

**PERCUTANEOUS NEPHROSTOMY VERSUS
RETROGRADE URETERAL STENTING FOR
ACUTE UPPER OBSTRUCTIVE UROPATHY: A
SYSTEMATIC REVIEW AND META-ANALYSIS**

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**DISSERTATION SUBMITTED IN PARTIAL
FULFILMENT OF THE REQUIREMENT FOR
MASTER OF MEDICINE (RADIOLOGY)**



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DISCLAIMER

I declare that this dissertation records the results of the study performed by me and that it is of my own composition.

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(ZUL KHAIRUL AZWADI BIN ISMAIL)

Date:

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LIST OF SYMBOLS, ABBREVIATIONS AND ACRONYMS

BPH	Benign prostatic hypertrophy
CCT	Controlled clinical trial
CI	Confidence interval
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
MD	Mean difference
PCN	Percutaneous nephrostomy
QoL	Quality of life
RCT	Randomised controlled trial
RD	Risk difference
RR	Risk ratio
RUS	Retrograde ureteral stenting
VAS	Visual analogue scale
WBC	White blood cell count
WHO	World health organization

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ABSTRAK

Latarbelakang

Uropati obstruktif akut menimbulkan morbiditi yang ketara di kalangan pesakit dengan sebarang keadaan yang menyebabkan penyumbatan saluran kencing. Pengalihan kencing segera diperlukan untuk mengelakkan kerosakan pada buah pinggang. Dua pilihan rawatan utama yang dilakukan di banyak pusat termasuk nefrostomi perkutan (PCN) dan retrograde ureteral stenting (RUS).

Objektif

Untuk menilai keberkesanan PCN dalam rawatan uropati obstruktif berbanding dengan RUS.

Kaedah carian

Kami mencari Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, CINAHL, EMBASE dan WHO International Clinical Trials Registry Platform, dan ClinicalTrials.gov. Kami juga mencari senarai rujukan kajian yang disertakan untuk mengenal pasti sebarang percubaan tambahan.

Kriteria pemilihan

Kami merangkumi ujian terkawal secara rawak dan ujian klinikal terkawal yang membandingkan hasil peningkatan klinikal (parameter septik dan tempoh rawatan di hospital), kualiti hidup, gejala berkaitan dengan kencing, kadar kegagalan, kesakitan pasca prosedur (VAS) dan penggunaan analgesik.

Pengumpulan dan analisis data

Kami melakukan analisis statistik menggunakan model kesan rawak dan menyatakan hasilnya sebagai nisbah risiko (RR) dan perbezaan risiko (RD) untuk hasil dikotom dan perbezaan min (MD) untuk hasil berterusan, dengan selang keyakinan 95% (CI).

Keputusan

Sebanyak tujuh percubaan dikenal pasti yang merangkumi 667 pesakit. Meta-analisis data menunjukkan tidak ada perbezaan dalam dua metode dalam peningkatan parameter septik, kualiti hidup, kadar kegagalan, rasa sakit pasca prosedur (VAS) dan penggunaan analgesik. Pesakit yang menerima PCN mengalami kadar hematuria dan disuria yang lebih rendah selepas prosedur tetapi dengan tempoh rawatan di hospital yang lebih lama.

Kesimpulan

Kedua-dua kaedah ini berkesan dalam penyahmampatan sistem kencing yang terhalang tanpa perbezaan yang signifikan dalam kebanyakan hasil. PCN lebih disukai daripada RUS kerana kesan yang lebih rendah terhadap kualiti hidup pesakit selepas prosedur kerana hematuria dan disuria walaupun dikaitkan dengan jangka masa rawatan yang agak lama di hospital.

Kata kunci: nefrostomi perkutan, retrograde ureteral stenting, uropati obstruktif akut

ABSTRACT

Background

Acute obstructive uropathy poses significant morbidity among patients with any condition leading to urinary tract obstruction. Immediate urinary diversion is required to prevent further damage to the kidneys. Two main treatment options performed in many centres include percutaneous nephrostomy (PCN) and retrograde ureteral stenting (RUS).

Objectives

To assess the efficacy of PCN in the treatment of obstructive uropathy in comparison to RUS.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, CINAHL, EMBASE and the WHO International Clinical Trials Registry Platform, and ClinicalTrials.gov (1 September 2019). We also searched the reference lists of included studies to identify any additional trials.

Selection criteria

We included randomized controlled trials and controlled clinical trials comparing the outcomes of clinical improvement (septic parameters and duration of hospitalization), quality of life, urinary-related symptoms, failure rates, post-procedural pain (VAS) and use of analgesics.

Data collection and analysis

We performed statistical analyses using the random-effects models and expressed the results as risk ratio (RR) and risk difference (RD) for dichotomous outcomes and mean difference (MD) for continuous outcomes, with 95% confidence intervals (CI).

