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Effect of Nephrostomy Tube Calibre (12F *vs*. 24F) on the Safety and Outcome of PCNL - A Prospective Randomized Study

Iqbal Singh, Sunit Prakash Tiwari, Gaurav Garg and Sanjay Gupta*

Department of Surgery, Division of Urology, University College of Medical Sciences, University of Delhi and GTB Hospital, India

Abstract

Aim and Objectives: To compare the safety and clinical outcome of using 12F *vs*. 24F calibre Percutaneous Nephrostomy tube (PCN) in patients undergoing standard PCNL.

Materials and Methods: The present study was a prospective randomised study done at a tertiary care referral centre in North India between November 2014 and April 2016. Eligible patients undergoing PCNL were randomised to receive either (12F) or (24F) PCN tube. We analyzed duration of hematuria, change in the hematocrit, post operative pain using Visual Analogue pain Score (VAS) at 8 h, 16 h, 24 h and 48 h and total analgesic demand (mgs of Diclofenac sodium), duration of urine leak after PCN removal, PCN indwelling time (hours), and the post PCNL complications, using Clavien score.

Results: 12F nephrostomy group showed significantly less post-operative pain and analgesic requirement as compared to 24F nephrostomy group ($p<0.001$). There was no significant difference in duration of hematuria, PCN site leak, PCN indwelling time, stone clearance rates, hospital stay and complications between two groups.

Conclusion: A narrow caliber nephrostomy (12 Fr) was associated with significantly lower operative morbidity and complications than a wider caliber nephrostomy (24 Fr) in terms of post op pain and analgesic requirement.

Keywords: PCNL; Nephrotomy tube; Complications

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Correspondence:
Iqbal Singh, Department of Surgery, Division of Urology, University College of Medical Sciences, University of Delhi, Delhi, India, Tel: 91-11-22586262, 91-9810499222; Fax: 91-11-22590495; E-mail: iqbalsinghp@yahoo.co.uk

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Introduction

Percutaneous Nephrolithotomy (PCNL) is a standard procedure used for management of renal stones [1]. The Percutaneous Nephrostomy (PCN) tube is considered an important component of PCNL kept for drainage at the termination of procedure [1,2]. Most urologists prefer a PCN tube that is 2F to 3F lower than the calibre of the nephrostomy tract [3]. PCN tube drains the pelvicalyceal system, serves as way to tamponade the percutaneous tract [2] and provides an access to the pelvicalyceal system if a second look nephroscopy is needed for the residual calculi [1,2]. Some patients develop complications with pain and prolonged urinary leak at PCN site which may prolong the hospital stay [2]. Placing a Double J (DJ) stent in place of PCN tube (tubeless PCNL) may circumvent the problem of PCN tube however this may be feasible only in select patients with some reports suggesting a higher morbidity of tubeless PCNL [4-6], or when PCN tube is removed prematurely [5]. Thus a PCN tube continues to remain an integral part of PCNL [3]. A narrower calibre PCN tube could be associated with a superior patient outcome in terms of pain and complications *vs.* a wider calibre 24F PCN tube; this formed the rationale for the current study.

Material and Methods

This prospective randomised study was conducted at a large tertiary care referral centre in North India from September 2014 to April 2016. The sample size was calculated based on a study by Maheshwari et al. [2] considering a standard deviation of 8.13 in LBC (Large Bore Catheter) group and 10.38 in PTC (Pigtail Catheter) group [2], to obtain a significant difference of 6.5 h in durations of hematuria, a sample of 32 cases was required in each group at alpha error 5% and power of study =80%, adding 10% of attrition rate, the final sample size chosen was taken as 35 in each group.

