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A study to compare the efficacy of autologous platelet rich plasma and leukocyte platelet rich fibrin matrix in trophic ulcers of Hansen's disease

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ABSTRACT:

Background: Non-healing ulcers in Hansen's disease, particularly in the lower extremities, pose significant treatment challenges due to sensory deficits and ischemia from peripheral nerve damage, resulting in prolonged treatment and poor outcomes. Global prevalence ranges from 1.9% to 13.1%, affecting physical health and quality of life. Despite available treatments, comparative studies on advanced therapies like PRP and PRFM are limited. This study aims to evaluate the safety, efficacy, and cost-effectiveness of PRP versus PRFM, enhancing outcomes and reducing morbidity in these ulcers.

Methods: This randomized prospective interventional study was conducted at the Dermatology, Venereology, and Leprology Department of Basaveshwara Teaching and General Hospital, Kalaburagi, involving patients aged 18 and above with Hansen's disease and non-healing trophic ulcers from August 2022 to January 2024. Participants were randomized into Group A (PRP) and Group B (PRFM), receiving weekly treatments for four weeks with bi-weekly follow-ups. Efficacy was evaluated using wound dimensions, NPUAP grading, and improvement metrics. Data analysis was done using SPSS version 26.0.

Results: Most participants were males aged 41-60 years from lower socio-economic backgrounds. Ulcers were primarily on the great toe, with similar initial dimensions. PRF showed superior outcomes, with a mean final ulcer volume of 11.58 cm^3 compared to 19.3 cm^3 for PRP, and 96.7% achieving over 80% improvement versus 23.3% in the PRP group. PRF also had better NPUAP ulcer grading improvements and no adverse effects, unlike PRP, which had 20% injection site pain. Both groups had similar ulcer duration and disease characteristics. Overall, PRF proved to be more effective and safer than PRP for treating non-healing trophic ulcers.

Conclusion: The study found PRF significantly more effective and safer than PRP, with 96.7% achieving over 80% improvement and no adverse effects, compared to 23.3% improvement and 20% injection site pain for PRP, supporting PRF's superior healing outcomes.

KEYWORDS: Efficacy, Platelet Rich Plasma, Leukocyte Platelet Rich Fibrin Matrix, Trophic Ulcers, Hansen's Disease

I. INTRODUCTION

Non-healing ulcers in Hansen's disease (leprosy) pose a significant therapeutic challenge globally, particularly in the lower extremities, often resulting in prolonged treatment, high costs, and unsatisfactory outcomes. The pathogenesis is linked to peripheral nerve damage, leading to sensory deficits, anesthesia, and increased ischemia, complicating wound healing.[1]The prevalence of these ulcers ranges from 1.9% to 13.1% worldwide, contributing substantially to the burden of physical disability and reduced quality of life for affected individuals.[2]

While conventional treatments like multidrug therapy, wound dressings, and debridement are commonly used, their effectiveness remains limited. There is a notable gap in robust, comparative studies that evaluate advanced therapies, such as Platelet Rich Plasma (PRP) and Platelet Rich Fibrin Matrix (PRFM), specifically in the context of Hansen's disease-related ulcers. Existing research largely consists of small-scale studies and case reports, which lack generalizability and consistent methodologies.[3]

This proposed study aims to fill this gap by directly comparing the safety and efficacy of PRP and PRFM in treating non-healing ulcers associated with Hansen's disease. PRP, rich in

growth factors like PDGF, TGF-β, and IGF, plays a key role in promoting tissue remodeling, angiogenesis, and cellular proliferation—essential processes for wound healing. PRFM, derived from PRP, potentially offers enhanced benefits due to the sustained release of growth factors and additional structural support provided by its fibrin matrix.[4]

The study holds clinical relevance as it addresses the urgent need for effective treatment strategies to improve outcomes for individuals with leprosy-related ulcers, thereby reducing morbidity. Additionally, it contributes to scientific advancement by providing insights into the comparative effectiveness of PRP and PRFM, highlighting their relative benefits and limitations in this specific patient population. Furthermore, assessing the cost-effectiveness of these therapies could lead to significant reductions in healthcare expenses associated with prolonged ulcer treatment and repeated interventions.[5]

