



# The effect of platelet-rich plasma injection on post-internal urethrotomy stricture recurrence

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## Abstract

**Purpose** Local injection of platelet-rich plasma (PRP) is postulated to work by delivering growth factors and cytokines that recruit healer cells and enhance recovery process at the injection site. As new scar formation leads to stricture recurrence after internal urethrotomy, we proposed to improve post-internal urethrotomy stricture recurrence rate by injecting local submucosal PRP at the time of urethrotomy.

**Methods** From July 2015 to June 2018, 87 male patients with symptomatic bulbar urethral stricture (diagnosed by retrograde urethrography) randomized into two groups of internal urethrotomy and submucosal normal saline injection (control group, 43 patients), and internal urethrotomy with submucosal autologous platelet-rich plasma injection (PRP injection group, 44 patients). According to the endpoint, which happened sooner, each patient was followed at 3-month intervals for 2 years after internal urethrotomy or until urethral stricture recurrence.

**Results** Twelve-month recurrence rates were 26.82 and 9.09% in the control and the PRP injection groups, respectively ( $p$  0.032). After 2 years of follow-up, stricture recurrence was identified in 18 (43.90%) and 9 (21.95%) patients in the control and the PRP injection groups, respectively ( $p$  0.34).

**Conclusion** In our study, submucosal PRP injection at the site of internal urethrotomy decreased the rate of stricture recurrence a year after the intervention. This protective effect lasted for 24 months, at least. Submucosal PRP injection at the time of internal urethrotomy also decreased the length of stricture in case of recurrence.

**Keywords** Urethral stricture · Internal urethrotomy · Platelet-rich plasma

## Introduction

Injures to the urethral epithelium or the underlying corpus spongiosum that result in a scar can cause urethral stricture [1]. This damage to the urethra often goes unrecognized until the patient presents with voiding symptoms resulting from the obstruction of the narrowing or scar. Most urethral

strictures are the result of trauma (usually straddle, or iatrogenic trauma during urologic instrumentations). Most often presentations of urethral stricture are obstructive voiding symptoms or urinary tract infections such as prostatitis and epididymitis. Some patient are also present with urinary retention [2]. Treatments include dilatation, internal urethrotomy and open urethral reconstruction [3].

In internal urethrotomy, the narrowing scar is incised with a knife under direct vision to widen the urethral lumen. Since the resulting wound margins broaden, healing is by secondary intention. This in turn leads to scar formation, explaining the high recurrence rate [3]. It is reported that after internal urethrotomy, stricture recurs in 26.9%–58% of patients and some authors report long-term success rates of only 20% [4–6]. Repetitive internal urethrotomy will not improve the success rate. Good prognostic characteristics of bulbar urethral strictures include single or primary strictures, length shorter than 10 mm, and caliber wider than 15 F [3, 5]. It is shown that although large caliber urethrotomy may

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result in a longer symptom-free period postoperatively, it will not improve long-term recurrence rate [7].

It is suggested that supra-physiological concentration of platelet will produce a locally increased concentrations of growth factors [8]. Thus, a local injection of platelet-rich plasma (PRP) is postulated to work by delivering growth factors and cytokines that recruit healer cells, and enhance healing process at the injection site. Based on these assumptions, PRP administration has been studied in a variety of clinical problems including orthopedics and sports medicine [9–14]. In this context, Tavukcu et al. demonstrated that PRP application in the rat model of urethral injury inhibited fibrosis and type I collagen augmentation, and had a preventive effect on stricture formation [15].

It is indicated that a week after urethrotomy inflammatory cells recruit in the incision site and with time, loss of vascular network, narrowing of urethral lumen and increase in connective tissue will emerge [1]. Since after internal urethrotomy, new scar formation leads to stricture recurrence, we evaluated whether local submucosal PRP injection, which may enhance the healing process, can improve post-internal urethrotomy recurrence rate.