Results

A total of seven trials were identified that included 667 patients. Meta-analysis of the data revealed no difference in the two methods in improvement of septic parameters, quality of life, failure rates, post-procedural pain (VAS) and use of analgesics. Patients receiving PCN experienced lesser rates of haematuria and dysuria after the procedure but with longer duration of hospitalization.

Conclusion

Both methods are effective in the decompression of an obstructed urinary system with no significant difference in most outcomes. PCN is preferable to RUS because of a lesser impact on patient quality of life after procedure due to haematuria and dysuria although associated with slightly longer duration of hospitalization.

Keywords: percutaneous nephrostomy, retrograde ureteral stenting, acute obstructive uropathy

CHAPTER 1: BACKGROUND

1.1 Description of the Condition

Obstructive uropathy is one of the most common conditions affecting the urinary system. It has been recognized as a significant cause of renal impairment leading to the debilitating consequence of end-stage renal failure. In Malaysia, a study showed a linear increase in the incidence of urolithiasis, which is one of the main causes of obstructive uropathy(Khan *et al.*, 2014). The prevalence of this condition is expected to have an upward trend due to the increasing incidence of urinary tract calculus as well as abdominal or pelvic neoplastic conditions that potentially obstruct the urinary system.

Obstructive uropathy is a condition where the impedance of urinary flow causes dilatation of the pelvicalyceal system resulting in damage to renal parenchyma(Tseng and Stoller, 2009). It is estimated that 9.2% of chronic kidney disease is caused by obstruction of the urinary tract(Khan *et al.*, 2014). Myriads of causes are known to be associated with this condition and can be broadly divided into intrinsic and extrinsic causes(Table 1). Diseases affecting each level of the urinary tract, i.e. kidney, ureter, or bladder, can lead to obstruction in each of the groups of causes mentioned. Calculous disease affecting kidney, ureter and bladder is one of the most common intrinsic aetiologies. Ureteropelvic junction obstruction at the renal level and gynaecologic malignancy, on the other hand, may lead to extrinsic compression. At the level of the bladder, intrinsic obstruction by malignancy or neurogenic bladder and external compression by prostatic diseases, e.g. benign prostatic hypertrophy or prostatitis can impede urinary outflow distally. Untreated or suboptimal treatment will lead to inevitable permanent chronic kidney disease through a combination of ischemic or disuse-induced tubular injury, inflammation and interstitial renal fibrosis(Klahr, 1983; Vaughan *et al.*, 2004).

Causes of urinary tract obstruction		
	Intrinsic	Extrinsic
Kidney	Calculous disease Cystic disease Renal cell carcinoma Transitional cell carcinoma of the renal pelvis Obstructive pyelonephritis Congenital fibrous ureteropelvic junction obstruction	Ureteropelvic junction obstruction as a result of a crossing vessel
Ureter	Calculous disease Stricture Transitional cell carcinoma Congenital megaureter	Aortic or iliac artery aneurysm Compression because of a vascular graft Retroperitoneal malignancy or fibrosis Pelvic lipomatosis Gynaecologic malignancy
Bladder	Neurogenic bladder Bladder neck contracture Malignancy of the bladder or prostate Calculous disease	BPH Prostatitis Pelvic organ prolapse
Urethra	Stricture Phimosis Meatal stenosis Malignancy of the urethra	

Table 1 Causes of urinary tract obstruction. Adapted from (Tseng and Stoller, 2009)

1.2 Description of the Intervention

1.2.1 Percutaneous Nephrostomy

Fluid or material accumulation within an obstructed urinary tract must be evacuated to preserve renal function and must be performed urgently. Various techniques have been suggested and routinely performed to achieve satisfactory relief of obstruction. Percutaneous nephrostomy (PCN) is one of the most standard techniques done by utilizing image-guided assistance mostly by general radiologists or interventional radiologists where available. It is a two-pronged procedure that serves diagnostic purposes where the severity and possible contents of the accumulated fluid can be re-assessed as well as a therapeutic attempt that is subsequently employed as a way of urinary diversion. It was first described as one of the earliest minimally invasive techniques; it is promptly gaining ground as an effective procedure in the management of an obstructed urinary tract (Goodwin *et al.*, 1955). It does not only provide immediate relief of urinary obstruction, but it also enables diagnostic testing of collected samples and investigation of the primary cause of obstruction via antegrade pyelography. Moreover, this technique also serves as access for future therapeutic intervention.

Percutaneous nephrostomy insertion can be done under ultrasound-guided, fluoroscopic-guided or a combination of these approaches (Figure 1) (Mucksavage, 2018; Ramchandani *et al.*, 2003). It is usually done at interventional radiology suites by an interventional radiologist. It is also performed by general radiologists or urologists in centres without interventional radiology service. Briefly, to perform this procedure, ultrasound examination is done to assess the kidney as well as to plan the location and course of puncture. The puncture is recommended to be performed at the posterolateral aspect of the flank in order to target a specific area of the kidney, known as the Brodel's

area, where the kidney has the least vascularization. This is an essential precaution as it reduces the risk of haematoma or ischaemia to the renal parenchyma.