II. METHODOLOGY

The study was conducted at Basaveshwara Teaching and General Hospital, MahadevappaRampure Medical College, Kalaburagi. The study population consisted of 60 patients aged 18 years and above who were diagnosed with Hansen's disease and had developed non-healing trophic ulcers. These individuals were actively seeking care under the Department of Dermatology, Venereology, and Leprology, ensuring a relevant sample for evaluating interventional strategies for ulcer management. By focusing on adult patients with persistent ulcers, the study aimed to comprehensively assess the clinical response to novel therapeutic approaches for ulcer healing.

This was a randomized prospective interventional study conducted over a period of 18 months, from August 2022 to January 2024. Patients who met the inclusion criteria—aged 18 years or older, diagnosed with Hansen's disease, and experiencing non-healing trophic ulcers for at least 12 weeks without improvement following four weeks of conventional treatment—were enrolled. Patients with contraindications such as anticoagulant use, bleeding disorders, active infection, inadequate perfusion, ischemia, gangrene, or seropositivity for HIV or HBV were excluded to maintain the safety and validity of the results. All participants provided informed consent before enrollment.

The study was initiated following approval from the Institutional Ethical Committee. At the initial visit, a comprehensive history was recorded, and physical examinations were conducted, which included various laboratory investigations.

Subsequently, patients were randomized into two groups—Group A (PRP) and Group B (PRFM)—at the baseline visit.

PRP or PRFM was then prepared and applied to the ulcers following standardized procedures, with the treatment being repeated weekly for four weeks and monitored biweekly to assess wound healing progress.

Statistical analysis was performed using SPSS version 26. Categorical data was represented as frequencies and proportions, while continuous data were analyzed using appropriate statistical tests such as chi-square test. Graphical representations such as bar diagrams, were used to visually present the findings. A p-value of <0.05 was considered statistically significant.

III. OBSERVATIONS AND RESULTS

The study found no significant differences in age, gender, occupation, or socio-economic status between the PRP and PRF groups, indicating that these factors were well-matched and not confounding variables. The majority of subjects in both groups were aged 41-60 years, predominantly male, and from the upper-lower socio-economic class. Occupational distribution was diverse, with most subjects being agriculturists or laborers. (Table 1)

The duration and number of ulcers were comparable between the PRP and PRF groups, with no significant differences. In the PRP group, 46.7% of subjects had ulcers for 3-6 months, and 46.7% for 7-12 months, while in the PRF group, 53.3% had ulcers for 3-6 months, and 36.7% for 7-12 months. Most subjects in both groups had one ulcer, with no significant differences in the distribution of multiple lesions. These similarities allow for an unbiased evaluation of the efficacy of PRP and PRF treatments in patients with non-healing trophic ulcers. (Table 2)

The site of ulcers was similarly distributed between the PRP and PRF groups, with no significant differences. The most common site was the great toe, with 63.3% in the PRP group and 60.0% in the PRF group. Other sites included the first metatarsal, lateral malleolus, lateral border of malleoli, other toes, and interdigital clefts, with no significant differences between the groups. (Figure 1)

The initial ulcer dimensions were similar between the PRP and PRF groups, with mean lengths, breadths, depths, and volumes showing no significant differences, ensuring comparable

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baseline characteristics. Final dimensions revealed reductions in both groups, with PRF showing greater reductions in breadth (2.52 cm vs. 3.21 cm) and volume (11.58 cm^3 vs. 19.30 cm^3) compared to PRP, though differences in length and depth were not significant. The p-values for volume and breadth suggested a trend favoring PRF. Overall, these findings indicate that PRF might be more effective in reducing ulcer size. (Table 3)