## Materials and methods

It is a blind and controlled randomized clinical trial. From July 2015 to June 2018, 87 consecutive patients with symptomatic bulbar urethral stricture (diagnosed by retrograde urethrography) aged between 20 and 50 years were randomized into two groups of internal urethrotomy plus submucosal normal saline injection (control group, 43 patients) and internal urethrotomy plus submucosal autologous platelet-rich plasma injection (PRP injection group, 44 patients). Exclusion criteria were history or medical evidences of symptomatic benign prostatic enlargement, documented or suspicious prostate cancer, history of hypospadias, neurogenic disorders, previous internal urethrotomy or urethral reconstruction, strictures longer than 1.5 cm, multiple strictures, strictures in the other parts than bulbar urethra and the patients' desire not to take part in the study. Randomization sequence was created using Stata 9.0 (StataCorp, College Station, TX, USA) statistical software with a 1:1 allocation using random block sizes of 4, 6 and 8 by an independent statistician. Baseline stricture length and caliber, International Prostate Symptom Score (IPSS) and voiding  $Q_{max}$  were measured in all patients.

After obtaining written informed consent, single surgeon carried out direct vision internal urethrotomy using cold knife with multiple radial incisions at the 3, 6, 9 and 12 o'clock positions. Then urethra was dilated to readily pass a 25 Fr cystoscopy sheath. In the PRP injection group, after performing urethrotomy and dilatation, 1 ml of PRP was injected

submucosally at each 3, 6, 9 and 12 o'clock positions of stricture site. The same procedure was performed with normal saline in the control group. A 24 Fr Foley catheter was fixed for 2 weeks and the patient was trained to perform clean intermittent catheterization with a 16 Fr Nelaton catheter every other week for next 3 months. According to the endpoint, which happened sooner, each patient was followed at 3-month intervals for 2 years after urethrotomy or until stricture recurrence. At each visit, patients were catheterized with an 18 Fr Nelaton catheter and if any difficulty was identified during catheterization, a retrograde urethrography was carried out to identify stricture recurrence. Urethrography was also performed with recurrence of lower urinary tract symptoms (IPSS more than 7). Annually, to decrease the rate of lost follow-up, a trained nurse phone called the patients a week before each visit.

## PRP preparation

30 ml of peripheral blood was collected using blood collection tubes containing 0.5 ml citrate solution. The PRP preparation procedure consisted of two centrifugation steps. All steps were performed in a refrigerated centrifuge. After the first centrifugation ( $300\times g$ , 5 min, 18 °C), the whole plasma above the buffy coat was collected, separating platelets from red blood cells and leukocytes. After second centrifugation ( $700\times g$ , 17 min, 18 °C) the upper portion of the volume was removed and platelets were homogenized in lower 5 ml of plasma to create the PRP [16].

## Statistical analysis

Baseline age, stricture length and caliber, International Prostate Symptom Score (IPSS) and voiding  $Q_{max}$  were reported in mean  $\pm$  SD and range. Recurrence rate was reported in percentage. Based on our data characteristics, we used Chi square test for qualitative variables and Mann–Whitney  $U$  and Wilcoxon signed-rank tests for quantitative data.

Since there were no previous studies to evaluate the effect of PRP injection on the rate of post-urethrotomy stricture recurrence, we performed a pilot study. According to our findings and the study power of 90% and significance level of 5%, we calculated that the minimum size of our groups was 36 patients for each arm of the investigation. Because possible loss to follow-up in participants may affect the quality of the study, we decided to add more patients to each group and accordingly we enrolled 43 and 44 patients in the control and the PRP injection groups, respectively.

## Results

Eighty-seven consecutive men with symptomatic bulbar urethral stricture who fulfilled the enrollment criteria were entered into the study and were randomized to submucosal PRP injection and control groups. The causes of urethral strictures included 37(42.52%) previous urethral instrumentations, 16 (18.39%) previous external trauma to the urethra and 5(5.74%) previous urethritis. In 29 (33.33%) patients, no obvious cause was identified. The frequency distribution of strictures etiology and mean  $\pm$  SD age, stricture length and caliber, voiding  $Q_{max}$  and IPSS in the control and the PRP injection groups are shown in Table 1. The baseline characteristics were not significantly different between the two treatment groups ( $p > 0.05$ ) (Table 1).

