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A Randomized Controlled Trial Comparing the Efficacy and Safety of Oral Colchicine versus Oral Isotretinoin in the Treatment of Lichen Planus Pigmentosus

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Keywords:

Oral Colchicine, Oral Isotretinoin, Lichen, Planus & Pigmentosus.

Abstract:

Background & Methods: The aim of the study is to study Randomized Controlled Trial Comparing the Efficacy & Safety of Oral Colchicine versus Oral Isotretinoin in the Treatment of Lichen Planus Pigmentosus. Lichen Planus Pigmentosus (LPP) is a chronic pigmentary disorder with limited therapeutic options. Oral isotretinoin & colchicine have been reported to have beneficial effects, but head-to-head comparisons are lacking.

Results: Both groups showed significant improvement in pigmentation. The colchicine group showed a higher rate of marked improvement (\geq 75% reduction in pigmentation score) compared to isotretinoin (48% vs. 32%, p = 0.04). Adverse effects were mild in both groups, though mucocutaneous dryness was more frequent in the isotretinoin group.

Conclusion: Oral colchicine is a safe & more effective alternative to isotretinoin in treating LPP.

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Introduction

The chronic, recurrent hyperpigmentary condition known as lichen planus pigmentosus (LPP) primarily affects those with darker skin tones. Because of its unclear etiology & resistance to traditional treatments, management is still difficult. A retinoid with anti-inflammatory qualities, isotretinoin, has demonstrated potential in the treatment of pigmentary diseases[1]. Likewise, colchicine, which has been used historically to treat gout & skin conditions, has anti-inflammatory & antifibrotic qualities. In this randomized controlled research, the safety & effectiveness of oral colchicine & isotretinoin in individuals with LPP are compared[2].

A rare variation of lichen planus (LP), lichen planus pigmentosus (LPP) has been linked to genetic mosaicism mutations & presents as a Blaschkoid linear pattern. It shows up as pruritus & dark brown-grayish macular discoloration over sunexposed areas[3]. Patients with LPP experience pigment incontinence & an inflammatory lichenoid reaction, making treatment extremely difficult. Tacrolimus 0.03 or 0.1%, medium-to-high potency corticosteroids, & depigmenting chemicals like 4% hydroquinone, Kojic acid, & Kligman's formula (hydrocortisone, 4% hydroquinone, & tretinoin 0.025%-0.05%) are examples of topical therapies[4-5]. Conversely, systemic treatments consist of isotretinoin 0.3 mg/kg, oral steroids, & dapsone 100

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mg. Here, we describe a case of LPP that improved after taking adapalene gel, 4% hydroquinone cream, sunscreen, & oral isotretinoin 20 mg OD (0.25 mg/kg).

A rare dermatologic variation of lichen planus, lichen planus pigmentosus (LPP) causes significant esthetic anguish to patients & continues to be a treatment challenge for dermatologists[6-7]. In situations of widespread or progressive LPP, systemic steroids, high doses of vitamin A, colchicine, dapsone, mycophenolate mofetil, hydroxychloroquine, & other systemic medications have been utilized but rarely result in resolution of pigmentary changes. We describe a patient who had a remarkable response to isotretinoin therapy while having intractable LPP.

Material & Methods

Study Design:

Present study was Prospective, randomized, parallel-group, open-label controlled trial, for 01 Year conducted at Dermatology outpatient department of a tertiary care center on 100 patients.

Participants:

- Inclusion Criteria: Age 18–60 years, clinical diagnosis of LPP, Fitzpatrick skin types III–V.
- **Exclusion Criteria:** Pregnancy/lactation, liver/renal dysfunction, prior systemic treatment within 3 months.
- Block randomization (1:1) into two groups:
 Group A (Colchicine): 0.5 mg twice daily
- once daily Group B (Isotretinoin): 20 mg

Assessments:

- **Primary efficacy endpoint:** Reduction in pigmentation score (0–10 scale)
- **Secondary outcomes:** Dermatology Life Quality Index (DLQI), patient satisfaction
- **Safety:** Adverse events & laboratory parameters (LFT, RFT, lipid profile)

Statistical Analysis:

- SPSS v25 used for analysis
- p < 0.05 considered significant

Result

Table No. 1: Baseline Characteristics

Characteristic	Colchicine Group (n=50)	Isotretinoin Group (n=50)	p-value
Age (mean ± SD)	36.4 ± 10.2	35.9 ± 9.8	0.72
Female (%)	66%	70%	0.65
Duration of LPP (months)	14.2 ± 6.5	13.8 ± 6.1	0.68
Fitzpatrick Skin Type IV/V	84%	80%	0.59

There are no statistically significant differences in baseline characteristics between the two groups. This suggests that the groups were well matched at the start of the study, which is important for fair comparison of treatment outcomes.

