

Original Research

Single Dose Diclofenac and Tamsulosin Effectiveness in Patients Undergoing Double J-Stent Removal Under Local Anaesthesia

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Article Information

Received: April 26th, 2022; Accepted: May 12th, 2022; Published: May 17th, 2022

Cite this article

Godse S, Kumar A, Singh H, Chhabra MK. Single dose diclofenac and tamsulosin effectiveness in patients undergoing double J-stent removal under local anaesthesia. *Urol Androl Open J.* 2022; 6(1): 4-7. doi: [10.17140/UAOJ-6-141](https://doi.org/10.17140/UAOJ-6-141)

ABSTRACT

Purpose

The purpose of this study was to see effectiveness of diclofenac sodium and tamsulosin combination on patients' pain perception after ureteral stent removal.

Materials and Methods

Study was carried out from October 2019 to March 2021. All patients with unilateral stent placement after renal or ureteric stone endoscopic surgery were randomized in 3 groups. Group-A include 20 patients who were given placebo drug 2-hours prior to double J (DJ) removal. Group-B included 20 patients who were given oral diclofenac 2-hours prior to DJ removal. Group-C included 20 patients who were given oral diclofenac and tamsulosin 2-hours prior to DJ removal. All patients received 10 cc 2% viscous lidocaine intraurethral before cystoscopy. No sedatives or analgesics were administered during the procedure. All patients provided consent before the procedure and they were asked to record their pain experience on a visual analog pain scale as soon as the procedure was finished. The pulse rate and systolic and diastolic blood pressure (BP) were also recorded 5-minutes before the procedure and during the procedure

Results

General characteristic of age, gender and indication for DJ-stenting were comparable in all groups. The mean pain score on the visual analogue scale (VAS) in Group-C was significantly lower than that in Group-A and B ($p < 0.001$). A statistically significant difference was found between the two groups in terms of anxiety scores after cystoscopy, intraoperative systolic BP and pulse rate. Patients who were given oral diclofenac and tamsulosin two hours prior to DJ removal experienced less pain and anxiety.

Conclusion

Oral diclofenac plus tamsulosin combination prior to DJ removal improves patient's comfort.

Keywords

Diclofenac; Tamsulosin; DJ removal.

INTRODUCTION

Urologists are increasingly using ureteral stents following endoscopic stone removal either by percutaneous nephrolithotomy or by ureteroscopy. Patients often experience severe morbidity as a result of their use such as pain, hematuria, storage and voiding lower urinary tract symptoms (LUTS).¹ Majority of stents are removed under local anaesthesia and patients experience significant pain and anxiety during the double J (DJ) removal. A number of studies have been undertaken to assess the issues that can occur

when a stent is removed.² Diclofenac, a long-acting non-steroidal anti-inflammatory drugs (NSAIDs) with a fast start of action, has been shown to be very successful in the treatment of renal colic.³ This medication works by suppressing the formation and release of prostaglandins, which helps to relieve pain during DJ removal. Tamsulosin is a medication that works as a selective alpha 1 blocker. Prostate, bladder, and ureter all have alpha 1 receptors. Tamsulosin can help to minimise ureteral contractions as well as irritation in the trigonal area. A single dose of a NSAID was used by Tadros et al⁴ to prevent severe discomfort after the removal of

a ureteral stent. In other studies, the combination of silodosin and diclofenac sodium was found to be useful in decreasing discomfort following ureteral stent removal.⁵ In patients with DJ-stents, the combination of tamsulosin and propiverine reduced irritative voiding symptoms, suprapubic pain, and improved quality of life.⁶ In study by Hadibrata et al⁷ tamsulosin along with diclofenac was found to be effective therapy to decrease pain after stent removal.

MATERIALS AND METHODS

The study was done between October 2019 to March 2021. A total of 60 patients scheduled for outpatient DJ removal were included in the study. A 5 Fr DJ polyurethane ureteral stent was used in all of the patients. Before being removed, the DJ-stent was retained for 3-4 weeks.

Participants were divided into three equal groups using a computer-based generated random number sequence before starting the study. Group-A included patients who were given placebo. Group-B included patients who were given diclofenac prior to DJ removal and Group-C included patients who were given combination therapy with diclofenac and tamsulosin two hours before procedure.

Inclusion Criteria

1. Age > 18-years.
2. All patients with unilateral DJ-stent in situ following percutaneous nephrolithotomy (PCNL) or ureteroscopic lithotripsy (URL).

