

Original article:

Study on evaluation of safety and efficacy of Local injections of autologous platelet rich plasma in treatment of chronic cutaneous ulcers

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Abstract:

Introduction: Chronic wounds are catastrophic health problem worldwide. These stubborn wounds fail to heal in an expected manner of healing process. The overall increase in the incidence of chronic wounds makes them a tremendous socioeconomic burden globally. Wound healing is a complex and dynamic process.

Materials and methods: This study was carried out in the Department of General Surgery, B.L.D.E.U's Shri B.M Patil Medical College, Hospital and Research centre, Vijayapur. Prospective, comparative study of efficacy of local injection of platelet rich plasma in wound healing versus conventional dressing with 10% povidone iodine solution in wound healing. Total of 90 with 45 in each group i.e., 45 patients in study group and 45 patients in control group.

Results: In this study Wager's grade II ulcers were most commonly considered in both PRP group and control group i.e., 17 (37.8%) in PRP group and 28 (62.2%) in control group with mean average of 50%. Most of the ulcers in the study were included once the culture from the wound swab was sterile i.e., 28 (62.2%) in PRP group and 25 (55.6%) in control group and the others comprised of S. aureus, Acinobacter and citrobacter.

Conclusion: Local injections of autologous PRP in chronic cutaneous ulcers is more effective when compared to conventional dressing with povidone iodine dressing in achieving faster and complete wound healing and promoting growth of healthy granulation tissue.

Introduction:

Chronic wounds are catastrophic health problem worldwide. These stubborn wounds fail to heal in an expected manner of healing process. The overall increase in the incidence of chronic wounds makes them a tremendous socioeconomic burden globally. Wound healing is a complex and dynamic process.⁽¹⁾ Once a wound begins healing, normally the process resolves with complete wound closure. However, healing of acute or chronic wounds can become impaired by patient factors (i.e., co-morbidities) and/or wound factors (i.e., infection). Wound with impaired healing is difficult to treat because good standard wound care does not always provide an improved healing outcome and often more advanced therapies are employed.⁽¹⁾ The standard management includes advance therapeutics with drugs (antibiotics), intense local dressings (such as negative pressure/antimicrobial) and multiple surgical interventions/reconstructions. Such intervention and modalities requires experts and large resources. Still outcomes are unpredictable and associated with morbidities.⁽²⁾

This study is undertaken to evaluate the safety and clinical efficacy of local injection of autologous platelet rich plasma with the conventional type of dressing in management of chronic cutaneous ulcers.

Materials and methods:

This study was carried out in the Department of General Surgery, B.L.D.E.U's Shri B.M Patil Medical College, Hospital and Research centre, Vijayapur. Prospective, comparative study of efficacy of local injection of platelet rich plasma in wound healing versus conventional dressing with 10% povidone iodine solution in wound healing. Total of 90 with 45 in each group i.e., 45 patients in study group and 45 patients in control group.

Study was approved by the institutional medical ethics committee and written informed consent was obtained from all patients participating in the study. Patients came with chronic ulcers Wagener's grade I-III ulcers during the study period were initially subjected for detection of general health of the patient and culture of wounds and other routine investigations.

- And while allocating cases, age of patient and size of the ulcer was matched.

A proforma was used to collect all the relevant data from the patients.

Detailed history was taken; thorough clinical examination and investigations were performed on all the patients included in the study. All the cases were followed up to discharge and subsequently for a follow up till wound healing.

- "Primary efficacy end point" was complete ulcer closure and "Secondary efficacy end point" was time taken to achieve ulcer closure by either secondary suturing or skin grafting.

□ **INCLUSION CRITERIA:**

- Highest dimensions within 5cm breadth, 5cm Width, 0.5cm Depth
- **Wagner's Classification Of Diabetic Ulcer Upto Grade-III**
- Traumatic Non-Healing Ulcers
- Bedsores
- Venous Ulcers
- Other non-specific ulcers.

□ **EXCLUSION CRITERIA:**

- Anemia – Hb <10gm% in adults, <12gm% in children <14 years
- Uncontrolled Diabetes
- Gross Nutritional Deficiency BMI <18 , Albumin <2gm/Dl of blood
- Dyslipidemia

Wagner’s Classification Of Ulcer Grade-IV or More

- Patient on immunosuppressive drugs
- Known malignancies
- Patient with bleeding disorders.
- Radiotherapy to local area of ulcer.

Results:

TABLE 1: DISTRIBUTION OF CULTURE GROWTH BETWEEN PRP AND CONTROL GROUP.

Culture from wound	Study group	%	Control group	%	Total	%	Chi square test
Sterile	28	62.2	25	55.6	53	58.89	P=0.5737 NS
S. aureus	10	22.2	9	20	19	21.11	
Acinobacter	3	6.7	3	6.7	6	6.67	
Citrobacter	3	6.7	4	8.9	7	7.78	
Klebsiella	1	2.2	4	8.9	5	5.56	
Total	45	100.0	45	100	90	100	

Table show the organisms isolated between both the groups. In this study most of the ulcers were considered once the culture was sterile with mean of 58.89%.

