

When the three study groups were compared at end of the 2nd and 4th week the change in mean composite score was not statistically significant implying that luliconazole 1% cream and oxiconazole 1% were equally efficacious in patients of tinea corporis and cruris receiving oral itraconazole. ($p>0.05$). (Table 7) This can be explained by the ability of oral itraconazole to sustain antifungal skin levels at the dose of 200mg/day.(30) A study by Rana D et al showed similar results where the combination of topical luliconazole with oral itraconazole in comparison to oral itraconazole was as effective as the combination of emollient with oral itraconazole at the end of the 6th week. (28).

Manual labourers in Group A showed statistically significant change in composite score as compare to manual labourers in other groups.($p<0.05$)(Table 8). This can be attributed to the better retention of topical luliconazole in the stratum corneum.(31) Manual labourers need topical antifungal owing to lack of hygienic practices like changing clothes or taking bath regularly and wearing loose-fitting light clothing among them.(32,33)

Improvement in composite score was similar if other occupations of the patients of the three study groups were compared. So, any study drug combinations or itraconazole alone can be prescribed to the patients of tinea corporis and cruris of various occupations except manual labourers. (Table 8)

Luliconazole 1% cream and oxiconazole 1% cream were equally cost effective in patients of tinea corporis and cruris receiving oral itraconazole.(Table 9) When cost effectiveness was compared, Group C treatment was more cost effective as compared to other study drug combination($p<0.05$) (Table 9) This denotes that oral itraconazole 200mg per day alone was more cost effective than luliconazole 1% cream and oxiconazole 1% cream in patients of tinea corporis and cruris receiving oral itraconazole 200mg per day. This was also noted in the study by Rana D et al (28).

Limitations

The present study conducted had relatively small sample size (106) and short duration of follow up (4 weeks). To determine more substantial results regarding cost-effectiveness of antifungal treatment indirect and incremental costs should be taken into consideration in addition to direct cost.

Conclusion

The results of the present study suggests that topical luliconazole and oxiconazole are equally efficacious and cost effective in patients of tinea corporis and cruris receiving oral itraconazole. Topical luliconazole with oral itraconazole can be prescribed in manual labourers. Oral itraconazole had similar efficacy but was more cost effective as compared to other study drug combinations. So, oral itraconazole alone can be recommended for patients of tinea corporis and cruris.

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Conflict of Interest

None

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None

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