The NPUAP grading of ulcers showed initial and final assessments in both PRP and PRF groups. Initially, stages 1 to 4 were observed with no significant differences between the groups. Final assessments showed that both groups had improvements, with more subjects in the PRF group achieving stage 0 and fewer remaining in stage 3. The p-values for initial and final stages were not significant, indicating similar baseline and final NPUAP distributions. This suggests that both treatments are effective in improving ulcer stages, with PRF showing slightly better outcomes. (Table 4)

Significant improvement in the condition of ulcers was observed, with the PRF group showing markedly higher improvements. In the PRP group, 10.0% showed less than 60% improvement, 66.7% showed 60-80% improvement, and 23.3% showed more than 80% improvement. In contrast, the PRF group had 0% showing less than 60% improvement, 3.3% showing 60-80% improvement, and a striking 96.7% showing more than 80% improvement. The mean improvement was 74.71% for PRP and 87.80% for PRF, with a statistically significant p-value of <0.001. This indicates that PRF is significantly more effective in enhancing ulcer healing compared to PRP. (Figure 2)

The study found no significant differences between the PRP and PRF groups regarding the duration of Hansen's disease, disease spectrum, deformities, callosities, nerve involvement, or sensory loss, ensuring fair and unbiased treatment comparisons. The mean duration of Hansen's disease was comparable between groups, as were the distributions of disease type, deformities, callosities, and nerve involvement, indicating that these factors were well-matched. Adverse effects were significantly higher in the PRP group (20% injection site pain) compared to none in the PRF group (p = 0.010), highlighting PRF as the safer option for treating non-healing trophic ulcers in Hansen's disease. (Table 5 & Figure 3)

IV. DISCUSSION

In terms of age distribution, most participants in our study were aged 41-60 years, similar to those reported by Anandan V et al[6] (41.9 years) and Raju SP et al[7] (41.37 years). However, other studies, such as Luz BSR et al[8] (61.88 years) and Napit IB et al[9] (54.0 years), reported older average ages, indicating a broader demographic range among ulcer patients. Deshmukh NS et al[10] reported a younger mean age (36.5 years). These variations suggest that while chronic ulcers primarily affect middle-aged to older adults, there are instances of younger populations being affected as well.

Table 1: Comparison of characteristics of the study subjects

Subjects (N=60)		Groups				p-value[#]
		PRP (N=30)		PRF (N=30)		
		N	%	N	%	
Age group	<20 years	1	3.3%	0	0.0%	0.619
	21 to 40 years	5	16.7%	8	26.7%	
	41 to 60 years	14	46.7%	13	43.3%	
	>60 years	10	33.3%	9	30.0%	
Gender	Male	24	80.0%	22	73.3%	0.542
	Female	6	20.0%	8	26.7%	
Occupation	Homemaker	5	16.7%	7	23.3%	0.840
	Labourer	9	30.0%	10	33.3%	
	Agriculturist	10	33.3%	9	30.0%	
	Security	6	20.0%	4	13.3%	
Socio-economic status	Lower Middle	3	10.0%	4	13.3%	0.848
	Upper Lower	22	73.3%	20	66.7%	
	Lower Class	5	16.7%	6	20.0%	

Table 2: Comparison of characteristics of the ulcers

Subjects (N=60)	Groups		p-value[#]
	PRP (N=30)	PRF (N=30)	

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		N	%	N	%	
Duration of ulcers	**3-6 months**	14	46.7%	16	53.3%	0.707
	7-12 months	14	46.7%	11	36.7%	
	>12 months	2	6.7%	3	10.0%	
Number of ulcers	**One lesion**	24	80.0%	22	73.3%	0.686
	Two lesions	4	13.3%	4	13.3%	
	More than two	2	6.7%	4	13.3%	

