

A prospective randomized study comparing the analgesic effects of intravenous nalbuphine with intravenous tramadol on postoperative pain and postoperative analgesic requirement for patients undergoing percutaneous nephrolithotomy

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Abstract

Background: Providing effective pain relief for the patients undergoing surgery is one of the major goals of postoperative management. Opioid based therapy represents the traditional choice for the management of postoperative pain. The aim of this study is to compare the analgesic effects of intravenous nalbuphine with intravenous tramadol on postoperative pain and postoperative analgesic requirement for patients undergoing percutaneous nephrolithotomy. **Methods:** This is a randomized controlled study which included 60 patients divided into two groups of 30 each undergoing percutaneous nephrolithotomy performed under general anesthesia, received either Nalbuphine at a bolus dose of 0.2 mg/kg 30 mins before extubation and Tramadol at a bolus dose of 1 mg/kg 30mins before extubation. The primary outcomes measured were Post-operative visual analog score and Systolic blood pressure(SBP), diastolic blood pressure(DBP), mean arterial pressure(MAP), heart rate(HR), respiratory rate(RR) and oxygen saturation(Spo2). The secondary outcomes measured were Post-operative rescue analgesic initiation time and Side effects and any other complications. **Results:** The mean visual analog score was less in nalbuphine group when compared to the tramadol group from 30 minutes to 8 hours time intervals, which was statistically significant. In both the groups, the hemodynamic changes and respiratory parameters in the post operative period were comparable and statistically insignificant. The nalbuphine group showed an increased occurrence of drowsiness, while the tramadol group showed an increased occurrence of nausea and vomiting. **Conclusion:** Nalbuphine appears to be an effective and safe analgesic for postoperative pain relief than tramadol in patients undergoing percutaneous nephrolithotomy, providing good sedation with minimum circulatory effects.

Keywords: Nalbuphine, postoperative analgesia, tramadol.

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Received Date: 08/12/2019 Revised Date: 10/01/2020 Accepted Date: 30/01/2020

DOI: <https://doi.org/10.26611/10151725>

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Quick Response Code:	Website: www.medpulse.in
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INTRODUCTION

Percutaneous nephrolithotomy is generally done for the management of large intranephric stones, mainly those resistant to shock wave lithotripsy, staghorn calculi and some proximal ureteral stones. Initially a ureteral stent is kept in lithotomy and then patient is repositioned to the prone position for the percutaneous puncture. General anaesthesia with endotracheal intubation is commonly used for this procedure. It allows for a secure airway for

positioning into the prone position. Nalbuphine and Tramadol when administered intravenously intraoperatively, tend to maintain better post-operative hemodynamics causing excellent post-operative pain relief. Hence the ill effects of post-operative pain are prevented by the two drugs. Tramadol is a centrally acting synthetic opioid analgesic^{2,3}. - a pure agonist (non-selective) at mu, delta and kappa opioid receptors with a higher affinity for the mu receptors and Weak inhibition of reuptake of norepinephrine and serotonin and as a serotonin releasing agent. Nalbuphine binds to mu, kappa, and delta receptors¹: but not to the sigma receptors. Nalbuphine hydrochloride is primarily a kappa agonist and partial mu antagonist analgesic. It is a potent analgesic and its potency is equivalent to that of morphine and has an opioid antagonist activity of about 1/4 as potent as nalorphine and 10 times that of pentazocine. The current study aims to compare the postoperative analgesic properties of Nalbuphine and Tramadol in equianalgesic doses in patients undergoing percutaneous nephrolithotomy

MATERIALS AND METHODS

This prospective randomized study was done on 60 patients coming for percutaneous nephrolithotomy, the procedure being done under general anaesthesia at Rajiv Gandhi Govt General Hospital, Madras Medical College.

INCLUSION CRITERIA: Age : 20 -60 years, Sex : both, Weight : BMI < 30 Kg/m². AS : I and II. Surgery: Elective. Mallampatti scores : I and II. Who has given valid informed consent.

