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Treatment of Recalcitrant Gastrocutaneous and Enterocutaneous Fistula using Platelet-Rich Plasma -Fibrin Glue Through The External Orifice

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ABSTRACT

The treatment of refractory Gastrocutaneous Fistulas (GCFs) and Enterocutaneous Fistulas (ECFs) is extremely difficult and still is one of the most challenging clinical management. Today, there is no standardized management for them and these fistulas need complex surgery. They cause massive fluid loss which leads to electrolyte imbalance, severe dehydration, malnutrition and sepsis, and even death. This study was undertaken to investigate the effect of autologous or allogeneic platelet-rich plasma-fibrin glue (PRP-FG) on the closure of refractory GCF and ECF. Five recalcitrant GCF patients and three ECF patients were recruited. Special autologous or allogeneic PRP-FG were prepared and applied for the treatment of eight patients through an external orifice of the fistula. All fistulas closed with no complications during and after injection. Since the injection of PRP-FG through the external orifice of the fistula is safe, easy, and non-invasive, it can be repeated as long as is needed to close the fistula. PRP-FG can be used as a non-invasive method for the treatment of persistent GCF and ECF. Further research is needed to substantiate the efficacy of the injection of PRP-FG through the external orifice of the fistula for the treatment of GCF, ECF, and other types of fistulas, too.

Keywords: Gastrocutaneous fistula; Enterocutaneous fistula; Platelet rich plasma; Fibrin glue

INTRODUCTION

Gastrocutaneous (GCF) and Enterocutaneous Fistulas (ECF) are abnormal connections between the stomach and intestinal with the skin, respectively, that the contents of the stomach or intestine leak through the fistula to the skin. GCF and ECF occur due to a surgical complication, trauma, malignancy, inflammatory bowel disease, or ischemia which result in significant morbidity and mortality. The mortality rate varies from 6 to 35 percent.[1]

Despite of great advances in surgical critical care, the management of GCF and ECF is not standardized and is still one of the most challenging surgical problems. Untreated fistulas can cause a lot of discomfort and serious complications such as dehydration, diarrhea, malnutrition, and bacterial infection, which may lead to low blood pressure, organ damage, sepsis, and or even death. The conservative treatment for postoperative GCF and ECF comprises intestinal rest, correction of electrolytic disturbances, parenteral nutrition, protection of the skin surrounding the fistula, and treatment of any local or systemic septic complications.[2] Under this treatment, spontaneous closure of GCF happens in only 6% of cases[3] and ECF occurs after 6-8 weeks in 60%-70% of cases.[4] If the fistula did not close spontaneously, it needs complex surgery and is associated with high morbidity and mortality.[5]

There is a risk of developing cancer in untreated fistulas if it is left for a long period of time.[6] Due to the high morbidity and mortality associated with these fistulas, prompt and effective treatment is needed.

Fibrin glue (FG), also stated as fibrin sealant or fibrin tissue adhesive is a surgical hemostatic agent prepared from plasma coagulation proteins and used widely in all fields of surgery.[7] FG is applied for hemostasis, wound closure, as well as tissue sealing, and in compared with a synthetic sealant, FG is biocompatible and biodegradable and not associated with inflammatory processes, foreign body reactions, tissue necrosis, or extensive fibrosis. In normal wound healing, depending on the type of surgery, the proteolytic activity at the treated place, and the amount of adhesive used, FG absorbs within days to weeks of application.[8]

In this study, we report the successful application of autologous or allogenic platelet-rich plasma (PRP)-fibrin glue (FG) for the treatment of persistent GCF and ECF which did not respond to conventional therapies.

MATERIALS AND METHODS

Patients

For 5 patients with persistent GCF and 3 patients with persistent ECF, which did not respond to conventional therapies and the output fistula did not decrease, PRP-FG was applied. Autologous PRP-FG was prepared for those patients that could give sufficient blood, otherwise, allogenic PRP-FG was prepared. All patients signed an informed consent to authorize the utilization of their clinical data for research purposes and we also obtained an agreement from an ethical committee (Ethical committee code: 900943).

