ORIGINAL PAPER

UROLITHIASIS

Day care PNL using 'Santosh-PGI hemostatic seal' *versus* standard PNL: A randomized controlled study

Santosh Kumar, Shivanshu Singh, Prashant Singh, Shrawan Kumar Singh

Department of Urology, Post Graduate Institute of Medical Education and Research, Chandigarh, India

Citation: Kumar S, Singh S, Singh P, Singh SK. Day care PNL using 'Santosh-PGI hemostatic seal' versus standard PNL: A randomized controlled study. Cent European J Urol. 2016; 69: 190-197.

Article history
Submitted: Feb. 12, 2016
Accepted: May 12, 2016
Published online: June 20, 2016

Corresponding author
Santosh Kumar
Post Graduate Institute of Medical Education and Research Department of Urology
160012 Chandigarh, India
phone: +91 941 737 4067
antoshsp1967jaimatadi@yahoo.co.in

Introduction To compare the outcomes of tubeless day care PNL using hemostatic seal in the access tract *versus* standard PNL.

Material and methods It was a prospective randomized controlled study. Cases were randomized to either the day care group with hemostatic seal (DCS) or the control group where patients were admitted and a nephrostomy tube was placed at the conclusion of surgery.

Results A total of 180 cases were screened and out of these, 113 were included in the final analysis. The stone clearance rates were comparable in both the groups .The mean drop in hemoglobin was significantly lower in DCS group than the control group (1.05 ±0.68 *vs.* 1.30 ±0.58 gm/dl, p = 0.038). Mean postoperative pain score, analgesic requirement (paracetamol) and duration of hospital stay were also significantly lower in the DCS group (3.79 ±1.23 *vs.* 6.12 ±0.96, 1.48 ±0.50 *vs.* 4.09 ±1.11 grams and 0.48 ±0.26 *vs.* 4.74 ±1.53 days respectively; p <0.05). The incidence of urine leakage through the access tract site was significantly lower in the DCS subgroup when compared to the controls (3.6% *vs.* 21.1%, p <0.05). Cases in the DCS group resumed their normal activities in a significantly shorter time (8.05 ±3.05 *vs.*18.42 ±4.42 days; p <0.05). Higher proportion of cases in the DCS group got re-admitted, although it was not a statistically significant number (7.1% *vs.* 1.8%; p = 0.21).

Conclusions Tubeless day care PNL with composite hemostatic tract seal is considered safe. It resulted in a significant reduction of blood loss and analgesic requirement with significantly reduced hospital stay, nephrostomy tube site morbidity and time required to resume normal activity when compared to the standard PNL. However, patients must be compliant with the given instructions and should have access to a health care facility, as few of them may need re-admission.

Key Words: day care PNL ‹› tubeless PNL ‹› hemostatic seal

INTRODUCTION

The prevalence of renal stone disease ranges from 4–20% with geographic variations [1]. With the advent of endourological and non-invasive interventions, the management of renal calculi has witnessed a marked improvement in outcome. Percutaneous nephrolithotomy (PNL) is one of the most commonly performed endourological procedures for stone management. PNL results in earlier stone-free status with lesser need of auxiliary procedures when compared to extra-corporeal shock wave lithotripsy (ESWL) [2]. However, one of the limiting factors of PNL over ESWL has been the need for hospitalization in the former, while the latter is a day care procedure. Reasons for perioperative hospitalization for PNL include the feared risk of bleeding from the access tract, nephrostomy tube management, fever, risk of sepsis or the need for a re-look procedure. Data regarding the performance of PNL on a day care protocol is limited. Few series have evaluated the feasibility and efficacy of the hemostatic

tract sealants as an adjunct to tubeless PNL [3]. Therefore, a randomized study for the head-to-head comparison of standard PNL using a nephrostomy tube with tubeless PNL using a composite hemostatic seal on a day care basis is needed.

This randomized controlled study was conducted to compare the outcome of tubeless day care PNL using an indigenous composite hemostatic access tract seal with standard PNL, where the cases were admitted preoperatively and a nephrostomy tube was placed at the end of surgery.

MATERIAL AND METHODS

It was a prospective randomized controlled study conducted from September 2014 to December 2015. The institutional review board (IRB) approved the study protocol. The IRB number is 9747/PG-2Trg/2013/22264-65. Cases with renal stone disease planned for PNL were screened for the study. Inclusion criteria were patients more than 18 years of age, body-mass index (BMI) less than 30 kg/m^2, isolated pelvic or pelvicalyceal calculi with the total stone burden less than 40 mm, no anatomical abnormalities , normal renal function, American Society of Anaesthesiologists' (ASA) Grade 1 or 2, residence within a short distance in order to have the ability to report to a hospital within an hour of any adverse complications and motivated and compliant with the instructions provided. Exclusion criteria included patients with BMI ≥30 kg/m^2, staghorn calculi, concomitant urinary tract infection, previous renal surgery, congenital anomalies, solitary kidney, patients without adequate family support or patients not willing for either day care or standard PNL.

