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A Comparative Study of Standard versus Tubeless Percutaneous Nephrolithotomy

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Abstract: *Percutaneous nephrolithotomy (PNL) is a minimally invasive surgical modality for the management of most renal stones. Technological advancements and refinements have contributed to further lowering the morbidity associated with this procedure. Such refinements include the use of a smaller working sheath and nephroscope (mini PNL), avoidance of a nephrostomy tube (tubeless PNL). This modification in technique allows earlier discharge from the hospital, reduction in postoperative pain, and more rapid recovery. Present study was designed to compare the standard percutaneous nephrolithotomy versus tubeless nephrolithotomy.*

Aims & Objectives: *Both the groups are compared and the main outcome measures were recorded which includes operating time, analgesia requirement, puncture site urinary leakage, puncture site blood leakage and hospital stay.*

Materials & methods: *People living in Kanchipuram and surrounding villages who are attending Urology op in Meenakshi Medical College with Renal and proximal Ureteric calculi of above 1.5cm. 100 cases with 50 cases in each group, group A being tubeless PCNL group and group B being standard PCNL group were allocated in a 2 year period from January 2017 to January 2019.*

Plan for statistical analysis: *Descriptive data were presented as number and percentages with mean and standard deviations wherever required. P value of 0.05 or less was considered to be statistically significant.*

Outcome expected out of the work: *Evaluate the role of tubeless PCNL in minimizing postoperative discomfort and reducing duration of hospital stay.*

Keywords: *Percutaneous nephrolithotomy, nephrostomy, tubeless PCNL, renal calculus, ureteric calculus.*

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I. Introduction

PCNL is considered to be the standard procedure in patients with large renal calculus. The essential step in standard percutaneous nephrolithotomy (PCNL) procedure is placement of a percutaneous nephrostomy tube for drainage. In recent years, the procedure has been reformed to one called as 'tubeless' PCNL in which a double-J stent without nephrostomy tube is placed for internal drainage. Urinary stones are defined as the poly crystalline aggregates composed of variable amounts of crystal and organic matrix components. The most common stone types are calcium oxalate, calcium phosphate, uric acid, struvite i.e., magnesium ammonium phosphate and cysteine. The occurrence of stone disease is 2 to 3 times more in young males than females in the past nevertheless this difference is now declining. The estimated prevalence of renal stone disease is 1% to 5%. Soucie et al proposed that the prevalence of stone disease is 10% in males and 4% in females[1]. Whites are commonly affected than Asians and Afro-Americans. The incidence of stone disease is highest in fourth to sixth decades. Hot arid climate, obesity and sedentary lifestyle predispose to stone formation. Hippocrates had described the renal colic symptoms as follows: "An acute pain is felt in the kidney, the loins, the flank and the testis of the affected side. The patient passes urine frequently. Gradually the urine is suppressed. With the urine, the sand is passed." Initially the management procedures had significant morbidity and sometimes mortality. PCNL had improved reasonably over the last twenty years as a result of technical advancements and perfections in surgical skill for doing PCNL. A milestone in the history of PCNL is the introduction and development of the 'tubeless PCNL' which is now been proposed to have a comparatively lesser morbidity rates than the standard procedure. The purpose of this study is to analyse the evidence -based literature regarding the 'nephrostomy-free' or 'tubeless' PCNL and to assess the safety, efficacy, possibility, and benefits of tubeless PCNL over standard PCNL.

II. Objectives

To systematically review and compare tubeless percutaneous nephrolithotomy (PCNL) with standard PCNL

- Safety
- Effectiveness & Feasibility
- Postoperative pain
- Morbidity & Decreased hospital stay

III. Materials And Methods

The material of this prospective study is formed by 100 patients who attended Urology op with renal and proximal ureteric calculus who underwent PCNL at Meenakshi Medical College, Kanchipuram from January 2017 to January 2019. Case sheets and investigation reports also form the material. The methods are clinical examination, biochemical and radiological investigations, surgical methods (tubeless PCNL or standard PCNL) and follow up. The patients on admission were subjected to physical examination, investigation, treated with IV fluids, antibiotics and were subjected to appropriate surgical procedure. Significant bleeding at the end of procedure was excluded. The post operative period was monitored for complications. After discharge follow up was done.

