African Journal of Urology (2017) **23**, 28–32

African Journal of Urology

Official journal of the Pan African Urological Surgeon's Association
web page of the journal

www.ees.elsevier.com/afju
www.sciencedirect.com

Original article

Impact of Tamsulosin, Tolterodine and drug-combination on the outcomes of lower urinary tract symptoms secondary to post-ureteroscopy ureteral stent: A prospective randomized controlled clinical study

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Received 17 March 2016; received in revised form 23 June 2016; accepted 23 June 2016
Available online 18 November 2016

KEYWORDS
Anticholinergics;
α-Adrenergic blockers;
Ureter stent;
Ureteroscopy

Abstract
Objectives: To compare the role of alpha-blocker (Tamsulosin) monotherapy, anticholinergic (Tolterodine) monotherapy or combination of both drugs *versus* analgesics in improving post-ureteroscopy (URS) lower urinary tract symptoms related to double-J ureteral stent.
Patients and methods: Between January 2009 and June 2013, 160 consecutive patients with ureteric stones were included in this study at 2 tertiary care centers'. Patients were randomized into 4 groups; group A ($n=40$) received 0.4 mg Tamsulosin once a day, group B ($n=40$) received 4 mg Tolterodine once a day, group C ($n=40$) received Tamsulosin 0.4 mg and Tolterodine 4 mg once a day and group D ($n=40$) as a control group, received placebo once a day. All patients received analgesics on demand. Pre-treatment evaluation was done followed by among-groups comparison after 14 days including ureteral stent symptom questionnaire (USSQ) [Urinary symptom index (USI), pain symptom index (PSI), general health index (GHI), work perform index (WPI), need for pain killer (PK), need for analgesia, visual analogue scale (VAS) for pain and quality of life (QOL)]. Side effects were recorded and compared.

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Peer review under responsibility of Pan African Urological Surgeons' Association.

http://dx.doi.org/10.1016/j.afju.2016.06.001

Results: Out of 160 patients, 153 patients (40, 38, 37 and 38 patients in groups A, B, C and D, respectively) completed the study with a mean age of 34.3 ± 7.6 (20–50) years. All groups were comparable in terms of age, gender, stone size and stone location, USSQ items and QOL. After 14 days, the USSQ and QOL were significantly lower in group A, B and C in comparison with group D ($p < 0.05$). Patients in group C had significantly much improvement than those of groups A and B ($p < 0.05$).
Conclusion: Combination of alpha blockers (Tamsulosin) and Anticholinergics (Tolterodine) seems to significantly improve post-URS lower urinary tract symptoms secondary to ureteral stents with lower need for analgesia and better quality of life. Adverse effect of used drugs mentioned as transient and tolerated by the patients without need for auxiliary medication.

Introduction

Ureteral stenting is a widespread procedure with variable indications in urology, including post endoscopic procedures, prior to SWL in selected cases, intolerable renal colic, and ureteral injury during ureteroscopy [1].

However, ureteral stent placement might be associated by bothersome lower urinary tract symptoms (LUTS) including bladder irritation, pain, frequency and dysuria. These symptoms usually affect the patient's quality of life and consequently the general health and work [2]. Alpha adrenergic blockers have been widely used to manage such stent related symptoms with encouraging results [3,4].

Similarly, anticholinergics alone or in combination with α-blockers have been used successfully to treat LUTS related symptoms associated with benign prostate hyperplasia (BPH) and overactive bladder (OAB) syndrome [5,6]. These latter pathologies usually presented by LUTS/storage symptoms which mimic that of the stent placement. Moreover, there are sparse of literature with level-1 evidence which compare the outcomes of these drugs, monotherapy or in combination, in the management of those bothersome symptoms.

Therefore, the aim of the present study was to evaluate the efficacy and safety of Tamsulosin and Tolterodine, either monotherapies or in combination, for improving LUTS/storage bladder symptoms secondary to post-ureteroscopy (URS) double-J ureteral stenting.

A great effort has been done by Joshi et al. [7] to develop USSQ as psychometrically valid measure to evaluate the stent related symptoms and QOL. USSQ explores six areas (sections) containing 38 items, the answers of which are based on a rating scale from 0 to 5 and the scoring system consists of a simple sum of the scores of individual questions in each section. Those sections include (Urinary symptom index, pain symptom index, general health index, work performance index, sexual matter and additional problem index) which contain 11, 8, 6, 7, 1 and 5 items, respectively. This USSQ is considered the as the first valid objective tool to evaluate stent related symptoms and their effect on QOL. Following this score, different versions has been published in Italian, Korean, Spanish and Turkish language. Recently, the validated Arabic version of the USSQ was introduced by El-Nehas et al. [8] that can be used to evaluate the stent related symptoms and QOL in Arabic patient.

Patients and methods

After institutional board approval of the study protocol, 160 patients who underwent URS for management of ureteric stones were included after giving an informed consent to participate in the study. Before URS, all patients were evaluated by history taking, clinical examination, laboratory investigations and radiological imaging including intravenous urography (IVU) and non-contrast spiral computer tomography (CT).

Patients between 20 and 50 years old (to avoid LUTS due to BPH), who had been managed for a single ureteral stone less than 10 mm in their longest diameter, were included in the current randomized cohort study. Patients with complicated URS, concurrent urinary tract infection (UTI), ongoing medication with alpha blockers, anticholinergics or chronic analgesics, bilateral ureteric stents, open ureteral surgery, previous pelvic or prostatic surgery, pregnancy or bleeding disorders were excluded from the study.

Procedure

Ureteroscopic lithotripsy using pneumatic lithotripter with removal of the stones was performed in all patients and double J ureteric stent, (consisting from polyurethane), 6 F, 26–28 cm (according to ureter length) polyurethane material was inserted for 2 weeks postoperatively. The ureteral stent symptom questionnaire (USSQ) was used to evaluate lower urinary tract symptoms and impact on quality of life of ureteral stents. The patients were prospectively randomized into four groups using a computer software; group A ($n = 40$) received 0.4 mg Tamsulosin once a day, group B ($n = 40$) received 4 mg Tolterodine once a day, group C ($n = 40$) received Tamsulosin 0.4 mg and Tolterodine 4 mg once a day and group D ($n = 40$) as a control group, received placebo once a day. All patients received pain killer on demand.

The patients used Diclofenac potassium Tab. 50 mg when needed (up to twice per day), and paracetamol Tab. 500 mg when needed as analgesic medication.

Pre-treatment evaluation was done followed by among-groups comparison after 14 days including ureteral stent symptom questionnaire (USSQ), using urinary symptom index (USI), pain symptom index (PSI), general health index (GHI), work performance index (WPI), need for pain killer (PK), visual analogue scale (VAS) and quality of life (QOL). Side effects were recorded and compared.