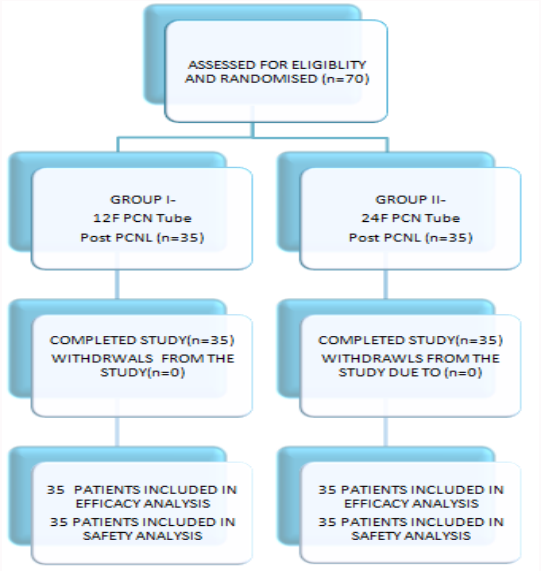

Figure 1: Flow diagram of the study.

After obtaining IEC and written informed consent from all participants of study, 70 eligible select patients underwent standard PCNL [7]. The study was registered with CTRI/2016/11/007443 and PCNL was performed in the manner similar to the technique as previously described by us elsewhere with modification of leaving a 24/12 Fr PCN tube and a temporary ureteral catheter/JJ ueteral stent after PCNL [6,7].

At the end of PCNL procedure patients were computer randomised (plan previously obtained from www.randomisation.com) to receive either a 12 Fr PCN tube (group-1) or 24 Fr PCN tube (group-2). We excluded patients with uncorrected coagulopathy, active UTI, stone burden exceeding 3 cm, patients with bilateral renal stones, and stones in solitary/anomalous kidneys.

We analyzed duration of hematuria, change in the hematocrit, post operative pain using self-assessed Visual Analogue pain Score (VAS) at 8 h, 16 h, 24 h and 48 h and total analgesic demand (mgs of Diclofenac sodium), duration of urine leak after PCN removal (two consecutive dry pads were assumed as stoppage of the leak), and PCN indwelling time (hours). We also recorded post PCNL complications (including UTI, sepsis, collection, urinoma etc), stone clearance on second post operative day (by X-ray/USG KUB), need for auxiliary procedures, mean hospital stay and Clavien score (overall complication).

Statistical analysis

All the analysis was done using Statistical Package for the Social Sciences (SPSS Inc.; Chicago, IL, USA) version 23. Qualitative data were analyzed using chi-square test and quantitative data was analyzed using student t-test. A p-value of <0.05 was considered significant.

Results

As depicted in Figure 1 after randomisation 70 patients (35 in each group) completed the study and were included in the final analysis. Both the groups were comparable in baseline demographic (age, sex, co-morbidities, kidney function etc) and stone characteristics ($p>0.05$) as shown in Table 1a. The mean post operative fall in hematocrit on day 1, duration of hematuria and number of patients requiring blood transfusion was higher in patients with large calibre PCN (24F) compared to patients with narrower calibre PCN (12F) group 1 however the difference was not statistically significant ($p>0.05$). The comparison of various intra-operative and post-operative parameters is depicted in Table 1b. The post operative VAS scores (measured at 8 h, 16 h, 24 h and 48 h) and total analgesic need was significantly lower in group 1 compared to group 2 ($p<0.05$). The total number of patients requiring DJ stent insertion was significantly less in group 1 *vs.* group 2 ($p=0.01$). The post-operative urinary leak duration, PCN indwelling time , mean stone free rates, mean hospital stay and overall Clavien complication scores were similar in both patient groups ($p>0.05$).

Discussion

PCNL is a well accepted minimally invasive therapeutic modality for the vast majority of renal calculi. The present study results re-confirmed the efficacy and safety of PCNL in removing renal stones with only 5.7% patients requiring blood transfusion and 92.8% patients having complete stone clearance on first post operative day.

In order to lower the morbidity of PCNL and ever since the initial description of tubeless PCNL by Bellman et al. [8] and others tubeless PCNL has been advocated mainly in uncomplicated cases in view of significantly lower analgesic requirements and a shorter hospital stay [8-11]. The PCN tubes facilitates unimpeded urinary drainage from the renal pelvicalyceal system, allows drainage of residual blood clot/stone debris and helps in accessing the pelvi-calyceal system in case

Table 1a: Depicting baseline parameters amongst both groups.