Exclusion Criteria

1. Analgesic or sedative drugs used within at least 24-hours from the procedure.
2. Contraindications for the procedure (e.g., lidocaine allergy, urinary tract infection, anatomical problems related to the urethra).

Urine routine microscope was routinely performed before cystoscopy. Patient were given placebo (Multivitamin tablet) in Group-A, Diclofenac in Group-B and Diclofenac and Tamsulosin in Group-C 2-hours prior to DJ removal.

After taking informed consent from the patients, the patients were placed in a lithotomy position. Perineum was cleaned with povidine iodine, and 10 ml 2% lidocaine gel was then injected into the urethra. A 17 Fr rigid cystoscope was used for all patients. No analgesic drugs were administered to the patients during the procedure.

Baseline vital parameters (pulse rate, systolic blood pressure and diastolic blood pressure) were documented before and during the procedure using pulse-oxymetry and non-invasive blood pressure monitoring. Subsequently, all these patients were given a visual analog scale (VAS) score sheet (Figure 1) to rate their pain sensation during the procedure on a scale of ranging from 0 to 10 after the completion of procedure. We defined no pain as a score of 0, mild pain as a score of 1 to 3, moderate pain as a score

of 4 to 7, and severe pain as a score of 8 to 10. Anxiety score were assessed using state trait anxiety scale (Figure 2).

Figure 1. Visual Analog Scale Score for Pain Sensation

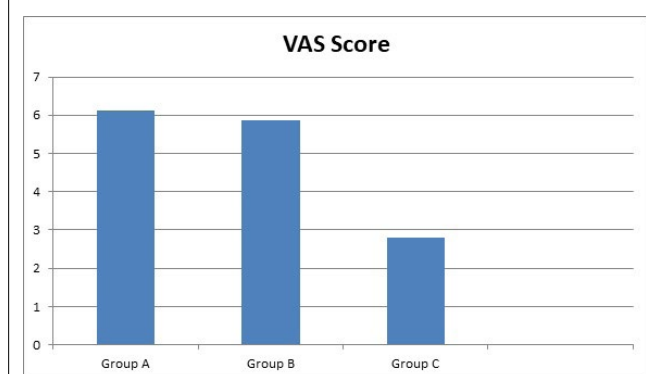
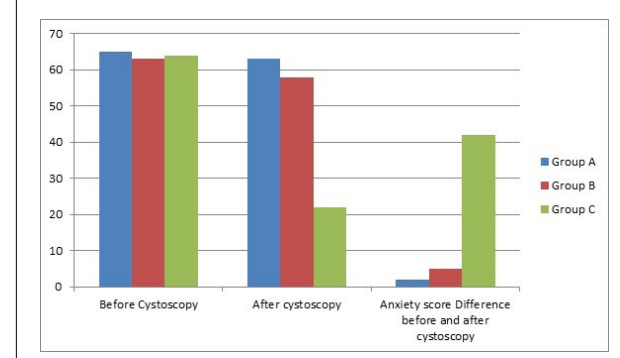


Figure 2. Median Anxiety Score as per State Trait Anxiety Scale



Number, percentage, mean, standard deviation and median were used for descriptive statistics of the data. Comparative analysis between two groups was performed using the Chi-square test for categorical data and independent *t*-test or Mann-Whitney U-test for continuous data. *p* value less than 0.05 was considered as significant. Statistical package for social sciences (SPSS) software was used for analysis (version 20, IBM Corporation, NY, and USA).

RESULT

A total of 60 patients were included. No participants withdrew from the study.

General Characteristic

The mean ($\pm$ standard deviation) patient age was 36.5 ± 9.3 -years in Group-A and 38.8 ± 10.6 in Group-B and 35.4 ± 10.2 in Group-C. The age distribution among groups were comparable without any significant differences. There was no statistical significant difference between the two groups in terms of body mass index, and educational status ($p > 0.05$) (Table 1).

VAS Score, Anxiety Score and Hemodynamic Parameters Related to Cystoscopy

There was no statistical difference between duration of surgery. The mean duration of the procedure was 7.7 ± 1.4 -minutes in Group-A, 8.1 ± 1.5 -minutes in Group-B and 7.4 ± 1.6 -minutes in Group-C ($p > 0.05$). Compared to the Group-A and Group-B, pain scores were significantly lower in Group-C (Table 2).

A statistically significant difference was found to be between the two groups in terms of anxiety scores before and after cystoscopy.

Anxiety scores before cystoscopy were similar in all groups, but anxiety scores after cystoscopy were significantly lower in Group-C than the Group-A and Group-B (Table 3).