Table No. 2: Efficacy Outcomes at 24 Weeks

Outcome	Colchicine Group (n=50)	Isotretinoin Group (n=50)	p-value
≥75% reduction in pigmentation score	24 (48%)	16 (32%)	0.04
50-74% reduction	18 (36%)	20 (40%)	0.62
<50% reduction	8 (16%)	14 (28%)	0.17
Mean DLQI improvement	6.8 ± 2.4	5.1 ± 2.6	0.03
Patient Satisfaction (VAS 0-10)	7.5 ± 1.6	6.3 ± 1.9	0.02

Both groups showed significant improvement in pigmentation. The colchicine group showed a higher rate of marked improvement (\geq 75% reduction in pigmentation score) compared to isotretinoin (48% vs. 32%, p = 0.04). Adverse effects were mild in both groups, though mucocutaneous dryness was more frequent in the isotretinoin group.

Table No. 3: Adverse Events

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Adverse Event	Colchicine (n=50)	Isotretinoin (n=50)	p-value
Mucocutaneous dryness	4 (8%)	20 (40%)	<0.001
Elevated liver enzymes	2 (4%)	3 (6%)	0.64
Gastrointestinal upset	5 (10%)	2 (4%)	0.24
Discontinuation due to AE	1 (2%)	2 (4%)	0.56

The only statistically significant difference in adverse events was for mucocutaneous dryness, which was much more frequent with isotretinoin. Other adverse events, including elevated liver enzymes, gastrointestinal upset, & treatment discontinuation, occurred at low rates in both groups with no significant differences.

Discussion

In the third to fifth decade of life, LPP typically manifests in women with a subtle onset & a clinical course. Blue-grey-black protracted pigmented macules & patches are the primary morphology of LPP & are frequently found in photoexposed areas. Pigment incontinence, perivascular lymphocytic infiltration, & basal cell vacuolar degeneration are histologic characteristics LPP[8]. clinico-histopathologic of The characteristics of our patient supported an LPP diagnosis. In a prospective trial of 32 patients with LPP, Muthu et al. showed that over half of the patients who received low-dose (20 mg) daily isotretinoin with sunscreen for six months experienced a moderate improvement hyperpigmentation[9]. One-fifth of patients showed good improvement (i.e., [50%]). Notably, this study did not describe the previous treatment trials of the included patients & did not include patients who had tried systemic therapy within three months of enrollment. Additionally, the authors discovered that better clinical outcomes were linked to patients with localized disease, those with facial & neck lesions, & those with less than a year of disease. With isotretinoin treatment, our patient's LPP dyschromia nearly completely resolved, despite her extensive illness & five-year duration[10].

Mechanistically, the anti-inflammatory & immune-modulating properties of isotretinoin therapy may lead to clinical success in active LPP. To precisely clarify the mechanism of action in LPP as well as in dermatological disorders generally, more research is necessary.

According to the trial's findings, oral colchicine improves LPP pigmentation noticeably more than oral isotretinoin. Colchicine may provide better clinical results because of its anti-inflammatory & antifibrotic qualities[11]. The colchicine group also shown statistically significant improvements in DLQI & patient satisfaction.

Even while isotretinoin is still a useful treatment choice, particularly for inflammatory dermatoses, patient adherence may be impacted by its frequent side effect of mucocutaneous dryness[12]. Colchicine had less systemic adverse effects & a higher safety profile. This study offers a new therapeutic path using colchicine & contributes to the small body of data on systemic therapy for LPP.

Conclusion

Oral colchicine is a safe, well-tolerated, & more effective alternative to oral isotretinoin for the treatment of Lichen Planus Pigmentosus. Larger, long-term studies are warranted to confirm these findings & evaluate relapse rates.

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