Parameters	Groups	N	MEAN	SD	SEM	P-VALUE
Age						
Sex						
Stone burden (cms)	I	35	2.45	0.50	0.84	0.494
	II	35	2.37	0.47	0.7	
KFT	B.Urea I	35	21.57	4.77	0.80	0.921 0.726
	S.Cteat I	35	1.07	0.27	0.04	
	B.Urea II	35	21.47	4.78	0.80	
	S.Creat II	35	1.05	0.26	0.04	
Pre-op baseline Hematocrit (%)	I	35	36.04	3.15	0.53	0.956
	II	35	35.99	3.26	0.55	

I: 12 Fr pig tail, II: 24 Fr nephrostomy, N: sample size

Table 1b: Showing intragroup comparision of primary outcome parameters.

Primary Outcome Parameters	(GROUP I) Mean	(GROUP II) Mean	P
1. Pre-op hematocrit (%)	36.04 ± 3.15	35.99 ± 3.2	0.956
2. Post op D1 hematocrit (%)	34.97 ± 3.0	35.21 ± 2.9	0.733
3. Hematocrit change	1.2 ± 0.9	0.73 ± 0.35	0.363
4. Duration of hematuria (h)	26.06 ± 7.6	24.03 ± 7.0	0.253
5. Analgesic Requirement*	438.57 ± 90.18	578.57 ± 133.00	<0.001
6. Duration of Urine leak (h)	24.31 ± 7.38	24.91 ± 8.30	0.75
7. Mean VAS score: 8 h	6.94 ± 0.98	8.14 ± l.37	<0.001
: 16 h	3.94 ± 0.90	5.14 ± 1.15	<0.001
: 24 h**	2.43 ± 0.94	3.80 ± 1.20	<0.001
: 48 h	1.00 ± 0.68	1.91 ± 0.88	<0.001
8. Mean Hospital stay (days)	4.57 ± 1.09	4.69 ± 0.93	0.639
9. Mean PCN Indwelling time	48.34 ± 5.011	50.03 ± 5.69	0.139
10. Quantative Stone Analysis	CaOx DH+MH (85%)	CaOx DH+MH (90%)	

* Analgesic requirement measured in mgs of Diclofenac Sodium
** VAS score at 24 h was construed to be the Primary endpoint of this study

Table 2: Comparision of outcome parameters in previous studies comparing different nephrostomy tube size after PCNL.

Author	Study	Nos.	PCN Tube Caliber (F)	Mean VAS	Mean Analgesic REQD	Mean Blood Loss	Mean Hospital Stay
Maheshwari et al. [2]	Prospective comparative	20	28	-	6.4[a]	24[e]	NA
		20	9		2.8	28.5	
Desai et al. [9]	Prospective Randomised	10	20	5.3	217[b]	3.9[f]	4.4
		10	9	3.75	140	3	4.3
Marco et al. [11]	Prospective comparative	24	22	4.25	1.6[c]	1.42[g]	3.8
		21	12	3.2	1.1	1.21	3.6
Cormio et al. [1]	Prospective Randomised	1985	>18 Fr	-	NA	3.0[g]	4.4
		1983	<18 Fr			4.3	4.2
Marcovich et al. [10]	Prospective Randomised	20	24	-	22.1[d]	15[h]	3.3
		20	8		22.1	10	3.7
Pietrow et al. [8]	Prospective Randomized	20	22	5.3	91[d]	-	-
		15	10	3.75	78		

[a]=diclofenac sodium, no of injections
[b]=diclofenac sodium in mg
[c]=ketorolac in mg
[d]=morphine equivalent in mg
[e]=change in hematocrit, NA = Not Available
[e]=duration of hematuria in hrs
[f]=decrease in hematocrit (%)
[g]=change in hemoglobin g/dl
[h]=blood transfusion (%)

a relook procedure is needed. In this study a narrower caliber PCN was preferred (over the "tubeless" PCNL) since it had the additional benefit of facilitating re-look nephroscopy in cases of significant residual stone burden.