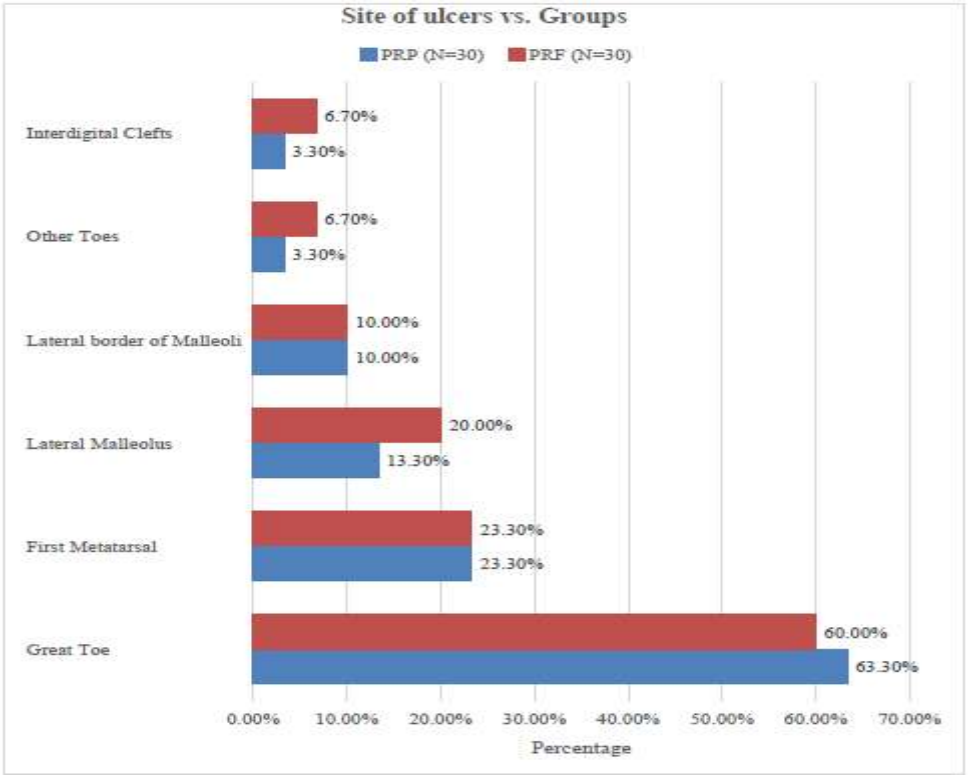

Figure 1: Comparison of site of ulcers

Table 3: Comparison of dimensions of the ulcers

Subjects (N=60)		**Groups**				**p-value#**
		PRP (N=30)		**PRF (N=30)**		
		Mean	**SD**	**Mean**	**SD**	
Initial	**Length (in cm)**	5.58	2.82	6.33	2.52	0.282
	Breadth (in cm)	4.54	2.58	4.97	2.52	0.513
	Depth (in cm)	1.48	0.75	1.59	0.82	0.589
	Volume (in cm^3)	67.43	75.84	81.17	83.66	0.508
Final	**Length (in cm)**	3.81	2.01	3.78	1.99	0.944
	Breadth (in cm)	3.21	1.71	2.52	1.16	0.074
	Depth (in cm)	0.83	0.54	0.68	0.43	0.228
	Volume (in cm^3)	19.30	20.63	11.58	13.45	0.091

Table 4: Comparison of NPUAP grading of the ulcers

Subjects (N=60)		**Groups**				**p-value#**
		PRP (N=30)		**PRF (N=30)**		
		N	**%**	**N**	**%**	
Initial	**Stage 0**	0	0.0%	0	0.0%	0.964
	Stage 1	7	23.3%	6	20.0%	
	Stage 2	10	33.3%	9	30.0%	

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	Stage 3	8	26.7%	9	30.0%	
	Stage 4	5	16.7%	6	20.0%	
Final	**Stage 0**	3	10.0%	2	6.7%	0.423
	Stage 1	8	26.7%	12	40.0%	
	Stage 2	15	50.0%	15	50.0%	
	Stage 3	4	13.3%	1	3.3%	
	Stage 4	0	0.0%	0	0.0%	

