ISSN: 0975-833X

Available online at http://www.journalcra.com

International Journal of Current Research
Vol. 11, Issue, 02, pp.1709-1710, February, 2019

DOI: https://doi.org/10.24941/ijcr.34586.02.2019

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

RESEARCH ARTICLE

DICLOFENAC VS PLACEBO IN MEN UNDERGOING DJ STENT REMOVAL- A RANDOMIZED DOUBLE-BLINDED STUDY

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ARTICLE INFO

Article History:
Received 22nd November, 2018
Received in revised form
20th December, 2018
Accepted 03rd January, 2019
Published online 28th February, 2019

Key Words:

Analgesia, Double J stent, Diclofenac.

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ABSTRACT

Introduction: Double J (DJ) stent removal requires local anesthesia and is done using rigid cystoscope. Patients experience significant pain during and after the procedure. We assessed the efficacy of preemptive oral diclofenac in analgesia for patients undergoing DJ stent removal by rigid cystoscopy compared to placebo. **Methods:** Only male patients undergoing DJ stent removal under local anesthesia between March 2017 and July 2018 were enrolled. Patients were randomized to receive 50 mg oral diclofenac (Group A) or placebo (Group B) 1 hour before procedure by randomization. Intraurethral 2% lignocaine gel (25 ml) was used in both groups. Pain during rigid cystoscopy, pain at the first void, and at 1 day after cystoscopy was assessed using visual analog scale (VAS) (0–100). Adverse reactions to diclofenac and episodes of acute urinary retention, if any, were assessed. **Results:** Totally 121 males (Group A [n = 62]; Group B [n = 59]) underwent stent removal. The median (Interquartile range) VAS during the procedure in Group A was 30 (30) and Group B was 60 (30) (P< 0.001), at first void was 30 (30) and 70 (30) (P< 0.001) and at 24 h postoperatively was 20 (20) and 40 (20) (P< 0.001). The incidence ofside effects was comparable in the two groups (P> 0.05). **Conclusions:** A single oral dose of diclofenac 1 h before DJ stent removal using rigid cystoscope under intra-urethral lignocaine anesthesia decreases pain significantly during and upto one day after the procedure,with minimal side effects.

Citation: Mohamed Noohu Bariz S.A.K., Balaji A.R. and Prakash J.V.S.. **2019.** "Diclofenac vs placebo in men undergoing dj stent removal- a randomized double-blinded study", *International Journal of Current Research*, 11, (02), 1709-1710.

INTRODUCTION

J (DJ) stents are removed under local anesthesia using a rigid cystoscope. Patients experience significant pain during and after the procedure for few days. Lignocaine gel during this procedure is not very effective (Kobayashi, 2004; Chen, 2005; McFarlane, 2001; Herr, 2001 and Komiya, 2009). Numerous reports exist on the effect of local anesthesia against cystoscopy-associated pain, but so far there has been no study on the preemptive analgesic effect of nonsteroidal anti-inflammatory drugs (NSAIDs) (Kobayashi, 2004 and Chen, 2005). Hence, our study was done to assess the effect of preemptive oral diclofenacfor analgesia in patients undergoing DJ stent removal by rigid cystoscopy when compared to placebo and to assess its safety.

MATERIALS AND METHODS

Trial design: The study was conducted from March 2017 to July 2018 in the Department of Urology, Government Stanley medical college, Chennai in 121 patients undergoing DJ stent removal using rigid cystoscope. Study design: double-blind, randomized, placebo-controlled trial.

Inclusion Criteria: All random male patients aged more than 18 years, undergoing DJ stent removal under local anesthesia (2% lignocaine gel), were eligible for the study after providing a written informed consent.

Exclusion criteria: The exclusion criteria were age <18 years, inability to understand visual analog scale (VAS) for pain, lower urinary tract symptoms (LUTS) before initial surgery, prostatitis or urethral stricture during cystoscopy, renal failure (serum creatinine>1.5 mg/dl), concomitant usage of nephrotoxic drugs, history suggestive of or known case of peptic ulcer disease or upper gastrointestinal bleed or upper abdominal surgeries Patients were randomized to receive oral diclofenac 50 mg or placebo by randomization. The patient and the investigator who assessed the outcome (pain) were also blinded.