This procedure is usually done in an interventional radiology suite under sedation. Once the puncture site is determined, local anaesthesia is infiltrated followed by a small incision. The puncture site is then widened with artery forceps and then punctured using a puncture needle under ultrasound guidance. Once the placement is confirmed either through direct visualization on ultrasound or evidence of urine in the needle, a guidewire is inserted, and the needle is removed. Serial dilatation of the track is then performed. Lastly, the placement of a pigtail drainage catheter, usually size 10Fr or 12Fr, within the renal pelvis is done(Dagli and Ramchandani, 2011).

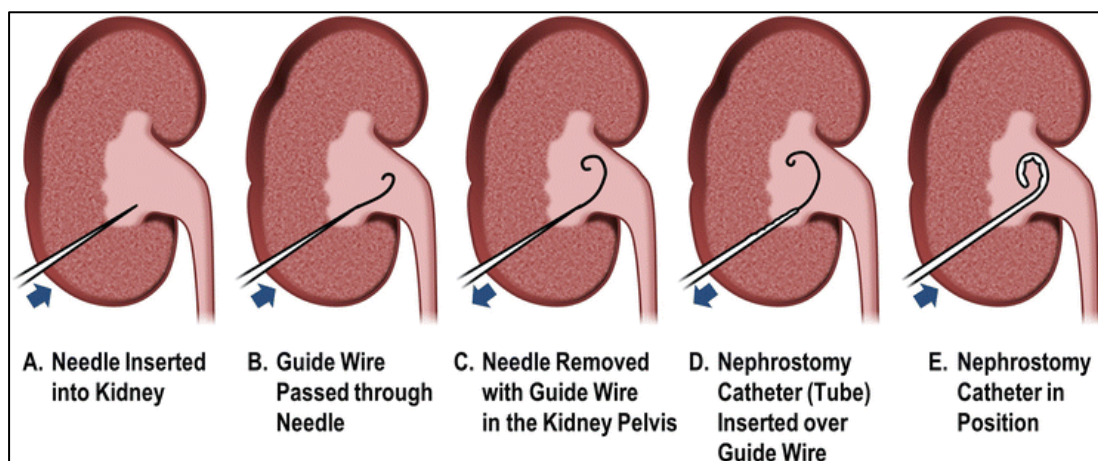


Figure 1. Steps in percutaneous nephrostomy tube insertion. Adapted from Mucksavage, P. (2018). Ureteral Stents, Nephrostomy Tubes, and Urethral Dilators. In: Newman, D. K., Rovner, E. S. and Wein, A. J. (eds.), *Clinical Application of Urologic Catheters, Devices and Products*. Cham: Springer International Publishing, pp 105-132.

1.2.2 Ureteral Stenting

Ureteral stenting is another approach to relieve the urinary tract obstruction. It allowed a means of bypassing the narrowed portion of the ureter to effectively drain the kidney(Morgenstern, 2001). A ureteral stent (also called a Double-J stent) is a hollow tube with multiple side holes made of polyurethane or silicone that is placed in the ureter to bypass an obstruction (Figure 2). Ureteral stents have a broad range of clinical uses. They can be used in the short term, such as in the case of obstructing stones or empirically after a urological procedure, to allow scaffolding to facilitate the patent healing of the ureter or in the long term in cases of malignant obstruction as a palliative care.

