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Research Article

A PROSPECTIVE RANDOMIZED CONTROLLED CLINICAL STUDY COMPARING THE EFFICACY OF AUTOLOGOUS PLATELET-RICH PLASMA VERSUS CONVENTIONAL DRESSING IN CHRONIC NON-HEALING ULCERS

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Abstract

Background: Chronic non-healing ulcers are difficult to treat and may persist despite appropriate wound care. Platelet-rich plasma (PRP) provides platelet-derived growth factors that may support tissue repair and wound healing.

Methods: A prospective, randomized controlled clinical study was conducted in the Department of General Surgery, Basaveshwar Teaching and General Hospital, attached to Mahadevappa Rampure Medical College, Kalaburagi, from 1 March 2021 to 31 August 2022. Forty-two patients with chronic non-healing ulcers were randomized into a PRP group (n=21) and a conventional-dressing control group (n=21). Patients were assessed clinically at baseline and during follow-up. The principal outcomes were wound healing time and number of dressings required for complete healing.

Results: The patients were 18–70 years old. Thirty-three patients (78%) were male and nine (22%) were female. Traumatic ulcers were the most common etiology (45%), followed by venous ulcers (38%). The lower limb was the most common site (86%). Mean ulcer size was 9.48±1.91 cm² in the control group and 9.56±1.87 cm² in the PRP group. Mean healing time was 7.3±1.91 weeks in the control group and 4.38±1.94 weeks in the PRP group (p=0.0001). The mean number of dressings required for complete healing was 12.8±1.94 in the control group and 7.60±2.9 in the PRP group (p=0.0001).

Conclusion: In this study, PRP dressing was associated with faster wound healing and fewer dressings required for complete closure of chronic non-healing ulcers.

Keywords: platelet-rich plasma; chronic non-healing ulcer; wound healing; conventional dressing; granulation tissue

INTRODUCTION

Chronic wounds are a major health challenge, and the goal of wound care is to facilitate healing using standardized wound-care protocols. A chronic wound is one that fails to proceed through an orderly and timely reparative process, and a practical classification of a non-healing wound is one that fails to heal spontaneously within 3 months.[1,2] Skin ulcers involve loss of the epidermis and dermis and may extend into subcutaneous tissue and deeper structures.

Conventional approaches to chronic ulcer management include appropriate wound assessment, wound cleansing, debridement, infection control, management of vascular factors, and suitable dressings. Various adjunctive methods have been investigated, including platelet-rich plasma (PRP) and collagen-based dressings.[3,4] Platelets contain growth factors within their alpha granules, including platelet-derived growth factor and epidermal growth factor, which participate in cellular recruitment, proliferation, angiogenesis, and tissue repair.[4]

Chronic non-healing ulcers are associated with substantial morbidity and financial burden. Reported prevalence varies between populations, and the burden is expected to increase with population ageing and the prevalence of conditions associated with impaired wound healing.[5,6] PRP has been investigated as an adjunct to standard wound care, and previous studies have reported beneficial effects in selected chronic wounds.[7-10]

The present study was undertaken to compare autologous PRP dressing with conventional dressing in patients with chronic non-healing ulcers, with particular emphasis on wound healing time and the number of dressings required for complete healing.

MATERIALS AND METHODS

Study design and setting

This prospective, randomized controlled clinical study was conducted in the Department of General Surgery at Basaveshwar Teaching and General Hospital, attached to Mahadevappa Rampure Medical College, Kalaburagi, from 1 March 2021 to 31 August 2022. Ethical committee approval was obtained before commencement of the study, and written informed consent was obtained from participants.

Participants

Forty-two patients with chronic non-healing ulcers were enrolled and randomized into two groups of 21 patients each: a PRP group (experimental group) and a conventional-dressing group (control group).

Inclusion criteria:

- Ulcers of more than 6 weeks' duration.
- Male and female patients aged 18–70 years.

Exclusion criteria:

- Bleeding disorders.
- Uncontrolled blood glucose levels in diabetic patients.
- Infected ulcers.