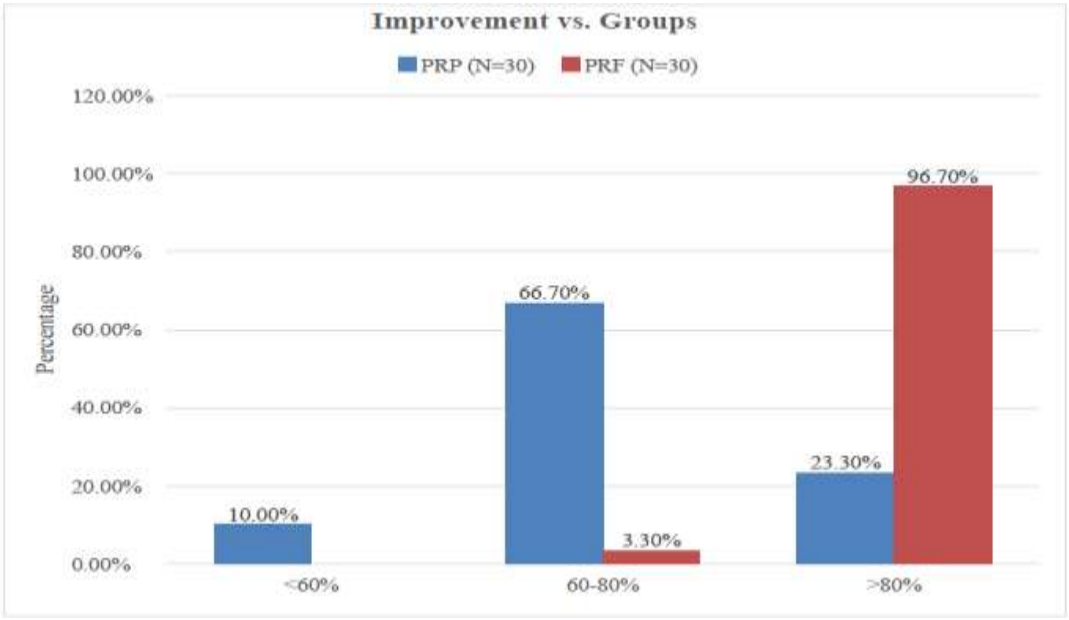

Figure 2: Comparison of improvement in condition

Table 5: Comparison of details of Hansen's disease

Subjects (N=60)		**Groups**				**p-value#**
		PRP (N=30)		**PRF (N=30)**		
		N	**%**	**N**	**%**	
Duration	**<5 years**	6	20.0%	8	26.7%	0.963
	6 to 10 years	10	33.3%	10	33.3%	
	11 to 15 years	6	20.0%	6	20.0%	
	16 to 20 years	5	16.7%	4	13.3%	
	>20 years	3	10.0%	2	6.7%	
Spectrum	**Borderline Tuberculoid**	13	43.3%	11	36.7%	0.852
	Borderline Lepromatous	12	40.0%	14	46.7%	
	Lepromatous Leprosy	5	16.7%	5	16.7%	
Deformity	**No deformity**	14	46.7%	11	36.7%	0.724
	Partial claw hand	13	43.3%	15	50.0%	
	Claw toes	3	10.0%	4	13.3%	
Callosities	**Yes**	8	26.7%	6	20.0%	0.542
	No	22	73.3%	24	80.0%	
Loss of sensation	**No loss**	6	20.0%	4	13.3%	0.766
	Partial loss	10	33.3%	10	33.3%	
	Glove & Stocking	14	46.7%	16	53.3%	
Adverse effects	**Yes**	6	20.0%	0	0.0%	0.010*
	No	24	80.0%	30	100.0%	

