# COMPARISON OF PAIN INTENSITY BETWEEN LIDOCAINE GEL AND INTRAURETRAL TRAMADOL WITH LIDOCAINE GEL IN THE DJ STENT REMOVAL

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#### **ABSTRACT**

Objective: To determine the difference in pain intensity between the administration of a combination of tramadol and intraurethral lidocaine gel with only lidocaine gel during the removal of DJ stents. Material & Methods: This study was a prospective randomized clinical trial with 22 patients that were divided into 2 groups. Group 1 was given a combination of tramadol and lidocaine gel urethral injection 3 to 5 minutes before DJ stent removal, whereas group 2 was given lidocaine gel urethral injection 3-5 minutes before the removal. The inclusion criteria in this study was all patients with a DJ stent placement with 1 to 3 months prior to release who were willing to participate. The Wong-Baker scale was used directly to determine the scale of pain during the procedure. Mann Whitney analysis was used to analyze the findings. Results: Most patients in group 1 are shown to have a pain rating of 2. There are 2 patients with a high pain rating scale of 6 and 7. In group 2, most patients claimed that the procedure was painless. The average Wong-Baker pain scale in group 1 (2.9) compared to group 2 (0.36) was significantly different. Conclusion: The combination of intraurethral tramadol and 2% lidocaine gel can significantly decrease pain during DJ stent removal more effectively than sole intraurethral 2% lidocaine gel based on the Wong-Baker pain scale.

Keywords: Lidocaine, tramadol, DJ stents, pain.

#### **ABSTRAK**

Tujuan: Mengetahui perbedaan intensitas nyeri antara pemberian kombinasi tramadol dan lidokain gel intrauretral dengan lidokain gel pada pelepasan DJ stent. Bahan & Cara: Penelitian ini merupakan uji klinis acak prospektif dengan 22 pasien yang dibagi menjadi 2 kelompok. Kelompok 1 diberikan kombinasi injeksi uretra gel tramadol dan lidokain 3 sampai 5 menit sebelum pencabutan DJ stent, sedangkan kelompok 2 diberi suntikan uretra gel lidokain 3-5 menit sebelum pengangkatan. Kriteria inklusi dalam penelitian ini adalah semua pasien dengan pemasangan DJ stent dalam 1 sampai 3 bulan. Skala Wong-Baker digunakan secara langsung untuk menentukan skala nyeri selama prosedur. Analisis Mann Whitney digunakan untuk menganalisis temuan. Hasil: Sebagian besar pasien dalam kelompok 1 terbukti memiliki nyeri tingkat 2. Ada 2 pasien dengan penilaian nyeri tinggi skala 6 dan 7. Pada kelompok 2, sebagian besar pasien menyatakan bahwa prosedur tidak menimbulkan rasa sakit. Rata-rata skala nyeri Wong-Baker pada kelompok 1 (2.9) dibandingkan dengan kelompok 2 (0.36) berbeda nyata. Simpulan: Kombinasi tramadol intraurethral dan gel lidokain 2% secara signifikan mengurangi nyeri selama pencabutan DJ stent dan lebih efektif daripada gel lidokain intrauretra 2% tunggal berdasarkan skala nyeri Wong-Baker.

Kata kunci: Lidokain, tramadol, DJ stent, nyeri.

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#### INTRODUCTION

Ureteral stents are widely used in the practice of urology since the beginning of the 19th century. The first endoscopic installation of a ureteral stent was performed by Zimskind in 1967.

The use of this ureteral stent in the management of upper urinary tract obstruction has proven to be beneficial.<sup>2</sup> The design most often used is a stent with a double coil (double J stent or DJ stent) with the ability to maintain its position. The design of the double coil at the functions of the proximal and distal

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end as an anchor in the upper urinary tract and the lower urinary tract. DJ stents prevent possible ureteric obstruction by ensuring urinary diversion.<sup>3</sup>

In some cases, the stent can be removed a few days after the procedure, whereas in other cases, some urologists would recommend it to stay for a longer period. In general, stents must be removed or replaced within 3 months. The removal of the DJ stent is usually done in the operating room using a rigid cystoscopy. Cystoscopy, a standard for releasing DJ stents, often causes discomfort and pain. Research by Loh-Doyle et al. has confirmed that 57% of patients experience moderate to severe pain during the removal procedure.

