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Original Research Article

A comparative study on the efficacy of platelet rich plasma vs conventional wound dressing in diabetic foot ulcers

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ABSTRACT

Background: The pathogenetic pathways and morbidity associated with diabetic foot ulcers render it a difficult clinical entity to manage. Newer biological methods such as platelet-rich plasma (PRP) are being investigated as improvements on conventional treatment techniques such as saline gauze antiseptic dressings.
Methods: The present study is a randomised controlled trial, with 25 subjects each in the PRP dressing and conventional dressing arms. It was conducted in the General Surgery wards of a tertiary care hospital among patients suffering from foot ulcers due to diabetes mellitus. PRP dressings were done biweekly for 4 weeks before final wound assessment.
Results: Most of the study population was males of more than 50 years of age. The lesions are predominantly on the plantar aspect. The inciting factor was trauma in around two-thirds of the cases. Nearly 80% of the subjects were on insulin for treatment. In the patients receiving treatment using PRP dressings, the wound contracted by more than 34% which was statistically significantly higher than those receiving conventional dressings.
Conclusions: Newer biological methods such as platelet-rich plasma (PRP) dressings offer a relatively novel safe and efficient technique for management of diabetic foot ulcers, compared to conventional methods.

Keywords: Diabetic foot ulcer, Platelet-rich plasma, Wound healing

INTRODUCTION

Diabetic foot ulcer (DFU) is a incapacitating impediment of diabetes mellitus that affects a significant proportion of the diabetic population. Lesions caused by diabetes mellitus lead to impaired neural responses to tactile stimuli and altered blood flow through the arterioles supplying the feet.[1] This phenomenon occurs among more than two-thirds of DFU patients who have poor control of their blood sugar levels.[1]

With the increase in lifestyle factors such as lack of physical activity and dietary patterns, the incidence of diabetes is predicted to continue to increase, and thus the risk of subsequent complications such as diabetic foot.[3,4]

The risk factors for developing diabetic foot ulcer are advanced age, overweight, increased blood pressure, history of tobacco use and prolonged history of diabetes.[5]

The significance of diabetic foot is that it is associated with a two-fold increased risk of dying when compared with non-ulcerated diabetics. It has been determined that the 5-year mortality rate following amputation for DFU has been determined to be between 39% and 68%, which is comparable to more aggressive forms and stages of cancer.[2]

The clinical findings suggestive of diabetic foot include, ulceration, lack of blood supply manifesting as gangrene, mycotic infections, skin fissures, maceration of

interdigital spaces, calluses, and foot deformities such as nail deformities, pes cavus, which predispose the foot to ulceration. Ischemic and infective/inflammatory changes may complicate the condition.[6] Previous studies found that most of the ulcers were of the higher grade (grades 2-4), and located in the plantar region.[7,8]

Secondary prevention methods including early diagnosis and treatment are the key to effective management of diabetic foot ulcers. In this respect, daily self-inspection of the feet of diabetic patients, foot examination at every hospital visit, patient education on the significance of adequate management of blood sugar levels, providing ideal footwear will go a long way in reducing the morbidity due to diabetic feet.[6] There is increasing evidence of the utility of Platelet Rich plasma in the use of wound dressing in diabetic foot ulcer. Studies have found that, if used along with correct tissue debridement and host tissue platelet-rich plasma therapy for diabetic foot ulcers is safe with superior healing outcomes and lower complication rates and may significantly help to decrease the burden of diabetic foot ulcers.[9–17]

The present study is an attempt to add to the existing body of literature on diabetic foot ulcer management using PRP, which is relatively limited in India. The aim of the study is to compare the efficacy of PRP dressing with conventional wound dressing with respect to wound reduction in patients with chronic DFU.

METHODS

The present study is a randomized controlled trial. Data was collected over a period of 1 year from January 2015 to January 2016. Patients admitted in the wards of the Department of General Surgery, Stanley Medical College, in Chennai, Tamil Nadu. Type I and II diabetics between 12 and 75 years of age, with ulcerated wound(s) for more than 4 weeks, documented etiology as a complication of Diabetes Mellitus, size less than 10X10 cm and fasting blood glucose levels between 140 and 200 mg/dl measured on two occasions 24 hours apart, were included in the study. Patients with pulseless limbs, associated osteomyelitis, skin malignancies, cellulitis, diabetic ketoacidosis, exposed bone and tendon in ulcer and immunocompromised status were excluded from the study. A total of 50 patients were recruited for the study and they were randomized into 2 groups of 25 each. The first group of 25 subjects was treated with Platelet-Rich Plasma dressings and the second group was treated with conventional wound dressings. A pre-tested and pre-structured proforma was used to obtain information from the study participants. Informed written consent was obtained, and all efforts were taken to preserve confidentiality. The choice to withdraw from the study in the case of any discomfort was explained and given to the subjects.

