Original Research Article

URETERIC STENTING AND PERCUTANEOUS NEPHROSTOMY INSERTION FOR ACUTE URETERIC OBSTRUCTION: A MULTI-CENTERED PROSPECTIVE STUDY TO COMPARE THE QUALITY OF LIFE BETWEEN BOTH PROCEDURES

Abstract

Background: To compare the quality of life and pain scores between double J ureteric stenting and percutaneous nephrostomy (PCN) insertion in patients who presented with acute ureteral obstruction secondary to urolithiasis.

Methods: This is a prospective, multi-centre study which compares the quality of life in patients who have either done nephrostomy tube insertion or double J ureteral stenting. This study was performed over a span of 18 months at two urology centres in Malaysia. 40 double J ureteric stents and 40 percutaneous nephrostomy tube patients were recruited for this study. Patients's pain scores and quality of life post procedures were assessed using the visual analogue scale and EuroQol questionnaires at 2 time points (Day1-2 and at 1 month post drainage).

Results: The patients' demographics and pre-drainage data were similar except for where the stones were located. Most of the patients with proximal ureteric stones (75%) and those who presented with fever or sepsis (76%) underwent PCN insertion. At time 0, although both groups achieved similar overall QoL and pain scores, more post PCN patients reported difficulties in self-care (p=0.002), mobility (p=0.041) and resuming usual activities (p=0.012). Symptoms in PCN group improved with time, translating in the higher QoL scores at time 1. In contrary, more double J ureteric stenting patients presented to the emergency room with complaints related to their procedure. Moreover, their assessments scores deteriorated over time, and they had a significant higher score in the pain domain compared to PCN patients at time1 (p=0.014).

Conclusion: Both double J ureteric stenting and PCN have negative impacts on a patient's quality of life. Particularly in usual activities, pain and mobility. If there is a delay in definitive treatment, this study supports the usage of PCN as opposed to double J ureteric stenting. This is evidenced by a marked improvement in a patient's quality of life score and wellness score with time. In contrary, with the use of double J ureteric stenting, the quality of life and wellness outcomes significantly deteriorates over time as compared to those who have PCN.

Keywords: *ureteric stent, nephrostomy tube, acute ureteral obstruction, quality of life*

Introduction

All urologists will concur that obstructing stones with sepsis, pain or acute kidney injuries will require immediate surgical actions. When such concerns arise, decompression of the urinary system either by nephrostomy tube insertion or ureteral stenting is commonly done.

Percutaneous nephrostomy tube is a procedure of which a pigtail drainage tube is inserted into the renal calyx system, often by an interventional radiologist [1]. On the other hand, ureteral stenting is usually done by urologists, which is the insertion of stents into the ureter. A urologist decision with regards to which drainage method to be used, is remarkably influenced by both the clinician's and patient's understanding of risks, complications, complexity and quality of life (QoL) issues which are related to these two drainage methods. Commonly, it takes an unknown period to achieve definitive treatment for the patients. Because of this, clinicians would be biased and will prefer the usage of ureteral stenting compared to the usage of nephrostomy tubes. These are in assumption that the patients would be less bothered by the stent during the waiting period. Thus, ureteral stenting is a more widely used practice, in treating subjects who present with symptoms of acute ureteric obstruction.

There are several studies which compares the efficacy of ureteral double J stent and percutaneous nephrostomy tube (PCN) in subjects diagnosed with obstructive ureteral stones. Out of these studies, two prospective studies [2, 3] incorporated QoL questionnaires (EuroQol EQ-5D and intervention-specific questionnaire) which compared patients perceptions of the two different drainage methods while awaiting definitive stone treatment. These were not conclusive with regards to the gross impact of the different drainage methods on the patients's QoL.