IV. RESULTS

A clinical study of 100 cases of renal calculus and proximal ureteric calculus who underwent standard and tubeless PCNL were compared and studied during the period of January 2017 to January 2019 and the analysis is as follows:

Table-1 Age Distribution-Descriptive Statistics

	N	MINIMUM	MAXIMUM
AGE IN YEARS	50	19	65

Table 1 explains that in group A, the lowest age was 19 and the highest age was 65.

Table-2 Comorbidity - Frequency Table

COMORBIDITY	FREQUENCY	PERCENT
NIL	36	72%
HYPERTENSION	5	10%
DM	7	14%
BOTH	2	4%
TOTAL	50	100%

The above table shows that in group A, 10% of patients had Hypertension, 14% had diabetes mellitus, and 4% had both diabetes mellitus and Hypertension .

Table-3 Preop Creatinine-Descriptive Statistics

	N	MINIMUM	MAXIMUM	MEAN	STD. DEVIATION
PRE OP CREATININE	50	.6	2.0	.908	.3200

Table 3 explains that in group A, the lowest creatinine was 0.6 and the highest creatinine was 2.0. Mean was 0.908 (table-3).

Table-4 Associated Stone Disease – Frequency Table

		FREQUENCY	PERCENT
	URETERIC CALCULI	3	6%
	BILATERAL	3(6 RENAL UNITS)	6%
	TOTAL	6	12%
	SYSTEM	41	82%
TOTAL		50	100%

The above table explains that in group A, 6% of patients had ureteric calculi and 6% had bilateral stone disease.

Table-5 Puncture Site - Frequency Table

PUNCTURE SITE		FREQUENCY	PERCENT
	INFERIOR CALYX	36	72%
	MIDDLE CALYX	9	18%
	SUPERIOR CALYX	5	10%
	TOTAL	50	100%

In group a, 72% underwent inferior calyceal puncture, 18% underwent middle calyceal puncture and 10% underwent superior calyceal puncture.

Table-6 Gender Distribution Cross Table

			GROUP		TOTAL
			GROUP A	GROUP B	
SEX	MALE	COUNT	32	32	64
		% WITHIN GROUP	64.0%	64.0%	64.0%
	FEMALE	COUNT	18	18	36
		% WITHIN GROUP	36.0%	36.0%	36.0%
TOTAL		COUNT	50	50	100
		% WITHIN GROUP	100.0%	100.0%	100.0%

On statistical analysis using Chi-square test, it was found that the gender distribution between those of group A and group B was not statistically significant. (p= 1.000) and this is explained in table 6.

Table-7 Laterality Distribution Crosstable

			GROUP		TOTAL
			GROUP A	GROUP B	
SIDE	LEFT	COUNT	26	21	47
		% WITHIN GROUP	52.0%	42.0%	47.0%
	RIGHT	COUNT	24	29	53
		% WITHIN GROUP	48.0%	58.0%	53.0%
TOTAL		COUNT	50	50	100
		% WITHIN GROUP	100.0%	100.0%	100.0%

On statistical analysis using Chi-square test, it was found that the laterality between those of group A and group B was not statistically significant (p= 0.423), (table- 7).

Table-8 Comorbidity Distribution Cross Table

			GROUP		TOTAL
COMORBIDITY			GROUP A	GROUP B	
	NIL	COUNT	36	35	71
		% WITHIN GROUP	72.0%	70.0%	71.0%
	HYPERTENSION	COUNT	5	4	9
		% WITHIN GROUP	10.0%	8.0%	9.0%
	DIABETS MELLITUS	COUNT	7	9	16
		% WITHIN GROUP	14.0%	18.0%	16.0%
	BOTH	COUNT	2	2	4
		% WITHIN GROUP	4.0%	4.0%	4.0%
TOTAL		COUNT	50	50	100
		% WITHIN GROUP	100.0%	100.0%	100.0%

In this study 16(16%) patients had diabetes mellitus, 9(9%) had hypertension and 4(4%) patients had both diseases. Among the group A patients, 7(14%) patients had diabetes mellitus, 5(5%) had hypertension and 2(4%) had both. Among the group B patients, 9(18%) patients had diabetes mellitus, 4(8%) had hypertension and 2(4%) had both. (table- 8). On statistical analysis using Chi-square test, it was found that the comorbidity between those of group A and group B was not statistically significant (p= 0.945).

