

Autologous Fibrin Sealant in Tubeless Percutaneous Nephrolithotomy;

A Prospective Study

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Purpose: To evaluate the efficacy of autologous single-donor fibrin glue after tubeless percutaneous nephrolithotomy (PCNL).

Materials and Methods: Forty-three patients were planned for tubeless PCNL in a prospective cohort study and randomized in two groups with or without using fibrin glue. Randomization method was based on the computer-generated random numbers.

Results: Transfusion, urinary leakage, or major complications were found in neither of the groups. There was no difference between two groups in stone free rate ($P = .53$), and changes in hemoglobin ($P = .61$) and serum creatinine ($P = .63$) level.

Conclusion: Although autologous fibrin glue did not play any significant role in improving results or decreasing complications after tubeless PCNL in our study, its use was safe and did not increase complications.

Keywords: percutaneous; surgery; kidney calculi, treatment outcome; fibrin tissue adhesive; wound closure techniques

INTRODUCTION

Renal stone disease is one of the most common diseases in the world with the lifetime prevalence of 1% to 15% worldwide⁽¹⁾ and 5.7% in Iran.⁽²⁾ Percutaneous nephrolithotomy (PCNL) is the gold standard method to treat large kidney stones.⁽³⁾ Hemorrhage and urine extravasation are the most common complications of PCNL.⁽⁴⁾ To decrease these complications, a nephrostomy tube is inserted.⁽⁵⁾ However, because the nephrostomy tube can cause pain and discomfort for patients, tubeless PCNL has been introduced as an alternative.

Adhesive and hemostatic substances, such as fibrin glue, have been used to decrease the risk of bleeding and extravasation after tubeless PCNL.⁽⁵⁻⁷⁾ Fibrin sealants usually used in PCNL are commercially available products prepared from large pools of blood plasma.⁽⁵⁻⁷⁾ In this study, we used autologous single-donor fibrin sealant to compare results of tubeless PCNL with and without fibrin sealant. To the best of our knowledge, this is the first prospective study evaluating autologous single-donor fibrin sealant application in PCNL.

MATERIALS AND METHODS

From September 2010 to December 2011, 43 patients were recruited into this prospective cohort study. Randomization method was done using computer-generated random numbers. To prepare autologous fibrin sealant, all the patients should have a body weight of over 40 kg, without any clinical restriction for plasmapheresis according to the national standards of the Iranian Blood Transfusion Organization (IBTO).⁽⁸⁾

Patients were randomly divided into two groups: experimental group, tubeless PCNL with the use of fibrin glue at the end of the procedure and control group, tubeless PCNL without fibrin glue. Of 43 patients, fibrin sealant was instilled in 15. At the beginning of the study, 28 patients were included in sealant group. Because many patients were coming from far cities and could not follow the necessary steps of fibrin glue preparation, their sealant was not prepared at the time of surgery. Therefore, 13 patients were added to the control group. The mean cost per case for fibrin sealant preparation was 5 000 000 Rials (# 150 US\$)

provided by IBTO.

The principles of fibrin sealant preparation have been described elsewhere.⁽⁹⁾ Total volume of fibrin glue was 10 cc, consisting of 5 cc fibrinogen and 5 cc thrombin.⁽¹⁰⁾

The study was approved by the ethics committee of our institute. The outcome of patients in the experimental group was compared with the control group using the independent sample t test with 95% confidence interval. Differences were considered significant at P values of less than .05.

RESULTS

No double-J catheter was placed in 43 subjects. According to Table 1, there was no significant difference in demographic data, side of surgery, and pre-operative hemoglobin and creatinine levels between two groups.

Table 2 shows post tubeless PCNL results in two groups. Transfusion, urine leakage, and major complications were seen in neither of the groups. In fibrin glue group, there was no complication. In the control group, only one patient had hematuria that improved with conservative management, and one patient had fever that was treated with one extra dose of antibiotic.

There was significant difference in mean catheterization days between two groups ($P = .027$), but no difference was seen in mean hospitalization ($P = .11$). There was no difference in hemoglobin and creatinine changes between two groups ($P = .29$ and $P = .46$, respectively). During follow-up period, 2 patients in the control group had residual stone that were managed with SWL.

DISCUSSION

To decrease urinary leakage and bleeding after tubeless PCNL, adhesive products, such as fibrin glue, have been studied. Fibrin sealants have been used in a broad spectrum of surgical specialties with a hemostatic or sealing role.^(11,12) There is an increasing tendency to use fibrin sealants in laparoscopic partial nephrectomy and tubeless PCNL.⁽¹³⁾ Fibrinogen and thrombin constitute the components of fibrin sealants. The components are extracted from two main sources; plasma pools or single-donor plasma donation, which are described as commercial and blood bank products, respectively. The use of commercial sealants has been

Table 1. Patients' demographic and pre-operative data.

Variables	With fibrin glue	Without fibrin glue	P
No. of patients	15	28	
Male/Female, n (%)	11 (73.3%)/4 (26.7%)	16 (57.1%)/12 (42.9%)	.29
Mean age \pm SD, y	39.87 \pm 10.35	43.89 \pm 13.74	.32
Mean weight \pm SD, kg	74.2 \pm 8.66	74.89 \pm 10.39	.82
Mean stone size \pm SD, cm	2.77 \pm 0.86	2.71 \pm 1.27	.86
Right/Left side, n (%)	9 (60%)/6 (40%)	14 (50%)/14 (50%)	.53
Mean pre-op hemoglobin \pm SD, mg/dL	14.97 \pm 1.09	14.20 \pm 1.58	.06
Mean pre-op creatinine \pm SD, mg/dL	1.02 \pm 0.12	1.08 \pm 0.31	.05

SD indicates standard deviation.

Table 2. Post tubeless percutaneous nephrolithotomy results.

Postoperative data	With fibrin glue	Without fibrin glue	P
Approach			.20
Supracostal	2 (13.3%)	11 (39.3%)	
Intercostal	2 (13.3%)	2 (7.1%)	
Subcostal	11 (73.3%)	15 (53.6%)	
Mean post-op creatinine \pm SD, mg/dL	1.22 \pm 0.26	1.22 \pm 0.30	.63
Mean post-op hemoglobin \pm SD, mg/dL	12.93 \pm 1.43	12.54 \pm 1.55	.61
Transfusion	0	0	
Residual stones at day 1, n of patients	0	1	1
Residual stones at 2 weeks, n of patients	0	2	.53
Mean catheterization \pm SD, day	2.2 \pm 0.41	1.79 \pm 0.62	.02
Mean hospitalization \pm SD, day	2.27 \pm 0.59	2.0 \pm 0.47	.11

SD indicates standard deviation.

associated with some safety issues including the transmission of blood-borne diseases, bleeding, anaphylaxis, allergic reaction, and prions.⁽¹⁴⁻¹⁸⁾

To decrease the concerns of using commercial products, autologous blood was applied to prepare fibrinogen and fibrin glue. In our preparation method, mean fibrinogen concentration measured by ELISA and Clauss method was 73 \pm 8 mg/mL and 71 \pm 7 mg/mL, respectively.⁽¹⁰⁾ The tensile strength of Tisseel® could be provided by a fibrinogen concentration of 30 to 60 mg/mL.⁽¹⁹⁾ Autologous fibrin glue has been applied in various surgeries, such as ophthalmologic procedures, hernia repair, urological procedures, and lung surgery.⁽²⁰⁻²⁷⁾ To the best of our knowledge, there is no report about its application in PCNL.

Shah and associated compared tubeless PCNL with and without instillation of Tisseel retrospectively. They showed significant decrease in analgesic consumption ($P = .05$) and

earlier discharge (7 hours) in the fibrin glue group. There were no differences in hemoglobin drop, transfusion rate, and other complications between two groups.⁽²⁸⁾ In another retrospective study, Mikhail and colleagues compared tubeless PCNL with and without fibrin glue. Fibrin glue led to significant decrease in hospitalization by 0.71 day ($P < .05$), but there was no significant difference in hematocrit drop, analgesic use, and operative time. Postoperative fever and wound seroma had occurred in fibrin glue group.⁽²⁹⁾ In our study, there was no statistical difference between two groups regarding complications and hospital stay. There was no complication due to fibrin glue, urinary leakage, or significant change in hemoglobin.

Possible obstruction of the pyelocaliceal system is a concern about fibrin glue application in PCNL,^(16,30) In the present study, although fibrin glue did not play any significant role in reduction of complications or improvement of

tubeless PCNL results, no complication was seen due to fibrin glue. Short-term follow-up period and small number of included patients are our study limitations. Additional prospective randomized trials with larger number of patients are required to evaluate the efficacy and outcome of fibrin glue application after tubeless PCNL.

CONCLUSION

Although fibrin glue did not play any significant role in improving results or decreasing complications of tubeless PCNL in our study, our results suggest that it can be used safely. Due to numerous applications of this substance in a wide variety of surgical fields, the autologous method used to produce fibrin sealant could be a solution to some safety concerns.

CONFLICT OF INTEREST

None declared.

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