PRP & PRP-FG preparation

PRP and fibrinogen were prepared as described previously.[9] Three days before the injection, from patients 60 ml peripheral blood was taken in 10 ml citrate buffer for preparation of autologous PRP and fibrin glue. In the case of allogenic fibrin glue preparation, at Blood Transfusion Organization, 450 ml of blood was taken from a healthy

donor and all safety regulations for blood transfusion were followed.

PRP was prepared from 60 ml peripheral blood in 10 ml citrate buffer, by two centrifugations, the first centrifugation at 1500 g for 3 min, and then a second centrifugation of the supernatant at 3800 g for 9 min. The supernatant platelet-poor plasma (PPP) was collected until 8 ml was left in the tube where platelets were resuspended forming platelet-rich plasma (PRP).[6] One ml PRP was mixed with 1 ml fibrinogen concentrate (step 3) to make the platelet-rich fibrinogen plasma (PRFP) [final volume: 2 ml].

The fibrinogen was prepared from PPP by a cryoprecipitate method. PPP was frozen at -70ºC for 24 hours and thawed at 4ºC, PPP was then centrifuged at 6,600 g for 6 min. The supernatant plasma was removed up to 8 ml.

Thrombin preparation: to 12 ml plasma from step 3, 2 ml 10% calcium gluconate was added. The clot was formed after 35 min, it is shaken and centrifuged at 4500 g for 4 min and 5 ml plasma (containing thrombin) was separated.

Platelet-rich fibrin glue preparation (PRP-FG): 2 ml PRFP was mixed with 0.5 ml thrombin at the time of injection.

PRP-Fibrin Glue injection

PRP-Fibrin Glue was injected through the external orifice. Since the injection of PRP-FG through the external orifice of the fistula is safe, easy, and non-invasive, it can be repeated as long as is needed to close the fistula. Cases included in the study are presented in Table 1.

Table 1: Description of cases included in this study.

Patient	Age/Sex	Etiology	Fistula	Output* (ml/day)	Duration‡	PRP-FG injections	Time to closure
1	43/M	Sleeve gastrectomy	GCF	400	3 months	35/Al & Au	3 months
2	48/M	Trauma	GCF	30	1 month	1/Al	3 days
3	47/M	stomach Cancer	GCF	55	1 month	1/Al	5 days
4	32/F	Sleeve gastrectomy	GCF	75	2 months	4/Al & Au	18 days
5	26/F	Intragastric balloon	GCF	90	2 months	12/Al	28 days
6	61/M	small intestine Cancer	ECF	50	1 month	3/Al	14 days
7	45/F	small intestine Cancer	ECF	10	3 months	2/Au	8 days
8	41/M	small intestine Cancer	ECF	12	4 months	3/Au	12 days

Note: Male (M), Female (F), Gastrocutaneous (GCF) fistulas, Enterocutaneous fistula (GCF), Autologous (AU), Allogenic (AL), * Output before PRP-FG injection. ǂ Time of nonhealing fistula before PRP-FG injection

RESULTS

Patient's Characterizations, type of fistula, daily output, duration of symptoms, number of autologous and allogenic injections, and time to closure are presented in Table 1. One patient is explained in detail.

Patient 1 in detail

On April 7, 2022, a 43-year-old male, with a BMI of 44 and a history of multiple sclerosis in remission state and interferon beta-1 was injected weekly for him. He was gone under standard sleeve gastrectomy and at the end of the surgery, there was no sign of leakage which was tested by methylene blue. On April 8, 2022, the patient was discharged from the hospital with no sign of leakage which was tested by an upper GI study. Gastric acid secretion was suppressed by proton pump inhibitors.