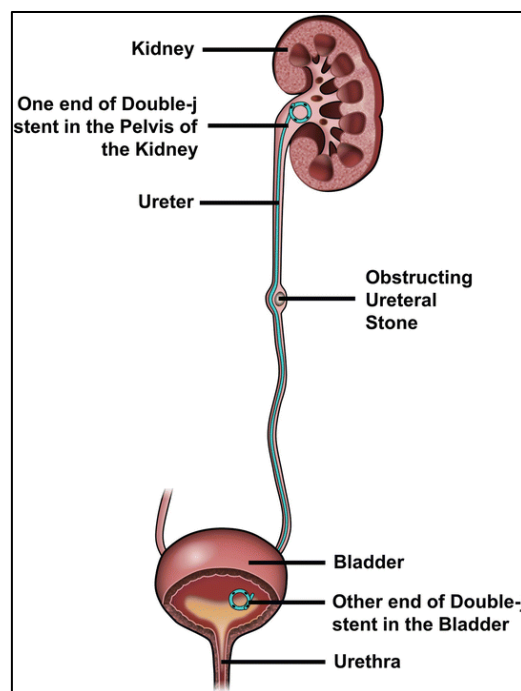
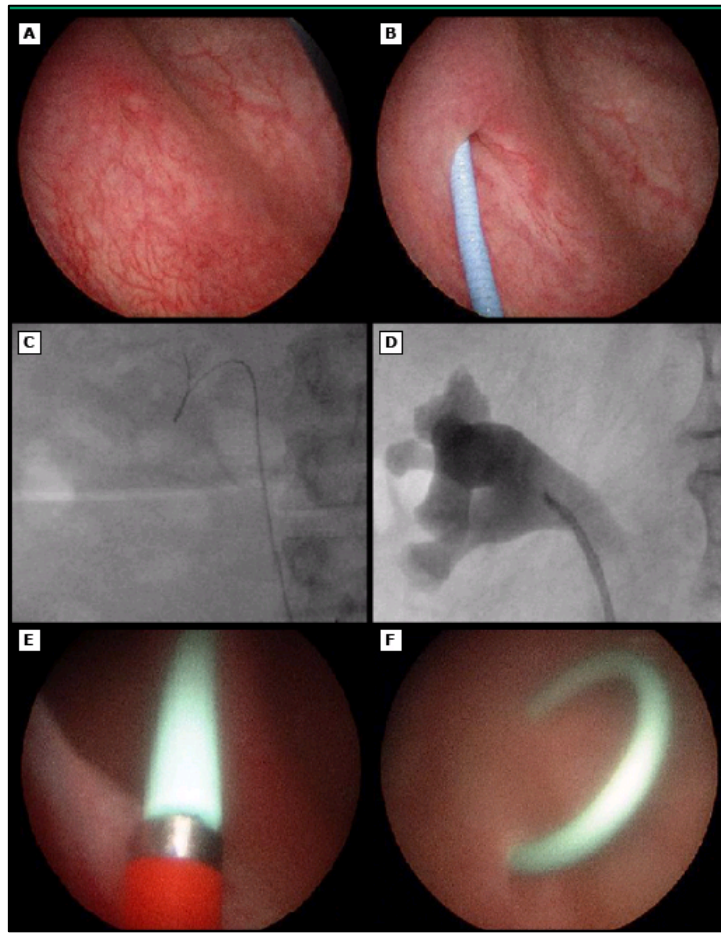


Figure 2. Ureteral stent. Adapted from Mucksavage, P. (2018). Ureteral Stents, Nephrostomy Tubes, and Urethral Dilators. In: Newman, D. K., Rovner, E. S. and Wein, A. J. (eds.), *Clinical Application of Urologic Catheters, Devices and Products*. Cham: Springer International Publishing, pp 105-132.



The ureteral orifice is first identified (A) and cannulated with a guidewire (B). The guidewire is placed beyond the area of obstruction and into the renal pelvis (C). A ureteral access catheter is placed over the guidewire. The guidewire is then removed, and contrast is injected to opacify the renal pelvis aiding accurate stent placement (D). The guidewire is replaced into the renal pelvis through the access catheter, which is then removed (not shown). The red metal-tipped pusher is used to manoeuvre the stent over the wire and up the ureter (E). The end of the ureter stent can be seen at the bladder neck. Finally, the wire is removed, and the stent is fully deployed (F). A full pigtail curl should be visualised in the bladder. Fluoroscopy can also be used to verify an adequate curl in the renal pelvis (not shown).

Figure 3. Retrograde ureteral stent placement. Adapted from (Nakada and Patel, 2020).

There are two techniques based on the direction of the procedure performed, namely antegrade and retrograde. Antegrade stenting is performed by both urologists and interventional radiologists. In this method, the skin at the level of the kidney is punctured to provide access into the pelvicalyceal system for the introduction of urinary stents. The initial steps of this approach are almost similar to percutaneous nephrostomy insertion. It requires skin incision, dilatation of puncture tract and insertion of a stent in the affected ureter. Therefore, trials that include this method is not included in this meta-analysis because of the similarities.

Retrograde ureteral stenting (RUS) is performed by direct visualization of the distal ureteric using a cystoscope to guide the insertion of a stent (Figure 3). Commonly, this approach requires the patient to be put under general anaesthesia in an operating theatre. In this technique, the patient is positioned in low dorsal lithotomy. Cystourethroscopy is done after administration of anaesthetic jelly via the urethra. Once in the bladder, the ureteral orifice is identified and cannulated. A guidewire is placed in the ureter into the renal pelvis under fluoroscopic guidance. Subsequently, a 5 Fr catheter is placed over the wire to the renal pelvis, followed by wire removal. Pelviureterography is then performed. After removal of the catheter, a stent is pushed upward under fluoroscopy guidance. Once the placement is confirmed, the wire is removed, leaving the stent within the ureter(Dyer *et al.*, 2002).