Intervention: All patients were administered the drugor placebo 1 h before the procedure. A 20 Frcystoscope was used for DJ stent removal in all patients. 25 ml of 2% lignocaine gel was injected intraurethrally and was allowed to act for 10 minutes. Cystourethroscopy was performed and DJ stent was removed with a DJ stent removal forceps. Postoperative pain score was evaluated with the 100-point VAS (Aubrun, 2003 and Jensen, 2003). VAS was assessed during procedure, first

void, and 24 h after DJ stent removal. The presence of nausea, vomiting, epigastric pain, and urinary retention was recorded.

Statistical analysis: Statistical analysis was performed using SPSS version 20.Independent samples t-test or Mann–Whitney U-test as appropriate was used based on the normality of the distribution. Chi-square/Fisher's exact test was used for categorical variables. The P< 0.05 was considered statistically significant.

RESULTS

The baseline patient characteristics such as age, side, weight, duration of stent, and operative time were almost similar [Table 1].

Patient characteristics		Groups	p
	A(n = 62)	B (n = 59)	
Age, mean +/- SD (years)	47.5 +/- 9.76	46.05 +/- 9.12	0.22
Right : Left (n)	41:21	30:29	0.47
Duration of stent, mean +/- SD (days)	20.93 +/- 5.36	21.36 +/- 5.45	0.87
Weight, mean +/- SD (kg)	51.35 +/- 10.12	51.75 +/- 10.49	0.18
Duration of procedure, mean +/- SD (min)	2.30 +/- 1.20	2.50 +/-1.31	0.60

SD = Standard deviation

Pain: The median pain score was lower in the Group A during, at first void, and 1 day after DJ stent removal. Statistically significant difference was observed between Groups A and B [Table 2].

Timing		Visual analog scale	P
	A (n=62)	B (n = 59)	<0.001
Pain during procedure, median (IQR)	30 (30)	60 (30)	
Pain during first void, median (IQR)	30 (30)	70 (30)	<0.001
Pain after 24 hours, median (IQR)	20 (20)	40 (20)	<0.001

Adverse reactions: Epigastric pain, nausea and vomiting were slightly higher in the patients receiving diclofenac,but not statistically significant. No patient developed acute urinary retention [Table 3].

Adverse reactions		Number of patients	P
	A (n=62)	B (n = 59)	
Epigastric pain	10 (16)	6 (10)	0.08
Nausea and vomiting	8 (13)	5 (8.5)	0.06

DISCUSSION

This study was performed to assess if diclofenac is effective in reducing pain during DJ stent removal using rigid cystoscopy. Preemptive analgesia before cystoscopy under local anesthesia should be considered as the standard of care to reduce pain experienced by the patient. Lignocaine gel has little analgesia only.[2],[3],[4]So far there has been no objective evaluation of the preemptive analgesic effect of NSAID In rigid cystoscopy,pain score during cystoscopy was maximum, followed by the first and second urination after cystoscopy, injection of gel, and urination the day after cystoscopy (Chen, 2005). We found that oral diclofenac was effective in reducing pain during stent removal and up to 24 h after the procedure in our patients. We included only male patients to avoid the confounding effect of urethral length in assessing the efficacy of diclofenac. Surgical trauma induces cyclooxygenase-2 (COX-2) enzyme causing release of prostaglandins, which sensitize the peripheral nociceptors and produce localized primary hyperalgesia. This resultant central sensitization produces pain hypersensitivity in the surrounding uninjured tissue (Aida, 1999). After nociception, central sensitization induces c-Fos expressed in spinal dorsal neurons which augments the nociceptive sensitivity. Wind-up is the mechanism of central sensitization, mainly by the activation of N-methyl-D-aspartate (NMDA) and neurokinin receptors. Preoperative NSAIDs before tissue trauma set in prevent the development of hyperalgesia (Aida, 1999). NSAIDs, by inhibiting the early production of prostanoids before surgical trauma more effectively, prevent the development of both peripheral and central sensitization and hyperalgesia. They also block the nociceptive impulses, increase the threshold of nociceptive neurons by opioids, block the wind-up using NMDA receptor antagonists, and suppress local inflammation. It is possible to produce a painless postsurgical state with NSAIDs. Diclofenac is a nonspecific COX inhibitor. Since patients are preemptively treated with diclofenac, inflammation incited by the stent removal procedure is lesser, and consequently, pain incited is lesser. In our study, pain assessment by VAS was done up to 24 h.

Conclusion

A single preproceduraloral dose ofdiclofenac administered 1 h before DJ stent removal done by rigid cystoscope under intraurethrallignocaine anesthesia decreases pain significantly during and up to 24 h postprocedure with minimal side effects and can be safely prescribed for office endo-urological procedures.

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