TABLE 2 : DITRIBUTION OF WAGNER GRADE OF ULCER BETWEEN PRP AND CONTROL GROUP:

WAGNER'S ULCER GRADING	Study group	%	Control group	%	Total	%
I	15	33.3	3	6.7	18	20
II	17	37.8	28	62.2	45	50
III	13	28.9	14	31.1	27	30
Total	45	100.0	45	100.0	90	100

TABLE 3: DISTRIBUTION OF GRANULATION TISSUE BETWEEN PRP AND CONTROL GROUP.

GRANNULATION TISSUE	Study group	%	Control group	%	Total	%	Chi square test
Satisfactory	31	68.9	17	37.8	48	53.33	P=0.0031*
Unsatisfactory	14	31.1	28	62.2	42	46.67	
Total	45	100.0	45	100.0	90	100	

Table show distributio of grannulation tissue among two groups. A significant satisfactory grannulation tissue was observed in PRP group with P value of 0.0031 when compared to conventional dressing.

TABLE 5: COMPARISON OF HEALING PROGRESS IN % BETWEEN PRP AND CONTROL GROUP.

Healing Progress in %	Study group	%	Control group	%	Total	Chi square test
20-30	5	11.1	10	22.2	15	P=0.00105*
30-40	18	40	27	60	45	
40-50	14	31.1	7	15.6	21	
50+	8	17.8	1	2.2	9	
Total	45	100.0	45	100	90	

Table showing comparison between healing progress in % among both the groups after 20 days of observation. In this study healing of the ulcers were maximum in PRP group with 31.1% patients having >50% healing in PRP group with significant P value of 0.0015%

TABLE 6 : DISTRIBUTION OF 3 MONTHS FOLLOW-UP BETWEEN PRP AND CONTROL GROUP:

3 MONTH FOLLOW-UP	Study group	%	Control group	%	Total	%
Contraction Of Wound	19	42.2	8	17.8	27	30
Skin Grafting	8	17.8	14	31.1	22	24.44
Suturing	12	26.7	17	37.8	29	32.22
Did not follow up	6	13.3	6	13.3	12	13.34
Total	45	100.0	45	100	90	100

Discussion:

Worldwide accepted standard therapy for chronic ulcers are debridement of wound surgically/chemically, local wound dressings with topical bacterostatic and bacterocidal agents such as povidone iodine, silver preparations etc, which are thought to accelerate granulation tissue and promote wound healing. The prevalence and incidence of chronic ulcers and the complications associated with them continue to escalate even with proper and timely interventions.⁽¹⁾

Most common mode of onset in the study was trauma in both the groups. 20 patients (44.4%) in PRP group and 12 patients(26.7%) in control group with average of 35.55%. ulcers following abscess drainage was seen in 12 (26.7%) in

PRP group and 10 (22.2%) in control group. Other mode of onset were insidious more commonly due to scratching, long standing varicose veins. Immobilization leading to bedsores were seen in 1 patient in PRP group and 3 patients in control group.

Driver et al. (2006) carried out the first reported prospective, randomized, controlled multicenter trial in the United States regarding the use of PRP for treatment of diabetic ulcers. It included 32 patients. ⁽³⁾The authors found that 68.4% in PRP group and 42.9% in control groups had complete closure of wounds with P value of 0.036 which was significant. ⁽³⁾

Sarvajnamurthy S et al. in 2013 studied on 12 patients with 17 chronic venous ulcers were treated with PRP application and treatment outcome was measured by percentage of improvement in area and volume of the ulcer. ⁽⁴⁾ The mean duration of healing of the ulcers was 5.1 weeks and 100% improvement in the area of the ulcers was seen in 13 (76%).

In this study Wager's grade II ulcers were most commonly considered in both PRP group and control group i.e., 17 (37.8%) in PRP group and 28 (62.2%) in control group with mean average of 50%.

Most of the ulcers in the study were included once the culture from the wound swab was sterile i.e., 28 (62.2%) in PRP group and 25 (55.6%) in control group and the others comprised of *S. aureus*, *Acinobacter* and *citrobacter*.

Coming to the healing progression in percentage, clearly healing was better and faster in PRP group when compared to conventional dressing with 14 patients 40- 50% healing in PRP group when compared to conventional group i.e., 7 patients (15.6%) and >50% healing seen in 8 (17.8%) of PRP group with high significant P value of 0.00105.

In a study by Li L et al. (wound repair regen 2015) which was a prospective, randomized controlled trial showed that standard treatment plus autologous platelet rich plasma was statistically more effective than standard treatment. The subjects defined as healing grade 1 were 85.4% while 67.3% in control group with significance p value.

Conclusion:

Local injections of autologous PRP in chronic cutaneous ulcers is more effective when compared to conventional dressing with povidone iodine dressing in achieving faster and complete wound healing and promoting growth of healthy granulation tissue.

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