On April 18, 2022, because of sudden severe abdominal pain, the patient was hospitalized and in chest X-ray, there was a presence of free air in the abdominal cavity, and sepsis evidence such as high CRP, leukocytosis, elevated procalcitonin were seen. After complete reanimation, the patient was transferred to the operating room. At first, laparoscopy was done because of high deposits of fibrin, pus, and generalized peritonitis then laparotomy was done for irrigation of the abdomen cavity by normal saline. The leakage site was in the proximal stomach near (5-10 centimeters) the gastroesophageal junction and the drainage tube was placed to save patients from the sepsis phase.

On April 20, 2022, in the operating room, the abdominal cavity was irrigated again. A jejunostomy tube (J-tube) was inserted and two corrugated drains were inserted in the gastric bed and one corrugated drain in the pelvis. A colostomy bag was placed at the site of the leak and the amount was about 400 ml within 24 h. Feeding is initiated at 20-50 ml/h through the jejunostomy tube.

Pleural effusion was seen in the patient and there was no respiratory distress and no drop of SPO_2.

On April 30, 2022, the patient was discharged from the hospital.

On May 14, 2022, the output volume from the fistula was 400 ml within 24 h and the overall health of the patient was very ill.

On May 15, 2022, an endoscopy was done and the finding was a perforated sleeve and there was no sign of tortuosity.

On May 18, 2022, in the endoscopy procedure, an Over-The-Scope Clip (OTSC®, Ovesco Endoscopy GmbH, Tübingen, Germany) was used for the closure of sleeve perforation.

On June 20, 2022, the output volume from the fistula still was 400 ml within 24 h and the overall health of the patient was very ill.

After 2 weeks, pleural effusion was observed again and respiratory distress and a drop of SPO_2 (88%) were seen and pleural pigtail drain was inserted in the pleural cavity, and drainage was continued for 4 days and stopped and respiratory distress disappeared and SPO_2 back to 96 and drain tube was removed.

On July 11, 2022, the output volume from the fistula still was 400 ml and the 1st injection of autologous PRP-fibrin glue was done from an external orifice.

The output volume on July 12, 13, and 14, 2022 was 160, 140, and 120 ml, respectively.

On July 20, 2022, the 2nd injection of PRP-fibrin glue was done from the external orifice, and after 3 days, the output volume reached 90 ml.

On July 24, 2022, the 3rd injection of PRP-fibrin glue was done from the external orifice, and after 3 days, the output volume reached 50 ml.

On July 28, 2022, the 4th injection of PRP-fibrin glue was done from the external orifice, and after 3 days, the output volume reached 40 ml.

On August 3, 2022, the 5th injection of PRP-fibrin glue was done from the external orifice, and after 3 days, the output volume reached 20 ml.

On August 5, 2022, one hemoclip was excited from the external orifice (Figure 1. A). The drainage bag was removed and three sterile gauzes were placed on the external orifice of the fistula and changed every 4 hours.

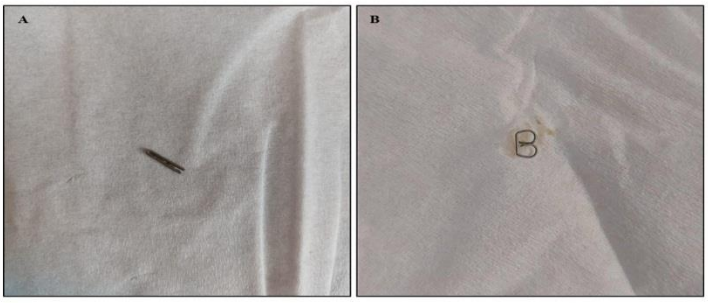

Figure 1: (A) a hemoclip and (B) a staple that were excited from the external orifice.

On August 6, 2022, the patient started liquid oral feedings such as 200 ml of almond milk, 200 ml of intrameal protein, 200 ml of soup, 200 ml of watermelon, 200 ml of carrot juice, 200 ml of banana milk, and 200 ml of mango milk. Abdominal discomfort decreased little by little.

On August 9, 2022, the 6th injection of PRP-fibrin glue was done from the external orifice, and after 3 days, the output volume reached 10 ml, and three sterile gauzes were placed on the external orifice of the fistula and changed every 12 hours.