A study carried out by Joshi et al. [4] was conducted at a single time point, upon patients admission for lithotripsy. In conclusion, there was no notable difference in the overall health condition, suggesting a patient's preference for either modality of treatment. Conversely, in the study by Mokhmalji et al. [5] QoL was assessed with EQ-5D questionnaire at two time points (immediately following drainage and 2–4 weeks thereafter). Although the results were not statistically significant, a tendency to favour PCN was evident. This is seen particularly in male patients and in patients aged less than 40. QoL progressively improved in the PCN group but deteriorated in the stenting group. Another recent prospective non-randomized study [6] evaluated the QoL before and after the drainage procedure with Wisconsin Stone QOL questionnaire. The double J stent group of patients recorded a poorer QoL after drainage while PCN subjects had similar ratings. Double J stent patients also had worse urinary symptoms and the need for painkillers increased as well.

The aim of this study was to ascertain if, in the setting of acute ureteral obstruction with urolithiasis, whether these two renal drainage techniques truly have impacts on a patient's QoL. This study also looks at whether the effect changes over time while awaiting definitive treatment. Quality of life was assessed using EQ 5D questionnaire. This is a validated self-assessed, health related, quality of life questionnaire which has been extensively used in trial, population studies and clinical settings. Such data is important to help the physician and patient decide on the preferred drainage technique.

Methods

This prospective, multi-centre study is an Institutional Review Board approved study which work towards comparing the quality of life in patients who have either done nephrostomy tube insertion or retrograde ureteral stenting. This study was performed over a span of 18

months at two urology centres in Malaysia. A total of 45 patients from Hospital Sultanah Bahiyah, Alor Setar and 41 patients from Hospital Selayang were assessed for enrolment for this study. Among them, 3 cases were excluded for declining to participate. However, 2 patients from the stenting group and 1 patient from the PCN group dropped out from the subsequent follow up. Making a total of 80 patients who participated in this study. These patients were informed of the study during their hospital admissions and clinic visits. If they choose to participate, the consent forms will be signed and dated.

Patients who presented with urolithiasis with obstructing uropathy were offered renal drainage options when definitive therapy was not available immediately or when a two-stage procedure was considered a safer approach. Diagnosis of the obstructing ureteral stone was made by either a non-contrasted CT or a combination of renal ultrasound and abdominal radiograph. Patients who were in the inclusion criteria were those with obstructing ureteral stones with either fever (> 38°c), acute renal failure (eGFR ≤ 60 ml/min), intractable pain, those with stone in solitary kidneys or those with stones in both kidney. Exclusion criteria were those whose age were less than 18 years, pregnant women and patients with contraindications to either form of drainage (e.g. uncorrected coagulopathy excluding percutaneous drainage, hemodynamic instability or abnormalities of the urinary tract).

Decision either for percutaneous nephrostomy or double J stenting is based on the surgeon's preferences and experience. Percutaneous nephrostomy insertion is preferred in patients who present with sepsis or proximal ureteric stones while double J stenting is often done in patients with distal ureteric stones.

Demographic and preoperative data of eligible patients were obtained. These included a subject's age, race, gender, body mass index (BMI), co-morbidities, urine culture, stone size and its locations. Each subject's baseline and pre drainage estimated GFR and the indications for either type of drainage method were documented as well.

PCN was performed in the angiographic suite by certified interventional radiologists. Local anaesthesia (1% Lidocaine, 5–10 cc) was used routinely and when required, additional parenteral analgesia either with Intravenous Pethidine (50-75 mg) or Intravenous Midazolam (1-5 mg) was administrated. A percutaneous pigtail polyurethane 8.5-french, 25 cm catheter (Cook medical) was then introduced. On the other hand, ureteral stents were inserted by the urologists in the operating room with sedation. Transurethral lignocaine gel (Cathegel) and parenteral analgesia such as intravenous tramadol 50mg and sedation with Intravenous Midazolam (1-5mg) was given prior to each procedure. For this procedure, a guide wire was inserted into the kidney via the rigid cystoscope, this is then followed by a ureteral 5FR catheter insertion. A 6 FR, Percuflex (Boston Scientific) stent of the appropriate length was used. Most commonly, a stent length of 24 to 28 cm was utilized.

