

## Comparison of tramadol drip versus local application of prilocaine for ESWL

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### Abstract

**Background:** Calculus of the urinary tract affects a large amount of population. Extracorporeal shock-wave lithotripsy (ESWL) has become the treatment of choice in patients with renal calculus. However pain during the procedure is one of the major limitations of the procedure.

**Aims:** This study was aimed to compare IV drip of tramadol versus local application of prilocaine as the choice of analgesic during ESWL procedure.

**Materials and Methods:** This was a prospective, double blind study conducted in a tertiary care hospital of Karnataka. Patients who met the inclusion criteria were randomized into two groups of 18 each. Primary and secondary outcomes were compared.

**Results:** Patients in Group A tolerated the procedure well with better stone clearance rates.

**Conclusions:** IV Tramadol achieves a better stone fragmentation rate with less pain and decreased duration than local application of prilocaine.

**Keywords:** Eswl, Tramadol, Prilocaine, Renal calculi.

### Introduction

Calculus of the urinary tract affects around 8.8% of the population.<sup>1</sup> Fragmentation of the calculus with Extracorporeal shock-wave lithotripsy (ESWL) has become the treatment of choice in patients with urinary calculi especially if the calculus is present in the renal pelvicalyceal system.<sup>1</sup> Extracorporeal shockwave lithotripsy (ESWL) involves fragmentation of the stone with shock waves generated from electrohydraulic, electromagnetic or piezoelectric generators.<sup>2,3</sup>

ESWL is intolerable for many patients. During lithotripsy, shock waves release energy as they pass through the interface between substances of different acoustic densities. The impact of the shock waves on the skin is the most painful stimulus during the procedure.<sup>4</sup> Analgesia during extracorporeal shockwave lithotripsy for renal stone is an essential component. With analgesia patient tolerates the procedure better thus increasing the stone free rate. A variety of intravenous, intramuscular, local and oral analgesic combinations have been suggested in the literature.<sup>5</sup> These include topical preparations, transcutaneous electrical nerve stimulation (TENS), anaesthetic injections (local, epidural, extradural), intravenous sedation (propofol), inhaled agents (nitrous oxide) and non-pharmacological methods (music, acupuncture).<sup>6</sup> Despite that, there is no uniform consensus on the type of analgesia and agent used. Tramadol HCL being an opioid depresses motor and sensory responses of the spinal nociceptive system by spinal and supraspinal action. The side effects of tramadol are much less severe than other opioids like morphine. We have conducted this study to determine the efficacy of intravenous tramadol for the control of pain during ESWL for urinary stones in contrast with topical application of prilocaine plus lignocaine mixture.

### Materials and Methods

The prospective double blind study was performed at a tertiary care hospital in the state of Karnataka in India from

August 2020 to January 2021 after availing the Institutional Ethical Committee clearance. The sample size was calculated with the help of G\* Power software version 3.1.9.2 (Heinrich-Heine-University, Düsseldorf, Germany) after calculating an effect size of 0.8 and power of 0.05 to be significant. After written informed consent 36 patients were divided according to computer generated randomization into two groups (A and B) of 18 each. Group A patients were given 50 mg of tramadol hcl diluted in 100 ml normal saline as analgesic during Extra corporeal shock wave lithotripsy procedure and group B patients were given lignocaine + prilocaine gel form as a topical analgesic during Extra corporeal shock wave lithotripsy procedure. CONSORT guidelines were followed.

Patients with renal calculus of size 5–15 mm were screened. Routine clinical examination and investigations were performed according to institutional protocol. Routine antibiotic prophylaxis was given in all cases with single dose of tablet levofloxacin 500 mg one hour before the procedure. Primary outcomes of the study were pain assessment during ESWL procedure and success or failure of procedure. The pain was cataloged based on the VAS (visual analogue scale) score with score of 1 to 10, with 10 being the worst pain. Success of procedure being defined as complete clearance of stone or clinically insignificant fragment size of <4mm size after 4 weeks of the session. Secondary outcomes were number of shocks, number of sittings required and level of energy tolerated. Complications, if any were denoted by Modified Clavien-Dindo (MCD) classification. All statistical calculations were done using SPSS 21 version (Statistical Package for the Social Science) statistical program for Microsoft Windows. Data was calculated in terms of mean  $\pm$  standard deviation ( $\pm$ SD), median, frequencies (number of cases) and percentage. Independent t-test was used for comparison between two groups. The association between categorical variables was examined using Chi-square and Fisher-exact tests. Statistical significance was kept below 0.05, and the confidence interval was selected at 95%.

