Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/bz79c090

COMPARISON OF NALBUPHINE VS DEXAMETHASONE WITH LEVOBUPIVACAINE IN ULTRASOUND-GUIDED ERECTOR SPINAE PLANE BLOCK FOR PCNL SURGERIES: A COMPARATIVE OBSERVATIONAL STUDY

Dr. Swathi Gundlakunta[1], Dr. G. Chaitanya Kumar[2], Dr. R. Prabavathi[3], Dr. Dhanasri. Y[4], Dr. Avula Charan Teja Reddy[5], Dr. Rupa Reddy[6]

[1]Assistant Professor, Department of Anaesthesiology, Narayana Medical College, Nellore, Andhra Pradesh, India
[2]Associate Professor, Department of Anaesthesiology, Narayana Medical College, Nellore, Andhra Pradesh, India
[3]Professor, Department of Anaesthesiology, Narayana Medical College, Nellore, Andhra Pradesh, India
[4]Post Graduate, Department of Anaesthesiology, Narayana Medical College, Nellore, Andhra Pradesh, India
[5]Senior Resident, Department of Anaesthesiology, Narayana Medical College, Nellore, Andhra Pradesh, India
[6]Senior Resident, Department of Anaesthesiology, Narayana Medical College, Nellore, Andhra Pradesh, India

***Corresponding Author:** Dr.swathi Gundlakunta
*Assistant Professor, Department of Anaesthesiology, Narayana Medical College, Nellore, Andhra Pradesh, India

Abstract:

Background: The erector spinae plane (ESP) block is a safe, simple interfascial plane block that provides good analgesia after thoracolumbar surgeries. Percutaneous nephrolithotomy (PCNL) is a minimally pervasive surgery used for renal stones. Opioids, non-steroidal anti-inflammatory drugs (NSAIDs), and other regional analgesia techniques have been described previously in managing postoperative pain, but there is still controversy in finding an ideal method. Hence, the current study was undertaken to investigate.

Objective: This study was done to compare the efficacy of adding 10 mg Nalbuphine or 8mg Dexamethasone to 20 ml of 0.25% levobupivacaine in patients receiving ESP block scheduled for percutaneous nephrolithotomy surgery.

Methods: 100 cases of the American society of anesthesiologists grade I & II patients who were posted for percutaneous nephrolithotomy were enrolled and divided into two groups of 50 each.Group(N) received 20 ml of 0.25%Levobupivacine with 10 mg Nalbuphine. Group (D) received 20 mlof 0.25%levobupivacaine with 8 mg dexamethasone., The visual analogue scale score at 30 mins, 2nd ,4th,6th,8th,12th,16th,24hrs and the time required for 1st rescue analgesia and consumption of opioid in 24 hrs after surgery for both groups were measured.

Results: The visual analogue scale score at 8th,12th 16th, and 24 hrs. in group N were significantly lower than GROUP D ($p< 0.05$). The time for first rescue analgesia was longer in group N (784.33 ±

11.47mins) compared to group D (384.77 ±13.55mins) (P< 0.001). Total opioid consumption was lower in Group N (82.73 ±12.49) compared to Group D (254.97 ±13.11) (P < 0.001)
Conclusion: Nalbuphine is more effective than dexamethasone in prolonging the duration of analgesia, delaying the time of first rescue analgesia, and reducing total opioid consumption when added to local anaesthetics inerector spinae block.

Keywords: Dexamethasone, Levobupivacaine, Nalbuphine, Percutaneous nephrolithotomy (PCNL), Erector spinae plane block (ESPB)

Introduction

Percutaneous nephrolithotomy (PCNL) is a minimally pervasive surgical procedure used for renal stones. Conventional or open nephrolithotomy requires more surgical time and is associated with more complications, along with delayed ambulation. Postoperative pain management, immediately after surgery remains a matter of concern for various thoracic surgeons and anaesthesiologists.[1] Nephrostomy tube can cause local inflammatory reactions, leading to pain. This pain can be alleviated using various medications like opioids and non-opioid analgesics like non-steroidal anti-inflammatory drugs (NSAIDs). Higher doses of opioids can cause respiratory depression and NSAIDs cannot be used for patients with renal dysfunction.[2-3] Techniques like paravertebral block, and epidural analgesia may provide good analgesia but are not the first choice.[4]