1.3 How the Intervention Might Work

Urgent decompression is warranted in cases of acute obstructive uropathy; either percutaneously via a nephrostomy tube or retrogradely via placement of a ureteral stent. This decompression is to prevent further worsening of renal function, inflammation and ischemia to the renal parenchyma that will eventually progress to irreversible chronic kidney disease. Urinary diversion of an obstructed system will lead to clinical improvement in terms of septic parameters, quality of life as well preservation of renal function.

The choice depends on operator preference, availability of interventional radiologists or urologists and centre-based standard protocol. Currently, percutaneous nephrostomy is the widely accepted approach in many centres due to better availability of radiologists compared to urologists, simpler technique and cheaper equipment. However, retrograde ureteral stenting may have similar or superior efficacy, less invasive and better post-procedural quality of life.

1.4 Why It Is Important To Do This Review

To date, there are no standard guidelines in the preferred method of urgent urinary tract decompression in the settings of acute obstructive uropathy. There is conflicting evidence in the literature regarding these two methods. Percutaneous nephrostomy has the advantages of avoiding general anaesthesia and instrumentation of the urinary tract. In contrast, RUS requires general anaesthesia, thus carries the additional risks of tracheal intubation and its complications. It is also a more difficult procedure with a higher failure rate compared to PCN(Mokhmalji *et al.*, 2001a). However, PCN is associated with higher rates of sepsis and mortality(Lynch *et al.*, 2006). Other outcomes such as time to definitive stone management, rates of spontaneous stone passage, and initiation of stone metabolic workup were not statistically different(Bansal *et al.*, 2009). Therefore,

evidence-based comparison of these two approaches is warranted to serve as a potential ground to establish a standard guideline in the management of obstructive uropathy.

1.5 Objective

To compare the efficacy and safety of percutaneous nephrostomy and retrograde ureteral stenting in acute urinary tract obstruction.

CHAPTER 2: METHODOLOGY

2.1 Eligibility Criteria

2.1.1 Types of Studies

Randomized controlled trials (RCTs) and controlled clinical trials (CCTs) comparing percutaneous nephrostomy and retrograde ureteral stenting.

2.1.2 Types of Participants

We included patients with acute obstructive uropathy secondary to any cause who receive percutaneous nephrostomy or retrograde ureteral stenting.

2.1.3 Types of Interventions

Percutaneous nephrostomy performed by a physician, using any nephrostomy tube size, under ultrasound or fluoroscopy-guided. Comparison: retrograde ureteral stenting.

2.1.4 Types of Outcomes

We reviewed data on clinical success rates described as improvement of septic parameters in terms of duration to defervescence and normalization of white blood cells count and length of hospitalization. We assessed information on the quality of life and analysed data on urinary-related symptoms including haematuria, dysuria, frequency and urgency. For secondary outcomes, we reviewed information regarding failure rates of each procedure, post-procedural pain and use of analgesics.

2.2 Search Strategies

We searched the Cochrane Central Register of Controlled Trials CENTRAL (latest Issue), MEDLINE, EMBASE and CINAHL on 16 October 2019. We used the search

strategy in Appendix 1 to search these databases. We adapted the search strategy for other databases. We restricted the publications to English language only.

We checked the reference list of identified RCTs, CCTs and review articles in order to find unpublished trials or trials not identified by electronic searches. We searched for ongoing trials through the World Health Organization International Clinical Trials Registry Platform <http://www.who.int/ictrp/en/> and www.clinicaltrials.gov.

2.3 Trial Selection

We screened the titles and abstracts from the searches and obtained full-text articles when they appear to meet the eligibility criteria, or when there is insufficient information to assess the eligibility. We assessed the eligibility of the trials independently and documented the reasons for exclusion. We resolved any disagreements between the review authors by discussion.

2.4 Data Extraction

Using data extraction form, from each of the selected trials we extracted study settings, participant characteristics (age, sex, ethnicity), methodology (number of participants randomized and analyzed), duration of white blood count (WBC) normalization, duration to defervescence, duration of hospitalization, quality of life based on questionnaires, urinary-related symptoms e.g. hematuria, dysuria, urgency, frequency, technical success of each procedure to assess failure rate, pain score based on a visual analogue scale (VAS) and use of analgesics.

2.5 Risk of Bias Assessment

We assessed the risk of bias based on random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors,

completeness of outcome data, the selectivity of outcome reporting and other bias(Higgins 2019). We resolved any disagreements by discussion.

2.6 Grading Quality of Evidence

We assessed the quality of evidence for primary and secondary outcomes according to GRADE methodology for risk of bias, inconsistency, indirectness, imprecision, and publication bias; classified as very low, low, moderate, or high(Guyatt *et al.*, 2011).