For conventional dressings, the ulcer was cleaned with normal saline and saline-soaked gauze pieces were kept over the ulcer which was covered with pad and roller bandage. For the PRP dressings, the platelet-rich plasma was produced manually by withdrawing 10 ml of the blood by venipuncture. Five ml of blood was put each in two test tubes and anticoagulant citrate dextrose (ACD) was added. Centrifugation was done at 2000 rpm for 10 minutes. Three layers were observed – top plasma layer, middle buffy coat layer and the bottom RBC layer. The plasma and the buffy coat layers were removed using a pipette and put in a test tube mixed with calcium chloride ($CaCl_2$). Second centrifugation was then done for 10 minutes at 2000 rpm. This results in top platelet poor plasma (PPP), middle platelet rich plasma (PRP) and the bottom RBCs. The platelet poor plasma is then discarded and PRP is separated and taken in a syringe and injected in the wound site. Such PRP dressings is done biweekly for four weeks and assessed for wound contracture.

The collected data was entered in Microsoft Excel 2013 and the master sheet was imported into the Statistical Package for Social Sciences (SPSS) v.22 for data analysis.

RESULTS

A total of 50 patients were studied. The age distribution of the study subjects is summarized in Table 1.

Table 1: Age distribution of the study subjects.

Age (years)	No. of cases	Percentage (%)
18-30	0	0
31-40	6	12
41-50	9	18
51-60	23	46
>60	12	24

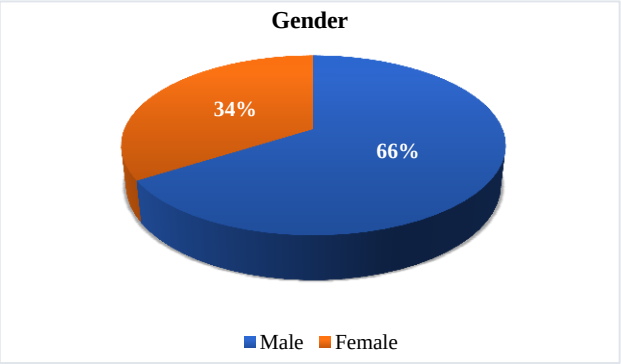

Figure 1: Gender of the study population.

Most of the subjects belonged to the above 50 years age group. Nearly two-thirds (66%) of the cases were male (Figure 1).

Regarding the site of the diabetic foot ulcer, it was found that most of the lesions were on the plantar aspect of the foot 62% on the plantar aspect and 38% on the dorsal

aspect. Trauma was a causative factor of ulcer in 64% of the subjects while the remaining cases were spontaneous in onset. Most of the patients (78%) were on insulin for glycemic control while the remaining 22% were on oral anti-diabetic medications.

Table 2: Wound contraction in the PRP dressing group and conventional dressing group.

Group	Mean reduction (%)	SD	Median	P value
Study	34.42	2.52	34.58	<0.001
Control	13.52	2.55	13.2	

When comparing the effect of PRP dressings and conventional dressings on the rate of wound contraction, it was found that the diabetic foot ulcers in the PRP dressing study group had better mean% wound contraction of 34.4% while the conventional dressing group had a mean% wound contraction of 13.5%. The difference in the mean% wound contraction between the two groups was analyzed using the unpaired Students' t-test and found to be statistically significant with a p-value of less than 0.001 (Table 2).

DISCUSSION

In the present study, out of the 50 study participants, 70% of the patients were more than 50 years of age. This is expected as usually older age is associated with a longer duration of diabetes which directly increases risk of diabetic foot ulcer. Previous studies such as Pedras et al (mean age of 66 years), Hirase et al (mean of 58.4 years), Goda et al (mean age of around 56 years) and Tripathi et al also report a predominance of older age individuals in their study population.[15,17-19] The study population in the present study was mostly male. This finding was in line with findings in former studies.[17,18,20]

The site of the ulcer was determined, and it was found that most ulcers (62%) were on the plantar aspect of the foot. This finding has been shown to be due to higher and multiple pressure points on the plantar aspect.[21] Other studies such as Tindong et al (58.4% on plantar side) also had similar findings.[7] In 64% of the cases, trauma was identified as a precipitating factor. Previous studies such as Iraj et al and Rosyid et al also recognize this risk.[22,23] The finding that 78% of the study subjects were on injectable insulin is predictable as the duration of diabetes is directly linked to use of insulin and the risk of DFU.

The present study found there was a statistically higher rate of wound healing and contraction in the group treated with PRP dressings compared to those treated with conventional saline gauze antiseptic dressings. Various studies have clinically proven that administration of PRP dressings achieve a faster healing rate and much shorter healing times, better wound closure, lesser adverse effects such as maceration and contact dermatitis, minimal chances of infections, and lesser reopening of wounds.[10,11,13,15,19,20,24,25]

CONCLUSION

The reinforcement of positive association between PRP dressings and safe and effective wound healing in diabetic foot ulcers, as has been determined in the present study, strongly suggests that the use of such dressings should be a major component in the management of DFU, which is a long-term, debilitating and recurrent complication in many patients suffering from diabetes mellitus.

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