Ultrasound (US)-guided erector spinae plane (ESP) block has recently been identified as helpful in managing thoracic neuropathic pain.[5] ESP block can successfully deposit a local anesthetic deep into erector spinae muscle that lies near the transverse processes. It is a simple, safe and effective technique sensory and visceral analgesia, acute post-operative, and chronic neuropathic thoracic pain in adults and children[6-7]. It can be achieved by blocking dorsal and ventral rami of spinal nerve roots. It can provide effective analgesia from T6 to L2. segments. Other indications of US guided ESPB include rib fractures, nephrectomy, pyeloplasty, Ventral hernia repair, Laparoscopic cholecystectomy, Orchidopexy, Hip surgeries[8].

Nalbuphine is a mixed opioid agonist-antagonist from the phenanthrene series, providing analgesia without the respiratory depression often associated with pure agonists. Its analgesic and anti-pruritic effects are mediated by mu and kappa receptors. it has been used safely in epidural, intrathecal, and brachial plexus blocks.[9-10] Dexamethasone is a glucocorticoid receptor agonist that reduces the release of inflammatory markers and inhibits potassium channels, which helps decrease the activity of C-fibers.

Materials and Methods:

This was a Comparative Observational study conducted at Narayana Medical College, Nellore, Andhra Pradesh, India, between September 1st, 2023 and February 28, 2024, with the approval of the Institution's Ethics Committee (IEC/NMC/ 29 August 2023/18). A total of 100 patients undergoing Percutaneous nephrolithotomy were enrolled in the study, all patients were informed about the study protocol, the assessment of pain using visual analogue scale score and written informed consent was obtained during the Preanesthetic Check (PAC) clearance.

The primary outcomes measured included duration of analgesia and VAS scores. Secondary outcomes included the time to first rescue analgesia, the number of rescue analgesic doses. These parameters were assessed after extubation and continued until 24 hours postoperatively. The Declaration of Helsinki ethical guidelines were followed. Details of the Consolidated Standards of Reporting Trials (CONSORT) are shown in [Fig-1].

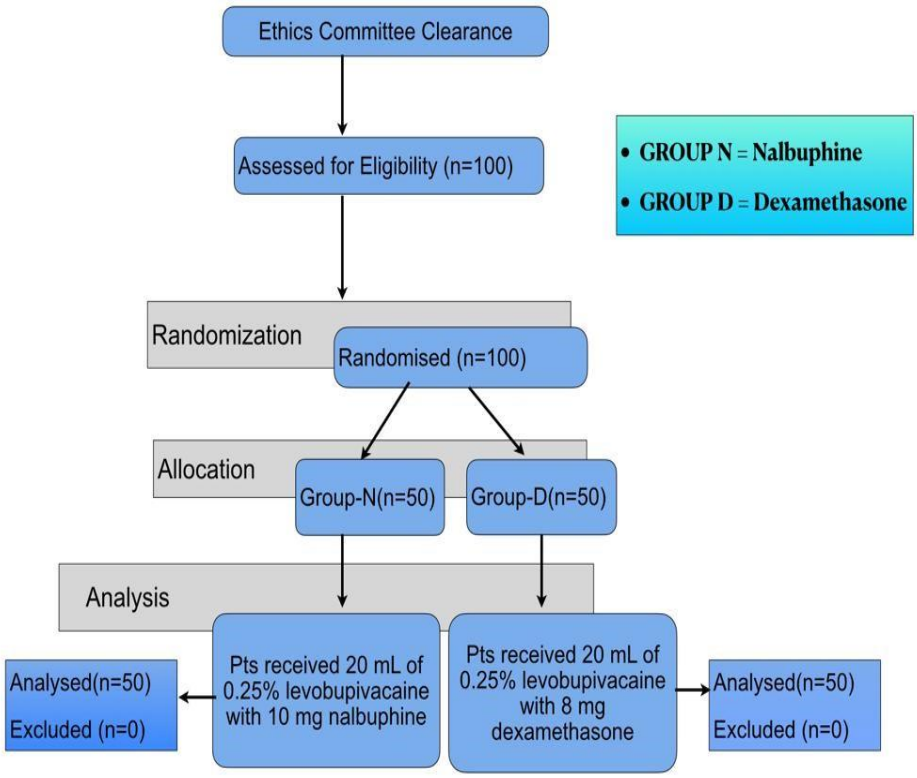


Fig 1. Consort Flow Diagram

SAMPLE SIZE: 100 patients (Two groups of 50 each)