Table-9 Puncture Site Distribution Crosstable

			GROUP		TOTAL
			GROUP A	GROUP B	
PUNCTURE SITE	INFERIOR CALYX	COUNT	36	38	74
		% WITHIN GROUP	72.0%	76.0%	74.0%
	MIDDLE CALYX	COUNT	9	8	17
		% WITHIN GROUP	18.0%	16.0%	17.0%
	SUPERIOR CALYX	COUNT	5	4	9
		% WITHIN GROUP	10.0%	8.0%	9.0%
TOTAL		COUNT	50	50	100
		% WITHIN GROUP	100.0%	100.0%	100.0%

In this study, 74 (74%) patients underwent lower calyceal puncture, 17 (17%) patients underwent middle calyceal puncture and 9(9%) underwent upper calyceal puncture.In group A, 36(72%) patients underwent lower calyceal puncture, 9(18%) patients underwent middle calyceal puncture and 5(10%) underwent

upper calyceal puncture. In group B, 38(76%) patients underwent lower calyceal puncture, 8(16%) patients underwent middle calyceal puncture and 4(8%) underwent upper calyceal puncture (table-9). On statistical analysis using Chi-square test, it was found that the puncture site between those of group A and group B was not statistically significant (p= 0.894).

Table-10 Complications Distribution Cross Table

			GROUP		TOTAL
			GROUP A	GROUP B	
COMPLICATIONS	NO COMPLICATIONS	COUNT	44	43	87
		% WITHIN GROUP	88.0%	86.0%	87.0%
	HEMATURIA	COUNT	1	2	3
		% WITHIN GROUP	2.0%	4.0%	3.0%
	UROSEPSIS	COUNT	5	5	10
		% WITHIN GROUP	10.0%	10.0%	10.0%
TOTAL		COUNT	50	50	100
		% WITHIN GROUP	100.0%	100.0%	100.0%

In this study, 3(3%) patients developed hematuria and 10(10%) patients developed urosepsis. Among those in group A, 1(2%) patient had hematuria and 5(10%) patients had urosepsis. In group B, 2(4%) patients had hematuria and 5(10%) patients had urosepsis (table-10). All these patients were managed conservatively. One patient in group A had urosepsis with PCS dilatation and underwent PCN (table-10). On statistical analysis using chi-square test, it was found that the complication rate between those of group a and group b was not statistically significant (p= 0.842).

Table- 11 Complications

COMORBID				GROUP		TOTAL	P-VALUE
				GROUP A	GROUP B		
NIL	COMPLICATION	NO COMPLICATION	COUNT	33	35	68	0.218
			% within group	91.7%	100.0%	95.8%	
		BLEEDING	COUNT	1	0	1	
			% within group	2.8%	0%	1.4%	
		URO SEPSIS	COUNT	2	0	2	
			% within group	5.6%	0%	2.8%	
	TOTAL		COUNT	36	35	71	
			% within group	100.0%	100.0%	100.0%	
HYPERTENSION	COMPLICATION	NO COMPLICATION	COUNT	4	2	6	0.455
			% within group	80.0%	50.0%	66.7%	
		BLEEDING	COUNT	0	1	1	
			% within group	0%	25.0%	11.1%	
		URO SEPSIS	COUNT	1	1	2	
			% within group	20.0%	25.0%	22.2%	
	TOTAL		COUNT	5	4	9	
			% within group	100.0%	100.0%	100.0%	
DM	COMPLICATION	NO COMPLICATION	COUNT	6	6	12	0.383
			% within group	85.7%	66.7%	75.0%	
		UROSEPSIS	COUNT	1	3	4	
			% within group	14.3%	33.3%	25.0%	
	TOTAL		COUNT	7	9	16	
			% within group	100.0%	100.0%	100.0%	
BOTH	COMPLICATION	NO	COUNT	1	0	1	0.368

		COMPLICATION					
			% within group	50.0%	0%	25.0%	
		BLEEDING	count	0	1	1	
			% within group	0%	50.0%	25.0%	
		UROSEPSIS	count	1	1	2	
			% within group	50.0%	50.0%	50.0%	
	TOTAL		COUNT	2	2	4	
			% within group	100.0%	100.0%	100.0%	

In this study there is no difference between complication rate in patients with comorbidity between two groups**.(**tab-11)

Table-12 Stone Clearance Distribution Crosstable

			GROUP		TOTAL
			GROUP A	GROUP B	
STONE CLEARANCE	COMPLETE	COUNT	48	47	95
		% WITHIN GROUP	96.0%	94.0%	95.0%
	INCOMPLETE	COUNT	2	3	5
		% WITHIN GROUP	4.0%	6.0%	5.0%
TOTAL		COUNT	50	50	100
		% WITHIN GROUP	100.0%	100.0%	100.0%

In this study, 94(94%) patients had complete stone clearance. Among group A patients, 48(96%) had complete stone clearance. Among group B patients, 46(94%) had complete stone clearance (table-12). On statistical analysis using Chi-square test it was found that the stone clearance between those of group A and group B was not statistically significant (p= 0.845)(table- 12).

