Original Article

Prospective audit of complications after ultrasonography-guided percutaneous nephrostomy for upper urinary tract obstruction using modified Clavien classification system

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Abstract

Introduction: Percutaneous nephrostomy (PCN) is a commonly performed intervention in urology for various benign and malignant conditions causing upper urinary tract obstruction. We present a prospective audit of complications of ultrasonography (USG) guided PCN using modified Clavien classification system (mCCS).

Methods: The data were prospectively collected for 368 PCN performed in 344 patients from June 2015 to January 2017, for various benign and malignant diseases causing upper urinary tract obstruction. Patients were followed for 1 month, and complications arisen of PCN were noted.

Results: PCN was successful in 356 renal units. The 12 patients in which PCN failed was due to minimal pelvicalyceal dilatation and PCN was successfully performed after 48 h by a senior urologist. 207 patients had malignant disease and 161 patients had benign condition. Most common malignant disease was carcinoma cervix. 238 were noninfected while 130 had infected renal units. 62 (16.84%) patients had Grade I (self-limiting hematuria/cot/debris/fever). 37 (10.0%) patients had Grade II (7 - transfusion and 30 - urinary tract infection). 34 (9.2%) had Grade III a (repositioning/change/reinsertion of PCN tube under local anesthesia) and 4 (1.1%) had Grade III b (repositioning under anesthesia). 8 (2.2%) Grade IV a (Sepsis), 0 Grade IV b, and 0 Grade V complications were observed.

Conclusion: USG-guided PCN is a safe, minimally invasive, and effective procedure for upper urinary tract diversion with a low rate of morbidity. Individual complications are within the threshold limits set by the American College of Radiology, the Society of Interventional Radiology. mCCS is well applicable and easily reproducible tool for reporting the complications of PCN.

Keywords: Clavien–Dindo classification, complications, percutaneous nephrostomy, ultrasound guidance

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INTRODUCTION

Percutaneous nephrostomy (PCN) is a commonly performed surgical procedure in urology for upper urinary tract obstruction caused by various benign and malignant conditions. This procedure may be performed either

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temporarily or with a permanent intention, as in advanced pelvic malignancies. As with any surgical procedure, there are complications inherent to nephrostomy tube placement. These complications may be dependent on preprocedural clinical and laboratory parameters, actual procedural technique, and level of expertise.[1] There is a paucity of literature reporting PCN-related complications in a standardized manner.

The complications of PCN have been traditionally reported on the guidelines advocated by the Society of Interventional Radiology (SIR).[2,3] In recent years, modified Clavien classification system (mCCS) is being employed for grading of complications across all surgical disciplines enabling a uniform method of reporting.[4] Modified Clavien classification can be of help in comparing morbidity and mortality data across healthcare providers and thereby improving the quality of care.[5] Degirmenci *et al.* have published the first study reporting the complications of ultrasound-guided PCN placement using the mCCS and comparing it to the widely used SIR practice guidelines in a retrospective setting.[6]

The purpose of this prospective study was to utilize the mCCS to stratify the complications of PCN and their management in a standardized manner. This, we believe so that it can facilitate adoption and be reproducible among the treating physicians.

METHODS

This study was performed in the department of urology in a university hospital in South India from June 2015 to January 2017 in a prospective manner. The study was approved by the institute ethical committee. The PCN was performed by the urologists of varying level of expertise.