Local anesthesia has long been used for cystoscopy using a rigid cystoscope. Recent reports indicate that lidocaine gel does not affect pain during cystoscopy. The efficacy of various lidocaine gels may be due to slow and incomplete topical lidocaine absorption. Some groups have shown that maximum lidocaine absorption requires 15 to 60 minutes. 10

Tramadol, a synthetic analog of 4phenylpiperidine is an analgesic that has a mechanism of action in the central nervous system used in the treatment of moderate to severe pain without causing respiratory and cardiovascular side effects.11 However, recently Tramadol was discovered to also have a local anesthetic effect. Kajhavi et al discovered that the combination of tramadol and lidocaine for cystoscopy can reduce pain more significantly compared to sole lidocaine gel. 12 Therefore, we aimed to examine the difference in pain intensity between intraurethral injections of tramadol combined with lidocaine gel and sole lidocaine gel during DJ stent removal. The addition of intraurethral tramadol is hoped to be an option for urologists as an alternative to other analgesics in patients undergoing DJ stent release.

# **OBJECTIVE**

We aimed to examine the difference in pain intensity between intraurethral injections of tramadol combined with lidocaine gel and sole lidocaine gel during DJ stent removal.

## **MATERIAL & METHODS**

This study was a prospective randomized clinical trial examining the difference in pain intensity between intraurethral injection of lidocaine gel combined with tramadol and lidocaine gel during DJ stent removal.

Patients were divided into 2 groups, in which group 1 was given a combination of tramadol and lidocaine gel urethral injection 3 to 5 minutes before DJ stent removal, whereas group 2 was given lidocaine gel urethral injection 3-5 minutes before the removal. The inclusion criteria in this study was all patients with a DJ stent placement with 1 to 3 months prior to release who were willing to participate.

Before the procedure, informed consent was taken from each subject. Randomization was performed by randomly drawing and assigning names to each group. The procedure was carried out aseptically with antibiotic prophylaxis given beforehand. Group 1 was injected with 10 ml of 2% lidocaine gel mixed with 2 ml sterile aquadest through the external urethral meatus using a 20cc syringe. Group 2 was injected with 10 ml of 2% lidocaine gel mixed with 100 mg of tramadol dissolved in 2 ml sterile aquadest through the external urethral meatus using a 20cc syringe. After the injection, a clam was placed posterior to the coronary sulcus for 3-5 minutes. The value of the degree of pain was determined by each patient using the Wong-Baker Faces Pain Rating Scale.

### **RESULTS**

Table 1. Subjects' Characteristics.

Variable	n	%
Gender		
Male	5	22.7
Female	17	77.3
Age		.4 years
Duration of DJ stents use	x = 12	2.3 days
Encrustation		
Yes	3	13.6%
No	19	86.4%

**Table 2.** Comparison of data between the two groups.

Variable	Group 1	Group 2
Gender		
Male	3	2
Female	8	9
Age (Mean)	41.9 years	46.9 years
Duration of DJ stents use (Mean)	104.36 days	140.27 days
Encrustation		
Yes	2	1
No	9	10

The total sample of the study was 22 people. The variable characteristics of the subjects displayed in this study were: age, gender, duration of DJ stent placement, and the incidence of encrustation.

In this study, the majority of subjects were females with a total of 17 subjects (77.3%). The average age of the subjects was 44.4 years, with 122.3 days of DJ stents use was. Most of the study subjects (86.4%) did not experience encrustation.

Both groups were dominated by female. Group 1 subjects had an average age of 41.9 years, while group 2 had an average age of 46.9 years. In group 2 the average length of DJ Stent placement was longer, which was 140.27 days, compared to 104.36 days in group 1. Most study subjects in both groups did not experience encrustation.

The intensity or pain scale felt by the patient during the release of the DJ stent was then measured using the Wong-Baker scale. A normality test was done using the Shapiro Wilk test as shown in table 3 because the number of samples was fewer than 50 subjects.

Both groups had the abnormal distribution of Wong-Baker scale variables. Therefore, the analysis was performed using the Mann-Whitney test to evaluate the difference in Wong Baker's pain scale between the two study groups.

In the distribution of pain intensity scale data shown in figure 1, most patients in group I are shown to have a pain rating of 2. There are 2 patients with a high pain rating scale of 6 and 7. In group 2, most patients claimed that the procedure was painless.

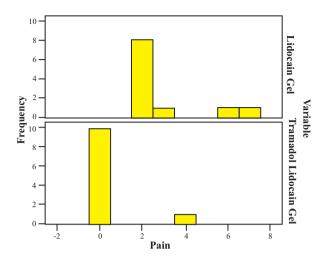
Comparing the pain scale of both groups using the Mann Whitney test's resulted in a significant difference between the pain scale of both groups shown in table 4. Table 5 shows a higher mean rank of the pain scale in group 1 compared to group 2.