No stricture recurrences were identified in both groups 3 months after internal urethrotomy. The 9-month recurrence rates were not significantly different between two groups ( $p > 0.05$ ). After 12 months of follow-up, the rates of recurrence in the control and the PRP injection groups were 26.82% and 9.09%, respectively ( $p 0.032$ ). The difference between recurrence rates continued to remain significant until the end of study with 24-month recurrence rates of 43.90% in the control group and 21.95% in the PRP injection group ( $p 0.034$ ) (Table 2).

In the patients with recurrence, pretreatment stricture lengths and calibers were not significantly different in both groups ( $p 0.781$  and  $0.085$ , respectively) but recurred stricture lengths were significantly shorter in PRP injection group than in the control group ( $p 0.003$ ). The recurred stricture calibers were not significantly different between two groups ( $p 0.106$ ).

In the submucosal PRP injection group, recurred stricture lengths were significantly shorter than primary stricture lengths ( $p 0.008$ ) but this was not true for the calibers and pretreatment, and recurred stricture calibers were not significantly different ( $p 0.131$ ). In the control group, neither the lengths nor the calibers were significantly different between

primary and recurred strictures ( $p 0.133$  and  $0.634$ , respectively) (Table 3).

Early postoperative complications were minor (grade I, based on Clavien–Dindo grading system) and they were not significantly different in both groups ( $p > 0.05$ ) (Table 4). Excluding urethral stricture recurrence, which is reported as the endpoint of the study, no long-term adverse events occurred in both groups.

5 patients lost to follow-up, 2(4.7%) in the control and 3(6.8%) in the submucosal PRP injection group. In 82 patients who completed the study, overall recurrence rate was 32.92%.

## Discussion

In adult humans, favorable wound healing depends on rapid hemostasis, appropriate inflammation, mesenchymal cell migration, proliferation and differentiation in the wound site, appropriate microvasculature development, prompt regrowth of epithelial tissue, and proper deposition and arrangement of collagen to provide strength to the healing tissue [17]. These events are mediated through inflammatory cytokines and growth factors such as transforming growth factor (TGF)- $\beta$ , platelet-derived growth factor (PDGF), fibroblast growth factor (FGF), and epidermal growth factor (EGF)

**Table 2** Urethral stricture recurrence rate at 3-month interval visits

Recurrence after	Control <i>n</i> (%)	PRP injection <i>n</i> (%)	<i>p</i> value
3 months	0 (0%)	0 (0%)	–
6 months	3 (6.97%)	0 (0%)	0.075
9 months	6 (14.63%)	2 (4.54%)	0.111
12 months	11 (26.82%)	4 (9.09%)	0.032
15 months	13 (31.70%)	5 (11.62%)	0.025
18 months	15 (36.58%)	7 (17.07%)	0.046
21 months	16 (39.02%)	7 (17.07%)	0.027
24 months	18 (43.90%)	9 (21.95%)	0.034

**Table 1** Baseline patients' age, stricture length, caliber and etiology, voiding  $Q_{max}$ , and IPSS: mean  $\pm$  SD (range)

	Control	PRP injection	<i>p</i> value
Age	30.79 $\pm$ 7.51 (21–45)	33.11 $\pm$ 6.99 (21–46)	0.115
Stricture length (mm)	8.77 $\pm$ 2.26 (5–13)	8.65 $\pm$ 2.63 (5–13)	0.786
Stricture caliber (Fr)	7.16 $\pm$ 4.07 (2–15)	8.30 $\pm$ 3.78 (2–15)	0.156
Baseline $Q_{max}$ (ml/s)	9.26 $\pm$ 3.47 (5–16)	10.39 $\pm$ 3.24 (5–16)	0.095
Baseline IPSS	24.84 $\pm$ 5.69 (15–34)	23.89 $\pm$ 6.18 (15–34)	0.499
Etiology of urethral stricture			
Urethral instrumentations	20 (46.51%)	17 (38.63%)	0.458
External trauma	7 (16.28%)	9 (20.46%)	0.615
Urethritis	2 (4.65%)	3 (6.82%)	0.664
Idiopathic	14 (32.56%)	15 (34.09%)	0.879