$$n = \frac{2[(a+b)^2\sigma^2]}{(\mu_1 - \mu_2)^2}$$

Fig 2. Sample Size Formula

Using the above formula, sample size was determined while maintaining two-sided alpha error at 5% and power at 80%. Each group needed at least 46 individuals, but for greater validation, 50 patients were chosen for each group. Patients were randomly assigned into two groups. Patients of Group N (n=50) received 0.25% levobupivacaine(20ml) with 10 mg Nalbuphine. Patients in Group D (n=50) received 0.25% levobupivacaine(20ml) with 8 mg dexamethasone

Patients aged between 18 and 65, belonging to ASA categories I, II regardless of gender, who were listed for Percutaneous nephrolithotomy (PCNL) surgery met the inclusion criteria (n=100) included in the study, individuals allergic to local anesthetic agents, those with local skin infections, patients with hepatic, renal, or cardiac ailments, individuals with bleeding diathesis and those using anticoagulants are excluded in the study.

Methodology:

The patient was transferred to the operating room where all standard ASA monitors were connected. A large-bore IV cannula was secured, and IV fluids were administered. Baseline vital signs, including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and SpO2, were recorded. Preoxygenation was performed for 3 minutes using a face mask. Induction was achieved with using intravenous Inj. Propofol 2 mg/kg, Inj. Cisatracurium 0.2mg/kg

and maintenance with O2, air, Inj. Cisatracurium 0.02 mg/kg and sevoflurane at 1-2 MAC. Airway was secured with an appropriately sized ET tube using direct laryngoscopy.

At end of surgery, under sterile and aseptic conditions, skin preparation was performed with 2% chlorhexidine. The Sonosite M-Turbo ultrasound machine was used for all patients. The USG high frequency linear probe(6-13MHz), covered with a sterile sleeve, was placed in the cephalocaudal direction over the midline, at the level of T8. The probe was slowly moved until the transverse process of T8 was identified. The Trapezius muscle, Rhomboid major, and erector spinae muscles were identified superficial to the transverse process. A 20G needle was inserted in cephalo -caudal approach and advanced towards the transverse process. Once the needle tip was positioned below the erector spinae plane within the fascial plane, small aliquots of local anesthetic solution were injected. The erector spinae muscle was visualized as separating from the transverse process. After negative aspiration to avoid intravascular injection, local anesthetic (LA) was injected. Group N received 20 ml of 0.25% Levobupivacaine with 10 mg of Nalbuphine, while Group D received 20 ml of 0.25% Levobupivacaine with 8 mg of Dexamethasone solution into the erector spinae plane at the level of T8.

Postoperative analgesia needs were assessed using the Visual Analogue Scale (VAS), with 0 indicating no pain and 10 indicating severe pain. Evaluations were performed at 30 mints 2, 4, 6, 8, 12, 16, and 24 hours post-surgery. A VAS score of ≥ 4 indicated the need for additional pain relief. The duration of analgesia and time for first rescue analgesia .and total consumption of opioid of inj Tramadol was recorded. Inj.tramadol 100mg was used as Rescue Analgesia.