EXCLUSION CRITERIA: Patients not satisfying inclusion criteria. Patients posted for emergency surgery. Patients with difficult airway. Patients with respiratory or cardiac disease. Lack of written informed consent. H/O seizures and any neurological deficit or on psychotropic drugs. H/O tolerance, dependence or allergy to opioids. Patients with diminished mental competence, deafness and visual disturbances.

MATERIALS

DRUGS: Inj. Glycopyrrolate. Inj.Fentanyl. Inj.Thiopentone sodium. Inj,Atracurium. Inj.Neostigmine. Inj.Nalbuphine Inj.Tramadol. All the emergency drugs were kept ready.

INTRAVENOUS FLUIDS:

Normal saline (NS). Ringer lactate (RL)

MONITORS: NIBP. ECG. SpO₂. EtCO₂. Temperature. Urine output

Procedure Methodology

The patient was shifted into the operating room. Monitors like non-invasive blood pressure, ECG, pulse oximetry were connected. The baseline vitals like the diastolic and systolic blood pressure, heart rate, SpO₂ were recorded.

Then an intravenous access with a 18G intravenous cannula was obtained. Premedication was done with inj.glycopyrrolate 0.2 mg and inj.fentanyl 2mcg/kg. The patient was then preoxygenated with a 100 % O₂ for 5 minutes. Induction was done with inj.Thiopentone and muscle relaxation was obtained with inj.Atracurium. The patient was then ventilated with a N₂O : O₂ in the ratio of 50% : 50% along with desflurane 6% for a time interval of 3 minutes. Endotracheal intubation was then done with the cuffed endotracheal tube of appropriate size. Maintenance of anesthesia was attained with N₂O :O₂ in the ratio of 50 % : 50 % along with desflurane 3 - 6%. Towards the end of the surgery the patients were randomized into 2 groups,

GROUP A (Nalbuphine): received a bolus dose of 0.2mg/kg 30 mins before extubation.

GROUP B (Tramadol) : received a bolus dose of 1mg/kg 30 mins before extubation.

After the end of the surgery, reversal was done with inj.glycopyrrolate 0.01 mg/kg and inj.neostigmine 0.05 mg/kg and extubated after thorough oral suctioning. Vitals and visual analog score were then monitored immediately and also post operatively at regular intervals in the post-operative ward. When the vas score was greater than 3, the patients were given rescue analgesic, inj.diclofenac 75 mg intramuscularly.

The study was done on 60 patients coming for percutaneous nephrolithotomy, the procedure being done under general anesthesia.

PARAMETERS MONITORED

PRIMARY OUTCOME MEASURES:

Post-operative visual analog score and Systolic blood pressure(SBP), diastolic blood pressure(DBP), mean arterial pressure(MAP), heart rate(HR), respiratory rate(RR) and oxygen saturation(Spo₂) were measured at baseline and at intervals of 1,5 15,30 mins and 1,2 4,6,8,10 hours postoperatively.

SECONDARY OUTCOME MEASURES: POST-OPERATIVE RESCUE ANALGESIC INITIATION TIME. SIDE EFFECTS AND ANY OTHER COMPLICATIONS.

The time interval between the administration of the study drug and the time when the VAS score becomes greater than 3 is known as the rescue analgesic initiation time. Inj.diclofenac im was used as the rescue analgesic

RESULTS

OBSERVATIONS AND ANALYSIS

The study is a prospective, randomized study comparing the analgesic effects of intravenous nalbuphine with intravenous tramadol on post-operative pain and post-operative analgesic requirements for patients undergoing percutaneous nephrolithotomy.

GROUP A (NALBUPHINE) : received a bolus dose of 0.2 mg/kg nalbuphine iv , 30 minutes before extubation
 GROUP B (TRAMADOL) : received a bolus dose of 1 mg/kg tramadol iv, 30 minutes before extubation.
 Descriptive statistics was done for all data and were reported in terms of mean values and percentages.

Suitable statistical tests of comparison were done. Continuous variables were analyzed with the unpaired t test. Categorical variables were analyzed with Fisher Exact Test. Statistical significance was taken as $P < 0.05$. The data was analyzed using SPSS version 16 and Microsoft Excel 2007.

