Autologous Platelets Gel versus Conventional Methods in Managing Chronic Wounds

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1. Introduction

Wound healing is a complex process of cellular, hormonal and immunological components that interact to form a healing wound. Studies on chronic wound fluid suggest that growth factor levels are reduced and perhaps protease levels are high.¹ Thus, there may be internal molecular defects in chronic wound cells that prevent their healing. This opened a new window of treatment by promoting the healing of chronic wounds by exploiting the necessary growth factors.

Platelet extraction has been shown to improve and accelerate both soft tissue and hard tissue healing.² Its effectiveness is based on high levels of growth factors such as platelet-derived growth factor (PDGF), transformation factor- β (TGF- β), epidermal growth factor (EGF), Vascular endothelial growth factor (VEGF), and insulin-like growth factor (IGF).

It has been found to be used in maxilla facial surgery and orthopedic surgery, dental surgery, orthopedic surgery, bone reconstruction, plastic and cosmetic surgery, eye surgery to repair a retinal cavity, and sports medicine for cartilage and tendon repair.^{4,5} Platelet extract can be made using recombinant technology, using platelet concentrate in a blood bank, or using autologous blood.

Since not all patients can afford the commercially available recombinant platelet gel or blood bank platelet gel for dressing, autologous platelet gel promises an easy and inexpensive way to treat chronic ulcers. As only a few studies address this issue an effort has been made to determine the therapeutic efficacy of autologous platelet gel application while compared to conventional dressings, to treat chroniculcers.

Aims

To compare the efficacy of autologous platelets gel with conventional methods in patients with chronic wounds

Objectives

The objective of this study is to test the efficacy of autologous platelet gel in Epithelialization and Reduction in size of the wound in chronic wounds in comparison with the conventional method of treatment.

2. Methodology

This is a prospective randomized controlled study, to test the efficacy of autologous platelet gel in epithelialization and wound reduction in chronic wounds. The study was conducted in the department of surgery, Kamineni Institute of Medical Sciences, Narketpally, from October 2020-September 2022.

The source of data was patients attending the outpatient regularly or those admitted as inpatients for the management of chronic wounds. 60 patients were studied. 30 cases were randomly chosen for study with autologous platelet gel and 30 cases received conventional dressing for the chronic wounds.

Sample size: 60 cases

| Inclusion criteria: | Exclusion criteria: |
|--|--|
| Age group – 18-80yrs | Age group <18 and>80yrs |
| Ulcer ≥ 8weeks | Ulcers < 8weeks |
| Hb>10g% | Hb< 10 g% |
| $FBS \le 110 mg\%$ and $PPBS \le 140 mg\%$ if diabetic | FBS >110mg% and PPBS > 140 mg% (ifdiabetic) |
| | Activeinfection |
| | Ulcers with exposed tendons, ligaments orbone |
| | Ulcers with evidence of malignancy and on radiation/chemotherapy |

Study type: Prospective and Comparative study

Method of Collection of data:

A detailed history was taken in all cases regarding the duration, mode of onset, progression, and associated symptoms. The etiological factor that might be responsible for chronicity was also elicited.

Ulcer examination was done in all cases and wound assessment of its characteristics. dressings were done 3-4 days apart for each patient (Day 1,4,7,10). The size of the ulcer was plotted over a graph and a photograph was taken of the wound, at the beginning and the end of the study (Day 1 and Day 14), and a photographic wound assessment tool (PWAT) for comparison