Post-procedural pain was measured on the day of the procedure using a verbal visual analogue scale (VAS). The length of hospital stays and days needed to reach baseline eGFR were documented post procedure before the patients were discharged home. QoL was assessed twice: once at post-operative day 1–2 ("time 0") and during their 1 month postoperative follow up at the clinic ("time 1"). Patients were requested to fill out the

designated questionnaires: EuroQol EQ-5D questionnaire on both occasions (time 0 and time 1). EuroQol EQ-5D is a validated tool of general health assessment, consisting of 5 QoL questions and a thermometer indicating general well-being. A higher questionnaire score is associated with lower QoL, while a higher thermometer score is associated with better QoL. During the follow up session at Time 1 (1 month post procedure), a patient's pain score and any complications related to the drainage procedure was reassessed and documented.

This study did not present any direct benefit or risks to the participants. The study procedures are all routine procedures for the disease studied. There is thus minimal risk for subjects. It was conducted after approval from the Head of Urology of respective hospitals, hospital directors and medical research and ethics committees (MREC). The study was conducted in compliance with ethical principles outlined in the Declaration of Helsinky and Malaysian Good Clinical Practise Guidelines.

Statistical analysis

The data was analysed using Statistical Package for the Social Sciences (SPSS) software version 27. Descriptive data was expressed as mean ± standard deviation (SD) unless otherwise stated. Pearson's Chi Square was used to determine the difference if the samples are normally distributed. If non- normally distributed, Fisher's Exact Test was used instead. P value of less than 0.05 is considered statistically significant. The sample size was estimated to be 74 subjects (37 subjects in each group). All patients who have given their feedback to the designated questionnaires at both time points (post procedures and 1 month clinic visit) were included in the statistical analysis.

Results

In total, 40 double J stent patients and 40 PCN patients were analysed. Patient's demographics and pre-drainage data are presented in Table 1. Pre-treatment differences in age, male to female ratio, BMI and pre-morbidities were not significant. Stone diameters, the numbers of patients presented with fever and positive urine growth were also comparable. However, the proportion of stone location (either proximal or distal ureter) was significant between the groups ($p < 0.05$) in which more patients with proximal stones underwent percutaneous nephrostomy tube insertion while more patients with distal stones underwent ureteric stenting. The other significant difference between the groups were length of hospitalisation: patients in the PCN group were found to have longer length of hospital stay on average (mean 3.7 vs 2.2 days). Moreover, they have longer time for renal recovery (2.9 vs 1.8 days) compared to stenting group although it is not statistically significant. Post procedural pain was similar in both groups as measured with VAS at Time 0 but statistically different at Time 1 ($p<0.032$). During the study period there were no cases of failed procedures or conversion from one technique to the other. However, there were statistically significant more double J stent patients presented to the emergency room with complaints related to their procedure compared to PCN patients (17.5% vs 5% respectively, $p = 0.019$), mostly complaining of stent syndrome (haematuria, storage urinary symptoms, dysuria) which required anticholinergic and analgesia. 2 patients in the PCN group presented with dislodged tube and required reinsertion under local anaesthesia. All complications in both groups were Clavien Dindo grade 2 and 3a.

	DJ Stent (n =40)	PCN (n =40)	P value

The indications for drainage were almost similar between the groups (Table 3). The only significant difference between the groups were the presence of sepsis or fever (p<0.042). Patients who presented with fever or sepsis were more likely to undergo nephrostomy tube insertion rather than ureteric stenting (n=19 vs 6). There were more patients with intractable pain who had underwent stenting compared to PCN (n= 18 vs 8), but it was statistically not significant.