Table-13 Ancillary Procedure Distribution Crosstable

			GROUP		TOTAL
			GROUP A	GROUP B	
ANCILLARY PROCEDURE	NIL	COUNT	44	43	87
		% WITHIN GROUP	88.0%	86.0%	87.0%
	L URS	COUNT	1	2	3
		% WITHIN GROUP	2.0%	4.0%	3.0%
	R URS	COUNT	2	3	5
		% WITHIN GROUP	4.0%	6.0%	5.0%
	ESWL	COUNT	2	2	4
		% WITHIN GROUP	4.0%	4.0%	4.0%
	PCN	COUNT	1	0	1
		% WITHIN GROUP	2.0%	0%	1.0%
TOTAL		COUNT	50	50	100
		% WITHIN GROUP	100.0%	100.0%	100.0%

In this study, 3(3%) patients required LT URS for left ureteric calculus, 5(5%) patients required RT URS, 4 (4%) patient needed ESWL and 1(1%) patient underwent PCN.In group A, 1(2%) patient required LT URS for left ureteric calculus, 2(4%) patients required RT URS, 2(4%) patients needed ESWL and 1(2%) patient underwent PCN. In group B, 2(4%) patients required LT URS for left ureteric calculus, 3(6%) patients required RT URS, 2(4%) patient needed ESWL and no patient underwent PCN (table-13). On statistical analysis using Chi-square test, it was found that the number of ancillary procedures done between those of group A and group B was not statistically significant (table-13).

Table-14 T-Test-Group Statistics

	GROUP	N	MEAN	P-VALUE
AGE IN YEARS	GROUP A	50	37.78	0.409
	GROUP B	50	39.86	
STONE SIZE	GROUP A	50	2.998	0.333
	GROUP B	50	3.088	
OPERATION TIME	GROUP A	50	54.94	0.693
	GROUP B	50	54.62	

DROP IN HB	GROUP A	50	.744	0.777
	GROUP B	50	.760	
NO. OF BLOOD TRANSFUSION	GROUP A	50	.10	0.448
	GROUP B	50	.16	
ANALGESIC REQUIREMENT	GROUP A	50	121.00	0.000
	GROUP B	50	170.00	
HOSPITAL STAY	GROUP A	50	3.32	0.000
	GROUP B	50	4.16	
PRE OP CREATININE	GROUP A	50	.908	0.847
	GROUP B	50	.920	

In this study, average age in group A was 37.78 yrs and group B's average age was 39.89 yrs. Group A's average stone size was 2.998 cm and group B's average stone size was 3.088 cm. Group A's average operation time was 54.94 min and group B's average operation time was 54.62 min. Group A's average drop in HB was 0.744 g% and group B's average drop in HB was 0.760 g%. In group A, 10% of patients required blood transfusion and in group B, 16% of patients needed blood transfusion. In group A, the average amount of analgesic requirement was 121 mg of tramadol and in group B, the average amount of analgesic requirement was 170 mg of tramadol. Average no. of days of hospital stay for group A patients was 3.32 days and for group B, the average no. of days of hospital stay was 4.16 days. In group A, the average preop creatinine value was 0.908 mg/dl and in group B, the average preop creatinine value was 0.920 mg/dl (table-14). On statistical analysis,

1. Age of the patient between those of group A and group B was not statistically significant (P-0.409) (table-14).
2. Stone size between those of group A and group B was not statistically significant (P-0.333) (table-14).
3. Operation time between those of group A and group B was not statistically significant (P-0.693) (table-14).
4. Drop in HB between those of group A and group B was not statistically significant (P-0.777) (table-14).
5. Blood transfusion rate between those of group A and group B was not statistically significant (P<0.001) (table-14).
6. Analgesic requirement between those of group A and group B was statistically significant (P<0.001) (table-14).
7. Preop creatinine between those of group A and group B was not statistically significant (P-0.847) (table-14).