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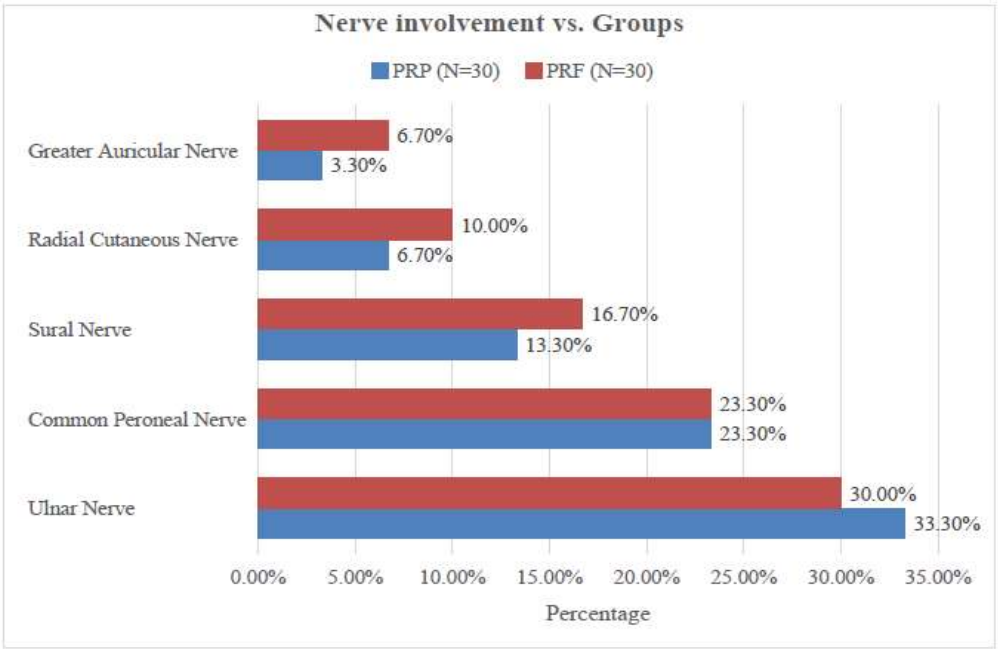

Figure 3: Comparison of nerve involvement

Regarding gender distribution, our study found a predominance of males (80%), consistent with findings in studies by Anandan V et al[6] (66% males), Deshmukh NS et al[10] (60% males), Gole PV et al[11] (66.7% males), Raju SP et al[7] (66.7% males), and Napit IB et al[9] (79.2% males). Luz BSR et al[8], however, reported a higher proportion of females (65.1%). The consistent trend of male predominance in most studies could indicate that males are either more prone to developing chronic ulcers or more likely to seek treatment, possibly due to socio-economic and lifestyle factors.

Occupation-wise, our study observed that most patients were agriculturists and laborers, a finding supported by Anandan V et al[6], who also reported a significant proportion of farmers and manual laborers among ulcer patients. This observation highlights the influence of socio-economic factors and occupational hazards in chronic ulcer development. Physically demanding and low-income jobs are associated with higher risks, underlining the need for targeted interventions to improve occupational health and safety among these populations.

Socio-economic status was predominantly in the upper-lower class in our study, with Napit IB et al[9] providing context that many participants never attended formal schooling, indicating a low socio-economic background. Luz BSR et al[8] reported an average per capita income of $313.79, also indicative of a lower socio-economic status. This trend reveals that patients from lower socio-economic classes are disproportionately affected by chronic ulcers, emphasizing the need for economic support and improved healthcare access.

Ulcer duration in our study ranged from 3 to 12 months, indicating chronicity. This duration aligns with SomaniA et al[12] (>6 months), Deshmukh NS et al[10] (mean 9.1 months), Gole PV et al[11] (3 months to 2 years), and Raju SP et al[7] (2 to 12 months). Luz BSR et al[8] reported a broader range (6 months to 44 years), while Anandan V et al[6] observed a shorter mean duration of 11.62 weeks. Chronic ulcers are characterized by prolonged persistence, underscoring the need for intensive, long-term management strategies.

Regarding the number of ulcers, most patients in our study had a single ulcer. Similarly, Raju SP et al[7] reported only two patients with multiple ulcers, suggesting that chronic ulcers are typically solitary. The sites of ulcers in our study included the toe, metatarsal, and malleolus, similar to locations reported by Anandan V et al[6] (forefoot, lateral malleolus, and heel) and Gole PV et al[11] (sole of the feet and legs). Ulcers are predominantly located on the feet, which are prone to pressure points and reduced blood flow, emphasizing the need for specific preventive measures and treatment strategies targeting foot ulcers.