Patients who were eligible for the study were randomized using a computer-generated table to either the day care surgery with seal (DCS)group or the control group. Cases in whom any of the following intraoperative events occurred were excluded from the final analysis. These intraoperative events were more than two access tracts, intraoperative bleeding needing transfusion, perforation of the pelvicalyceal system, anesthesia related complications, residual stone needing a re-look PNL or a procedure lasting more than 2 hours.

Operative technique

Patients were operated under general anesthesia. Initially, a 6Fr ureteric access catheter was placed using a cystoscope. PNL was performed in the prone position. Puncture was done under fluoroscopic guidance using contrast or air pyelogram. The tract was dilated using a 12Fr Amplatz fascial dilator (Cook Medical, USA) followed by a cobra catheter (Cook Medical, USA), 30Fr Amplatz dilator (Cook Medical, USA) and lastly, a 30Fr Amplatz sheath insertion. A rigid nephroscope (27-French, Karl Storz, Germany) was used. For lithotripsy: Swiss pneumatic lithoclast® was implemented. In the DCS group , following the stone clearance, the access tract was occluded with a 'Santosh-PGI hemostatic seal.' The steps of seal deployment are highlighted in Figure 1. Following the stone clearance, the Amplatz access sheath was withdrawn to the junction of pelvicalyceal system with the parenchyma. Approximate length of the seal was determined by subtracting the length of the Amplatz sheath outside the skin surface from the total length of the sheath. The composite seal was prepared by wrapping a strip of oxidized regenerated cellulose over a gelatin-sponge and was soaked in a solution of 250 mg of tranexamic acid with 5 ml of 1:1000 dilution of noradrenaline and 20 ml of 76% Trazograf®. The seal was deployed by pushing the seal through the Amplatz sheath under fluoroscopic guidance using the non-conical end of the Amplatz dilator as the plunger up to the level of the skin surface (Figure 1). Keeping the plunger position stable, the Amplatz sheath was withdrawn. The skin was sutured with a nylon 2-0 suture on a curved cutting needle. 'Santosh-PGI' refers to the name of the urologist (Santosh) and the institute (Post-Graduate Institute of Medical Education and Research, Chandigarh, India) where the study was conducted. The constituents of the seal included a strip of oxidized regenerated cellulose (Surgicel® from Ethicon, a division of Johnson and Johnson, New Jersey, USA), 80 X 50 X 10 mm gelatin-sponge (Gelspon® from Eucare Pharmaceuticals, India), 250 mg tranexamic acid (Inj. Tenacid® from Leeford Healthcare, India), 5ml of 1:1000 dilution of nor-adrenaline (Injection Adrenor® from Samarth Pharma, India) and 20 ml of 76% iodinated contrast agent (Injection Trazograf ® 76%, from JB chemicals and Pharmaceuticals Ltd., India).

In the control group, an 18 French nephrostomy tube was placed. Once the urine was clear and the patient had no fever, the nephrostomy was clamped on the third postoperative day. The nephrostomy tube was removed if no pain or urine leakage was observed.

Postoperative parameters that were recorded included the verbal numerical rating score (VNRS 1 to 10) for pain at the 6th hour, paracetamol analgesic requirements (in the recovery room and thereafter 'rescue analgesics'), the need for blood transfusion, urinary leakage from the wound or peri-nephrostomy leak, fever, postoperative drop in hemoglobin and the duration of hospital stay. Patients in the DCS group were discharged within 24 hours if they were afebrile

