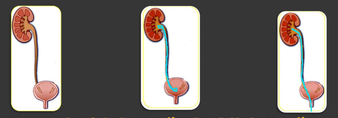
A PROSPECTIVE RANDOMIZED STUDY ASSESING SAFTEY & EFFICACY OF COMPLETELY TUBELESS PCNL VS PCNL WITH DJ STENT VS PCNL WITH URETERIC CATHETER



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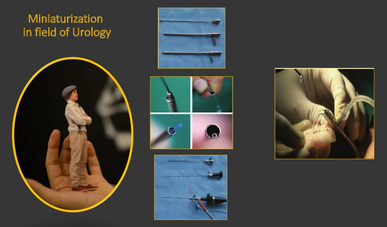
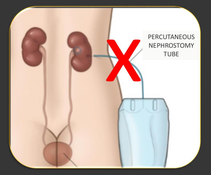
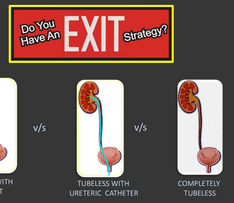
Miniaturization in field of Urology



Trends are towards Tubeless PCNL



Exit strategy after Tubeless PCNL ??



Aim

To observe the outcomes of 3 EXIT STATERGIES following Tubeless PCNL with reference to Safety & Efficacy –

1) Completely tubeless PCNL (TL)
2) Tubeless PCNL with DJ stent (TLDJ)
3) Tubeless PCNL with ureteric catheter (TLUC)

Patients and Methods

- Prospective randomised study
- Conducted in S.S. UROLOGICAL INSTITUTE, MUMBAI, INDIA
- August 2014 to August 2016
- 102 patients (77 men and 25 women) were included

Inclusion Criteria

- Renal calculi,
- upper 1/3rd ureteric calculi,
- PUJ calculi

taken up for PCNL were included in the study.

Exclusion Criteria

PRE OPERATIVE

- Patients with Solitary kidney
- Patients with compromised renal function
- Patients with partial and complete staghorn calculi
- Patients with Infection stones

INTRA OPERATIVE

- Patients undergoing concomitant ureterolithotripsy
- Intra-operative uncontrolled bleeding
- Major Pelvic/ Infundibular injury
- Patients with retained stone-fragments in kidney or ureter

Patients and Methods

Sample size

1. No prior studies to guide the sample size
1. Based on the approximate case load extrapolated from Medical records data- Period of 2 years or 120 cases whichever is earlier

Randomization

1. 120 Sealed covers prepared before the start of the study and opened at the end of each procedure
1. 102 patients operated during the 2 year period

Patients and Methods

4 patients were excluded from the study after they required nephrostomy placement because of bleeding and infundibular injury.

3 patients had intra-operative bleeding

1 patient had infundibular injury due to infundibular stenosis

Subjective and Objective assessment

- Safety - evaluated by Clavien-Dindo score
- Efficacy -Post-operative pain (VAS), Hospital stay, Time taken to revert to daily activities, Stone free status
- All Patients were operated in prone position and under General Anaesthesia

TRACT DILATATION	SCOPE USED	ENERGY USED
< 16 F	8/9.8 F URETEROSCOPE	LASER
18 F	15 F MINI NEPHROSCOPE	LASER
24-26 F	24 F NEPHROSCOPE	PNEUMATIC LITHOCLAST

Results

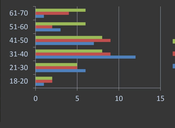
- Out of 98 patients-

Completely Tubeless PCNL	Tubeless with DJ stent	Tubeless with Ureteric catheter
32	31	35

- There were 76 males and 22 females
- Majority of Patients were 20-30 years of age (18-79 Years)

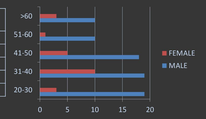
AGE DISTRIBUTION

Age	Group I (COMPLETELY TUBELESS) (n=32)		Group II (TUBELESS WITH DJ STENT) (n=31)		Group III (TUBELESS WITH URETERIC CATHETER) (n=35)	
	Male	Female	Male	Female	Male	Female
18 – 20	1	0	2	0	2	0
21 – 30	5	1	5	0	4	1
31 – 40	7	5	5	4	6	2
41 – 50	4	3	7	2	8	0
51 – 60	2	1	2	0	6	0
61 – 70	0	1	3	1	5	1
71 - 80	2	0	0	0	0	0