2.7 Statistical analyses

We undertook meta-analyses using Review Manager 5.3 software (RevMan 2014) and used the random-effects model to pool data. We assessed the presence of heterogeneity in two steps. First, we assessed apparent heterogeneity at face value by comparing populations, settings, interventions and outcomes. Second, we assessed statistical heterogeneity using the I^2 statistic(Higgins 2019).

Thresholds for the interpretation of the I^2 statistic can be misleading since the importance of inconsistency depends on several factors. We used the guide to the interpretation of heterogeneity as outlined: 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity, and 75% to 100% would be considerable heterogeneity(Higgins 2019).

We measured the treatment effect for dichotomous outcomes using risk ratios (RRs) and risk difference (RD), and for continuous outcomes, we used mean differences (MDs); both with 95% confidence intervals (CIs). No subgroup analysis was performed in this meta-analysis.

We checked included trials for the unit of analysis errors. Unit of analysis errors can occur when trials randomise participants to intervention or control groups in clusters, but analyse the results using the total number of individual participants. We adjusted results

from trials showing unit of analysis errors based on the mean cluster size and intraclass correlation coefficient(Higgins 2019).

We contacted the original trial authors to request missing or inadequately reported data. We performed analyses of the available data if missing data were not available.

We performed a sensitivity analysis to investigate the impact of risk of bias for sequence generation and allocation concealment of included studies. We used funnel plots to assess the possibility of reporting biases or small study biases, or both.

CHAPTER 3: MANUSCRIPT

Percutaneous nephrostomy versus retrograde ureteral stenting for acute upper obstructive uropathy: A systematic review and meta-analysis

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Keywords: percutaneous nephrostomy, retrograde ureteral stenting, acute obstructive uropathy

ABSTRACT

Acute obstructive uropathy is associated with significant morbidity among patients with any condition that leads to urinary tract obstruction. Immediate urinary diversion is necessary to prevent further damage to the kidneys. In many centres, the two main treatment options include percutaneous nephrostomy (PCN) and retrograde ureteral stenting (RUS). The purpose of this study is to compare the efficacy and safety of PCN and RUS for the treatment of acute obstructive uropathy.

We searched the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, CINAHL, EMBASE, the World Health Organisation International Clinical Trials Registry Platform and ClinicalTrials.gov. We also searched the reference lists of included studies to identify any additional trials. We included randomised controlled trials and controlled clinical trials comparing the outcomes of clinical improvement (septic parameters), hospitalisation duration, quality of life, urinary-related symptoms, failure rates, post-procedural pain [measured using a visual analogue scale (VAS)] and analgesics use. We conducted statistical analyses using random effects models and expressed the results as risk ratio (RR) and risk difference (RD) for dichotomous outcomes and mean difference (MD) for continuous outcomes, with 95% confidence intervals (CIs).

Seven trials were identified that included 667 patients. Meta-analysis of the data revealed no difference in the two methods in improvement of septic parameters, quality of life, failure rates, post-procedural pain (VAS), or analgesics use. Patients receiving PCN had lower rates of haematuria and dysuria post-operatively and longer hospitalisation duration than those receiving RUS. PCN and RUS are effective for the decompression of an obstructed urinary system, with no significant difference in most outcomes. However, PCN is preferable to RUS because of its reduced impact on the patient's post-operative

quality of life due to haematuria and dysuria, although it is associated with slightly longer hospitalisation duration.

INTRODUCTION

Obstructive uropathy is one of the most common conditions affecting the urinary system and is a significant cause of renal impairment, leading to end-stage renal failure. It is a condition wherein impedance of urinary flow causes dilatation of the pelvicalyceal system, resulting in damage to the renal parenchyma¹; 9.2% of chronic kidney disease cases are caused by obstruction of the urinary tract². No or suboptimal treatment will lead to inevitable permanent chronic kidney disease through a combination of ischaemic or disuse-induced tubular injury, inflammation, and interstitial renal fibrosis^{3,4}.

Urgent decompression is warranted in cases of acute obstructive uropathy, either percutaneously via a nephrostomy tube or retrogradely via ureteral stent placement. This decompression prevents further worsening of renal function, inflammation and ischaemia to renal parenchyma that can eventually progress to irreversible chronic kidney disease.

The choice of technique depends on operator preference, availability of interventional radiologists or urologists and the centre's standard protocol. Currently, PCN is the widely accepted approach in many centres because of the better availability of radiologists than urologists, its simpler technique and less expensive equipment. However, RUS may have similar or superior efficacy, is less invasive and is associated with better post-procedural quality of life.