**Table 3.** Wong Baker pain scale normality test results.

Variable	Shapiro Wilk (Sig.)
Wong Baker's Pain Scale	
Lidocaine Gel	0.000
Lidocaine Gel + Tramadol	0.000

**Table 4.** Comparative analysis of the Wong-Baker pain scale between the two groups

Variable	Group	Group	P
	1	2	value
Wong Baker's Pain Scale (Mean)	x = 2.9	x = 0.36	0.000



**Figure 1.** Histogram of pain intensity among both study groups.

**Table 5.** The Mean Rank of the Wong-Baker Pain Scale for Each Group.

Variable	Mean Rank
Wong Baker's Pain Scale	
Lidocaine Gel	16.18
Lidocaine Gel + Tramadol	6.82

#### **DISCUSSION**

The removal of the Double J (DJ) Stent was often performed under local anesthesia using a rigid cystoscope. Patients generally experienced significant pain during this procedure and continued to feel discomfort during urination for several days. <sup>13</sup>. In this study, the majority of subjects were female with a total of 17 subjects (77.3%). This finding was different in some other studies which showed that the average research subject was male. A study by Ahmad et al evaluated similar parameters with 72.67% male subjects. Another study by Ozgur et al. was also dominated by male subjects, 70 male subjects compared with 60 female subjects. <sup>14-15</sup>

The average age of subjects in this study was 44.4 years. This finding was slightly different from a study related to DJ Stent by Kose et al. which reported the average age of  $58.39 \pm 9.21$ . Another study by Abdelazil et al. involved similar parameters with an average age of  $49.3 \pm 12.6$  years. <sup>16-17</sup>

The average time of DJ Stents used in this study was 122.3 days. This finding showed a longer duration compared to other studies with the length of DJ stents ranging from 2 to 61 days. <sup>18</sup> In some cases, the DJ stent could be removed only a few days after

the procedure, while in other cases the urologist could recommend that the stent stayed longer. In general, stents must be removed or replaced within 3 months.<sup>4</sup>

In this study, the majority of study subjects (86.4%) did not experience encrustation. This indicates a lower level of encrustation compared to a study by Nerli et al. who reported 9.2% encrustation when DJ Stent was used for less than 6 weeks. The rate increases to 76.3% when it was left in place for 12 weeks. The use of longer DJ stents in the ureter carried a higher risk and tendency for microorganisms with biofilms on the surface of DJ stents. The formation of biofilms ultimately triggered the phenomenon of encrustation and increases morbidity. 19-20

The removal procedure of DJ Stent could generate pain. A study showed that the majority of patients undergoing stent removal had moderate to severe pain, with a Visual Analogue Scale (VAS) of 4 or more. The scale variation was due to the difference of methods used. Removing DJ Stents with cystoscopy produces the highest level of pain.<sup>7</sup>

In this study, the intensity or pain scale felt by the patient was measured using the Wong-Baker scale or the Wong-Baker Faces Scale (WBFS). The Wong-Baker Face scale combines numbers and faces for pain assessment. WBFS used facial images to represent facial expressions during various levels of pain. The face scale used a self-reported method to evaluate pain intensity. The face scale can be used on individuals with literacy problems. Images of facial expressions could convey different messages.<sup>21</sup> It has a degree of reliability and validity that has been tested in various languages.

In the distribution of pain intensity scale data it was found that the majority of Wong Baker's pain scale results in group 1 was 2, whereas in group 2, it was mostly 0. The average Wong-Baker pain scale in group was 2.9, compared to group 2 with an average scale of 0.36. The difference of pain between the groups was significantly based on the Mann Whitney test (p<0.05).

Conservatively, the use of lidocaine gel was reported to be no more effective at controlling pain during the DJ Stent release procedure. Recent reports indicated that lidocaine gel had an insignificant effect in pain during cystoscopy. The varying effectiveness of lidocaine gel might be due to the slow and imperfect absorption of topical lidocaine. Several studies show that maximum lidocaine absorption requires 15 to 60 minutes.

To overcome the limited analgesic effect of lidocaine gel, several methods need to be combined. Tramadol hydrochloride was widely used in daily anesthetic practice and its monoaminergic activity made it suitable for analgesic approaches, especially for short duration surgical procedures. Tramadol was chosen in this study because it could be safely administered before and after surgery as preemptive or preventive analgesia without modification of anesthetic depth.<sup>22</sup> In the setting of the DJ Stent procedure, tramadol was an intermediate analgesic agent.<sup>23</sup> Urologists need to focus on the impact of cystoscopy during stent removal. The conservative method of using lidocaine gel was necessary to be combined with other analgesics/anesthetic agents to suppress pain and discomfort experienced by patients.

#### LIMITATION

This study did not divide the groups based on gender due to the limited number of samples and study period. In the future, studies focusing on specific genders should be performed. Other limitations of this study were the assessment of post-procedural pain which was only evaluated in the short term.

# CONCLUSION

The combination of intraurethral tramadol and 2% lidocaine gel can significantly decrease pain during DJ stent removal more effectively than sole intraurethral 2% lidocaine gel based on the Wong-Baker pain scale.

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