Statistically significant differences were also found between the Group-C and the Group-A and B in terms of intraoperative systolic pressure and pulse rate. These parameters were significantly lower in the Group-C (Table 4).

DISCUSSION

The patients planned for DJ removal are often worried about the pain associated with the procedure and frequently enquire regarding the measures that would be undertaken for pain relief during the procedure. Several studies have been conducted to reduce stent-related pain and discomfort using drugs such as alpha blockers, anticholinergics, and phosphodiesterase inhibitors, as well as new stent designs, stent materials, and stent dimensions.⁸⁻¹²

In our study groups were comparable to age, body mass

Table 1. Coding Results

Characteristic	Group A (n=20) n%	Group B (n=20) n%	Group C (n=20) n%
Age (mean $\pm$ SD)	36.5 $\pm$ 9.3	38.8 $\pm$ 10.6	35.4 $\pm$ 10.2
BMI (mean $\pm$ SD)	25.4 $\pm$ 5.2	26.2 $\pm$ 4.9	24.2 $\pm$ 4.9
Educational Status			
Primary school	10(50%)	12(60%)	12(60%)
Secondary school	4(20%)	5(25%)	4(20%)
Higher education school	6(30%)	3(15%)	4(20%)

Table 2. Comparison between Pain Score (VAS Score)

	Group A (n=20) n%	Group B (n=20) n%	Group C (n=20) n%	p value
VAS Score (after cystoscopy)	6.12 $\pm$ 1.85	5.87 $\pm$ 1.47	2.80 $\pm$ 1.47	<0.001

p < 0.05 value is significant. Bold values are statistically significant. Mann-Whitney U test

Table 3. Median Anxiety Score before and after Procedure

	Group A (n=20) n%	Group B (n=20) n%	Group C (n=20) n%	p value
Before cystoscopy	65.0	63.0	64.0	0.08
After cystoscopy	63.0	58.0	22.0	<0.001
Anxiety Score difference before and after cystoscopy	2.0	5.0	42.0	<0.001

p < 0.05 value is significant. Bold values are statistically significant. Mann-Whitney U test

Table 4. Median Blood Pressure and Pulse Rate before and During Procedure

	Group A (n=20) n%	Group B (n=20) n%	Group C (n=20) n%	p value
Preoperative systolic BP (mm Hg)	134	136	130	0.78
Preoperative diastolic BP (mm Hg)	90	90	94	0.82
Preoperative pulse rate	86	86	86	0.68
Intraoperative systolic BP	154	158	138	0.018
Intraoperative diastolic BP	108	96	93	0.72
Intraoperative pulse rate	114	116	88	<0.001

p < 0.05 value is significant. Bold values are statistically significant; Mann-Whitney U test.

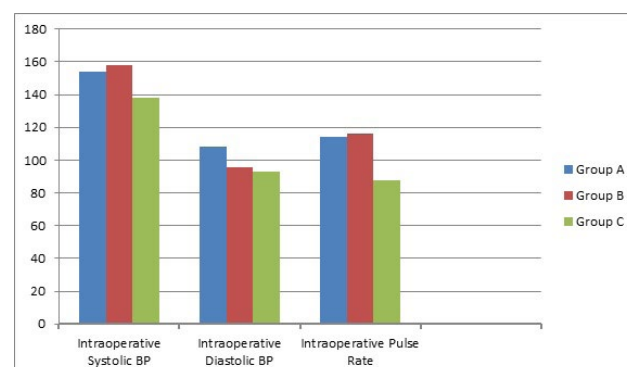
index (BMI) and educational status. Operative time was also comparable in all groups. VAS scored decreased significantly in patients who received combination therapy with diclofenac and tamsulosin. There was significant reduction of anxiety on state trait anxiety scale. Systolic BP, diastolic BP and pulse rate were comparable in all groups before procedure however during the procedure a statistically significant difference was found in these parameters (Except diastolic BP).

CONCLUSION

Combination therapy with tamsulosin and diclofenac reduces subjective pain sensation and there is an objective change in the sympathetic response to pain as demonstrated by the change in vital parameters.

This is a simple method to decrease pain, anxiety and hemodynamic parameters (Figure 3) in patients undergoing DJ removal.

Figure 3. Median Hemodynamic Parameters during Cystoscopy



LIMITATION

DJ removal was not done by same urologist in every patient. Pain score and anxiety score were assessed immediately after DJ removal and patient were not followed-up for development of any symptoms. Finally, objective assessment is difficult because pain is subjective.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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