VITALS:

✓ **HEART RATE**

Table 1:

Heart Rate Status		Baseline	PO-10 mins	PO-15 mins	PO-30 mins	PO-60 mins
Group	N	30	30	30	30	30
Nalbuphine	Mean	77.17	94.43	94.03	89.7	84.2
	SD	8.28	9.46	8.5	7.32	7.12
Group	N	30	30	30	30	30
Tramadol	Mean	77.07	94.33	94.73	88.5	84
	SD	7.41	7.28	6.67	6.85	5.73
P value Unpaired t Test		0.9609	0.9636	0.724	0.5148	0.905

Table 2:

Heart Rate Status		PO-2 hrs	PO-3 hrs	PO-4 hrs	PO-6 hrs	PO-8 hrs	PO-10 hrs
Group	N	30	30	30	30	30	9
Nalbuphine	Mean	80.77	77.87	79.03	78.33	80.30	87.33
	SD	6.56	6.07	5.46	6.33	6.73	4.33
Group	N	30	30	30	30	30	4
Tramadol	Mean	82.13	80.70	79.90	79.00	80.10	81.75
	SD	5.24	5.21	5.92	6.96	7.05	2.75
P value Unpaired t Test		0.3766	0.1472	0.2480	0.1293	0.4109	0.0705

Majority of the Nalbuphine Group patients had mean heart rate ranging from 77.17 bpm at baseline to 87.33 bpm at 10 hours postoperatively. Similarly majority of the Tramadol Group patients had mean heart rate ranging from 77.07 bpm at baseline to 81.75 bpm at 10 hours postoperatively. The association between the intervention groups and heart rate is considered to be not statistically significant since $p > 0.05$ as per 2 tail unpaired t test.

SYSTOLIC BLOOD PRESSURE

Table 3:

Systolic Blood Pressure Status		Baseline	PO-10 mins	PO-15 mins	PO-30 mins	PO-60 mins
Group	N	30	30	30	30	30
Nalbuphine	Mean	119.53	127.2	127.1	125.97	120.73
	SD	7.07	7.52	7.09	7.25	5.65
Group	N	30	30	30	30	30
Tramadol	Mean	120.07	127.17	127.8	126.03	120.5
	SD	6.52	6.24	6.6	6.82	6.14
P value Unpaired t Test		0.7625	0.9852	0.6937	0.9709	0.8788

Table 4:

Systolic Blood Pressure Status		PO-2 hrs	PO-3 hrs	PO-4 hrs	PO-6 hrs	PO-8 hrs	PO-10 hrs
Group	N	30	30	30	30	30	9
Nalbuphine	Mean	114.37	114.20	114.23	116.50	120.07	128.33
	SD	5.26	4.94	5.36	3.94	5.35	5.66
Group	N	30	30	30	30	30	4
Tramadol	Mean	115.10	113.50	114.27	117.43	122.43	128.50
	SD	5.97	4.90	4.69	4.99	4.25	0.58
P value Unpaired t Test		0.6158	0.5835	0.9796	0.4246	0.0630	0.9324

Majority of the Nalbuphine Group patients had mean systolic blood pressure ranging from 114.37 mm Hg at baseline to 128.33 mm Hg at 10 hours postoperatively. Similarly majority of the Tramadol Group patients had mean systolic blood pressure ranging from 115.10 mm Hg at baseline to 128.50 mm Hg at 10 hours postoperatively. The association between the intervention groups and systolic blood pressure is considered to be not statistically significant since $p > 0.05$ as per 2 tail unpaired t test.

DIASTOLIC BLOOD PRESSURE

Table 5:

Diastolic Blood Pressure Status		Baseline	PO-10	PO-15	PO-30	PO-60
			mins	mins	mins	mins
Group	N	30	30	30	30	30
Nalbuphine	Mean	75.73	84.7	80.47	77.63	74.57
	SD	7.18	7.24	6.34	4.68	4.3
Group	N	30	30	30	30	30
Tramadol	Mean	75.67	84.37	83.1	78.43	74.7
	SD	6.38	5.35	4.78	4.71	4.98
P value Unpaired t Test		0.9698	0.84	0.0748	0.5119	0.912