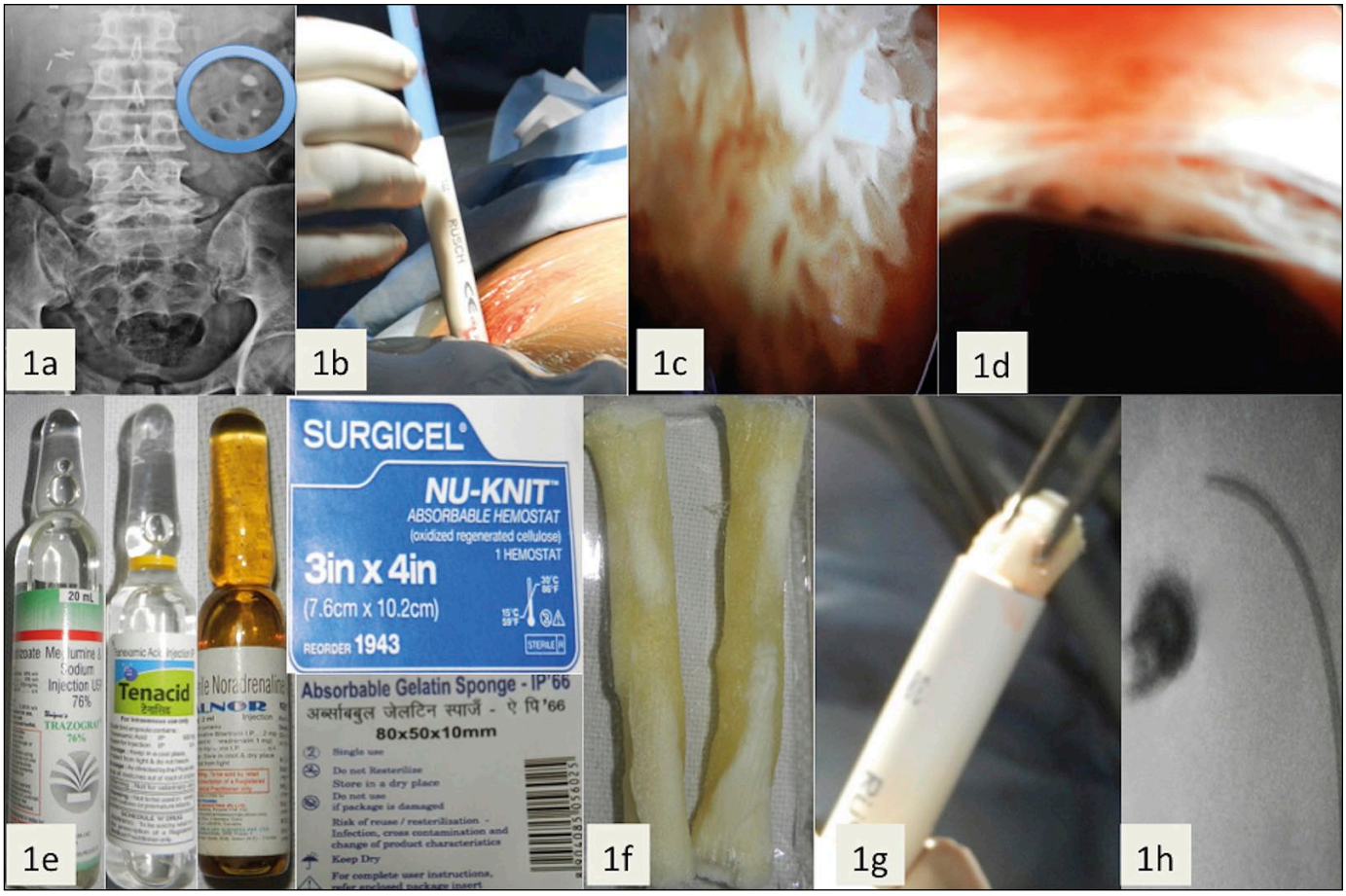

Figure 1. *X-ray KUB of the patient showing left renal calculi (a), tract dilatation using Amplatz dilator and sheath (b), the target calculus (c), following stone clearance the Amplatz sheath withdrawn up to parenchymal margin (d), components of composite seal (e), seal prepared (f), seal being deployed (g), fluoroscopic view of deployed seal (h).*

with no hematuria and minimal to no pain. The ureteric catheter was removed at the time of discharge in the DCS group. They were also prescribed rescue analgesics (paracetamol 650 mg) and were instructed to take them when they felt that the pain was severe or intolerable. They were advised to keep a record of the days of analgesic intake and the number of times the drug was taken on that day. They were asked to report to the emergency department in case of hematuria, urinary soakage, intractable pain or fever. Patients in the control group were shifted to the ward and were discharged later after the removal of the nephrostomy tube.

The patients were followed up at the end of 6 weeks. At follow-up, the parameters evaluated were rescue analgesic requirements, any complications, readmissions and days needed to return to normal work.

The primary goal of the study was to assess whether the use of hemostatic seal without nephrostomy would result in a significant reduction in hemoglobin and analgesic requirement. The secondary endpoints were to assess the feasibility of the day care protocol for PNL and whether it would help in the earlier resumption of normal daily activities.

Data was recorded using Microsoft Office Excel 2008 and analyzed using SPSS software v23.0. For normally distributed data, continuous variables were compared using the student t test. For skewed data, the Mann-Whitney U test was used. Pearson Chi-square test and the Fisher exact test were implemented for comparison of qualitative variables. A p-value of <0.05 was considered as statistically significant.