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| Domain | Assessment | Date |
|---------------------------------------|---|-------|
| I. Edges | 0 = Indistinct, diffuse, none clearly visible 1 = Distinct, outline clearly visible, attached, even with wound base 2 = Well-defined, not attached to wound base 3 = Well-defined, not attached to base, rolled under, thickened 4 = Well-defined, fibrotic, scarred or hyperkeratonic | Score |
| 2. Necrotic Tissue Type | 0 = None visible I = White/gray nonviable tissue and/or nonadherent yellow slough 2 = Loosely adherent yellow slough 3 = Adherent, soft, black eschar 4 = Firmly adherent, hard, black eschar | |
| 3. Necrotic Tissue Amount | 0 = None visible I = < 25% of wound bed covered 2 = 25% to 50% of wound covered 3 = > 50% and < 75% of wound covered 4 = 75% to 100% of wound covered | |
| 4. Skin Color Surrounding Wound | 0 = Pink or normal for ethnic group I = Bright red 2 = White or gray pallor or hypopigmented 3 = Dark red or purple 4 = Black or hyperpigmented | |
| 5. Granulation Tissue | $\begin{array}{l} 0 = \mbox{Skin intact or partial-thickness wound} \\ I = \mbox{Bright, beefy red; 75\% to 100\% of wound filled and/or tissue overgrowth} \\ 2 = \mbox{Bright, beefy red; < 75\% and > 25\% of wound filled} \\ 3 = \mbox{Pink, and/or dull, dusky red and/or fills } 25\% of wound} \\ 4 = \mbox{No granulation tissue present} \end{array}$ | |
| 6. Epithelializatio n | 0 = 100% wound covered, surface intact I = 75% to < 100% wound covered and/or epithelial tissue extends > 0.5 cm into wound bed 2 = 50% to < 75% wound covered and/or epithelial tissue extends > 0.5 cm into wound bed 3 = 25% to < 50% wound covered 4 = < 25% wound covered | |

Statistical analysis: Unpaired students' "t" test and paired "t" test were used to find out the statistical significance. A 'P' < 0.05 was taken as significant.

Preparation of Platelet gel

Step 1: Collection of Blood

Under all aseptic precautions, 12 mlof blood was drawn intravenously from the antecubital region into 2 bulbs containing CPDA (0.7 ml) each. The bulbs were shaken thoroughly to ensure mixing of the anticoagulant withdrawn blood

Step 2: Preparation of Platelet Poor plasma

The blood was centrifuged at 3000 rpm for 10 mins. The supernatant formed is Platelet Poor Plasma (PPP) and buffy coat. 2 ml of PPP was aspirated and kept aside for use in the preparation of autologous thrombin (see step 4)

Step 3: Preparation of Platelet-rich plasma

The remaining PPP, Buffy coat (upper 1 mm of RBC) layer is collected in another vacutainer and again centrifuged at 1000 rpm for 10 mins. The upper half is discarded and the lower half yields concentrated platelet-rich plasma.

Step 4: Preparation of autologous thrombin

2 ml of PPP which was kept aside is thoroughly mixed with 0.08 ml of 10% Calcium gluconate. This resulted in clot formation and a supernatant which is the autologous thrombin, after 20 mins.

Step 5: Preparation of PRP gel

0.5 ml of the autologous thrombin is added to the concentrated PRP which forms a transparent PRP gel after a few minutes.

3. Results

The present study was conducted in the Kamineni Institute of Medical Sciences, Narketpally, and the findings are tabulated below. During the study years from October 2020-September 2022, 60 patients with chronic ulcers were randomized into the study (PDGF) and control (conventional dressing) groups. These groups were studied for the effect of conventional dressing versus PDGF on epithelialization and wound reduction.

Analysis was done using Fischer's Exact Test for categorical data and students paired 't' test for continuous variables within the groups and unpaired 't' test for continuous variables between cases and controls

Patient's Demography

| Table 1: Age at Presentation | | | | | |
|------------------------------|------------|------------|------------|--|--|
| Age (Years) | Patients | Cases | Controls | | |
| Age (Tears) | n=60(%) | n=30 (%) | n=30 (%) | | |
| 0-20 | 2 (3.3%) | 0 (0%) | 2 (6.7%) | | |
| 20-40 | 14 (23.3%) | 8 (26.7%) | 6 (20%) | | |
| 40-60 | 32 (53.3%) | 16 (53.3%) | 16 (53.3%) | | |
| 60-80 | 12 (20%) | 6 (20%) | 6 (20%) | | |

Observation: In this study, the age of the patients ranged from 18 years to 78 years. 53% in the 40-60 years group. This includes 53% in the cases and 53% in the control group.