Table 6:

Systolic Blood Pressure Status		PO-2 hrs	PO-3 hrs	PO-4 hrs	PO-6 hrs	PO-8 hrs	PO-10 hrs
Group	N	30	30	30	30	30	9
Nalbuphine	Mean	73.40	74.60	74.83	75.67	78.10	82.11
	SD	4.94	4.51	4.91	5.45	6.25	3.14
Group	N	30	30	30	30	30	4
Tramadol	Mean	74.53	75.37	77.53	79.10	81.57	88.25
	SD	5.32	5.14	5.40	5.04	4.12	2.22
P value Unpaired t Test		0.3958	0.5416	0.4473	0.3140	0.5144	0.0936

Majority of the Nalbuphine Group patients had mean diastolic blood pressure ranging from 75.73 mm Hg at baseline to 82.11 mm Hg at 10 hours postoperatively. Similarly majority of the Tramadol Group patients had mean diastolic blood pressure ranging from 75.67 mm Hg at baseline to 88.25 mm Hg at 10 hours postoperatively. The association between the intervention groups and diastolic blood pressure is considered to be not statistically significant since $p > 0.05$ as per 2 tail unpaired t test.

MEAN ARTERIAL PRESSURE

Table 7:

Mean Arterial Pressure Status		Baseline	PO-10	PO-15	PO-30	PO-60
			mins	mins	mins	mins
Group	N	30	30	30	30	30
Nalbuphine	Mean	90.33	98.93	96	93.73	89.97
	SD	6.96	7.06	6.18	4.95	4.43
Group	N	30	30	30	30	30
Tramadol	Mean	90.43	98.53	98	94.3	89.9
	SD	6.35	5.17	5.01	5.17	4.87
P value Unpaired t Test		0.9538	0.8033	0.1741	0.6662	0.956

Table 8:

Systolic Blood Pressure Status		PO-2 hrs	PO-3 hrs	PO-4 hrs	PO-6 hrs	PO-8 hrs	PO-10 hrs
Group	N	30	30	30	30	30	9
Nalbuphine	Mean	87.03	87.80	88.00	89.23	92.07	97.67
	SD	4.34	3.84	3.57	3.74	4.70	3.61
Group	N	30	30	30	30	30	4
Tramadol	Mean	88.07	88.17	89.77	91.93	95.13	101.75
	SD	4.64	4.60	4.60	4.59	3.89	1.71
P value Unpaired t Test		0.3768	0.7387	0.1023	0.3154	0.1180	0.2185

Majority of the Nalbuphine Group patients had mean arterial pressure ranging from 90.33 mm Hg at baseline to 97.67 mm Hg at 10 hours postoperatively. Similarly majority of the Tramadol Group patients had mean arterial pressure ranging from 90.43mm Hg at baseline to 101.75 mm Hg at 10 hours postoperatively. The association between the intervention groups and mean arterial pressure is considered to be not statistically significant since $p > 0.05$ as per 2 tail unpaired t test.

RESPIRATORY RATE

Table 9:

Mean Arterial Pressure Status		Baseline	PO-10 mins	PO-15 mins	PO-30 mins	PO-60 mins
Group	N	30	30	30	30	30
Nalbuphine	Mean	13.00	13.30	12.40	11.93	12.40
	SD	1.20	1.42	0.72	0.74	1.00
Group	N	30	30	30	30	30
Tramadol	Mean	13.40	14.33	13.27	12.67	12.70
	SD	1.22	1.71	1.01	0.92	0.84
P value Unpaired t Test		0.2063	0.1136	0.2564	0.9713	0.2137

Table 10:

Respiratory Rate Status		PO-4 hrs	PO-6 hrs	PO-8 hrs	PO-10 hrs
Group	N	30	30	30	9
Nalbuphine	Mean	12.73	12.83	12.60	14.67
	SD	1.08	0.83	1.61	0.71
Group	N	30	30	30	4
Tramadol	Mean	12.67	13.10	12.80	15.25
	SD	1.03	1.06	1.16	0.50
P value Unpaired t Test		0.8075	0.2841	0.5829	0.1268

Majority of the Nalbuphine Group patients had mean respiratory rate ranging from 13 bpm at baseline to 14.67 bpm at 10 hours postoperatively. Similarly majority of the Tramadol Group patients had mean respiratory rate ranging from 13.40 bpm at baseline to 15.25 bpm at 10 hours postoperatively. The association between the intervention groups and respiratory rate is considered to be not statistically significant since $p > 0.05$ as per 2 tail unpaired t test.

