

EVALUATION OF THE OUTCOMES OF PLATELET RICH PLASMA (PRP) THERAPY IN MANAGING COMPLEX PERIANAL FISTULAS AS A PROSPECTIVE STUDY

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Abstract

Objectives: To evaluate the outcomes of platelet rich plasma therapy in management of complex perianal fistulas. **Study design:** Prospective descriptive study. **Place and Duration of the study:** Combined Military Hospital, Lahore from February-2025 to May-2025. **Methodology:** A total of 151 patients with complex perianal fistula were included. Complexity was defined by using magnetic resonance fistulogram. All the patients, after undergoing the surgical fistulectomy, were injected with the platelet rich plasma injection into the operated tract from the external opening side. Outcomes were assessed at week one, four and twelve after therapy. Data was analyzed using SPSS version 22. **Results:** In this study, 151 patients were included. Median age was 55.00 (11.00) years. There were 117 (77.50%) male and 34 (22.50%) female patients. Median BMI was 33.90 (9.10) kg/m². At one week follow up, pain, bleeding and infection was observed in 28.50%, 3.30% and 2.60%, respectively. At week four follow up, 142 (94.00%) were able to rejoin their workplace. At twelve weeks follow up, the success rate of surgery was 89.4% along with patient satisfaction rate of 87.4% and recurrence rate of 10.6%. **Conclusion:** Use of platelet rich plasma therapy can improve the outcomes of surgically managed complex perianal fistulas.

INTRODUCTION

Anal fistula is an abnormal irregular channel lined with epithelial cells that links the anal canal to the perianal skin which presents as a painful lump in the anal region.¹ A study reported that amongst every ten thousand people in the world, 1.2 to 2.8 people suffer from anal fistula.² There are several risk factors that can lead to development of anal fistula including presence of Crohn's disease, presence of anal abscess (particularly the ischioanal and intersphincteric type), prior surgery of the anal region and history of repeated episodes of abscess in this anatomical region.^{3,4}

To diagnose patients for having anal fistula, magnetic resonance imaging (MRI) has been considered as a gold standard investigation in which the whole by the use of intravenous contrast the whole fistulous tract is mapped.⁵ Clinically, the severity and complexity of anal fistula is assessed by utilization of various types of classifications including the Park's classification and a much newer Garg classification.⁶

Management of this condition involves both non-surgical and surgical methods. Among non-surgical techniques, pharmacological agents like antibiotics, anti-TNF alpha drugs, calciurenin inhibitors and thiopurines are useful.⁷ Similarly, there are a number of surgical procedures that can be highly useful in effectively managing this condition.^{7,8} However, one major issue with the complex form of this anal condition is the chances of recurrence and delayed healing, for which a newer therapy, which is platelet-rich plasma (PRP), has been hypothesized to improve the surgical outcomes of the patients with complex anal fistulas.⁹ In Pakistan, studies regarding the effectiveness of this useful intervention are generally lacking. Present study was thus conducted to evaluate the outcomes of post-procedural PRP therapy in management of complex perianal fistulas.

METHODOLOGY

This quasi-experimental study was conducted at Combined Military Hospital, Rawalpindi from March-2024 to March-2025 after getting approval from institutional ethical committee (Ref No:

_____). Sample size calculation was performed using WHO sample size calculator using following formula:

Sample size calculation was performed by using confidence level of 95%, precision of 7.5% and anticipated frequency of procedural success after PRP therapy of 66.7%.⁹ This gave a sample size of 151. Study sample was selected by using non-probability consecutive sampling technique.

Inclusion criteria: Male and female patients, aged 18 years or above who presented with complex perianal fistula were included. Complex fistula was defined based on Garg classification by presence of ≥ 2 of the following features; multiple tracts, involvement of the external anal sphincter of more than 30% and any fistula which was trans-sphincteric.

Exclusion criteria: Patients with recurrent fistula, previous anal surgery, history of immune compromised state, diabetes, steroid use due to any autoimmune or rheumatological condition, chemotherapy exposure for any malignancy, inflammatory bowel disease and intestinal tuberculosis were excluded.

