



THE EFFECTIVENESS OF PLATELET RICH PLASMA IN THE HEALING OF NON-INFECTIVE DIABETIC ULCERS

General Surgery

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ABSTRACT

Introduction: Diabetic Ulcers have since long been a challenge to both the patient and the treating doctor. Laden with factors like microangiopathies, high blood glucose levels, dropping morale of the patient- management of this condition has been more of a war. Amidst the multifactorial approach towards this issue including glycemic control, wound debridement, antibiotic administration, Platelet Rich Plasma has been a major breakthrough as a treatment option for the diabetic ulcers. **Material and Methods:** Observational study was conducted at KD Medical College, Mathura, over two years, involving 80 patients. Preliminary assessment included Culture Swabs and ruling out vascular pathologies. Patients were treated in two groups with one group (Group A) being administered with PRP with aseptic dressings while the Group B was treated with aseptic dressings only and observations noted over eight weeks. Assessment was made over factors like presence of bluish hue at margins, changes in wound dimensions and glycemic control. **Results:** Ulcer healing was better and faster in patients of Group A which had been administered PRP injections on a weekly basis. Most of the changes began appearing after 2 weeks of treatment which became prominent over the following 2 weeks. **Conclusion:** Wound infection was controlled and vascularity was optimised, injected platelet-rich plasma (PRP) demonstrated significantly better outcomes compared to conventional dressings in the management of diabetic foot ulcers.

KEYWORDS

Platelet-rich Plasma, Diabetic Foot Ulcers, Granulation Tissue, Bluish Hue

INTRODUCTION

Diabetic ulcers represent a significant and prevalent complication for individuals with diabetes, particularly affecting the feet and legs. Diabetic foot ulcers are characterized by open sores or wounds resulting from a combination of diabetes-related conditions.¹ Diabetic ulcer development is primarily influenced by peripheral neuropathy, vascular insufficiency, and immune dysfunction.² Peripheral arterial disease (PAD) significantly impairs healing and vascular insufficiency leads to ischemia, a major cause of non-healing ulcers.³ Peripheral neuropathy exacerbates the issue by reducing sensation, allowing unnoticed injuries to worsen, and altering gait, which increases ulcer risks.⁴ Current treatments for diabetic ulcers focus on resolving root causes while promoting healing and preventing complications. This can be done surgically, enzymatically, or autolytically, depending on ulcer severity.⁵ Platelets in PRP are rich in growth factors that regulate inflammation, angiogenesis, and cell migration, all crucial for effective healing.⁶ PDGF, produced mainly by platelets, macrophages, and fibroblasts, is vital for attracting cells to the injury site and encouraging new blood vessel formation, both critical for wound repair.⁷ PRP enhances macrophage activity, clearing dead tissue and facilitating healing progression.⁸ PRP's effectiveness in tissue remodeling and collagen synthesis remains clear, minimizing scarring and strengthening healed tissue.⁹ PRP offers quick, preservative-free preparation and is safe since it uses the patient's own cells, minimizing the risk of immune reactions and contamination. It has shown promise in treating musculoskeletal injuries.¹⁰ In India, very few researches have been done on effectiveness of platelet rich plasma in the healing of non-infective diabetic ulcers. Furthermore, nothing was known regarding on effectiveness of platelet rich plasma in the healing of non-infective diabetic ulcers, which is why this study was designed.

MATERIALS AND METHODS

Observational study was conducted on OPD/ Emergency patients of KD Medical College Hospital and Research centre, Mathura. Ethical approval was obtained from Institutional Ethical Committee KD Medical College Mathura. Written informed consent was taken from every participant of the study. The study was conducted over a period of two year. Controlled Diabetes (Type 1 and 2), Ulcer present for a period of more than 4 weeks, Age group 10-65 years and willing participants were included in the study. Evidence of gangrene in ulcer, uncontrolled diabetic patient, past history of peripheral vascular surgery in patient and Unwilling participants were excluded from study. A total of 100 patients were taken up for study.

METHODOLOGY

Overall the participants were divided into 2 groups and one group was administered Platelet Rich Plasma as an intralesional injection on the ulcer bed at 1 ml/cm (weekly) along with normal saline dressing(daily). Participants were followed up every week and were assessed on basis of the selected parameters and the data was collected in the proforma assigned to the participants. Patients who fail to maintain the specified blood sugar levels and sterility of the ulcer were excluded from the study.

Parameters

1. Granulation tissue- Was assessed by taking photographs in each follow-up.
2. Ulcer dimensions- Was measured using a vernier calliper.
3. Bluish hue at margins- Was assessed by taking photographs at every follow-up.
4. Controlled diabetes- HbA1C less than 7% and fasting blood sugar less than 126mg/dl.

Statistical Analysis

The comparison in between two groups were quantitative in nature was analysed using Independent t test. The comparison of the two groups which were qualitative in nature was analysed using Chi-Square test. $p \leq 0.05$ was considered significant. SPSS vs 25 used to analysed the data.

RESULTS AND OBSERVATIONS

Out of 100 patients, 80 were included in the study and 20 were excluded.