**Table 3** Pretreatment and recurred urethral stricture length and caliber in patients with recurrence: mean  $\pm$  SD (range)

	Pretreatment stricture		Recurred stricture	
	Control	PRP injection	Control	PRP injection
Length (mm)	9.85 $\pm$ 1.88, (5–13)	9.07 $\pm$ 3.02, (5–12) 0.781*	9.28 $\pm$ 1.36, (6–12) 0.133**	6.67 $\pm$ 2.12, (4–10) 0.003* 0.008**
Caliber (Fr)	6.33 $\pm$ 3.29, (2–12)	8.67 $\pm$ 3.00, (4–14) 0.085*	6.44 $\pm$ 3.58, (3–13) 0.634**	9.22 $\pm$ 3.23, (4–12) 0.106* 0.131**

\**p* versus control; \*\**p* versus pretreatment**Table 4** Frequency distribution of early postoperative complications

Early postoperative complications	Control <i>n</i> (%)	PRP injection <i>n</i> (%)	<i>p</i> value
Urethral bleeding	32 (74.41%)	29 (65.90%)	0.386
Hematuria	20 (46.51%)	23 (52.27%)	0.591
Urethral pain, discomfort and/or burning sensation	34 (79.06%)	31 (70.45%)	0.355
Pelvic pain	18 (41.86%)	17 (38.63%)	0.759
Urine leakage around catheter	19 (44.18%)	22 (50.00%)	0.587
Symptomatic urinary tract infection	0 (0%)	0 (0%)	–
External genitalia/perineal swelling	11 (25.58%)	10 (22.72%)	0.709

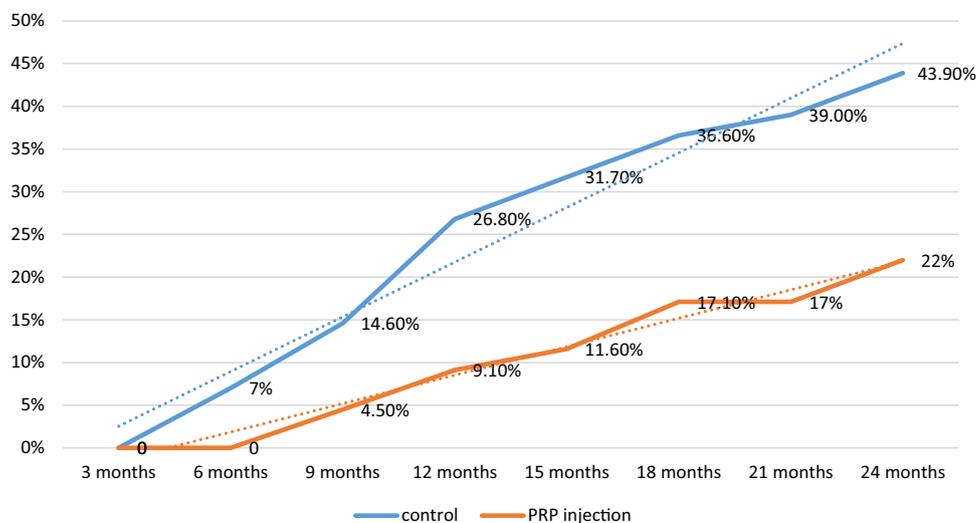
released by clot and surrounding injured tissue [18, 19]. Any interruptions in these events may lead to abnormal healing [20].