Before inclusion in the study, an informed written consent was obtained from every patient and the risk & benefits of surgery and PRP therapy were explained to the patients. After that baseline characteristics including age, gender and body mass index (BMI) were documented.

Open fistulectomy involves first situating the patient correctly, then doing a proctoscopic inspection to identify the exterior and internal fistula opening. A gauze piece was then inserted into the rectum and hydrogen peroxide solution was poured into the exterior entrance to help locate the internal opening. Following fistulectomy, a probe was inserted to core out the tract identified. After this, inner tract of the fistula was closed up using the VicrylTM 2/0 suture and before ending the surgery and leaving the wound open for secondary intention healing, 1.5 ml of PRP (prepared by taking the venous blood if the operated patient, putting it in centrifuge for gradient density centrifugation and getting a PRP solution) was injected into the opening. It was ensured that all the patients received similar pre-procedural and post-procedural management as per institutional protocol.

$$n = \frac{z_{1-\alpha/2}^2 P(1-P)}{d^2}$$

Post-operatively patients were assessed through follow up visits for procedural outcomes. At week one follow up, patients were assessed for presence of pain (defined as pain visual analogue scale (VAS) score > 3), bleeding and/or infection. At week four follow up, patients were assessed for getting back to work and recurrence. At week 12 follow up, final assessment was made for success of the procedure (defined by achievement of complete epithelialization of the wound without presence of any anal discharge), recurrence and patient satisfaction (with satisfaction defined as patient satisfaction VAS score of 8-10).

Data was analyzed using Statistical Package for Social Sciences (SPSS) version 22. Quantitative variables normality was checked by Shapiro-Wilk test which showed that age and BMI were not distributed normally and were thus presented as median

interquartile range (IQR). Qualitative variables (gender, pain, bleeding and/or infection, getting back to work, procedure success, recurrence and patient satisfaction) was presented as frequency and percentages. Data was presented in tabulated form.

RESULTS

In this study, 150 patients were included. Median age was 55.00 (11.00) years. There were 117 (77.50%) male and 34 (22.50%) female patients. Median BMI was 33.90 (9.10) kg/m².

At one week follow up, presence of pain was observed in 43 (28.50%) patients, bleeding persisted in 5 (3.30%) patients and infection was observed in 4 (2.60%) patients. Outcomes of PRP therapy at one week follow up is given in Table-I:

Table-I: Outcomes of PRP therapy at one week follow up (n = 151)

Outcome	n (%)
Pain	
Yes	43 (28.50%)
No	108 (71.50%)
Bleeding	
Yes	5 (3.30%)
No	146 (96.70%)
Infection	
Yes	4 (2.60%)
No	147 (97.40%)

Abbreviations: PRP = Platelet Rich Plasma

At week four follow up, a total of 142 (94.00%) were able to rejoin their workplace while none of the patients exhibited recurrence of the treated anal

fistula. Outcomes of PRP therapy at week four follow up is given in Table-II:

Table-II: Outcomes of PRP therapy at four weeks follow up (n = 72)

Outcome	n (%)
Rejoined the workplace	
Yes	142 (94.00%)
No	9 (6.00%)
Recurrence	
Yes	0 (0.00%)
No	151 (100%)

Abbreviations: PRP = Platelet Rich Plasma

At final follow up visit scheduled at twelve weeks, success of procedure was observed in 135 (89.40%)

patients. Perianal fistula recurrence was observed in 16 (10.60%) patients. Among all the patients, 132 (87.40%) were satisfied with their operative outcome

while 19 (12.60%) patients were not completely satisfied with their procedural outcome. Outcomes of

PRP therapy at twelve weeks follow up is given in Table-III:

Table-III: Outcomes of PRP therapy at twelve weeks follow up (n = 151)

Outcome	n (%)
Procedural success	
Yes	135 (89.40%)
No	16 (10.60%)
Recurrence	
Yes	16 (10.60%)
No	135 (89.40%)
Patient satisfaction	
Completely satisfied	132 (87.40%)
Not completely satisfied	19 (12.60%)