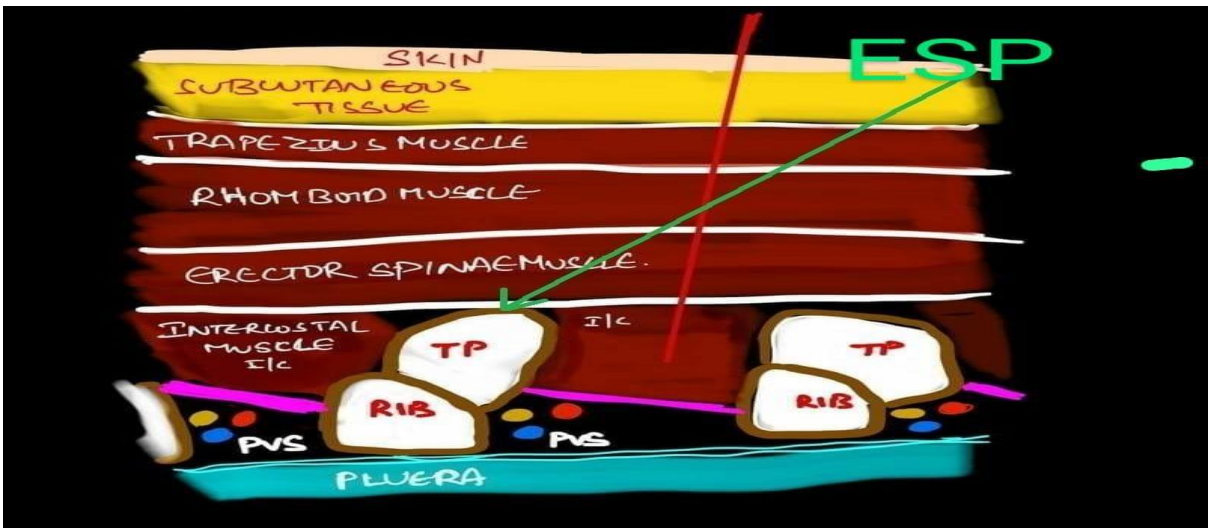


Fig 3. ESP BLOCK (line diagram)

Fig 4. ESP BLOCK (USG Image)

RESULTS:

Table 1: Demographic characteristics of patients &operative date in study (Mean±SD)

	GROUP N (n=50)	GROUP D (n=50)	P-Value
Age(years)	51.0±13.01	50±9.26	0.99
Gender(M/F)	26/24	32/18	0.22
ASA(I/II)	43/7	40/10	0.42
Height(cm)	158.1±6.1	156.75±71	0.35
Bodyweight (Kg)	56.2±12	54.3±9.9	0.45
BMI	26.15±4.8	25.82±2.82	0.46
Surgery time(hrs)	4.6±27	4.2±26	0.47

BMI: body mass index, ASA: American society anaesthesiologist grade

This table depicts the comparsion of Nalbuphine and dexamethasone in regard to age gender, weight, Height, BMI, ASA grade and surgical time, there was no statistically significant difference among the two groups.

Table 2: Mean VAS score

Time (HRS)	Mean VAS score (Group N)	Mean VAS score(Group D)	P value
30 mins	0.79±0.45	0.89±0.45	0.243
2	0.61±0.72	0.73±0.46	0.32
4	1.29±0.41	2.13±0.92	0.13
6	1.86±1.2	2.13±1.52	0.448
8	1.83±0.61	3.28±0.79	<0.0001
12	3.04±1.02	5.08±1.26	0.03
16	2.41±1.06	4.56±1.14	0.02
24	4.84±0.76	5.23±0.61	<0.0001

Table 3: Mean Dynamic VAS score

Time(HRS)	Mean VAS score (Group N)	Mean VAS score (Group D)	P value
30 mins	0.61+0.72	0.73+0.46	0.32
2	1.89±0.41	2.13±0.92	0.13
4	1.93±2.0	2.133±1.52	0.673
6	1.74±0.90	2.6±1.47	0.344
8	2.59±0.96	4.01±0.69	0.001
12	5.08±1.25	3.04±1.02	0.01
16	3.89±1.34	5.56±0.62	0.0001
24	5.77±0.29	6.23±0.39	< 0.0001

There is statistically significant difference in mean VAS and dynamic vas scores in between two groups of patients in the current study at 8 hrs,12hrs, 16 hrs, 24 hrs (P value <0.05)

Table 4: Duration of Analgesia

Groups	Duration of analgesia in mints	P value
N	723.43 + 4.89	<0.0001
D	351.87 + 14.63	