However, due to some concerns of pain and hemorrhage with an increasing size of PCN tube that may increase the morbidity of PCNL and may at times prolong the hospital stay. The ideal size of PCN tube to be placed after PCNL is yet to be decided. Thus to decrease the problem of post operative PCN tube discomfort following PCNL some investigators explored the utility of deploying a lower caliber PCN tube [2]. This rationale appeared to be based on the premise that technically one would expect that using a narrow/smaller caliber PCN tube could reduce bleeding due to lesser degree of trauma to the renal parenchyma [12,13]. Table 2 depicts a summary of previous publications on the effect of nephrostomy tube calibre on the outcome of PCNL.

Maheshwari et al. [2] reported significant reduction in PCN site urine leak and lower analgesic requirements using a narrow bore catheter (10 Fr) compared to patients with 28 Fr PCN [2].

Pietrow et al. [9] also demonstrated lower post operative pain/analgesic requirement in their 10 Fr group compared to 22F group. The authors concluded that there was no increase in patient morbidity from the use of the narrow calibre PCN tubes.

Similarly Desai et al. [10] compared three groups (group 1 with 20 Fr PCN tube, group 2 with 10 Fr PCN tube and third group with JJ stent only) demonstrated that patients with 20 Fr PCN tube had significantly higher urine leak and analgesic requirement. These

authors concluded that a small-bore PCN tube drainage could be a viable option in patients to avoid stent dysuria. The present study results also showed that there was significant reduction in VAS scores, total analgesic requirements with small size PCN (12F) compared to patients with large size PCN (24F). The difference might also have occurred due to the fact that significantly less number of patients in small PCN group had indwelling stent *in situ* avoiding stent dysuria. Shah et al. [14] also compared narrow bore (8F) PCNL drainage randomized with tubeless PCNL in 33 patients in which the authors demonstrated benefits of decreased postoperative pain, analgesic requirement, and hospital stay without increasing the complications at the expense of stent discomfort in 39% of their patients.

In a published literature review of PCNL using, large tube, small tube, tubeless, or totally tubeless [15], Agarwal et al. [16] reviewed that it was by and large documented that narrower PCN tubes could offer better benefit in terms of reduced post-operative pain and morbidity while simultaneously avoiding stent dysuria, which was demonstrated by our current study too, with the authors concluding that there had been a paradigm shift from the conventional large calibre tube drainage [14], with the appreciation that smaller calibre tubes could offer significant benefit in terms of reduced postoperative pain and morbidity.

Current literature reviews pointedly suggests a definite trend towards minimising the percutaneous tract size in PCNL for renal stones, by deviating away from open surgery towards standard PCNL, mini-PCNL, ultra-mini and micro-PCNL techniques with a greater tendency to apply instruments smaller than 12F size, however their long term outcome is still awaited [17].

Limitations

This study was attempted in a limited small sized adult population with relatively straight forward renal stone burdens up to 3 cm undergoing uncomplicated PCNL. It did not include nephrolithiasis cases with multiple, complex, staghorn stones, pediatric renal stones, compromised stones in renal units and stones with concurrent PUJ obstruction (due to current evidence of using the same being weak and due to paucity of relevant prospective randomized trials documenting the safety of narrow bore PCN in such cases) [18].

Conclusion

A lower caliber (12F) PCN tube facilitates a PCNL may provide an ultimate compromise for managing most uncomplicated PCNL cases by allowing maintenance of the PCN tract and simultaneously maximizing patient comfort in terms of significantly lowering the early post operative pain scores and the analgesic requirement and simultaneously precluding the necessity of an indwelling JJ ureteral stent. While this study demonstrated the efficacy and safety of using narrow calibre PCN tubes in a standard uneventful PCNL, however we feel that larger randomised controlled studies are still be required to elucidate the precise role and efficacy of routine usage of narrow calibre nephrostomy tubes for post PCNL drainage.

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