RESULTS

A total of 180 patients with renal stone disease were screened for eligibility. Sixty-eight cases were excluded. Finally, 122 cases were randomized to either day care surgery with the seal group (DCS) or the control group (Figure 2). Five cases in the DCS group and 4 cases in the control group were excluded due

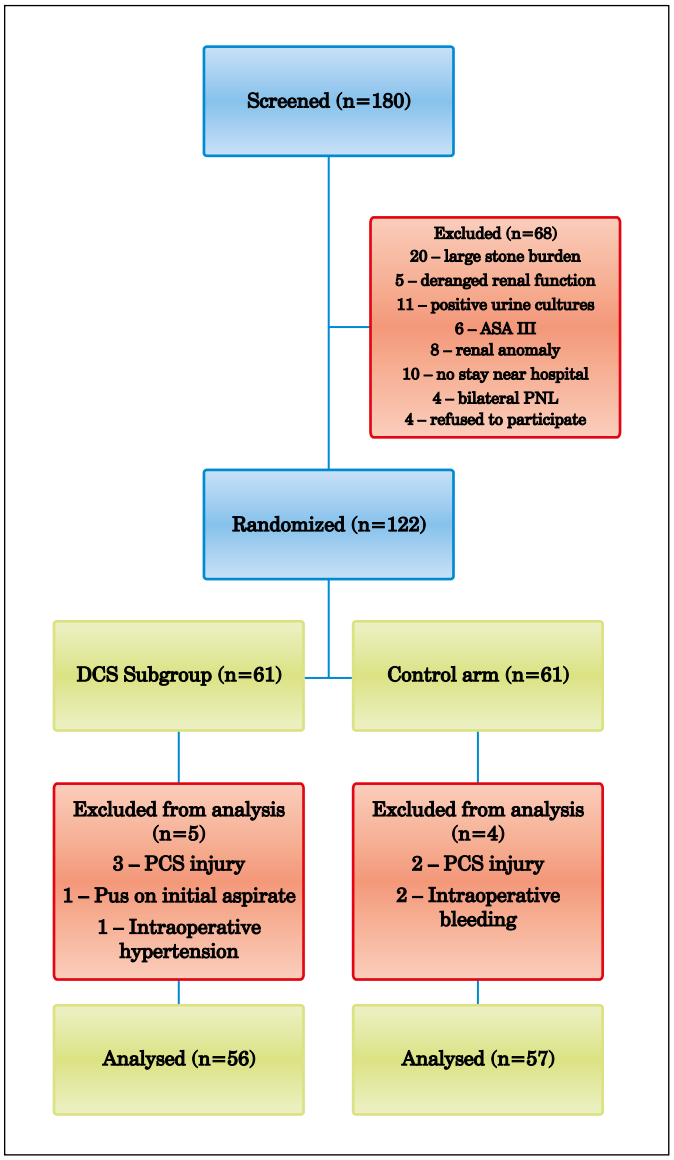

Figure 2. *CONSORT flow diagram of the study.*

to intraoperative adverse events. Finally, 56 cases in the DCS group and 57 in the control group were included for analysis.

The baseline demographic profile, s tone characteristics and operative profiles were comparable in both the groups (Table 1). In the DCS group, 58.9% of the cases were male with mean age of 36.20 ±13.32 years. Seventy-five percent of the cases in the DCS group while 71.9% in the control group had a single calculus. Mean preoperative hemoglobin and serum creatinine levels were comparable in both the groups (13.20 ±1.85 vs. 12.78 ±1.75; p = 0.216 and 0.86 ±0.19 *vs.* 0.79 ±0.19; p = 0.071, respec-tively). Majority of the cases in both the DCS and control groups needed a single access tract (94.6 *vs.* 96.5% respectively; p = 0.63) and an inferior calyceal access (78.5% *vs.* 59.6% respectively; p = 0.09). The mean duration of surgery was comparable in both the groups (41.3 ±11.6 minutes in the DCS group *vs.* 43.2 ±10.9 minutes in the control group , p = 0.371).

Results of the postoperative outcome are shown in Table 2. In the postoperative period, the pain score at the 6th postoperative hour and the total analgesic requirement in the recovery room were significantly lower in the DCS group when compared to the control group (3.79 ±1.23 *vs.* 6.12 ±0.96 and 1.48 ±0.50 *vs.* 4.09 ±1.11; p <0.05, respectively). Mean drop in hemoglobin was significantly lower in the DCS group than in the control group (1.05 ±0.68 *vs.* 1.30 ±0.58 gm/dl respectively, p <0.05). Mean duration of postoperative hospital stay in the DCS group was 0.48 ±0.26 days while it was significantly higher in the control group (4.74 ±1.53 days, p <0.01). The stone-free rates were comparable in both the groups. Cases in the control group consumed significantly higher amounts of rescue analgesics (3.90 ±2.53 grams in the DCS group *vs.* 16.72 ±4.43 grams in the control group, p <0.05).