On August 12, 2022, the patient was instructed to stop oral liquid feeding in order to decrease the fluid pressure beyond the fibrin clot. The 7th PRP-fibrin glue was injected into the external orifice.

Surprisingly, abdominal discomfort increased significantly and the output volume increased to 30 ml and 6 staples were excited from the external orifice (Figure 1B).

On August 14, 2022, oral feeding was initiated and the 8th injection of PRP-fibrin glue was done from the external orifice, and after 3 days, the output volume reached 25 ml, and three sterile gauzes were placed on the external orifice of the fistula and changed every 6 hours.

On August 18, 2022, the 9th injection of PRP-fibrin glue was done from the external orifice, and after 3 days, the output volume reached 20 ml, and two sterile gauzes were placed on the external orifice of the fistula and changed every 6 hours.

On August 22, 2022, the 10th injection of PRP-fibrin glue was done from the external orifice, and after 3 days, output volume reached 15 ml, and two sterile gauzes were placed on the external orifice of the fistula and changed every 6 hours.

On August 26, 2022, the 11th injection of PRP-fibrin glue was done from the external orifice, and after 3 days, the output volume reached 10 ml, and two sterile gauzes were placed on the external orifice of the fistula and changed every 6 hours.

On August 30, 2022, the 12th injection of PRP-fibrin glue was done from the external orifice, and after 3 days, the output volume was 5 ml and two sterile gauzes were placed on the external orifice of the fistula and changed every 6 hours. The patient started the oral solid feeding, and on September 4, the jejunostomy tube was removed.

On September 7, 2022, 3 clips exited and the 13th injection of PRP-fibrin glue was done from the external orifice. The output volume was 5 ml and two sterile gauzes were placed on the external orifice of the fistula and changed every 12 hours.

On September 11, 2022, another clip exited and the 14th injection of PRP-fibrin glue was done from the external orifice. The output volume reached 2.5 ml and one sterile gauze was placed on the external orifice of the fistula and changed every 12 hours.

On September 15, 2022, the 15th injection of PRP-fibrin glue was done from the external orifice, the output volume reached 1 ml and one sterile gauze was placed on the external orifice of the fistula and changed every 24 hours. The jejunostomy site did not heal completely and it turn into an enterocutaneous fistula. PRP-fibrin glue was applied.

DISCUSSION

GCF is a life-threatening problem and ECF is a very uncomfortable situation for patients and they need a careful approach to closure of the fistula. Some surgeons wait up to 6 weeks to increase the chance of spontaneous closure of the fistula before the surgical correction. This study showed that PRP-FG can be used to the close recalcitrant fistula which is not closed spontaneously. Also, PRP-FG can be applied as a non-invasive approach during the first week of fistula formation in order to expedite the closure of the fistula and minimize significant patient distress.

FG plays as a topical biological sealant and creates a strong fibrin clot at the site of application which is 10 times stronger than a physiological clot. This clot provides an important provisional extracellular matrix to stimulate the local proliferation of fibroblasts, collagen synthesis, new blood vessel formation, preventing fibrosis, and delivery of growth factors.[10]

PRP, at a concentration 4-5 times more than baseline in blood, provides an optimal concentration of growth and bioactive factors for fistula closure. The growth and bioactive factors are in the α-granules and the dense granules of platelets, respectively. These growth factors stimulate cell proliferation, chemotaxis, cell differentiation, and angiogenesis. The bioactive factors enhance capillary permeability at the fistula site, which stimulates the healing process of the fistula. Also, the antimicrobial activity of PRP has been demonstrated against Escherichia coli, Staphylococcus aureus, Candida albicans, and Cryptococcus neoformans.[11]