Clinical assessment and investigations

Detailed history and clinical examination were performed using a structured proforma. The duration, mode of onset, progression, associated symptoms, and etiological factors were recorded. Ulcers were assessed for anatomical site, size and depth, edge characteristics, mobility, fixity, induration, local blood supply, wound perimeter, systemic features, regional lymph-node status, limb or part function, joint movements, distal pulses and sensation, and evidence of infection.

Investigations included blood sugar testing, arterial or venous Doppler studies and angiography when indicated, examination of wound discharge by culture and sensitivity and AFB study, edge biopsy when indicated, radiography of the affected part for periostitis or osteomyelitis, FNAC of palpable draining lymph nodes, and chest radiography and Mantoux testing in suspected tuberculous ulcers. Complete blood count, renal function tests, liver function tests, HIV and HBsAg

testing were also performed as part of the study evaluation.

Randomization and treatment

Patients meeting the eligibility criteria were randomized using a random number table to receive either PRP dressing or conventional dressing. The wound was assessed at baseline and at each dressing, with clinical documentation and photographs during follow-up.

For conventional dressing, the ulcer was cleaned with 0.9% saline and covered with a pad and roller bandage. Conventional management included adequate debridement, local measures for infection control, systemic antibiotics when used, and avoidance of undue pressure on the wound.[11-13]

For the PRP group, freshly prepared PRP was obtained from the hospital blood bank and injected around the healing margins using a 26-G insulin syringe after cleaning the ulcer with 0.9% saline. Up to 5 mL of PRP was used in one sitting and applied uniformly around the healing margin, followed by dressing with a pad and roller bandage. Dressings were changed on alternate days in both groups. PRP was screened for routine blood-transmitted diseases before use.

Outcome assessment

Ulcer dimensions were assessed by measuring length and width using a metric scale. Wound characteristics including granulation tissue, pain, colour and wound edges were documented. The study endpoint was complete wound closure or the end of follow-up. The principal outcomes for comparison were time to complete healing and the number of dressings required for complete healing.

Statistical analysis

Statistical analysis was performed using IBM SPSS software version 20.0. Chi-square testing was used for qualitative data, while t tests and analysis of variance were used for quantitative data. A p value <0.05 was considered statistically significant.

RESULTS

Forty-two patients were included, with 21 patients in each treatment group. The age range was 18–70 years, with the largest proportion in the 51–60-year age group. Overall, 33 patients (78%) were male and 9 (22%) were female. The most common ulcer duration was 16–19 weeks.

Table 1. Age distribution of study participants

Age group (years)	Patients, n	Percentage
18–20	1	2%
21–30	10	24%
31–40	4	10%
41–50	10	24%
51–60	14	33%
61–70	3	7%
Total	42	100%

Table 2. Sex distribution by study group

Sex	Control, n	PRP, n	Total, n
Male	17	16	33
Female	4	5	9
Total	21	21	42

Ulcer duration ranged from 12 to 26 weeks. Nineteen patients (45%) had ulcers of 16–19 weeks' duration, followed by 13 patients (31%) with ulcers of 20–23 weeks' duration.

Table 3. Distribution according to ulcer duration

Ulcer duration (weeks)	Control, n	PRP, n	Total, n	Percentage
12–15	3	4	7	16%
16–19	10	9	19	45%
20–23	6	7	13	31%
24–26	2	1	3	8%
Total	21	21	42	100%

Traumatic ulcers were the most common etiology, accounting for 19 patients (45%), followed by venous ulcers in 16 patients (38%), trophic ulcers in 5 patients (12%), and vasculitic ulcers in 2 patients (5%).

Table 4. Etiology of chronic non-healing ulcers

Etiology	Control, n	PRP, n	Total, n	Percentage
Venous	9	7	16	38%
Traumatic	9	10	19	45%
Trophic	2	3	5	12%
Vasculitic	1	1	2	5%
Total	21	21	42	100%

The lower limb was the most frequent ulcer location, accounting for 36 patients (86%), followed by the torso in 4 patients (9%) and the upper limb in 2 patients (5%).