V. Discussion

Renal stone disease is one of the most common urological problems. Medical management may not be feasible in all circumstances. Surgical management is more effective in treatment of stone disease. Furthermore medical management is more helpful in preventing recurrences following surgical removal rather than as primary therapy. Surgical management as previously explained comprises both open and endourological procedures. In the contemporary age renal calculus surgery is always done through minimal access procedures. Over a period, PCNL has developed to be a safer and relatively less morbid procedure when compared to an open stone surgery. Due to its lesser cost, shorter operative time, minimal requirement for blood transfusion and analgesics and ability of the patients to regain their routine daily life activities sooner make PCNL the preferred procedure at recent times. The procedure when attempted initially was time consuming, tedious for both patient and treating surgeon and with considerable morbidity and some mortality. Because of technical improvements in imaging and optics and with better understanding of the pathology behind the significant morbidity, the procedure has been standardized. To begin with, gaining an access was believed to be a crucial step in the success of the procedure. With an excellent preoperative imaging provided by the reconstructed computerised tomography nowadays, localization and delineation of the extent of calculi is far better. Excellent demarcation of pelvicalyceal anatomy has facilitated in gaining an easier access to the pelvicalyceal system. Furthermore technical advancements like fluoroscopic and ultrasonographic guided attempts to gain an access helped out in effectively creating a tract into the pelvicalyceal system. As already mentioned there are antegrade and retrograde techniques of access into the pelvicalyceal system but still the most preferred route is the antegrade access. Surgical skills in PCNL improved a lot during the years and the procedure has become more perfect, meaning that the tract made is just sufficient for the procedure to be done and unnecessary tissue handling is avoided. This is an important step in the increase in success rates of the procedure in recent years. Dilatation of the tract is accomplished by various types of dilators like coaxial Alken dilators, Amplatz semi rigid dilators and balloon dilators. Improvements in optics and miniaturization of endo instruments have also lessened the morbidity rates and thus increased the success rate. With the introduction of flexible instruments, we have a better access to all parts of the collecting system without a necessity for additional tracts. Improvements in intracorporeal lithotripters have also increased the success rate of percutaneous nephrolithotomy. Smaller sized

lithotripter probes and effective retrieval of stone fragments have enhanced the outcome of the procedure. Despite the advancements and subsequent perfections, a few morbidities continue to affect the patients. Nephrostomy tube kept after the procedure adds to the patient's discomfort. In our study we compared tubeless PCNL Vs standard PCNL in patients with stone disease. Tubeless PCNL was performed with success in patients of age 19 yrs to 65 yrs. Tubeless PCNL was done even in patients with elevated renal parameters as 5(10%) patients in group A had elevated renal parameters. The highest creatinine value in group A is 2mg/dl. Tubeless PCNL was safely done even in patients with DM, HTN as 5(10%) patients had HTN and 7(14%) patients had DM and 2(4%) had both in tubeless PCNL group. Tubeless PCNL was done in patients with stone disease irrespective of tract location (upper, middle or lower). In tubeless PCNL group 3(6%) of the patients had B/L stone disease and underwent B/L tubeless PCNL in two sittings. 3(6%) patients had associated ureteric calculi and underwent URS and PCNL in the same sitting. Operative time in both the groups was similar(GROUP A 54.92 Minvs GROUP B 54.62 Min). The postoperative drop in HB and blood transfusion rate was similar in both groups under study. Presence of residual calculi was similar in both the groups and these residual calculi were treated with ESWL. The need for post op analgesia was less with tubeless PCNL group. The Group A patients needed 121 mg of Tramadol whereas Group B needed 170mg.This is statistically significant with a p value of <0.001. A study conducted by both Madhu S. Agrawal etal & B.Lojanapiwat et al showed similar results. Post op complications were similar in both groups. Post op complications in both the groups were managed conservatively. But one patient from group A developed urosepsis with PCS dilatation. This patient underwent PCN. Length of Postoperative hospital stay was longer in standard PCNL group (4.16 days) compared to the tubeless PCNL group(3.32 days).This is statistically significant with a p value of <0.001. Studies conducted by Madhu S. Agrawalet al,B.Lojanapiwat et al,Hemendra Shah et al also showed similar results.

VI. Conclusion

Tubeless PCNL is a relative safe procedure even in patients with elevated renal parameters and in those with associated comorbid conditions. Tubeless PCNL is safe in any tract location (upper, middle, lower). Tubeless PCNL can be safely done even in patients with bilateral disease. Tubeless PCNL requires less analgesics and less hospital stay. Both standard and tube less PCNL have similar post op complication rate. Tubeless PCNL is a very safe and very effective procedure if done in selected group of patients.

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