SEX DISTRIBUTION

AGE	SEX	
	MALE	FEMALE
20-30	19	3
31-40	19	10
41-50	18	5
51-60	10	1
>60	10	3

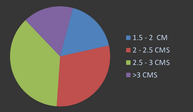


STONE SIZE

STONE SIZE (CM5)	NUMBER
1.5 – 2 CM	17
2 – 2.5 CM	29
2.5 – 3 CM	36
>3 CM	16

The maximum stone size was 3.8 cm

Stone size was measured with Ultrasound and NCCT KUB

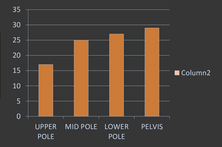


STONE SIDE

RIGHT	41
LEFT	57

STONE SITE (LOCATION)

SITE	NUMBER
UPPER POLE	17
MID POLE	25
LOWER POLE	27
PELVIS	29



PATIENTS COMPLICATIONS

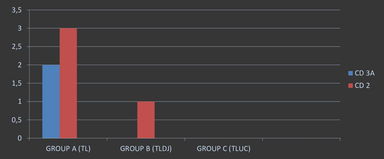
GROUP 1	NO OF PATIENTS	DESCRIPTION	COMPLICATION	CD GRADE
COMPLETELY TUBELESS	2 PATIENTS	40/MALE , RT UPPER POLE 18F DILATATION 26/FEMALE , LT LOWER POLE 26 F DILATATION	(1) POST OPERATIVE SEPSIS AND PERINEPHRIC COLLECTION (1) RETAINED CALCULUS - URETER	CD 3A REQUIRING DJ STENTING AND PERINEPHRIC DRAIN URS TRIPSY
	1 PATIENT	35/FEMALE, RIGHT LOWER POLE 26 F DILATATION	HAEMORRHAGE	CD 2 REQUIRING BLOOD TRANSFUSION
	2 PATIENTS	42/FEMALE, LEFT LOWER POLE, 18 F DILATATION 51/MALE, LEFT LOWER POLE 26 F DILATATION	POST OPERATIVE SEPSIS	CD 2 CONTROLLED WITH HIGHER ANTIBIOTICS – (IMIPENAM)

PATIENT COMPLICATIONS

GROUP 2	NO OF PATIENTS	COMPLICATION	CD GRADE
TUBELESS WITH DJ STENT	1	62/MALE, RIGHT MIDPOLE POLE 18 F DILATATION POST OPERATIVE HIGHER ANTIBIOTICS FOR SEPSIS (IMIPENAM)	2

GROUP 3	NO OF PATIENTS	COMPLICATION	CD GRADE
TUBELESS WITH URETERIC CATHETER	0	NIL	-

1. PATIENT COMPLICATIONS

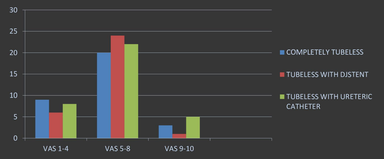


1. PATIENT COMPLICATIONS

GROUP	NO COMPLICATIONS	COMPLICATIONS	ROW TOTALS
TL	27 (30.04) [0.31]	5 (1.96) [4.72]	32
TL DJ	30 (29.10) [0.03]	1 (1.90) [0.42]	31
TL UC	35	0	35
COLUMN TOTALS	92	6	98 (GRAND TOTAL)

The chi-square statistic is 7.7626. The p- value is 0.020624. The result is significant at $p < 0.05$

2. PAIN SCORING BY VAS

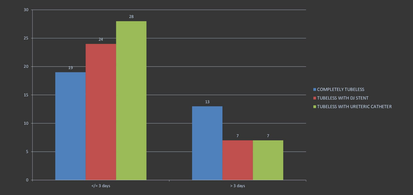


2. PAIN SCORING BY VAS

VAS	COMPLETELY TUBELESS	TUBELESS WITH DJ STENT	TURELESS WITH URETERIC CATHETER
1-4	9 (7.51) [0.30]	6 (7.28) [0.22]	8 (8.21) [0.01]
5-8	20 (21.55) [0.11]	24 (20.88) [0.47]	22 (23.57) [0.10]
9-10	3 (2.94) [0.00]	1 (2.85) [1.20]	5 (3.21) [0.99]
	32	31	35