Table 2: Distribution of study subjects according to Gender

| Gender | Patients n=60(%) | Cases n=30(%) | Controls n=30(%) |
|--------|---------------------|------------------|---------------------|
| Male | 54(90%) | 28(93.3%) | 26(86.7%) |
| Female | 6(10%) | 2(6.7%) | 4(13.3%) |

Observation: In this study, 90% of the patients were males,

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as compared to females who were 10%

 Table 3: Mean Age of Cases and Controls

| Variable | Cases(n=30) | | Controls (n=30) | | t | p-value |
|----------|-------------|------|-----------------|------|-----|---------|
| | Mean | SD | Mean | SD | 0.6 | 0.55 |
| Age | 48.9 | 15.3 | 46.7 | 14.5 | | |

Observation: The mean age of cases was 48.9 ± 15.3 years and the mean age of controls was 46.7 ± 14.5 years. The difference in mean age between cases and controls was not statistically significant (p =0.55)

Table 4: Various Aetiologies of Wounds

| Tuble 4. Various Methologies of Woulds | | | | | | | |
|--|-----------|-----------|-----------|--------|-------|--|--|
| Etiology | Cases | Controls | Total | Chi- | p- | | |
| Etiology | (n=30) | (n=30) | (n=60) | square | value | | |
| Non-Specific | | | | | | | |
| Traumatic Ulcers | 16(53.3%) | 14(46.7%) | 30(50%) | | | | |
| Pressure Sore | 6(20%) | 4(13.3%) | 10(16.7%) | 2.53 | 0.63 | | |
| Diabetic Ulcer | 2(6.7%) | 6(20%) | 8(13.3%) | 2.55 | 0.65 | | |
| Other Infected Ulcers | 4(13.3%) | 4(13.3%) | 8(13.3%) | | | | |
| Varicose Ulcers | 2(6.7%) | 2(6.7%) | 4(6.7%) | | | | |

Observation: In this study, 50% of the wounds were of non-specific traumatic etiology. The next most common wounds were pressure sores at 16.7%. There is no statistical difference between cases and controls about the Etiology of the wounds (p = 0.63)

Table 5: Site of the wound

| Site | Cases | Controls | Total | Chi squara | n voluo | |
|---------|-----------|-----------|-----------|------------|---------|--|
| Sile | (n=30) | (n=30) | (n=60) | Chi-square | p-value | |
| Leg | 12(40%) | 10(33.3%) | 22(36.7%) | | | |
| Dorsum | 10(33.3%) | 12(40%) | 22(36.7%) | | 0.79 | |
| Sole | 2(6.7%) | 4(13.3%) | 6(10%) | 1.69 | | |
| Gluteal | 4(13.3%) | 2(6.7%) | 6(10%) | | | |
| Sacrum | 2(6.7%) | 2(6.7%) | 4(6.7%) | | | |

Observation: 36.7% of all the wounds were present in the leg and 36.7% in the dorsum of the foot.

Table 6: Duration of wound

| Study Crown | Duration In Weeks | | т | | |
|-----------------|-------------------|-------|-------|---------|--|
| Study Group | Mean | Sd | 1 | p-value | |
| Cases (n=30) | 98.73 | 9.25 | 10.60 | < 0.001 | |
| Controls (n=30) | 52.2 | 23.71 | 10.00 | <0.001 | |

Observation: The mean duration of the wound in cases was 98.73 ± 9.25 weeks and 52.2 ± 23.71 weeks in the control group. The difference in the mean duration of the wound in cases and controls was statistically highly significant (p < 0.001)

 Table 7: Initial Wound Area Inmm²

| Table 7. Initial Would Area Initia | | | | | | |
|------------------------------------|---------------------------------------|--------|------|---------|--|--|
| Study Crown | Initial Wound Area In mm ² | | | n voluo | | |
| Study Group | Mean | Sd | 1 | p-value | | |
| Cases (n=30) | 517.96 | 100.06 | 0.02 | 0.97 | | |
| Controls (n=30) | 517 | 110.28 | 0.02 | 0.97 | | |

Observation: The mean area at the beginning of the study was $517.96 \pm 100.06 \text{ mm}^2$ in the cases and $517 \pm 110.28 \text{ mm}^2$ in the controls. There was no statistical difference between the two groups (p = 0.97) before initiation of treatment.