EQ-5D questionnaire outcomes are presented in Table 2. At time 0, PCN patients demonstrated more difficulties in resuming their daily activities and perform self-care ($p < 0.05$). Additionally, more PCN patients reported difficulties in mobility compared to stenting patients at both time points 47.5% vs. 5% ($p = 0.041$) at time 0 and 27.5% vs 10% ($p=0.64$) at time 1, respectively. Symptoms which were higher in PCN patients decreased over time, and at time 1, we observed no significant difference in the patient's estimation of their ability to perform self-care, mobility or get by daily activities. In both groups of patients, there was no difference in those who reported symptoms of depression or anxiety. It is important to note that both double J stent and PCN procedures caused either pain or discomfort to a large number of patients at both time points: 60% vs 52.5% at time 0 and 77.5% vs 30 % at time 1, respectively. These proportions were not significantly different at Time 0, although there were opposing trends in the different groups: over time the number of patients complaining of pain increased in the stent-treated group and decreased in the PCN-treated group ($p = 0.014$). While in the PCN group there were no differences between the genders in the pain/ discomfort domain, in the double J stent group, more male patients complained of pain compared to the female patients at Time 1 (n= 19 vs 11, men and women respectively) but this did not reach statistical significance ($p > 0.05$).

Comparing the thermometer rating (Table 3), representing overall health state as assessed subjectively by each patient, scores were similar in both groups at time 0 (73 ± 12 vs. 65 ± 18, $p > 0.05$). This is in line with other reported QoL assessments. Double J stent patients score deteriorated over time, and they had a lower score compared to PCN patients at time1 (65 ± 19 vs. 81.1 ± 11.9 respectively, $p > 0.05$). On univariate analysis, patients gender (male), older age, and decreased length of hospital stay were associated (all $p < 0.05$) with higher thermometer rating score at time 1. Patients BMI, premorbid, stone load, stone locations and drainage methods were not associated with overall health score at time 1. On multivariate analysis, no variable remained significantly associated with time 1 overall health score.

Table 1: Patient's demographics and outcomes

Age (years)	57 (39.5-70.5)	58 (46.5-61)	0.985
Gender- male	23	17	0.137
Gender female	19	21	0.233
BMI kg/m2	28 (24.8-31.1)	26 (23.4-32)	0.175
Hypertension	16 (40%)	13 (32.5%)	0.847
Diabetes	15 (37.5%)	18 (45%)	0.212
Ischaemia Heart disease	10 (25%)	6 (15%)	0.433
CKD	11 (27.5%)	7 (17.5%)	0.477
Baseline eGFR (MDRD, mL/min/1.73m2)	73 (22-103)	68.2 (23-99)	0.273
eGFR at presentation (MDRD, mL/min/1.73m2)	61.9 (41.3-71.6)	57.1 (33-60.2)	0.451
Fever	4 (10%)	13(32.5%)	0.069
Positive urine culture	7 (17.5%)	14 (35%)	0.961
Stone diameter (cm)	1.8(0.7-3.5)	2.1 (0.8-3.7)	0.026
Stone location – Proximal	7 (17.5%)	21 (52.5%)	**0.047**
Stone location – mid ureter	15 (37.5%)	10 (25%)	0.078
Stone location – distal	18 (45%)	9 (22.5%)	**0.043**
Post drainage outcome			
Hospitalization days	2.2 (1-5)	3.7 (1-7)	**0.035**
Time to baseline eGFR	1.8 (1-3.5)	2.9 (1-6)	0.079
Pain score (VAS) at Time 0	5.2 +-2.01	4 +-1.48	0.06
Pain score (VAS) at Time 1	7+-1.5	2.5+-1.19	**0.032**
Complications	7 (17.5%)	2 (5%)	**0.019**

Data presented as Median (IQR 25–75) or Mean ± STD as appropriate
MDRD The Modification of Diet in Renal Disease Study equation
In bold - statistically significant result