The chi-square statistic is 3.3997. The p-value is 0.4933. The result is not significant at $p < 0.05$

3. Duration of hospital stay

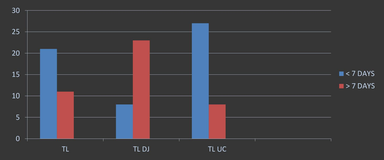


3. Duration of Hospital stay

GROUP	NUMBER OF DAYS		ROW TOTALS
	=< 3 DAYS	> 3 DAYS	
TL	19 (23.18) [0.75]	13 (8.82) [1.99]	32
TL DJ	24 (22.46) [0.11]	7 (8.54) [0.28]	31
TL UC	28 (25.36) [0.28]	7 (9.64) [0.72]	35
COLUMN TOTALS	71	27	98

The chi-square statistic is 4.1238. The p-value is 0.127215. The result is not significant at $p < .05$

4. Time taken to return to normal activities

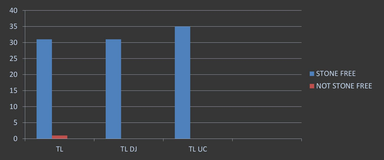


4. Time taken to return to normal activities

GROUP	TIME TAKEN		ROW TOTALS
	< 7 DAYS	> 7 DAYS	
TL	21 (18.29) [0.40]	11 (13.71) [0.54]	32
TLDJ	8 (17.71) [5.33]	23 (13.29) [7.10]	31
TL UC	27 (20.00) [2.45]	8 (15.00) [3.27]	35
COLUMN TOTALS	56	42	98 (GRAND TOTAL)

The chi-square statistic is 19.0869. The p-value is 0.000072. The result is significant at $p < 0.05$

5. Efficacy of the procedure



5. Efficacy of the procedure

GROUP	STONE FREE	NOT STONE FREE	ROW TOTALS
TL	31	1	32
TL DJ	31	0	31
TL UC	35	0	35
COLUMN TOTALS	97	1	98 (GRAND TOTAL)

The chi-square statistic is 2.0838. The p-value is 0.35279. The result is not significant at $p < 0.05$

Results

- 5 patients in the completely tubeless group had Clavien-Dindo grade 2-3 complications . No significant complications were observed in other groups (p-value 0.020624)
- Post-operative pain, Average hospital stay, Efficacy of the procedure were similar in all the groups.
- Time taken to return to daily activities was more in Tubeless with DJ stent group.

Salient features

- In past, there are many studies judging the feasibility of Tubeless PCNL or comparing Tubeless PCNL to standard PCNL with Nephrostomy
- This is one of the early studies based on the exit strategy in Patients undergoing Tubeless PCNL

- Our study gives an insight to strategical decision making while choosing the appropriate Exit Strategy.

TAKE HOME MESSAGE 1

Patients undergoing Tubeless PCNL with Ureteric catheter had better post operative outcomes with respect to

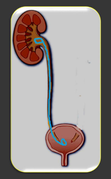
- fewer complications,
- faster recovery and
- better satisfaction as the need for a secondary procedure i.e. DJ stent removal was avoided.

TAKE HOME MESSAGE 2

Significant number of patients undergoing tubeless PCNL with DJ stent

- complained of dysuria,
- flank pain and
- had higher post operative VAP scores.

- Further, they had to undergo a secondary procedure of DJ stent removal 2 weeks post-operatively.



TAKE HOME MESSAGE 3

- Patients undergoing Completely Tubeless PCNL developed more complications and some required ancillary procedures
- so completely tubeless PCNL should be used judiciously as the complication rate is higher in that group.

Caution

- Randomised controlled trials like ours from multiple centres are required so as to fully establish the efficiency of the type of tubeless EXIT method

THANK YOU

Please choose your exit strategy wisely

v/s