Initial dimensions of ulcers in our study showed variations between groups, with PRP and PRF groups having initial volumes of 67.43 cm^3 and 81.17 cm^3, respectively. Luz BSR et al[8] reported initial areas of 15.25 cm^2 and 28.23 cm^2, while other studies, such as Somani A et al[12] and

Deshmukh NS et al[10], documented ulcer sizes ranging from 1 cm x 1 cm to 5 cm x 5 cm. Across studies, emphasis is placed on measuring and documenting ulcer dimensions to evaluate treatment efficacy comprehensively.

The final dimensions of ulcers in our study indicated a significant reduction, with the PRF group demonstrating greater improvement in volume (11.58 cm^3 vs. 19.30 cm^3 for PRP). Luz BSR et al[8], Anandan V et al[6], and other studies consistently reported significant reductions in ulcer size, emphasizing the effectiveness of different treatments. Notably, Anandan V et al[6] observed 92% complete healing, and Somani A et al[12] reported an 85.51% reduction, highlighting the importance of choosing appropriate interventions for chronic ulcer management.

NPUAP grading of ulcers was utilized in our study to track improvement, a valuable standardized approach that facilitates ulcer severity assessment and treatment response evaluation. However, most other studies did not provide NPUAP grading, suggesting a need for broader adoption of standardized grading systems to improve comparability across research.

Significant improvement in condition is noted in our study, particularly with the PRF group. Similar positive outcomes are reported in Luz BSR et al[8] with faster healing, Anandan V et al[6] with 92% complete healing, Somani A et al[12] with an 85.51% reduction, Deshmukh NS et al[10] with a 69.38% reduction, Gole PV et al[11] with 80% complete healing, Raju SP et al[7] with 73.08% complete healing, and Napit IB et al[9] with favorable healing rates. These consistent improvements underscore the effectiveness of different treatment approaches in managing chronic ulcers. The inference is that various treatments, including PRP and PRF, significantly enhance ulcer healing, reflecting their potential in clinical practice.

The duration of Hansen's disease was documented in our study, highlighting the need for long-term, specialized care for these patients. Napit IB et al[9] noted a mean disease duration of 19.7 years, underscoring the chronicity of Hansen's disease and the necessity of sustained intervention.

Deformity was another significant observation in our study, with many patients exhibiting motor deformities. Anandan V et al[6] also reported deformity data, highlighting its prevalence among chronic ulcer patients. Addressing deformities is essential, as they can complicate ulcer healing and require specific therapeutic strategies.

Callosities and nerve involvement were notable in our study, with nerve involvement reported by Napit IB et al[9] (100%). These findings underscore the importance of addressing callosities and neuropathy in ulcer management to mitigate complications and promote effective healing.

Finally, regarding adverse effects, our study reported no significant side effects in the PRF group, while 20% of patients in the PRP group experienced injection site pain. This safety profile is consistent with findings from Luz BSR et al[8], Anandan V et al[6], and other studies, demonstrating that both PRP and PRF are well-tolerated treatments for chronic ulcers.

V. CONCLUSION

Our study included 60 patients with non-healing trophic ulcers due to Hansen's disease compared PRP and PRF treatments at Basaveshwara Teaching and General Hospital. Both groups had similar demographics and ulcer characteristics, but PRF showed significantly better outcomes, with 96.7% achieving over 80% improvement compared to 23.3% in the PRP group. PRF also demonstrated superior NPUAP grading improvements and had no adverse effects, unlike PRP, which had 20% reporting injection site pain. PRF is thus a more effective and safer option for treating these ulcers.

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Declarations
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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

Autologous Platelet Rich Plasma (Before)

Autologous Platelet Rich Plasma (After 4 Sittings)

Leukocyte Platelet Rich Fibrin Matrix (brfore)

Leukocyte Platelet Rich Fibrin Matrix (After 4 Sittings)

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