 Table 8: Comparison of Before and After Area Inmm²

| Study Groups | Area before Treatment | | Areaafter Treatment | | p-value | |
|-----------------|--------------------------|--------|------------------------|--------|---------|--|
| | Mean | SD | Mean | SD | - | |
| Cases (n=30) | 524 | 99.84 | 272 | 50.77 | < 0.001 | |
| Controls (n=30) | 517 | 110.28 | 500 | 106.02 | 0.067 | |

Observation: There was a statistically highly significant difference between the area before the treatment and after the treatment among the cases (p < 0.001) whereas no statistical difference between the area before the treatment and after the treatment was present for the controls (p = 0.067)

 Table 9: Reduction of Mean Area of Ulcer of Cases and Controls After Treatment

| Study Groups | Mean Area Reduced in mm ² | SD | t | p-value |
|-----------------|---|-------|-------|---------|
| Cases (n=30) | 252 | 54.45 | 24.75 | < 0.001 |
| Controls (n=30) | 17 | 5.08 | 24.73 | <0.001 |

Observation: Mean reduction in the area of ulcer, 252 mm^2 for the cases was more than that of controls, 17 mm^2 after the initiation of treatment and the difference was statistically highly significant (p<0.001).

| Study Groups | Percentage R | Percentage Reduction | | n voluo |
|----------------|--------------|----------------------|-------|---------|
| | Mean | SD | Т | p-value |
| Cases (n=30) | 46.95 % | 15.16 | 84.16 | < 0.001 |
| Controls (n=30 | 2.28% | 2.54 | | |

Observation: The percentage reduction in cases was 46.95% \pm 15.16% and 2.28% \pm 2.54% in controls which was statistically highly significant (p < 0.001)

 Table 11: Comparison between Case and Control according to PWAT Score

| Study groups | Before treatment PWAT score | Before treatmentAfter treatmentPWAT scorePWAT score | | | |
|-----------------|--------------------------------|---|---------|--|--|
| | (average score) | (average score) | • | | |
| Cases (n=30) | 19 | 7 | < 0.001 | | |
| Controls (n=30) | 21 | 14 | | | |

Observation: Mean reduction in PWAT score before and after treatment is more for the cases than that of controls and the difference was statistically significant (p < 0.001).

4. Summary

The present study was conducted in the Kamineni Institute of Medical Sciences, Narketpally. From October 2020 To September 2022 on 60 patients with chronic wounds.

The objective of the present study was to know the efficacy of autologous platelet gel in epithelialization and wound reduction in chronic wounds in comparison with the conventional methods of treatment.

The two groups were randomized into cases group (PDGF) and control group. cases group received treatment in the form of autologous platelet gel and the control group received conventional dressing.

There was no statistical difference between the baseline characteristics like age, sex, location of the ulcer, duration of ulcer, and baseline laboratory investigations.

The final area reduced and the percentage of area reduced was statistically significant in the cases as compared to the control group. There were no adverse effects of auto logous platelet gel application.

5. Conclusion

With the use of autologous Platelet-Derived Growth Factor (PDGF) dressings in comparison with the control group for the treatment of chronic ulcers, the following conclusions were derived.

- PDGF showed faster and better healing among the studygroup
- Area reduction was statistically significant in the studygroup
- Therewerenoadverseeffectsorreactionsseenwhenautolog ousPlatelet-derived growth factors (platelet gel) were applied over theulcer.

It is a cost-effective procedure, helps in early skin grafting, and reduced hospital stay.

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