SpO2 :

Table 11:

Peripheral Capillary Oxygen Saturation Status		Baseline	PO-30 mins	PO-60 mins	PO-2 hrs	PO-3 hrs
Group	N	30	30	30	30	30
Nalbuphine	Mean	98.70	98.43	98.67	98.87	98.90
	SD	0.47	0.57	0.48	0.35	0.31
Group	N	30	30	30	30	30
Tramadol	Mean	98.73	98.40	98.60	98.77	98.83
	SD	0.45	0.62	0.50	0.43	0.38
P value Unpaired t Test		0.7790	0.8291	0.5995	0.3253	0.4562

Table 12:

Peripheral Capillary Oxygen Saturation Status		PO-4 hrs	PO-6 hrs	PO-8 hrs	PO-10 hrs
Group	N	30	30	30	9
Nalbuphine	Mean	98.90	98.90	98.83	98.78
	SD	0.31	0.31	0.38	0.44
Group	N	30	30	30	4
Tramadol	Mean	98.87	98.87	98.80	99.00
	SD	0.35	0.35	0.41	0.00
P value Unpaired t Test		0.6936	0.6936	0.7438	0.1690

Majority of the Nalbuphine Group patients had Peripheral Capillary Oxygen Saturation ranging from 98.70 % at baseline to 98.78 % at 10 hours postoperatively. Similarly majority of the Tramadol Group patients had mean Peripheral Capillary

Oxygen Saturation ranging from 98.73 % at baseline to 99 % at 10 hours postoperatively. The association between the intervention groups and Peripheral Capillary Oxygen Saturation is considered to be not statistically significant since $p > 0.05$ as per 2 tail unpaired t test.

VISUAL ANALOG SCORE :

The postoperative pain scores in the two groups, which were analysed by the visual analog score, were as follows,

Table 13:

Visual Analog Score		PO-30 mins	PO-1 hrs	PO-2 hrs	PO-4 hrs	PO-6 hrs	PO-8 hrs	PO-10 hrs
Group Nalbuphine	N	30	30	30	30	30	30	9
	Mean	1.33	0.33	0.20	0.07	0.57	2.57	3.67
	SD	0.55	0.48	0.41	0.25	0.57	0.73	0.71
Group Tramadol	N	30	30	30	30	30	30	4
	Mean	1.70	0.40	0.30	0.40	1.00	3.10	3.75
	SD	0.60	0.50	0.47	0.62	0.64	0.61	0.50
P value Unpaired t Test		0.0160	0.0395	0.0197	0.0098	0.0076	0.0032	0.8143

By conventional criteria the association between the intervention groups and Visual Analog Score is considered to be statistically significant between 30 minutes-8 hours since $p < 0.05$ as per unpaired t test. In simple terms, in patients belonging to Nalbuphine intervention group, the mean Visual Analog Score is decreased to an average of 0.84 points in comparison with patients belonging Tramadol intervention group in whom the mean Visual Analog Score is an average of 1.15 points. The mean Visual Analog Score was meaningfully less in Nalbuphine intervention group compared to Tramadol intervention group by a mean difference of 0.31 points. This significant difference of 27% decrease in mean Visual Analog Score in Nalbuphine intervention group compared to Tramadol intervention group indicates that there is a true difference among intervention groups and the difference is significant with a p-value of 0.0160, 0.0395, 0.0197, 0.0098, 0.0076 and 0.0032 according to unpaired t-test. In this study we can safely conclude that Nalbuphine results in significantly decreased mean Visual Analog Score compared to Tramadol when used on postoperative pain and as postoperative analgesic for patients undergoing percutaneous nephrolithotomy.