Overall, postoperative complications occurred in 11 cases (19.6%) in the DCS group, while its incidence was 47.4% in the control group (p <0.05). However, all complications ranged from Clavien-Dindo Grade 1 to 3. Fever was the most common complication reported. Nearly nine percent of the cases in the DCS group (5 out of 56) while 10.5% of the cases in the control group (6 out of 57) had fever in the postoperative period. One patient in the DCS group needed hospital stay for more than 24 hours for SIRS. The need for blood transfusion was lower in the DCS group when compared to the control population (1.8% *vs.* 7% respectively, p = 0.36). When peri-nephrostomy urine leak is taken in to consideration, the incidence of access tract site urine leakage was significantly lower in the DCS subgroup when compared to the controls (3.6% *vs.* 21.1%, p <0.05). The incidence of urinary tract infection and tract site abscess was 3.6% and 5.4% in the DCS group while it was 7% and 1.8% in the control group, respectively. Two cases in the control group had pleural effusion for which chest-tube drainage was needed in one of the cases. None of the cases in both the groups had organ failure, visceral injury or mortality. Two cases in the DCS group while 1 case in the control group had residual calculi, which were treated with ESWL. Relatively higher proportion of cases in the DCS group needed re-admission, however the difference was not statistically significant (7.1% *vs.* 1.8%; p = 0.21). Three cases in the DCS group were re-admitted for tract site abscess while one had hematuria that re-

Table 1. *Demographic, stone and operative profile of the DCS* and control group*

Parameter		DCS group (n=56)	Control group (n=57)	p value
Age (mean ±SD, years)		36.20 ±13.32	36.00 ±11.82	0.934
Males		33 (58.9 %)	31 (54.4 %)	0.626
Comorbidity	DM	1(1.8%)	3 (5.3%)	0.376
	HTN	2 (3.6%)	2 (3.5%)	
	COPD	0 (0.0)	1 (1.8%)	
	DM+HTN	3 (5.4%)	2 (3.5%)	
Laterality	Right side	27 (48.2%)	36 (63.2%)	0.110
	Left side	29 (51.8%)	21 (36.8%)	
Single Stone		42 (75.0%)	41 (71.9%)	0.712
Location	Pelvic	35 (62.5%)	20 (35.1%)	0.681
	Calyceal	15 (26.8%)	24 (42.1%)	
	Pelvic+Calyceal	6 (10.7%)	13 (22.8%)	
Stone burden (mean ±SD, mm)		30.2 ±4.6	29.5 ±4.2	0.400
Preoperative Hb (mean ±SD, gm/dl)		13.20 ±1.85	12.78 ±1.75	0.216
Preoperative s.Cr (mean ±SD, mg/dl)		0.86 ±0.19	0.79 ±0.19	0.071
Number of punctures	Single Puncture	53 (94.6%)	55 (96.5%)	0.633
	Two Punctures	3 (5.4%)	2 (3.5%)	
Calyx punctured	Superior	3 (5.4%	7 (12.3%)	0.089
	Middle	9 (16.1%)	16 (28.1%)	
	Inferior	44 (78.5%)	34 (59.6%)	
Operative duration (mean ±SD, minutes)		41.3 ±11.6	43.2 ±10.9	0.371

*DCS – Day Care Surgery, Hb – Hemoglobin, s.Cr – Serum Creatinine; DM – Diabetes mellitus, HTN – Hypertension, COPD – Chronic obstructive pulmonary disease.

solved with conservative management. Management of tract site abscess included incision and drainage of the tract, antibiotic course as per the culture report, with the need of a DJ stent placement in one case. The patient was discharged after two days. Daily wound dressing was done at the local health care center and the tract healed in about 2 weeks. Time to resume normal work was significantly lower in the DCS subgroup (8.05 ±3.05 days in the DCS group *vs.* 18.42 ±4.42 days in the control group; $p < 0.05$).

DISCUSSION

It is widely agreed upon that patients undergoing PNL should be hospitalized [4]. Several reasons point in favor of this traditional approach. These include observation for hematuria, indwelling nephrostomy tubes for hemostasis, intravenous antibiotics to prevent sepsis, serial hematological tests to look for bleeding, observation for medical and surgical complications. Overall, the incidence of major complications following a PNL is low. In a study by Tefekli and colleagues, the overall incidence of modified Clavien Grade 3 to 5 complication rate