Abbreviations: PRP = Platelet Rich Plasma

DISCUSSION

Present study addressed an important aspect of fistula in the perianal region management by addition of PRP therapy to find out whether this approach may provide more beneficial outcomes. To make the diagnosis of anal fistula prior to planning surgery, MR fistulogram was performed using MRI technology. This choice was driven by the fact that it is the gold standard investigation that provides accurate diagnosis, localization and the classification of fistulous tract.^{10, 11} To determine the complexity of fistula, MR fistulogram and Garg classification was utilized which are the well-validated and modern classification tools that have high level of accuracy in classifying the complexity and severity of this condition.^{12, 13}

In present study, average age of the patients who were suffering from this condition was fifty five years. This is similar to the previously available data that perianal fistula is much more common among patients with relatively older age, with highest reported burden in much older age group.¹⁴ Upon analysis of the gender distribution, it was observed that approximately 85% of the sufferers of this condition were males. Similar to this, a study was conducted by Hasan *et al.*¹⁵ who found that this proportion of males being affected by this condition was 81.7%. In another study, conducted by Javed *et al.*¹⁶ similar male predominance, with men making up 89.33% of the total patients of this condition, was evident. The exact

reason behind this higher chances of men to develop this condition is yet unknown but there are multiple factors that contribute to this male predominance including differences in the glandular anatomy, level of production of the androgen hormones and the stronger anal tone in males as compared to females.¹⁷ Another important finding of present study was high BMI of the patient which can be explained by the strong association of higher BMI with development of fistula in perianal region.^{18, 19}

Upon analysis of the outcomes of this therapy, it was observed that at early follow up, pain, bleeding and infection was observed in 28.50%, 3.30% and 2.60%, respectively. This shows that this add-on therapy to surgical intervention to treat perianal fistula can reduce the pain, persistent bleeding and infection rates. Similar to this, a study was conducted by Madbouly *et al.*²⁰ in which similar significant reduction of pain with the addition of PRP to the usual surgical intervention was observed. Similarly, reduction of infection rate by the use of PRP in addition to the surgery for managing perianal fistula has been observed by Rajasekaran *et al.*²¹, similar to present study. One possible reason for this is that PRP has been hypothesized to improve wound healing and inhibit the pain signals.²²

At four weeks follow up, it was observed that majority of the patients, 94% to be particular, were able to rejoin the place of their work and none of the patients had recurrence of their disease which added to the positive evidence in favor of PRP use to improve outcomes of patients surgically managed for their

perianal fistula. Compared to this, a study was conducted by Niknami et al.⁹ found that this frequency of patients to successfully rejoin their work place was 79.2% which was lesser yet comparable to present study.

Upon assessment of the final outcomes, it was observed that the success rate of surgery was significantly increased by PRP use with a reported rate of 89.4% along with a very high patient satisfaction rate of 87.4% and significantly lower recurrence rate of perianal fistula of 10.6% at the end of study period. Similar to this, a study conducted by Niknami et al.⁹ found that the success, recurrence and patient satisfaction rates upon addition of PRP therapy as an adjunct to fistula surgery were 66.7%, 79.2% and 10%, respectively. In another study conducted by Cwaliński et al.²³, it was observed that the success rate of perianal surgery upon addition of PRP injection as an adjunctive therapeutic intervention was 60% which was much lower compared to present study. In another study conducted by Hermann et al.²⁴, it was observed that the procedural success in perianal fistula surgery patients was achieved in 64% patients which is also much lower compared to present study. This difference was likely due to difference in the type of fistula in their studies and the difference in the approach of administration of PRP in these studies. Results of present study show beneficial impact of the PRP therapy on the outcomes of patients suffering from perianal fistula who undergo surgical intervention for management of this condition. Based on this a strong evidence is obtained in favor of PRP therapy use in this condition for which it is strongly recommended to use this intervention in managing complex perianal fistula.

LIMITATIONS

None.

CONCLUSION

In conclusion, use of platelet rich plasma therapy can improve the outcomes of surgically managed complex perianal fistulas.

CONFLICT OF INTEREST

None.

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None

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