RESCUE ANALGESIA INITIATION TIME

The time to initiation of rescue analgesic (inj.diclofenac) in the two groups were as follows,

Table 14:

Postoperative Rescue Analgesia Initiation Time	Group Nalbuphine	%	Group Tramadol	%
8 hours	21	70.00	26	86.67
10 hours	9	30.00	4	13.33
Total	30	100	30	100

Table 15:

Postoperative Rescue Analgesia Initiation Time	Group Nalbuphine	Group Tramadol
N	30	30
Mean	8.60	8.27
SD	0.93	0.69
P value Unpaired t Test	0.121609	

Majority of the Nalbuphine Group patients belonged to the 8 hours Postoperative Rescue Analgesia Initiation Time class interval (n=21, 70%) with a mean Postoperative Rescue Analgesia Initiation Time of 8.60 hours. In the Tramadol group patients, majority belonged to the 8 hours Postoperative Rescue Analgesia Initiation Time class interval (n=26, 86,67%) with a mean Postoperative Rescue Analgesia Initiation Time of 8.27 hours. The association between the intervention groups and Postoperative Rescue Analgesia Initiation Time is considered to be not statistically significant since $p > 0.05$ as per 2 tail unpaired t tes

SIDE EFFECTS:

The side effects which occurred in the two groups were as follows,

Table 16:

Side Effects	Group Nalbuphine	%	Group Tramadol	%	P value Fishers Exact Test
Headache	1	3.33	1	3.33	>0.9999
Drowsiness	5	16.67	2	6.67	0.4238
Nausea	2	6.67	5	16.67	0.4238
Vomiting	0	0.00	5	16.67	0.0522

Majority of the Nalbuphine Group patients had drowsiness as the major side effect (n=5, 16.67%). In the Tramadol group patients, majority had nausea and vomiting as the major side effect (n=5, 16.67%). The association between the intervention groups and side effects is considered to be not statistically significant since $p > 0.05$ as per 2 tail unpaired t test.

DISCUSSION

This prospective, randomized study was done to find a drug, which provided good relief of postoperative pain, in this study, we compared nalbuphine, an opioid agonist – antagonist with tramadol, which is very commonly used for relief of postoperative pain. The demographic profile of the patients in the study did not show any significant difference. All the pain evaluations were made by the same observer. Also, the premedication and the anaesthetic techniques used were similar. Equianalgesic doses of drugs were used, which was determined by previews and previous studies. At 30 minutes, the percentage of pain relief in nalbuphine group was highly significant as compared to tramadol group. Mean VAS in nalbuphine group was 1.33 and mean VAS in tramadol group was 1.70 at 30 mins. Visual analog score between 30 minutes-8 hours was statistically significant since $p < 0.05$ as per unpaired t test. In other words, in patients belonging to Nalbuphine intervention group, the mean Visual Analog Score decreased to an average of 0.84 points. In comparison, in patients belonging to the Tramadol intervention group, the mean Visual Analog Score is an average of 1.15 points. The mean Visual Analog Score was meaningfully less in Nalbuphine intervention group when compared to Tramadol intervention group by a mean difference of 0.31 points. This significant difference of 27% decrease in mean Visual Analog Score in Nalbuphine intervention group when compared to Tramadol intervention group has not occurred by chance and hence is true. This indicates that there is a true difference among the two intervention groups and the difference is significant with a p-value of 0.0160, 0.0395, 0.0197, 0.0098, 0.0076 and 0.0032 according to unpaired t-test. ($p < 0.05$). The cardiovascular parameters monitored were systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and heart rate (HR). The mean changes in these parameters did not show any statistically significant