Table 2. *Postoperative outcome in the DCS and control group*

	DCS group (n=56)	Control group (n=57)
Stone free status (n, %)	54 (96.4%)	56 (98.2%)
Pain Score (mean ±SD)*	3.79 ±1.23	6.12 ±0.96
Analgesic requirement in recovery room (mean ±SD, gms)*	1.48 ±0.50	4.09 ±1.11
Need of rescue analgesics after recovery room stay (mean ±SD, gms)*	3.90 ±2.53	16.72 ±4.43
Drop in Hemoglobin (mean ±SD, gm/dl)*	1.05 ±0.68	1.3 ±0.58
Blood transfusion (n, %)	1 (1.8%)	4 (7%)
Duration of hospital stay (mean ±SD, days)*	0.48 ±0.26	4.74 ±1.53
Post-operative complications (Clavien-Dindo grade I–III) (n, %)*	11 (19.6%)	27 (47.4%)
Fever	5 (8.9%)	6 (10.5%)
Urine leak from wound (including leak during/following nephrostomy removal)*	2 (3.6%)	12 (21.1%)
UTI	2 (3.6%)	4 (7%)
Tract site abscess	3 (5.4%)	1 (1.8%)
Pleural effusion	0	2 (3.5%)
Re-admission (n, %)	4 (7.1%)	1 (1.8%)
Days needed to resume normal activity (mean ±SD, days)*	8.05 ±3.05	18.4 2 ±4.42

*p <0.05: significant

was 10.5% while it was even lower for a simple calculus (isolated pelvic or calyceal calculi) [5]. In our study, none of the cases in either group had a Grade 4 or 5 complication. This was due to the fact that it was a cohort of highly selected cases with renal stone disease.

The potential advantages of day care PNL include quicker convalescence, decreased pain due to lack of nephrostomy tubes, lower risk of hospital acquired infections and significant cost savings. Ever since its first description by Preminger in 1986 [6], ambulatory day care PNL is still rarely performed by endourologists worldwide. However, with greater experience in the field of PNL, it is apparent that a subset of patients may be treated on a day care basis. As seen in our study, 90.2% of the cases who were initially randomized to the DCS group could be managed under the DCS protocol.

Nephrostomy tubes used for providing unobstructed urinary drainage and tract site hemostasis have been one of the factors for prolonged hospitalization. We observed that the mean drop in hemoglobin was significantly lower in DCS group when compared to the control group (1.05 ±0.68 *vs.* 1.30 ±0.58 gm/dl, p = 0.039). Also, the need for blood transfusion was lower in the DCS group (1.8% *vs.* 7%, p = 0.36). Sufficient evidence exists to suggest tubeless PNL to be equivalent or even superior to standard PNL for a select group of patients [7]. Various adjuncts have been tried to enhance hemostasis of the percutaneous tract, one of which is insertion/ instillation of hemostatic agents into the tract including oxidized cellulose, gelatin sponge, gelatin granules plus thrombin and fibrin glue [8–11]. Singh and colleagues found significantly less pain, lower analgesia requirement, and shorter hospital stay with lower wound soakage/discomfort in the gelatin-assisted tubeless PNL group *versus* the tubeless PNL without gelatin packing [9]. Nagele and colleagues found that closing the tract of the mini-PNL with gelatin matrix hemostatic sealant is a safe and fast alternative and provides the option of discharging the patient in good condition without the commonly used nephrostomy tube [10]. Kumar and colleagues reported that the use of systemic tranexamic acid in percutaneous nephrolithotomy is safe, and is associated with reduced blood loss and lower complication rates [12]. However systemic tranexamic acid has got its own side effects and is contraindicated in patients more than 50 years of age, in cases of chronic renal failure, coronary artery disease, subarachnoid hemorrhage and in cases of active intravascular clotting. In such cases low dose (250 mg) tranexamic acid can be used locally as its systemic toxicity would be less. Moreover, using tranexamic acid along with noradrenaline would further reduce its systemic absorption, hence contributing to lower systemic side effects. Emara and colleagues showed a significant reduction in blood loss by using the topical tranexamic acid when compared to the control group in pelvic hemiarthroplasty [13]. The potential of norepinephrine to reduce intraoperative blood loss has been explored in other surgeries too. In a study by Wuethrich and colleagues, continuous intraoperative norepinephrine infusion was shown to significantly reduce the need for blood transfusion in open radical cystectomy [14]. We made a composite tract sealant using a combination of a strip of oxidized regenerated cellulose wrapped over gelatin sponge soaked in 250 mg of tranexamic acid and 5 ml of 1:1000 dilution of noradrenaline and 76% solution of Trazograf®. Each component of this seal provided a distinct advantage. The contrast material helped to place the seal under fluoroscopic guidance outside the pelvicalyceal system into the PNL tract, noradrenaline helped by constricting smaller bleeding vessels, tranexamic acid helped by acting as an anti-fibrinolytic agent, while the gelatin sponge and oxidized regenerated cellulose strips helped by accelerating hemostasis by formation of a platelet plug. Since, each component has already been used in the human body, there were no concerns raised about their use in the composite seals. Blood transfusions are associated with well-known transfusion reactions and adverse events. A reduction in the transfusion rate would not only decrease the hospital stay, but would also reduce the incidence of transfusion-mediated reactions in post-PNL cases. Each of the individual constituents was available free of cost in our operating room. Therefore, there was no increment in the cost of surgery from the patients' perspective.