Currently, there are no standard guidelines on the preferred method of urgent urinary tract decompression in the setting of acute obstructive uropathy. There is conflicting evidence in the literature regarding these two methods. PCN has the advantages of avoiding general anaesthesia and instrumentation of the urinary tract, whereas RUS requires general anaesthesia and thus carries additional risks of tracheal intubation and its complications,

is more difficult and has a higher failure rate than PCN ⁵. However, PCN is associated with higher rates of sepsis and mortality ⁶. Other outcomes such as time to definitive stone management, rates of spontaneous stone passage and initiation of stone metabolic workup were not found to be statistically different ⁷. Therefore, an evidence-based comparison of these two approaches is warranted to provide a potential basis for establishing a standard guideline in the management of obstructive uropathy. The objective of this study was to compare the efficacy and safety of PCN and RUS in acute obstructive uropathy.

RESULTS

Search results

We retrieved 3786 records from the search databases and four additional records from other sources (Figure 1). In total, 563 records were screened after removing duplicates. We reviewed 30 full-text articles and excluded 23 articles, of which 17 were non-comparative trials and six investigated empirical treatment. Empirical treatment refers to the use of PCN or RUS as preventive measures in conditions wherein obstructive uropathy is anticipated but has not yet occurred.

Included studies

We included seven trials (N = 667) ^{5, 8-14}. These trials are summarized in Table 1.

Participants

All seven trials were conducted in healthcare settings. The total number of participants was 667. Four of the trials were conducted in the urology departments from referral cases ^{5, 10, 12, 14}, two trials included patients who presented to the emergency department ^{8, 13} and one trial included patients referred to a stone management unit ⁹. One multicentre trial was conducted in urology units in Germany and Syria ⁵. Two trials were RCTs ^{5, 10}, whereas five were CCTs ^{8, 9, 12-14}.

Intervention

All trials compared PCN and RUS as the intervention and control groups, respectively. In all trials, the procedures were conducted by urologists. Percutaneous nephrostomies were conducted under ultrasound guidance with local anaesthesia. Retrograde ureteral stents were inserted using a cystoscope after patients were put under general anaesthesia. All stents were double-J stents.

Outcomes

Two trials analysed parameters of clinical success, which included septic parameters and hospitalisation duration in patients with obstructive uropathy^{8, 12}. Three trials reported patients' quality of life and urinary-related symptoms^{9, 13, 14}. For the secondary outcomes, three trials reported failure rates^{5, 8, 10}, two trials reported post-procedural pain^{8, 14} and four trials reported analgesics use^{5, 9, 13, 14}.

All trials that reported quality of life used a similar questionnaire, that is, the EuroQol EQ-5D-3L®^{9, 14, 15}, which is the three-level version of the EQ-5D. This measure includes a descriptive system that contains five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels: no problems, some problems, and extreme problems. Participants were asked to express their health state for the most appropriate statement in each of the five dimensions.

Excluded studies

We excluded 13 trials. Seven trials had no control group¹⁶⁻²². Six trials analysed PCN and RUS as empirical treatment²³⁻²⁸.

Risk of bias in included studies

The risk of bias assessment is shown in Figures 2 and 3. The proportion of the assessment of included studies based on the risk of bias for each 'risk of bias' indicator is shown in Figure 2. The risk of bias analysis for the individual studies is shown in Figure 3.

Allocation

Three trials reported the use of the random number tables method of randomisation ^{8, 10, 12}. One trial used quasi-randomisation based on odd- or even-numbered birth year ²⁹. The remaining three trials did not use any randomisation; patients were allocated based on the preference of the performing surgeon, who was not aware of the trials ^{9, 14, 15}.

Blinding

Blinding of participants and personnel was not feasible because all trials involved a procedure.

Incomplete outcome data

In one trial, RUS insertion failure occurred in three patients who were then subjected to PCN as the urinary diversion method. These patients were still included in the analysis in the RUS group ¹⁰. In another trial, four of 20 patients in the RUS group had an unsuccessful procedure and thus were subjected to PCN ⁵. The four patients were analysed as a separate group; the outcomes in the RUS group were analysed based on the remaining 16 patients. In one trial, two patients were missing from both the PCN and RUS groups because of loss to follow-up ¹². These patients were not included in the final analysis. In one trial, four patients were missing for various reasons in each group ¹¹. They were included in the analysis of outcomes.

Selective reporting

All seven trials reported outcomes based on the objectives and measured in the methods ^{5, 8-14}.

Other potential sources of bias

There were no other potential sources of bias in the included studies.

Effects of interventions

Primary outcomes

All trials reported the primary outcomes of this meta-analysis ^{5, 8-14}.

1. Clinical success of PCN: Three trials reported the clinical success outcomes regarding improvement in septic parameters ^{8, 12, 14}.
 - a. Improvement in septic parameters:
 - i. WBC normalisation duration: Two trials compared the WBC normalisation duration (days) post-operatively ^{8, 12} (two trials; 149 participants; MD [95% CI] 0.33 [-0.07 to 0.74]; $I^2 = 0\%$; $P = 0.100$; moderate-quality evidence; Figure 4; Table 2).
 - ii. Duration to defervescence. Three trials reported the duration to defervescence ^{8, 12, 14}; however, one trial reported the median duration (interquartile range [IQR]) and thus was not included in the meta-analysis ¹⁴ (two trials; 142 participants; MD [95% CI] 0.33 [-0.46 to 0.53]; $I^2 = 0\%$; $P = 0.890$; moderate-quality evidence; Figure 5; Table 2).
2. Hospitalisation duration: Three trials reported the hospitalisation duration ^{8, 12, 14}; however, one trial reported the findings as median (IQR) and thus was not included in the meta-analysis ¹⁴ (two trials; 149 participants; MD [95% CI] 1.82 [0.79 to 2.85]; $I^2 = 0\%$; $P < 0.001$; moderate-quality evidence; Figure 6; Table 2).
3. Quality of life: Three trials reported patient quality of life ^{9, 14, 15}. All trials had a high risk of random sequence generation and allocation concealment.
 - a) Mobility: Three trials reported quality of life regarding mobility ^{9, 14, 15} (RR [95% CI] 0.78 [0.25 to 2.48]; RD [95% CI] -0.10 [-0.42 to 0.22]; $I^2 = 73\%$; $P = 0.670$; very low-quality evidence; Figure 7; Table 2).
 - b) Self-care: Three trials reported quality of life regarding self-care ^{9, 14, 15} (RR [95% CI] 2.76 [0.55 to 13.85]; RD [95% CI] 0.12 (-0.18 to 0.43); $I^2 = 50\%$; $P = 0.220$; Figure 8).

- c) Usual activity: Three trials reported quality of life regarding usual activity^{9, 14, 15}. (RR [95% CI] 1.57 [0.55 to 4.53]; RD [95% CI] 0.13 [-0.16 to 0.41]; $I^2 = 87\%$; $P = 0.400$; very low-quality evidence; Figure 9; Table 2).
- d) Pain/discomfort: Three trials reported quality of life regarding pain or discomfort^{9, 14, 15} (RR [95% CI] 0.97 [0.75 to 1.26]; RD [95% CI] 0.00 [-0.13 to 0.13]; $I^2 = 12\%$; $P = 0.830$; low-quality evidence; Figure 10; Table 2).
- e) Anxiety/depression: Three trials reported quality of life regarding anxiety or depression^{9, 14, 15} (RR [95% CI] 0.81 [0.56 to 1.16]; RD [95% CI] -0.12 [-0.26 to 0.03]; $I^2 = 0\%$; $P = 0.250$; Figure 11).
4. Urinary-related symptoms:
- a) Haematuria: Four trials reported haematuria post-procedure^{9, 10, 14, 15}. All trials had high risk of random sequence generation and allocation concealment (RR [95% CI] 0.56 [0.37 to 0.85]; RD [95% CI] -0.24 [-0.47 to -0.01]; $I^2 = 35\%$; $P < 0.001$; very low-quality evidence; Figure 12; Table 2).
- b) Dysuria: Two trials reported dysuria^{9, 15} (RR 0.28, 95% CI 0.15 to 0.54; RD -0.61, 95% CI -0.78 to -0.43; $I^2=0\%$; $P < 0.001$; moderate-quality evidence; Figure 13; Table 2).
- c) Frequency: Two trials reported urinary frequency post-procedure^{9, 15} (RR 0.46, 95% CI 0.23 to 0.94; RD -0.44, 95% CI -0.71 to -0.17; $I^2 = 47\%$; $P = 0.030$; Figure 14).
- d) Urgency: Two trials reported urinary urgency^{9, 15} (RR 0.56, 95% CI 0.15 to 2.13; RD -0.37, 95% CI -0.90 to 0.17; $I^2 = 91\%$; $P = 0.400$; Figure 15).

Secondary outcomes

1. Failure rates

Three trials reported the number of failure rates for each procedure^{10,29,30}. Two of these trials had a high risk of random sequence generation and allocation concealment^{10,29} (RR [95% CI] 0.95 [0.16 to 5.58]; RD [95% CI] -0.02 [-0.13 to 0.09]; $I^2 = 41\%$; $P = 0.950$; Figure 16).

2. Post-procedural pain (VAS)

Two trials reported quantitative assessment of post-procedural pain using VAS^{14,30} (two trials; 117 participants; MD [95% CI] 1.14 (-1.54 to 3.82); $I^2 = 63\%$; $P = 0.400$; Figure 17).

3. Analgesics use

Four trials reported analgesics use to alleviate post-procedural pain^{14,15,29,30}. Three trials had a high risk of random sequence generation and allocation concealment^{14,15,29} (RR [95% CI] 0.95 [0.31 to 2.93]; RD [95% CI] -0.02 [-0.37 to 0.33]; $I^2 = 81\%$; $P = 0.920$; Figure 18).