During wound healing and upon activation by contact with collagen, platelets secrete stored intercellular mediators and cytokines from the cytoplasmic pool. They also continue to produce more cytokines and growth factors from their mRNA reserves for at least another 7 days [21]. These substances have a paracrine effect on different cell types

involved in wound healing. Thus platelets can stimulate angiogenesis, cell migration and cell proliferation which enhance tissue regeneration [22]. Accordingly, platelet-rich plasma (PRP) derivatives have been used in regenerative medicine for the treatment of several clinical conditions including various gynecologic [23], orthopedic [9, 11, 14], maxillofacial [24] and dermatologic disorders [25].

Following internal urethrotomy, a process of wound healing begins in the incised tissue. The rationale for submucosal PRP injection after internal urethrotomy was to enhance wound healing process and therefore, to possibly decrease the post-urethrotomy stricture recurrence rate.

To date, this is the first blind randomized controlled study examining the effect of submucosal PRP injection on post-internal urethrotomy recurrence rate. In our investigation, during the first 9 months of follow-up recurrence rates were not significantly different between the control and the submucosal PRP injection groups, but at 12-month follow-up interval, urethral stricture recurrences were more common in the control (26.82%) than the PRP injection group (9.09%) (*p* 0.032). This protective effect of PRP injection lasted during the next 12 months of follow-up (*p* 0.034) and tended to persist for longer periods (Fig. 1).

**Fig. 1** Trends of urethral stricture recurrence over time in the control and the PRP injection groups

In accordance with previous studies [4–6], we found that in the population under study, stricture length was a risk factor for recurrence ( $p$  0.040; OR 1.23, 95% CI 1.009–1.510). In this study, in contrast to Pansadoro and Emiliozzi's report [5], stricture caliber did not significantly predict post-internal urethrotomy recurrence ( $p$  0.642).

Only few studies in this field were available, thus we could compare our results to theirs. In this context, Tavukcu et al. demonstrated that PRP had a protective effect on urethral stricture formation and prevented the increase in collagen type I/type III ratio in a rat model of urethral injury [15]. In an uncontrolled limited-size investigation, Scarcia et al. used autologous platelet-rich plasma gel to enhance vascularization of buccal mucosa graft and to reduce the fibrosis in bulbar and penile buccal mucosa urethroplasty. They reported no stricture recurrences and no significant complications [26].

Although in agreement with previous investigations [4–6], we found a sustained increase in stricture recurrence rate over time and it appeared that in our population the rate of recurrence may continue to rise beyond the 2-year follow-up period. Submucosal PRP injection delayed the recurrence and at least, slowed down the time-dependent increase of post-urethrotomy stricture recurrence rate (Fig. 1). We also demonstrated that in case of recurrence, submucosal PRP injection may result in a shorter stricture length (within- and between-group  $p$  value 0.008 and 0.003, respectively) and this in part may facilitate further reconstructive surgery.

## Conclusion

In our study, probably through enhancing the wound healing process, submucosal PRP injection decreased the rate of stricture recurrence following bulbar urethra internal urethrotomy. This protective effect lasted for at least 24 months postoperatively. Although it appeared that the recurrence rate may continue to increase over time, PRP decelerated the process. Submucosal PRP injection at the time of internal urethrotomy also decreased the length of stricture in case of recurrence.

**Author contributions** MR: protocol/project development, data analysis, manuscript writing/editing. RB: protocol/project development, data collection or management. RB: data collection or management, data analysis.

## Compliances with ethical standards

**Conflict of interest** The authors whose names are listed certify that they have no affiliations with or involvement in any organization or entity with any financial interest, or non-financial interest in the subject matter or materials discussed in this manuscript.

**Research involving human participants and/or animals** The protocol of this research was approved by the research ethics committee of Shiraz University of Medical Sciences, Shiraz, Iran on April 7, 2015. All therapeutic and diagnostic interventions performed in this study were in accordance with the ethical standards of the institutional (Shiraz University of Medical Sciences) and national (Iran) research committee, and with the 1964 Helsinki Declaration of the World Medical Association and its later amendments. Written informed consent was obtained from all participants before entering the study.

**Data sharing statement** Data are available for bonafide researchers who request it from the authors.

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