## Results

Thirty six patients were finally available for analysis. Demographic profile including age, gender and BMI was comparable among both the groups (Table 1). Stone characteristics i.e. stone size, density and location was also comparable among study groups (Table 2). Group B required more number of shocks and number of sittings than Group A [Table 2]. A higher energy level of shocks was tolerated by Group A patients. Mean pain score in Group A and B was 2.8 and 4.8, respectively [Table 2]. The successful outcome occurred in 72.2% and 61.1% of cases in Groups A and B,

respectively. MCD Grade I complications were observed in 50% and 44.4% of cases in follow-up period in Groups A and B, respectively. These include post procedure pain, suprapubic discomfort, nausea, and vomiting. They were managed by analgesic and antiemetic medications as needed. Grade II complications were reported by 27.7% of study participants [Table 2].

**Table 1:** Baseline clinical and stone parameters

Parameters	Group A (n=18)	Group B (n=18)	P-value
Age (years)	37.8 ± 10.8	41.2 ± 11.8	0.324
Gender	1:1	1:1.7	0.287
BMI (kg/m <sup>2</sup> )	27.74 ± 3.80	27.81 ± 2.76	0.924
Stone size (mm)	10.7 ± 2.8	9.8 ± 2.5	0.127
Stone density (HU)	920 ± 280	910 ± 290	0.674
Stone location			
L	9.12	7.18	1.0
NL	23.12	21.18	

BMI: Body mass index, L: Lower polar, NL: Non-lower polar

**Table 2:** Comparison of primary and secondary outcomes

	Group A (n=18), n (%)	Group B (n=18), n (%)	P-value
Vas score	2.8 ± 1.7	4.8 ± 1.8	0.000
Outcome			
Success	13 (72.2)	11 (61.1)	0.274
Failure	5 (27.7)	7 (38.8)	
Number of shocks (mean ± SD)	3691 ± 1131	4272 ± 1040	0.042
Number of sittings	1.8 ± 0.7	2.2 ± 0.6	0.036
Energy level (kV)	3.1 ± 0.8	2.4 ± 0.7	0.02
Complications			
Grade I	9 (50)	8 (44.4)	0.199
Grade II	2 (11.1)	3 (16.6)	
Grade IIIa	1 (5.5)	1 (5.5)	
Grade IIIb			

**Table 3:** List of studies evaluating analgesic effect of various agents

Author	Cases	Analgesic type	Result	Comment
Liu and Zang, 2013 <sup>9</sup>	105	IM diclofenac, EMLA gel, and Diclofenac gel	All are equal, P=1.34	Local reaction with gel occurred
Ozkan et al., 2012 <sup>10</sup>	95	Injection lornoxicam, injection PCM, and injection tramadol	L was better, P<0.05	IV administration needed for all
Akcali et al, 2010 <sup>11</sup>	90	Injection lornoxicam, injection PCM, and injection tramadol	All are effective	Similar adverse events
Erylidirim et al, 2009 <sup>12</sup>	120	EMLA gel, IM diclofenac, and combination	Diclofenac is better, P=0.002	Combination is no superior

## Discussion

ESWL is a non-invasive and safe technique for small sized renal and upper ureteric stones. Recent guidelines by European Association of Urology recommend it to be a first line treatment modality for renal stones of <10 mm size.<sup>7</sup> In case of >10 mm, lower pole location and density >1000 HU, its efficacy decreases to a great extent.<sup>8</sup> Various factors influence the outcome of procedure out of which good analgesia and complete relaxation of patient contribute to a great extent. They help in delivering high energy shockwaves thus improving targeting of stones.

Various modes of anaesthesia and analgesia including intravenous, intramuscular, topical, local infiltration and oral have been tried in recent times for better procedure outcome (Table 3). Reported efficacy of all these vary among the studies available in literature. We chose intravenous tramadol and topical application of EMLA because of their proven efficacy in various studies separately and also topical application being acceptable and comfortable for patients.

In our study group pain was better tolerated in tramadol group which was statistically significant. Overall outcome was similar among both groups. We noted a statistically significant decrease in number of shocks and number of sittings among tramadol group as compared to EMLA group. Also, higher energy level could be tolerated in group A. We didn't compare fragmentation and clearance rate among the study groups. Vergnolles et al has compared various predictive factors for pain during ESWL and had found out depression, anxiety, history of prior ESWL, homogenous stones and young age experiencing more pain and requiring greater analgesia.<sup>13</sup> We could not find any correlation of pain score with age, BMI, stone size and stone density. Limitations of this study could be a small sample size, comparison among two groups and no placebo control group.

## Conclusion

Patients receiving intravenous tramadol tolerated the procedure better than their counterparts. Though final outcome was similar in both groups, tramadol group achieved it in lesser number of sittings and with fewer number of high powered shocks.

## Conflicts of Interest

All contributing authors declare no conflicts of interest.

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