Procedure and technique

After obtaining consent for the procedure, the patient was given oral prophylactic quinolone antibiotic at least 30 min before the procedure. The patient was placed in the prone position. Under all aseptic precautions, ultrasound of the desirable kidney was performed and renal morphometry was recorded. The target calyx was chosen. Two percent xylocaine was infiltrated in the skin and subcutaneous plane. Subsequently, a 5 mm incision was made in the skin with 11 no. blade. With the help of guide attached to the ultrasound probe (Famio 8 SSA-530, Toshiba), puncture needle (18 G, 20 cm, 2 part) was introduced in the target calyx under real-time ultrasound guidance. Entry into the pelvicalyceal system was confirmed by aspiration of urine, and diluted radiocontrast was instilled to assess the PCS anatomy under fluoroscopy. In patients, when purulent urine or pus was aspirated, injection of contrast was avoided. Next, a 0.038 J-tipped guide wire (Nitinol, 80–150 cm, 0.025–0.038) was introduced into the pelvicalyceal system through the puncture needle, and the position of the guidewire was checked under real-time fluoroscopic guidance. The puncture needle was removed, and the tract was serially dilated with Teflon dilators till 12–14 Fr, and a 10 or 12 Fr pigtail catheters was placed. The pigtail catheter was secured to the skin with nonabsorbable suture material.

Patient's age, gender, body mass index (BMI), indication for PCN, prothrombin time/international normalized ratio (PT/INR), bleeding and clotting time, serum creatinine, electrolytes, total and differential count, and comorbidity were recorded. PCN was considered only in patients with INR <1.5. Intraoperatively, renal morphometry by ultrasonography (USG) was noted. Procedural complications such as opposite pelvic wall perforation and inadvertent entry into renal vessels were recorded. Postoperatively, patients were observed for occurrence and management of any hematuria, dyselectrolytemia, urinary tract infection (UTI), and perinephric urinoma/abscess. The change in serum creatinine and blood cell counts were observed. The patients were discharged after 2–5 days of the procedure and were followed for 1 month.

Statistical analyses

Continuous variables such as age, height, weight and BMI of the patient, serum potassium level, blood hemoglobin, serum creatinine, total leukocyte count, differential leukocyte count, platelet count, and PT/INR were presented as mean and standard deviation for normally distributed data and as median and interquartile range for other data. Categorical variables such as gender, nature of disease comorbid conditions were presented as frequency and/or proportions. The appropriate test of significance was performed (categorical variables Chi-square test or Fisher's test and for quantitative variables *t*-test). Univariate and bivariate analysis were performed to find the statistically significant value. To control the confounding variables, multivariate analysis was performed for variables identified as significant in univariate analysis.

Postoperative complications were classified according to mCCS. The analysis was performed for the factors influencing the success rate of PCN and its complications.

RESULTS

Three hundred and sixty-eight PCN were done in 344 patients. The mean age of patient was 51.1 ± 13.4 years (range 2–85 years). Two patients were below 15 years of age. All other patient characteristics are depicted in Table 1.

All 12 patients in which PCN failed initially were above 15 years, and on univariate analysis, age was not found to be a factor related to failure of PCN. Fifty-seven percent had malignant disease while rest had benign disease. The etiology of upper urinary tract obstruction varied [Table 1]. Unilateral PCN was done in 93.5%. Bilateral PCN was considered in only those circumstances where either patient was having infective etiology bilaterally, or renal function did not improve as expected after unilateral PCN [Table 1].

PCN was successful in 356 patients. The 12 patients in which PCN failed was due to minimal pelvicalyceal dilatation, and PCN was successfully performed after 48 h by an experienced urologist.

Among patients with dilated system (transverse pelvic diameter >1 cm), success rate was 97.7% ($P < 0.05$) which is slightly higher than the threshold set by American College of Radiology (ACR)-SIR. The success rate in nondilated system was 67% ($P > 0.05$), and it was significantly lower than ACR recommendations. This may be due to small number of patients in this subset as PCN is very uncommonly indicated in nondilated system. Univariate and multivariate analysis did not show any statistically significant association of successful PCN with any other factors such as age group, nature of disease, serum creatinine, preoperative infection, hemoglobin, leukocyte count, platelet count, comorbidities, or grade of hydronephrosis although it does depend on the presence or absence of hydronephrosis [Table 1].