Table 2: EQ 5D questionnaire QoL outcomes

	Post procedural Day 1 (Time 0)			Post procedural 1 month (Time 1)		
	DJS	PCN	P value	DJS	PCN	P value
1.Mobility	5 (12.5%)	19 (47.5%)	**0.041**	4 (10%)	11 (27.5%)	0.640
2.Self care	2 (5%)	23 (57.5%)	**0.002**	3 (7.5%)	7 (17.5%)	0.423
3.Usual activities	7 (17.5%)	26 (65%)	**0.012**	12 (30%)	18 (45%)	0.390
4.Pain/discomfort	24 (60%)	21 (52.5)	0.562	31	12 (30%)	**0.014**

				(77.5%)		
5.Anxiety/depression	18 (45%)	20 (50%)	0.122	5 (12.5%)	8 (20%)	0.943
Wellness Score	73+-12	65+-18	0.380	65+-19	81.1+-11.9	0.054

Data presented as numbers and percentage of patients reporting any disabilities/unwellness
In bold - statistically significant result

Table 3: Indication for drainage

Indications for intervention	DJS (n)	PCN (n)	P value
Sepsis/ infection	6	19	**0.042**
Impaired kidney function	11	12	0.911
Intractable pain	18	8	0.077
Solitary kidney	5	2	0.816
Bilateral obstruction	3	1	0.167

N= numbers of patients
In bold - statistically significant result

Discussion

Percutaneous nephrostomy tubes and 'JJ' stents are both established and are commonly used as alternate options for temporary relief of upper urinary tract obstruction. This is especially so in cases of infection, renal failure or intractable pain. Despite this frequently occurring situation, there are only few studies which compares the different renal drainage methods, both including clinical and QoL aspects. These two alternate methods of treatment may be expected to be equal in efficacy; however, a particular method may be expected to be less preferable if it confers deterioration in QoL. This study prospectively compared 40 double J stent procedures to 40 PCN procedures. Selection criteria ensured that all patients were potential candidates for both procedures and analysis revealed similar patient's characteristics in both groups. QoL was evaluated using the Euro- QoI questionnaire at two time points to evaluate symptoms dynamics over time. The aim of selecting EuroQol EQ-5D was to identify whether there were differences in gross defects in the physical and psychosocial well-being between these 2 groups.

Ramsey at el. [7] reported in their review that there appears to have little evidence in suggesting that retrograde stent insertion potentially lead to an increase in bacteraemia. There is also little evidence to ascertain that stent insertion is significantly more hazardous in patients who presented with acute obstructive symptoms. In contrary, PCN insertion is still a preferred drainage method for patient presenting with sepsis or fever. This is in view of its known effectiveness in improving symptoms related to sepsis [8]. Moreover, the difference in choice of the drainage methods for different stone locations can be explained by the feasibility of subsequent definitive treatments. Commonly, patients with distal ureteric stones were stented. This is also because stents can act to dilate the ureter and make future ureteroscopy lithotripsy procedures easier. Patients with proximal ureteric stones, often have percutaneous corporeal nephrolithotomy done for them, of which it would be more so easier if there was a nephrostomy tube inserted before.

Post procedural pain score are comparable in both draining methods, of which, patients from both groups reported high VAS scores. This is in league with results attained from former studies [4, 5]. The findings of higher post-operative pain in the stenting group in this study might be explained by the fact that the procedure was done by passing a rigid cystoscope with local anaesthesia given transurethral and was only done under sedation. In this study, patients in the PCN group took a longer time for renal recovery post drainage. This is supported and consistent with the study by Shoshany et al [9]. The longer hospitalization duration is probably associated with a slower recovery to baseline GFR in the PCN group, as subjects were kept under observation to assess the kidney recovery.