The mean operative time in DCS group was 41.3 ±11.6 minutes. It was less than that reported in previous studies. In a series of 10 cases of ambulatory day care PNL, Singh et al. reported the average operative time of 48.4 minutes, while it was 83.5 minutes in a study by Shahrour and colleagues [15, 16]. The differences in operative times may be attributed to the case selection. Furthermore, we calculated the time interval starting from the skin puncture and ending with the skin suture. Also, instead of sequential dilatation, we dilated the tract in three steps, which helped in reducing the operative time with no significant adverse consequences.

The stone clearance rate in our study was 96.4% in the DCS group and 98.2% in the control group, which was higher than in the studies by Giusti and Shoma (95.4 and 92% respectively) [17, 18].

The higher incidence of stone clearance may be explained by the favorable stone and renal anatomy while preoperatively selecting patients for the study.

We observed that the mean pain score assessed by the VNRS score at the 6th postoperative hour and total analgesic requirement in the recovery room were significantly lower in the DCS group when compared to the control group (3.79 ±1.23 *vs.* 6.12 ±0.96; p <0.05 and 1.48 ±0.50 *vs.* 4.09 ±1.11; p <0.05, respectively). The pain score in the DCS group was comparable to the study by Shoma et al. (3.2 ±1.8) on the day of surgery [18]. Undoubtedly, tubeless PNL in appropriately selected patients has been shown to be associated with significantly reduced postoperative pain and analgesic requirement [17, 18]. Instead of placing an antegrade DJ stent, we retained the ureteric access catheter that was removed at the time of discharge. This practice provided the benefits of tubeless PNL along with avoidance of additional cystoscopic procedure required for stent removal.

We found that the mean duration of postoperative hospital stay in the DCS group was 0.48 ±0.26 days, while it was significantly higher in the control group (4.74 ±1.53 days, p <0.01). In our study, 90.2% (55/61) of the cases who were initially randomized to the DCS group were discharged within 24-hours of the surgery. Sharma and colleagues reported that 85% of their preoperatively selected cases could successfully complete the study protocol and were discharged within 24 hours of surgery [19]. Alyami et al. reported that 66% of their cases could be safely discharged after an overnight stay [20]. In the study by Tabey and colleagues, 71.4% of the cases could be safely discharged from the hospital within 24-hours postoperatively [7]. Relatively higher proportion of cases could be discharged within 24 hours of surgery in our series. Possible reasons could be shorter operative time thereby decreasing the duration of anesthetic drug exposure, use of PNL-tract seals that could be the possible reason for lower postoperative blood loss, pain and access site morbidity in the form of urine leakage, liberal use of analgesics with avoidance of opioids in the postoperative period for pain control and avoidance of stent placement while retaining the ureteric catheter. The ureteric catheter was easily removed in the postoperative period once the urine was clear. This helped to prevent stent-related symptoms that could result in postoperative discomfort resulting in prolongation of hospital stay as well as avoided additional cystoscopic procedures for stent removal.

Time to resume normal work was significantly lower in the DCS subgroup (8.05 ±3.05 days in the DCS group *vs.* 18.42 ±4.42 days in the control group; p <0.001) suggesting that the day care protocol could decrease the number of leaves taken from work. However, the re-admission rates were relatively higher (although not statistically significant) in the DCS group thereby suggesting that these patients are vulnerable for certain postoperative complications which they must understand and comply with when given the instructions by the treating physician. Day care protocol should be avoided in patients who do not have immediate access to a health care facility.

In the review by Choe and colleagues, it was found that the majority of the studies did not consistently result in a significant decline in postoperative blood loss and need of blood transfusion [21]. However, the postoperative pain and the need of analgesic requirement was lower. One thing is clear that the use of hemostatic adjuncts do result in significantly decreased post-PNL morbidity. Very few randomized and retrospective/prospective studies are available evaluating the efficacy of hemostatic adjuncts in tubeless PNL for reducing postoperative bleeding. We chose a combination of easily available cheaper agents to augment PNL tract hemostasis which resulted in a significantly lower postoperative pain score and a fall in hemoglobin allowing early discharge of patients from the hospital. Limitations of our study include a small sample size and lack of critical cost-analysis from the patients' perspective. Implications of our study in the literature are that in carefully selected patients, the composite seal can serve as a useful adjunct for tubeless PNL. The major advantage is the low cost involved in the preparation of this composite seal compared to commercially available sealants like Tissel® and Floseal®.

CONCLUSIONS

Tubeless day care PNL with composite hemostatic tract seal is safe. It resulted in significant reduction of blood loss and analgesic requirement with significantly reduced hospital stay, nephrostomy tube site morbidity and time required to resume normal activity when compared to standard PNL. However, patients must be compliant with instructions and should have access to a health care facility, as few of them may need re-admission.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

COMPLIANCE WITH ETHICAL STANDARDS

(In case of Funding) Funding: This study did not need funding

ETHICAL APPROVAL

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study.

References

1. Trinchieri A. Epidemiology of urolithiasis: an update. Clin Cases Miner Bone Metab. 2008; 5: 101-106.
2. Deem S, Defade B, Modak A, Emmett M, Martinez F, Davalos J. Percutaneous nephrolithotomy versus extracorporeal shock wave lithotripsy for moderate sized kidney stones. Urology. 2011; 78: 739-743.
3. Pugh JW, Canales BK. New instrumentation in percutaneous nephrolithotomy. Indian J Urol. 2010; 26: 389-394.
4. Beiko D, Lee L. Outpatient tubeless percutaneous nephrolithotomy: the initial case series. Can UrolAssoc J. 2010; 4: E86-90.
5. Tefekli A, Ali Karadag M, Tepeler K, et al. Classification of percutaneous nephrolithotomy complications using the modified clavien grading system: looking for a standard. Eur Urol. 2008; 53: 184-190.
6. Preminger GM, Clayman RV, Curry T, Redman HC, Peters PC. Outpatient percutaneous nephrostolithotomy. J Urol. 1986; 136: 355-357.
7. El-Tabey MA, Abd-Allah OA-W, Ahmed AS, El-Barky EM, Noureldin YA-S. Preliminary Study of Percutaneous Nephrolithotomy on an Ambulatory Basis. Curr Urol. 2014; 7: 117-121.
8. Aghamir SM, Khazaeli MH, Meisami A. Use of Surgicel for sealing nephrostomy tract after totally tubeless percutaneous nephrolithotomy. J Endourol. 2006; 20: 293-295.
9. Singh I, Saran RN, Jain M. Does sealing of the tract with absorbable gelatin (Spongostan) facilitate tubeless PCNL? A prospective study. J Endourol. 2008; 22: 2485-2493.
10. Nagele U, Schilling D, Anastasiadis AG et al. Closing the tract of mini-percutaneous nephrolithotomy with gelatine matrix hemostatic sealant can replace nephrostomy tube placement. Urology. 2006; 68: 489-493.
11. Ziaee SA, Sarhangnejad R, Abolghasemi H, et al. Autologous fibrin sealant in tubeless percutaneous nephrolithotomy; a prospective study. Urol J. 2013; 10: 999-1003.
12. Kumar S, Randhawa MS, Ganesamoni R, Singh SK. Tranexamic acid reduces blood loss during percutaneous nephrolithotomy: a prospective randomized controlled study. J Urol. 2013; 189: 1757-1761.
13. Emara WM, Moez KK, Elkhouly AH. Topical versus intravenous tranexamic acid as a blood conservation intervention for reduction of post-operative bleeding in hemiarthroplasty. Anesth Essays Res. 2014; 8: 48-53.
14. Wuethrich PY, Studer UE, Thalmann GN, Burkhard FC. Intraoperative continuous norepinephrine infusion combined with restrictive deferred hydration significantly reduces the need for blood transfusion in patients undergoing open radical cystectomy: results of a prospective randomised trial. Eur Urol. 2014; 66: 352-360.
15. Singh I, Kumar A, Kumar P. 'Ambulatory PCNL' (tubeless PCNL under regional anesthesia) – A preliminary report of 10 cases. Int Urol Nephrol. 2005; 37: 35-37.
16. Shahrour W, Andonian S. Ambulatory percutaneous nephrolithotomy: initial series. Urology. 2010; 76: 1288-1292.
17. Giusti G, Piccinelli A, Maugeri O, Benetti A, Taverna G, Graziotti P. Percutaneous nephrolithotomy: tubeless or not tubeless? Urol Res. 2009; 37: 153-158.
18. Shoma AM, Elshal AM. Nephrostomy tube placement after percutaneous nephrolithotomy: critical evaluation through a prospective randomized study. Urology. 2012; 79: 771-776.
19. Sharma AK, Nagabhushan M, Girish GN, Kamath AJ, Ratkal CS, Venkatesh GK. Analysis of the Feasibility and Efficacy of Ambulatory/Day Care Percutaneous Nephrolithotomy: An Initial Experience. Uro Today Int J. 2013; 6: art 54.
20. Alyami F, Norman RW. Is an overnight stay after percutaneous nephrolithotomy safe? Arab J Urol. 2012; 10: 367-371.
21. Choe CH, L'Esperance JO, Auge BK. The use of adjunctive hemostatic agents for tubeless percutaneous nephrolithotomy. J Endourol 2009; 23: 1733-1738.