Patients were categorized according to BMI into underweight (<18.5), normal (18.5–22.9), overweight (23.0–24.9), obese I (25.0–29.9), and obese II (>30). Mean BMI was 20.9 ± 2.8 (range: 16.5–31.6). In patients with failed PCN in dilated system, 2 had normal BMI, 2 had undernutrition, 3 were overweight, and 1 patient was obese. In all 4 patients with failed PCN in nondilated system, BMI was normal. The mean BMI in successful and failed group of PCN was 20.9 ± 2.8 and 21.4 ± 3.3, respectively. There was no statistically significant difference between successful and failed groups ($P = 0.564$).

Post-PCN serum creatinine changed significantly ($P < 0.05$). Overall, there was no any significant change in platelet count, hemoglobin, and leukocyte count [Table 2].

64.7% of renal units were sterile at the time of PCN. Among infected renal units, most common isolated organism were *Escherichia coli, Proteus, Klebsiella,* and *Pseudomonas*. Post-PCN, only 46.2% patients remained sterile. Rest patients had grown some organism from their PCN output. Most of them were *E. coli* (15.8%). All those patients who had grown organism were not symptomatic, and it did not always warrant antimicrobial treatment. Remarkably, a significant proportion of this cohort had polymicrobial growth.

Various grades of complications according to modified Clavien classification observed and their standarized treatment are shown in Table 3. The complications were not affected significantly by age, BMI, preoperative creatinine, platelet count, leukocyte count and hemoglobin ($P < 0.05$).

Of 357 (97%) dilated renal units, Grade I, II, III a, III b, IV a, IV b, and V complications occurred in 61 (17.1%), 36 (10.1%), 33 (9.2%), 4 (1.1%), 0 (0%), 8 (2.2%), and 0 (0%), respectively. Among 11 nondilated systems, one Grade I, II, and III a complication occurred in each group. No other complication occurred in this subgroup. On univariate analysis, the occurrences of various complications were not associated significantly with the presence or absence of dilatation of PCS. Among 161 patients with benign disease, 23 (14.2%), 11 (6.8%), 15 (9.3%), and 3 (1.8%) suffered with Grade I, II, III a, III b, and IV a complication, respectively. No grade III b, IV b, and V were observed in this cohort. Patients with malignant disease ($n = 207$) had 18.8%, 12.5%, 9.1%, 0.4%, and 1.9% Grade I, II, III a, III b, and IV a complication, respectively. Again, nature of disease was not a risk factor for occurrence of complication.

DISCUSSION

PCN has been traditionally performed by interventional radiologists worldwide. Nowadays, it is being increasingly performed by urologists at many centers. The optimal method of PCN placement is by using USG guidance for choosing the desired calyx and guided initial puncture of pelvicalyceal system. It is followed by contrast instillation through initial puncture (IP) needle and subsequent tract dilation and PCN tube insertion under fluoroscopic guidance. According to ACR–SIR–SPR practice parameter, the success rate should be 95% and 80% in dilated and nondilated system, respectively.[1]

Our success rate in dilated system was 96.7% which was slightly higher than the recommended threshold, but it was statistically not significant ($P = 0.4$). Our success rate in nondilated system was 63.7% which is certainly less than the threshold of 80%. This finding could perhaps be attributed to the small number patients with nondilated system in our series. Our rate of success was similar to those of major case series.

Table 1: Patients' characteristics, indications, and success of percutaneous nephrostomy