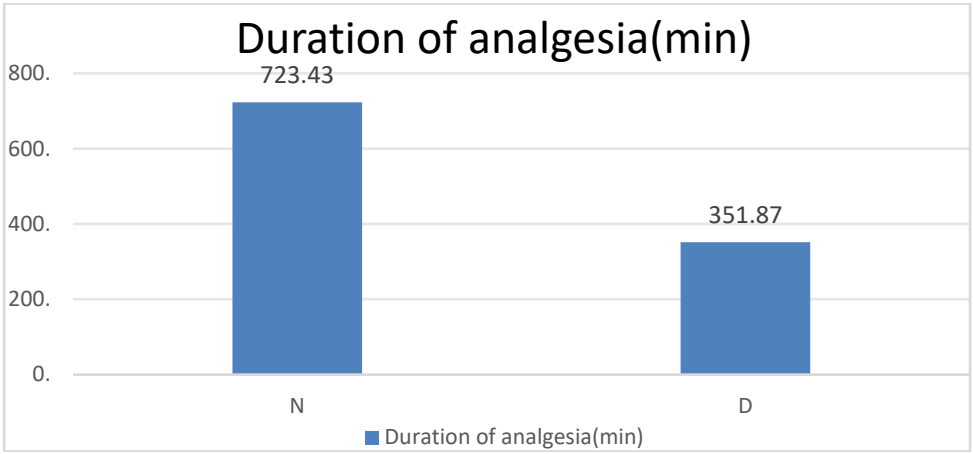


Table 5: Time for 1st rescue analgesia dose

GROUPS	Time for 1st Rescue analgesia dose	P value
N	784.33 + 11.47	<0.0001
D	384.77 + 13.55	