The ulcer healing progression over eight weeks showed a significant difference between Groups A and B. In the initial two weeks, no patients in either group experienced ulcer healing. By week 3, 12.5% of patients in Group A showed healing, while no healing was observed in Group B ($p=0.08$). The healing rate in Group A continued to improve, reaching 30% by week 4 and 47.5% by week 5, significantly higher than Group B ($p=0.009$ and $p=0.01$, respectively). By week 7, 90% of Group A had healed compared to 37.5% in Group B ($p<0.0001$). At week 8, all patients in Group A had fully healed, whereas 42.5% in Group B still had unhealed ulcers ($p=0.0008$). This data highlights a faster and more effective healing process in Group A compared to Group B. (Table 1)

Table 1: Comparison of Ulcer Healing Over Eight Weeks Between Groups A and B

Ulcer Dimension (in cm2)		Group A		Group B		P-Value
		No. of Patients	Percentage	No. of Patients	Percentage	
Week 1	Not Healed	40	100	40	100	1
	Healed	0	0	0	0	
Week 2	Not Healed	40	100	40	100	1
	Healed	0	0	0	0	
Week 3	Not Healed	35	87.5	40	100	0.08*
	Healed	5	12.5	0	0	
Week 4	Not Healed	28	70	37	92.5	0.009
	Healed	12	30	3	7.5	
Week 5	Not Healed	21	52.5	31	77.5	0.01*
	Healed	19	47.5	9	22.5	
Week 6	Not Healed	14	35	28	70	0.04*
	Healed	16	40	12	30	
Week 7	Not Healed	4	10	25	62.5	<0.0001*
	Healed	36	90	15	37.5	
Week 8	Not Healed	0	0	17	42.5	0.000
	Healed	40	100	23	57.5	

Test used- chi square, $p > 0.05$ insignificant and $p \leq 0.05$ significant.

The presence of a bluish hue decreased over time in both groups. Initially, 35% of patients in Group A and 37.5% in Group B exhibited this characteristic. By Week 3, only 5% of patients in both groups had a bluish hue, and from Week 4 onward, no cases were observed in either group. This indicates a progressive improvement in tissue condition over the treatment period. (Table 2)

Table 2: Comparison of Bluish Hue Presence Over Eight Weeks Between Groups A and B

Bluish Hue		Group A		Group B		P-Value
		No. of Patients	Percentage	No. of Patients	Percentage	
Week 1	Present	14	35	15	37.5	0.81
	Absent	26	65	25	62.5	
Week 2	Present	4	10	5	12.5	0.72
	Absent	36	90	35	87.5	
Week 3	Present	2	5	2	5	1
	Absent	38	95	38	95	
Week 4	Present	0	0	0	0	1
	Absent	40	100	40	100	
Week 5	Present	0	0	0	0	1
	Absent	40	100	40	100	
Week 6	Present	0	0	0	0	1
	Absent	40	100	40	100	
Week 7	Present	0	0	0	0	1
	Absent	40	100	40	100	
Week 8	Present	0	0	0	0	1
	Absent	40	100	40	100	

Test used- chi square, $p > 0.05$ insignificant

DISCUSSION

The ulcer healing progression over eight weeks showed a significant difference between Groups A and B. In the initial two weeks, no patients in either group experienced ulcer healing. By week 3, 12.5% of patients in Group A showed healing, while no healing was observed in Group B ($p=0.08$). The healing rate in Group A continued to improve, reaching 30% by week 4 and 47.5% by week 5, significantly higher than Group B ($p=0.009$ and $p=0.01$, respectively). By week 7, 90% of Group A had healed compared to 37.5% in Group B ($p=0.0001$). At week 8, all patients in Group A had fully healed, whereas 42.5% in Group B still had unhealed ulcers ($p=0.0008$). Similarly, the presence of a bluish hue decreased over time in both groups. Initially, 35% of patients in Group A and 37.5% in Group B exhibited this characteristic. By week 3, only 5% of patients in both groups had a bluish hue, and from week 4 onward, no cases were observed in either group. This indicates a progressive improvement in tissue condition over the treatment period. Although different studies have reported varying results, Abd El-Rahman M et al¹¹ found that PRP was more effective than conventional antiseptic dressing after the 4th week, with a significantly higher rate of healing per week ($p<0.05$). However, by the 8th week, the number of healed ulcers in the PRP group was higher but not statistically significant ($p > 0.05$). At the 12th

week, conventional dressing showed a higher healing rate, which was statistically significant ($p<0.05$), suggesting that overall, Group B healed faster than Group A. Although PRP has shown promise, Ahmed et al. (2017) noted that the healing rate was greater in the PRP group during the first eight weeks but declined afterward.¹² Various studies have presented divergent outcomes regarding PRP's success in treating diabetic foot ulcers (DFUs). Abdelhafez et al. reported a 96% success rate in complete healing with PRP injections for DFUs¹³, while Salem et al. documented a 97.6% success rate.¹⁴

Limitation of Study

Our study has several limitations, including a small sample size and the absence of a direct comparison group, which limits the generalizability of our findings.

Conclusion

The study concluded that once wound infection was controlled and vascularity was optimised, injected platelet-rich plasma (PRP) demonstrated significantly better outcomes compared to conventional dressings in the management of diabetic foot ulcers. However, to validate and strengthen these findings, further clinical trials are essential to more comprehensively evaluate the effectiveness of injected PRP across diverse patient populations.

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