Table 5. Distribution according to ulcer location

Ulcer location	Control, n	PRP, n	Total, n	Percentage
Lower limb	18	18	36	86%
Torso	2	2	4	9%
Upper limb	1	1	2	5%

Table 6. Complications recorded during follow-up

Complication	Control, n	PRP, n
None	18	19
Pain	1	2
Fever	0	0
Infection	2	0
Bleeding	0	0
Total	21	21

Table 7. Baseline ulcer characteristics

Ulcer characteristic	Control, n	PRP, n
No discharge	0	2
Serous/serosanguinous discharge	21	19

Table 8. Mean baseline ulcer size

Variable	Control group	PRP group
Mean ulcer size (cm^2)	9.48±1.91	9.56±1.87

The mean duration of healing was 7.3±1.91 weeks in the control group and 4.38±1.94 weeks in the PRP group. The difference was statistically significant (p=0.0001).

Table 9. Time to complete healing

Outcome	Control group	PRP group	p value
Mean healing time (weeks)	7.3±1.91	4.38±1.94	0.0001

The mean number of dressings required for complete healing was 12.8±1.94 in the control group and 7.60±2.9 in the PRP group. The difference was statistically significant (p=0.0001).

Table 10. Number of dressings required for complete healing

Outcome	Control group	PRP group	p value
Mean number of dressings	12.8±1.94	7.60±2.9	0.0001

DISCUSSION

Chronic wounds are a major health problem, and conventional management includes adequate debridement, control of infection, revascularization of ischemic tissue when required, and avoidance of undue pressure on the wound.[14,15] PRP has been investigated as an adjunct to standard wound care because it contains platelet-derived growth factors and other mediators involved in wound repair.[16]

In the present study, the baseline characteristics of patients receiving PRP and conventional

dressing were similar with respect to age, sex, ulcer location and initial ulcer size. The mean baseline ulcer size was 9.48±1.91 cm² in the control group and 9.56±1.87 cm² in the PRP group.

The principal finding was a shorter time to complete healing in the PRP group. Mean healing time was 4.38±1.94 weeks with PRP compared with 7.3±1.91 weeks with conventional dressing, with a statistically significant difference (p=0.0001). The number of dressings required for complete healing was also lower with PRP, with means of 7.60 and 12.8 dressings in the PRP and control groups, respectively (p=0.0001).

Previous clinical work has described beneficial effects of autologous platelet-derived factors in chronic non-healing wounds. Knighton et al. reported accelerated epithelialization and repair with autologous platelet-derived wound-healing factors.[20] The growth factors released from PRP have roles in mesenchymal-cell recruitment, proliferation and extracellular matrix synthesis.[21] PDGF, transforming growth factor-β and other platelet-derived mediators participate in cellular proliferation, collagen synthesis, angiogenesis and granulation tissue formation.[21-23]

Several clinical studies have reported healing of chronic wounds following PRP treatment. Frykberg et al. reported reduction in wound area among most ulcers in a prospective case series, with a mean treatment duration of 2.8 weeks and 3.2 treatments.[24] Steenvoorde et al. reported a mean treatment period of 4.2 weeks in hard-to-heal wounds treated with autologous platelet-rich fibrin.[25] Kakudo et al. reported complete healing in three of five intractable skin ulcers within 4 weeks, with epithelialization occurring over a longer period in some wounds.[26]

A randomized controlled multicenter study by Driver et al. reported healing in 13 of 16 patients treated with platelet-rich plasma gel compared with 8 of 19 patients receiving control gel.[27] The findings of the present study are consistent with the reported use of platelet-rich preparations to support wound healing.

The preparation of PRP varies among studies. Double-centrifugation methods have been described for concentrating platelets, and platelet preparation remains an important component of PRP-based wound treatment.[28-30]

CONCLUSION

In this prospective randomized controlled clinical study of 42 patients with chronic non-healing ulcers, PRP dressing was associated with faster complete wound healing than conventional dressing. The mean healing time and the mean number of dressings required for complete healing were significantly lower in the PRP group.

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