difference between two groups. ($p > 0.05$). Siddiqui⁴ *et al.* and Ouaki *et al.* also showed that there was no hemodynamic significance between the two groups. The respiratory parameters which were monitored were respiratory rate (RR) and oxygen saturation (SpO₂). There was no statistical significance in these parameters between the two groups. ($p > 0.05$). The respiratory parameters were also comparable in the study by Shaila⁶ *et al.* and Ouakiet⁵ *al.* The mean postoperative Rescue Analgesia Initiation Time in nalbuphine group was about 8.60 hours. In the Tramadol group, the mean Postoperative Rescue Analgesia Initiation Time was 8.27 hours. The association between the intervention groups and Postoperative Rescue Analgesia Initiation Time is considered not to be statistically significant since $p > 0.05$ as per 2 tail unpaired t test. Nalbuphine group showed an increased incidence of drowsiness (16.67%) when compared to the tramadol group (6.67). Shaila *et al.* also had an increased incidence of drowsiness (12.5%) in the nalbuphine group. However, the incidence of nausea and vomiting was more in the tramadol group (16.67%) when compared to nalbuphine group, which had nausea (6.67%) and none of them had vomiting. This is in concordance with studies by Solanki⁷ *et al.* and Shaila *et al.*, which had an increased occurrence of nausea and vomiting in tramadol group. These findings were similar to the results of shaila *et al.*, which stated that nalbuphine was a safe and effective analgesic for postoperative pain than tramadol. The safety profile of nalbuphine is been widely accepted by many studies such as those by siddiqui *et al.*, ouaki *et al.*, van den bergs *et al.*, shaila *et al.* and solanki *et al.*

SUMMARY

This study was conducted to compare the analgesic effects of intravenous nalbuphine with intravenous tramadol on postoperative pain and postoperative analgesic requirement for patients undergoing percutaneous

nephrolithotomy” The following observations were made: The mean visual analog score was less in nalbuphine group when compared to tramadol group from 30 minutes to 8 hours time intervals, which was statistically significant. The duration of action of both the drugs was about 8 hours as the time to rescue analgesia was similar in both the groups and statistically insignificant. In both the groups, the hemodynamic changes and respiratory parameters in the post operative period were comparable and insignificant. The nalbuphine group showed an increased occurrence of drowsiness, while tramadol group showed an increased occurrence of nausea and vomiting, though there was no statistically significant difference between two groups with respect to side effects.

CONCLUSION

It was concluded that nalbuphine appears to be an effective and safe analgesic for postoperative pain relief than tramadol in equianalgesic doses, in patients undergoing percutaneous nephrolithotomy, providing good sedation with minimum circulatory effects.

REFERENCES

1. Michel MS, Trojan L, Rassweiler JJ. Complications in

- percutaneous nephrolithotomy. *Eur Urol.* 2007; 51:899–906.
- Pharmacology and physiology in clinical practice, Robert.K.Stoelting, 4th edition, 117- 119
- Raffa RB, Friderichs E, Reimann W. Opioid and nonopioid components independently contribute to the mechanism of action of tramadol, an “atypical” opioid analgesic. *J Pharmacol Exp Ther.* 1992;260:275–285.
- Khalid Maudood Siddiqui, Ursula Chohan. Tramadol versus Nalbuphine in total intravenous anaesthesia for Dilatation and Evacuation. *JPMA* 2007; 57:67.
- Ouaki, J.; Rochette, A.; Raux, O.; Dadure, Ch.; Capdevila, X. Tramadol vs nalbuphine: analgesic efficacy and side effects. A prospective, randomized, double-blinded study in children. *European Journal of Anaesthesiology*: June 2007- Vol 24-issue- p 138-139.
- Shaila S. Kamath, Arun kumar B .C., Madhusudan Upadya, Sonal Bhat.A comparison of the analgesic effect of intravenous nalbuphine and tramadol in patients with post- operative pain. A double blind prospective randomised study. *Asian Journal of Pharmaceutical and Health Service.* 2013;13:786-90.
- Solanki R, N D Gosai, G M Joshi, B M Patel, H V Modi, R Jain. A Comparative Study of Intravenous Nalbuphine HCl and Tramadol HCl for Post- Operative Pain Relief Following Orthopaedic Surgeries. *asian pacific journal of health sciences,* 2015; 2(1): 155-160.
- Van den Berg AA, Montoya-Pelaez LF, Halliday EM, Baloch MS; Analgesia for adenotonsillectomy in children and young adults: a comparison of tramadol, pethidine and nalbuphine. *European Journal of Anaesthesiology,* 1999; 16(3):186-194.

Source of Support: None Declared
Conflict of Interest: None Declared