Whilst nephrostomy tubes are associated with complications such as bag leakage or displacement and infections [10, 11], procedure complication rates were generally higher in the double J stent group, opposing the outcomes from the former studies [7]. Ureteric stents are commonly associated with lower urinary tract symptoms and varying degrees of pain in the loin/bladder region [12, 13]. These in turn may have effects on a patient's general health [4]. The urinary symptoms may have had an impact on various domains of general health as indicated by the high percentage of patients reporting problems with daily activities, pain and mobility in the EuroQol analysis. A good proportion of patients with stents experienced pain in the loin region [12, 13]. Adding on to that, patients with stents also experienced pain in the bladder region which could possibly be due to mechanical bladder irritation. Furthermore, there was no alleviation over time, the prevalence and severity of these symptoms did not change, translating to a higher number of emergency room visits in double J stent group. In contrary to the stenting group, PCN patients initially suffered discomfort and difficulties in mobility, self-care, and personal hygiene domains. However, with time, they have adjusted to the presence of a nephrostomy tube. This is demonstrated in Table 2, of which there is a drop in nearly half of the patients reporting difficulties in this domains at time 1. Furthermore, this was reflected by higher overall health state scores in the PCN group at time 1. This finding is corroborated with other studies [3,6] which shown, with time, the general symptoms in PCN subjects improved but it worsened in double J stent patients.

Study Limitations

1. Selection bias may have been introduced through choice of drainage procedure according to a clinician's preference, recruitment rate, possibly influenced by severity of eGFR, or the presence of infection (To avoid any bias related to the underlying pathology, only subjects with urinary calculi as an underlying pathology were selected for the study).
2. Both drainage procedures were done under local anesthesia might lead to biased increase in pain score and discomfort in QoL domains at Time 0.
3. The EuroQol questionnaire may not be sensitive enough to detect all the differences in patients general health, unlike the intervention-specific questions. Subjective QoL can be objectively measured and many instruments have been developed and validated for the clinical use. However, there are no validated intervention-specific

instruments that could perform complete measurement of the impact of PCN or ureteric stents on a patient's QoL. A validated generic instrument along with the intervention-specific questions were necessary to perform such study.

4. The third time point was not assessed, especially at definitive treatment. (To compare the waiting time and symptoms resolution)

Nevertheless, over a period of time, the results of this study supported superior QoL in patients who had nephrostomy tube insertion. With such outcomes, urologists all around the world will have better perspectives regarding the long term consequences and to reconsider their choice of renal drainage, especially in health-care facilities of which definitive treatment might be delayed.

Conclusion

Obstructive ureteric stones which require urgent decompression are commonly seen in the field of Urology. However, both double J stent and PCN have negative impacts on a patient's quality of life, in terms of daily activities, pain and mobility. If there is a delay in definitive treatment for such cases, this study supports the usage of percutaneous nephrostomy (PCN). This is evidenced by a marked improvement in a patient's quality of life, which include post procedural pain scores and wellness scores (mobility, self-care, usual activities, pain score and psychological outcomes). In contrary, with the use of double J Stent , the quality of life and wellness outcomes significantly deteriorates over time as compared to those who have percutaneous nephrostomy (PCN).

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Questionnaire

Part 1

Attribute	Level	Description
Mobility	1	No problems in walking about
	2	Some problems in walking about
	3	Confined to bed
Self-care	1	No problems with self-care
	2	Some problems with washing or dressing self
	3	Unable to wash or dress self
Usual activities	1	No problems with performing usual activities (ie, work, study, housework)
	2	Some problems with performing usual activities
	3	Unable to perform usual activities
Pain or discomfort	1	No pain or discomfort
	2	Moderate pain or discomfort
	3	Extreme pain or discomfort
Anxiety or depression	1	Not anxious or depressed
	2	Moderately anxious or depressed
	3	Extremely anxious or depressed

EuroQol EQ-5D instrument for determining health-related quality of life

Part 2

We would to know how good or bad your health is today

0 is the worst health you can imagine

100 is best health that you can imagine

Draw a “X” on the scale

And write the number you marked here: