**Prospective single-centre randomised control trial of magnetic ureteric stents versus conventional ureteric stents**

**Investigators:**

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**Background:**

Ureteric stenting is a common procedure in urology. Ureteric stents are frequently used post ureterorenoscopic surgery to ensure urinary drainage, prevent infection and aid stone passage. However, these stents cause significant morbidity for some patients [1,2].

Unfortunately, up to 80% complain of irritative voiding symptoms after stenting. Fortunately, the stent is usually removed after 7-14 days. The standard procedure to remove the stent is by flexible cystoscopy. However, this procedure can be unpleasant for patients and require additional resources.

A newly designed magnetic stent allows removal in an outpatient setting by using two magnets, despite wide adoption of magnetic stents worldwide there is a relative dearth of data to support their use compared to non-magnetic stents.

The aim of this study is to compare the magnetic stent and conventional stent with regard to morbidity, pain on stent removal and cost-effectiveness.

**References:**

1] Song,T., et al. Meta-analysis of postoperatively stenting or not in patients underwent ureterscopic lithotrepsy. Urol Res, 2012. 40:67.

2] Nabi, G., et al. Outcomes of stenting after uncomplicated ureteroscopy: systematic review and meta-analysis. BMJ, 2007. 334: 572.

**Methods:**

**Participants:**

Patients undergo elective semi-rigid or flexible ureteroscopy for ureteric or renal urolithiasis and will have short term stent will be asked to participate in the study.

**Inclusion criteria:**

Patients aged between 18-80 years who will undergo planned elective unilateral semi-rigid or flexible ureteroscopy for ureteric or renal urolithiasis and will have short term ureteric stent placed (<21 days).

**Exclusion criteria:**

Patients who use alpha-blockers, anticholinergics, steroids, calcium channel blockers and analgesics. Also, patients who have neurogenic bladder, overactive bladder syndrome, residual stone fragments, previous history of pelvic surgery or radiotherapy, moderate to severe hypertension, hepatic dysfunction, single kidney and pregnant women.

All patients have to give their informed consent.

**Measures:**

**Demographics and clinical data:**

Quality of life with the indwelling DJ will be assessed by using the ureteral symptom questionnaire (USSQ) prior to DJ stent removal. After DJ‐removal, a visual analogue scale (VAS) will be used to document the discomfort caused by the D J‐removal.

**Procedure:**

All patients meeting inclusion criteria will be provided with an information leaflet at their admission for elective semi-rigid or flexible ureteroscopy. Once the information sheet has been read, the patient will be asked if they are interested in taking part in the study. Once written consent has been gained a random number generator will be used to generate a number, when an even number is generated a magnetic ureteric stent will be placed and an odd number means a conventional ureteric stent. When the patients return to have their stent removed, they will undergo a Quality of life assessment with a ureteral symptom questionnaire (USSQ). After the stent removed, a visual analogue scale (VAS) will be used to document the discomfort caused by the Dj removal.

**Number of patients to be studied:**

The proposed number of patients in the study group was determined by the power analysis with G Power 3.1.9.4. The sample size of 34 patients for each group was determined to be needed by accepting an α risk of 5% and a β risk of 10% in a 2-sided test with an effect size of 0.8.

**Data management:**

All personally identifiable data will be subject to the General Data Protection Regulation (GDPR) 2018 and Mercy University Hospital Data Protection Policy.

Participation in the research project and the identity of the participants will be treated as confidential, and no patient identifiable records or results relating to the study will be disclosed to any third party other than the authorised investigators.

A number will be assigned to each patient, and this number will be mapped to identify patient details in the form of an encryption key, held securely away from the data at the clinical site (Mercy University Hospital).

Data will be sorted on a password-protected computer. All identifiers will be removed from the data at the point of data entry.

**Data analysis:**

SPSS IBM’s Statistical Package for the Social Sciences (SPSS) version 25 will be utilised in the statistical analyses.

Data will be entered onto a spreadsheet and interval data will be analysed to examine for normality of distribution utilising examination of a combination of sources including Q-Q plots, histograms, skewness and kurtosis measurements.

**Potential risks and ethical concerns:**

This group of patients will be receiving a ureteric stent regardless of being in the study. Both types of stents are commonly used already, participating in this study poses no risk to their health.

Loss of anonymity is a potential risk to subjects taking part in this study, to reduce this patients names will not appear on any spreadsheet of data, or on the questionnaires to each risk factor question.