Patient characteristics	Total, *n* (%)	Successful	Failed
Age group (years)			
<15	2	2	0
15-44	89	86	3
45-59	169	163	6
>60	108	105	3
Total	368	356	12
Gender			
Female	201 (54.6)		
Male	167 (45.4)		
Side of PCN			
Right	161 (43.8)		
Left	183 (49.7)		
Bilateral	12 (3.3)		
Nature of disease			
Benign	161 (43.8)	154	7
EPN	15 (4.1)		
GUTB	18 (4.9)		
Miscellaneous*	41 (11.1)		
PUJO	4 (1.1)		
Pyelonephritis	7 (1.9)		
Pyonephrosis	31 (8.4)		
Renal stone	10 (2.7)		
Renal stone + ureteric stone	1 (0.3)		
Ureteric stone	34 (9.2)		
Ureteric stricture	2 (0.5)		
Malignant	207 (56.3)	202	5
Bladder	31 (8.4)		
Cervix	134 (36.4)		
Colorectal	14 (3.8)		
Miscellaneous	3 (0.8)		
Ovary	7 (1.9)		
Prostate	12 (3.3)		
Retroperitoneal tumor	4 (1.1)		
BMI			
Normal	242 (65.8)	236	6
Obese 1	15 (4.1)	14	1
Obese 2	6 (1.6)	6	0
Overweight	42 (11.4)	39	3
Undernutrition	63 (17.1)	61	2
PCS			
Sterile	238 (64.7)	231	7
Infected	130 (35.3)	125	5
HDN			
Yes	357	349	8
No	11	7	4
TPD category (cm)			
<1	15	12	3
≥1-<2	113	106	7
2-<3	155	153	2
≥3	85	85	0
Serum creatinine (mg/dl)			
Group 1 (<1.8)	23	22	1
Group 2 (≥1.8-<2.5)	108	104	4
Group 3 (≥2.5-<4)	56	55	1
Group 4 (≥4)	181	175	6
Comorbidity			
None	261 (70.9)	252	9
DM	37 (10.1)	37	0
HTN	46 (12.5)	44	2
DM + HTN	12 (3.3)	11	1
CAD	9 (2.4)	9	0
Others	3 (0.8)	3	0

*Miscellaneous: Nephrocutaneous fistula, primary obstructive megaureter, endometriosis, postoperative cases of PUJO, etc. EPN: Emphysematous pyelonephritis, PUJO: Pelviureteric junction obstruction, GUTB: Genitourinary tuberculosis, PCS: Pelvicalyceal system, DM: Diabetes mellitus, HTN: Hypertension, CAD: Coronary artery disease, TPD: Transverse pelvic diameter, BMI: Body mass index, HDN: Hydronephrosis, PCN: Percutaneous nephrostomy

Table 2: Change in serum chemistries and cell counts following percutaneous nephrostomy

Parameters	Preoperative	Postoperative	Mean difference	*P* (paired sample *t*-test)
Hemoglobin (mg/dl)	9.3±2.3	9.1±2.1	0.2±1.2	>0.05
WBC (cells/mm^3)	10538±5206	10813±4548	275±5149	0.310
Platelet (cells/mm^3)	339±115	367±125	27±100	>0.05
Serum creatinine (mg/dl)	5.32±4.4	3.16±2.4	2.1±2.97	<0.05

WBC: White blood cell

Table 3: Classification of percutaneous nephrostomy according to modified Clavien classification system and its management

Class	Definition	Management	Complication, *n* (%)
Grade I	Fever, pain, vomiting, transient hematuria (hematuria lasting <24 h)	Analgesic, antipyretic, antiemetic, conservative	62 (16.8)
Grade II	Severe hematuria, urinary tract infection, pyelonephritis	Blood transfusion, antibiotics	37 (10.0)
Grade III			
Grade IIIa	PCN tube dislodgment	Under LA reposition/change/reinsertion	34 (9.2)
	Urinoma/perirenal abscess	PCD	
	Renal hemorrhage	Angioembolization	
	Hemo/pneumothorax	ICD	
Grade IIIb	PCN tube dislodgment	Under Regional/general anesthesia	4 (1.1)
	Urinoma	Reposition/change/reinsertion	
	Perirenal abscess	PCD	
Grade IV			
Grade IVa	Bowel perforation	Exploratory laparotomy	0
	Hemorrhage not controlled by conservative/minimal invasive procedure	Nephrectomy	
Grade IVb	Sepsis, multiorgan dysfunction	ICU care	8 (2.2)
Grade V	Death		0

