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Drug treatment of bothersome lower urinary tract symptoms after ureteric JJ-stent insertion: A contemporary, comparative, prospective, randomised placebo-controlled study, single-centre experience

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KEYWORDS

Ureteric stent;
Anti-muscarinic;
Solifenacin;
Trospium chloride;
Alfuzosin

ABBREVIATIONS

BMI, body mass index;
ROC, receiver operating characteristic;
USSQ, Ureteric Stent

Abstract ***Objective:*** To provide a guide for medication to alleviate bothersome lower urinary tract symptoms (LUTS) in patients after JJ ureteric stenting.

Patients and methods: Between June 2011 and June 2015, a prospective randomised placebo-controlled study was conducted on 200 consecutive cases of ureteric stones that required JJ stents. All patients had signed informed consent and JJ-stent placement confirmed by X-ray. The patients were randomised into five groups: A, solifenacin 5 mg; B, trospium chloride 20 mg; C, antispasmodic; and E, α-blocker; and a placebo group (D). A standard model was created to lessen patient selection bias. Eligible patients were enrolled and assessed for side-effects and bothersome LUTS using the validated Ureteric Stent Symptoms Questionnaire. Appropriate statistical analysis was carried out.

Results: In all, 150 male patients in the five groups were compared. LUTS were less in groups A and B ($P < 0.05$), while dry mouth was significantly reported in

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Symptoms Questionnaire

Group A. Individual comparisons with the placebo group showed a non-significant difference with Group C, while Group E had significant nocturia improvement. Selective comparison of two best groups (A and B) showed less frequency in Group B, while the other LUTS were less in Group A with comparable side-effects.

Conclusions: In symptomatic patients following JJ-stent insertion, anti-muscarinic medication, namely solifenacin 5 mg or trospium chloride 20 mg, was the best. The advantage of trospium over solifenacin is in the control of frequency rather than the other symptoms. Addition of an α-blocker (alfuzosin 10 mg) is valuable when nocturia is the predominant symptom.

Introduction

Insertion of a JJ ureteric stent is a common urological procedure, which was introduced in 1967 [1]. The indications are varied and application has become easier. A JJ stent is widely used temporarily, e.g. as a conduit for pyeloplasty or pyleo- or nephro-lithotomy, stenting of the ureter for oedema due to stone impaction or perforation after endourological procedures, or auxiliary for shockwave lithotripsy. Furthermore, a JJ stent can be used as a permanent solution for ureteric obstruction, e.g. in cases of cervical cancer in women. However, stents may result in irritative LUTS that can negatively impact on quality of life [2].

Many attempts have been made to solve stent-related bother in patients, with the majority concentrating on pharmacological methods. Although there are many publications of various drugs and their results, a randomised study with different medications is lacking.

To the best of our knowledge, no consensus has been achieved regarding the best medical treatment for the symptomatic patient after JJ ureteric stenting.

In the present study, we aimed to find the best drug(s) that can relieve stent-related symptoms with high tolerability and minimal side-effects.

Patients and methods

A prospective randomised placebo-controlled single-blind study was conducted between June 2011 and June 2015. The study design was approved by the hospital medical committee and all patients signed a written informed consent. We enrolled 200 consecutive patients with ureteric stones for whom a temporary JJ stent was inserted (for $\geqslant 7$ days). Patients with single iliac or pelvic ureteric stones, with mild–moderate hydronephrosis, for whom a temporary JJ stent was indicated, were included. Exclusion criteria were elderly people (aged >60 years), any patient with a previous history of prostate disease or overactive bladder on medications, patients with a body mass index (BMI) of >30 kg/m^2, and any patient with an allergy or contraindications to the tested medications. LUTS were assessed preoperatively using the IPSS.

The indications for JJ-stent insertion in our patients were as follows: after ureteroscopy with stone retrieval, either for oedema at the site of stone impaction, expectant pyuria due to neglected hydronephrosis, or small ureteric perforation that inflected during the procedure. Postoperatively a plain abdominal radiograph of the kidneys, ureters and bladder was taken to ensure JJ-stent positioning. A short course of ciprofloxacin 500 mg (twice daily) was given postoperatively, as routine practice against infection.

All the procedures were performed in one centre, stents were supplied by the same manufacturing company (Coloplast A/S 3050, Denmark), and they were performed by one urologist to lessen bias. To make a standard model of testing, all patients were male, had a body mass index (BMI) of ~25 kg/m^2, and the JJ stent was 6 F in diameter and 24 cm in length.

The patient cohort was randomised in a single-blind, placebo-controlled study. The patients were divided into five groups according to the given medication: Group A, solifenacin 5 mg (once daily); Group B, trospium chloride 20 mg (twice daily); Group C, ordinary antispasmodic hyoscine butylbromide (buscopan®) 10 mg (once daily), Group D, placebo; and Group E, α-blocker alfuzosin 10 mg (once daily). The randomisation was carried out using sealed opaque envelopes; allocation concealment was achieved by using an independent person (assisting nurse).

The patients were assessed for bothersome LUTS, haematuria, and flank/suprapubic pain, as well as for side-effects of the used medications using a simplified questionnaire based on the Ureteric Stent Symptoms Questionnaire (USSQ), as a validated and widely applied questionnaire for stent-related symptoms by Joshi et al. 2003 [3,4]. USSQ scores of 0–2 were considered as no significant bother and scores of 3–5 were considered as significant bother.

The primary endpoint of the study was symptom relief and the secondary endpoint was removal of the