It is reported that the endoscopic management of GCF with FG is simple, safe, effective, and life-saving. This endoscopic application of FG has been proposed as a therapeutic option for the treatment of GCF which develops after bariatric surgery.[12] In GCF, the output should be evaluated daily for 1 week, if there is no sign of output decreasing, the endoscopist should proceed to endoscopic injection of FG. In the endoscopic approach for sealing

the inner orifice of the GCF by FG, it should be repeated in case of no success with 2–3-day intervals between them. The point that sealing should be stopped is guided by two parameters: (i) the propensity to closure; and (ii) the experience of the endoscopist in this procedure.[3]

However, other studies reported a low success rate (50%) of FG for the closure of ECF.[13,14] On the other hand, endoscopic procedures in the gastrointestinal tract increase the risk of iatrogenic complications such as perforation, bleeding, aspiration, and so on. Another problem in the endoscopic procedure is instrument damage which can result from sealant contamination, including obstruction of the working channel and sealant adherence to the tip of the endoscope. Adherence of the needle to varix has also been seen.[15] For 24 patients with GCF, Assalia applied fibrin glue by using fluoroscopic guidance under endoscopic visualization. The fistula was acute in 10 patients, subacute in 9, and chronic in 5. Sixteen patients (67%) had had previous failed endoscopic interventions. After a single application in 9 patients (39%), 2 applications in 8, 3 applications in 3, 5 applications in 2, and 6 applications in 1, the fistula was closed. Authors mentioned that "the disadvantages are the multiple applications, hospitalization for few days after injection with NPO for 2 days and a multi-disciplinary team for FG injection".[16]

Wu et al evaluated the efficacy and safety of autologous PRP-FG for the treatment of low-output enterocutaneous fistulae. Their results showed a remarkably shorter closure time in those treated with PRP-FG (median: 8 days) versus those receiving only supportive care (median: 25 days).[17]

Hwang et al used FG (along with bovine thrombin) in patients with very low-output ECF (< 20 mL). The time needed to close the fistulous tract and hospital stay was decreased significantly (2 ± 0.4 d) in 6 patients treated with external application of the adhesive in comparison to 7 control patients who received conventional treatment. In the control group, spontaneous closure was observed after 13 ± 2 d ($P < 0.01$). It was concluded that the use of fibrin glue is safe and effective for patients with stable and low-output enterocutaneous fistulas.[18]

Papavramidis reported the endoscopic application of FG for the treatment of GCF after bariatric surgery in three people with obesity with a 100% success rate.[12]

Lange et al injected FG through the endoscopic procedure for 17 patients with ECF. The success rate was 64.5%, some patients showed complications because of the high pressure of the FG application, and one patient died of pulmonary air embolism.[19]

Jorge Avalos-González et al showed that the FG application for patients with low-output digestive fistulas lead to a significant decrease in the closure time and the time needed to resume oral intake in comparison to patients who received the same medical treatment but without the use of FG.[2]

Lorenzo-Rivero reported the closure of one case of the gastrocutaneous fistula using autologous FG.[20]

The authors suggest that one of the reasons for unsuccessful fistula treatment in previous reports may be related to foreign bodies such as not fully attached staples or staples in necrotic tissue that may prevent the healing of the fistula. Repeated PRP-FG application causes the regeneration of tissue in the necrotic area and leads to detaching the staples and the exit of them from the external orifice along with leakage of fluid, and then closure of the fistula. Since injection of PRP-FG through the external fistula is simple and non-invasive, it can be repeated as much as needed.

CONCLUSION

According to the results, the authors recommend the use of PRP-FG as a noninvasive option for closure of GCF and ECF as soon as possible after sepsis control and diagnostic procedures in order to prevent the epithelization of the fistula tract. Using PRP-FG decreases the time needed for fistula resolution and reduces the rate of complications associated with the secretions of the fistula. The healing potential of PRP-FG can rescue patients from this disgusting illness, long-term discomfort, and costly hospital stay. A larger multi-center study would provide a more precise estimation of the effectiveness of this treatment aiming at the closure of the fistulas with minimal morbidity and mortality.

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Competing Interests: The authors declare that they have no conflict of interests.

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of Mashhad University of Medical Sciences (protocol code: 941101; approval date: June 23, 2017)

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

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