PCN: Percutaneous nephrostomy, LA: Local anesthesia, PCD: Percutaneous drainage, ICD: Intercostal chest tube, ICU: Intensive care unit

SIR has classified the complications of PCN into major and minor which are based on severity of clinical condition, the effort undertaken to manage them, and the length of hospital stay as well. Various authors have classified complications arbitrarily into major and minor groups. We have observed 4.2% major complication and 27.2% minor complication (SIR threshold 4% and 15%, respectively). Higher minor complication observed in our study is due to longer follow-up (1 month) and inclusion of UTI and tube dislodgement in minor complication. Degirmenci *et al.* has pioneered to address the reporting of complications of PCN according to CCS, although it was a retrospective analysis which is inherent to recall bias.[6]

Radecka and Magnusson has used computed tomography (CT) guidance along with USG and fluoroscope for PCN and found that UTI was most common complication apart from major life-threatening conditions such as cardiac arrest, hydropneumothorax, and bleeding requiring angioembolization.[7] Fortunately, we did not encounter these complications. Others authors have observed similar complications.[8-16] Farrell and Hicks found that platelet count <100,000/mm^3 was a significant risk factor for bleeding.[10] Transient hematuria (lasting < 24 h) is a frequent finding after PCN. We did not encounter any major bleeding in our patients who required major interventions like angioembolization or nephrectomy. The cause of bleeding may be uremia related coagulation abnormality and bleeding disorder like thrombocytopenia and thrombosthenia. Prior to PCN, patient should be optimized by correction of hydration status, acidosis, electrolyte imbalance, and many times, dialysis may be necessary. Lee *et al.* found that although emergency PCN is a safe procedure, diabetes mellitus, hypertension, and obesity are associated with increased risk of complication.[11,12] Similar to their finding, we also noticed an experienced urologist is needed when a repeat procedure is needed after a failed PCN. Egilmez *et al.* performed PCN in more than 1100 patients under CT guidance and found no major complication. He also advised that PCN in nondilated system should preferably be done with CT guidance.[17] Skolarikos *et al.* observed that outcome of PCN did not vary among operator experience and is not affected by duty hours.[13] In our series, most of the time PCN is done by resident of different level of experience and frequently in odd hours. Despite that we were able to achieve success rate at par with the recommended threshold. Rana *et al.*[14] concluded that PCN can be safely done even by urologist. They used renal anatomy and body landmarks for puncture of calyx rather than USG followed by fluoroscope for rest of the procedure. Skolarikos *et al.* used purely USG for entire procedure.[13] Although CT will be a versatile technology for performing PCN as shown by Egilmez *et al.*, having 100% success and nondilated system may not be an obstacle but it requires a radiology suite.[17] A useful substitute to it is combination of USG and fluoroscope which is easily available at a urology center. We used USG for initial puncture of PCS. Subsequent

tract dilation and nephrostomy tube placement were done with the help of fluoroscope. Bahu *et al.* observed that a preexisting infection and neutropenia are important risk factor for subsequent development of pyelonephritis in cancer patients having nephrostomy tube.[18] We also found that PCS is more likely to get infected if PCN was done in the background of infectious etiology. In our series, we observed that the most common cause of revisit to hospital was displaced nephrostomy tube. Repositioning of nephrostomy tube should be done promptly to avoid development of pyonephrosis and urosepsis in an obstructed system. Merely inserting nephrostomy tube is not an end of care, rather the proper care of the tube and closed drainage is equally important.

CONCLUSION

USG guided PCN is a safe, minimally invasive, and effective procedure for upper urinary tract diversion with a low rate of morbidity. Individual complications are within the threshold limits set by the ACR, the SIR. Modified CCS is well applicable and easily reproducible tool for reporting the complications of PCN. Urologist can safely perform PCN with reasonably high success rate and minimal complication.

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Conflicts of interest
There are no conflicts of interest.

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