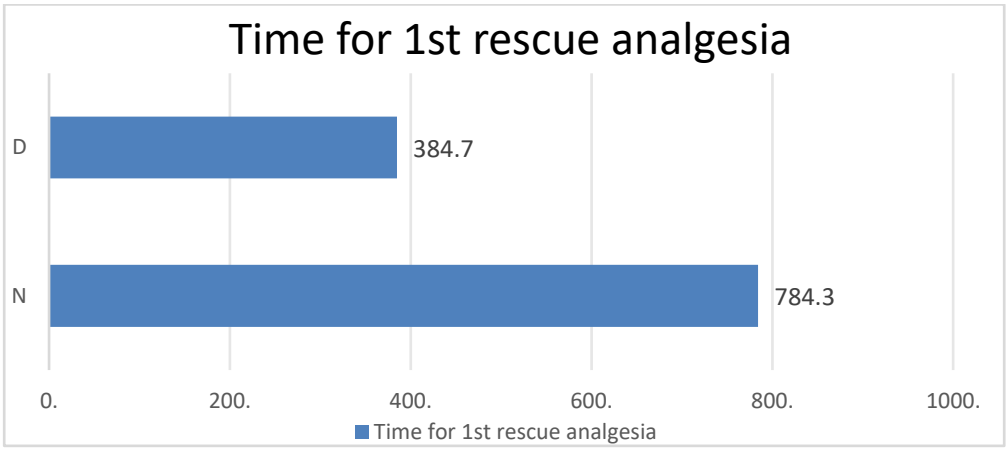


Table 6: No of analgesia doses

GROUPS	No of analgesia doses	P value
N	0.85+ 0.76	<0.0001
D	2.85 + 0.31	

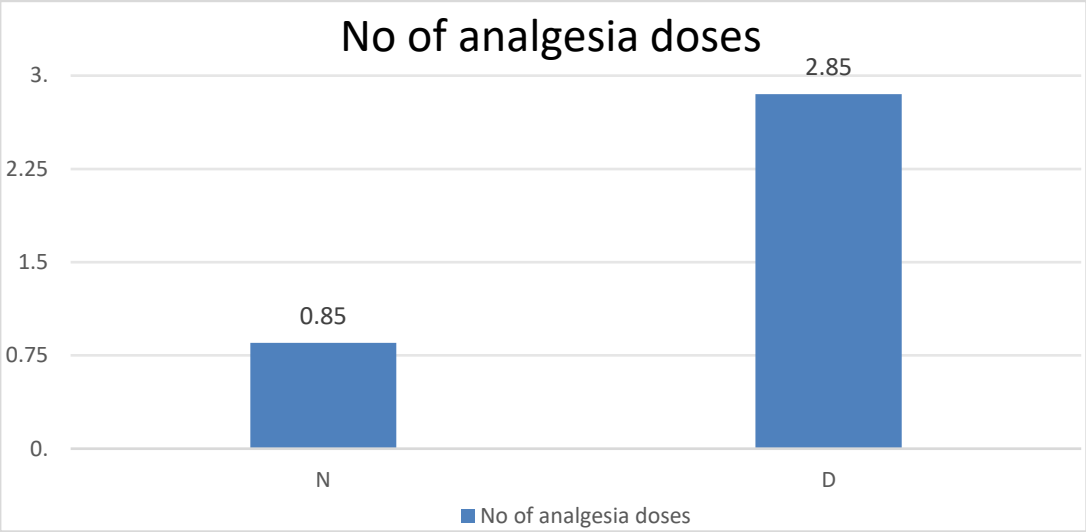
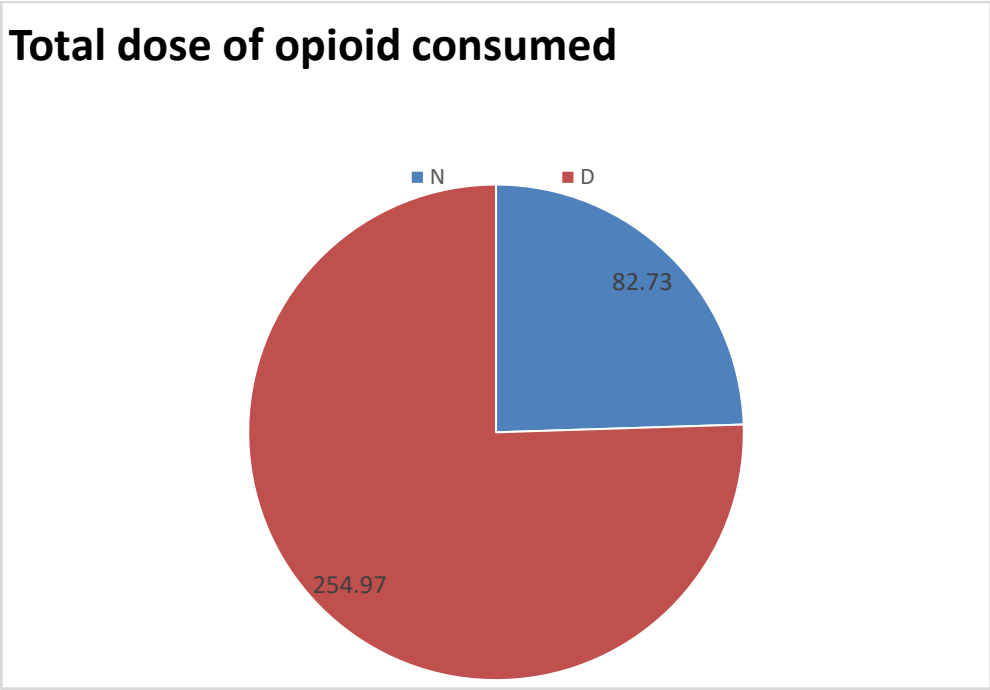


Table 7: Total dose of opioid consumption

GROUPS	Total dose of opiod consumption	P value
N	82.73 + 12.49	<0.0001
D	254.97 + 13.11	



There is statistically significant difference between two groups inTotal opioid consumption ,no of rescue analgesia doses, delaying time for first rescue analgesia ,was lower in Group N compared to Group D ($P < 0.001$).

Discussion:

The Erector Spinae Plane (ESP) block is increasingly utilized in urological surgeries to provide effective analgesia. This regional anesthesia technique involves injecting local anesthetic into the fascial plane deep to the erector spinae muscle, blocking both ventral and dorsal rami and providing substantial pain relief in the thoracolumbar region. Levobupivacaine is widely used as a local

anesthetic for regional blocks due to its safety profile. Various adjuvants, such as opioids, dexamethasone, dexmedetomidine, and magnesium sulfate, have been studied for regional blocks. Dexamethasone has gained popularity as an adjuvant compared to opioids of late. Among the opioids, nalbuphine has been the least studied for its role as an adjuvant. Nalbuphine is a kappa agonist-antagonist with very few side effects compared to other opioids. It is often used to treat opioid-induced pruritus; its role as an intravenous analgesic has been proven beyond doubt, but its role in regional blocks is not fully established.[11] Therefore, we conducted this study to evaluate the analgesic efficacy of nalbuphine compared to dexamethasone in the erector spinae block.

In our study, we evaluated the efficacy of adding 10 mg of nalbuphine and 8 mg of dexamethasone to 0.125% levobupivacaine for ESP block in PCNL surgeries. We observed that 10 mg of nalbuphine provided better pain scores in the postoperative period compared to 8 mg of dexamethasone. The nalbuphine group had a significantly longer duration of analgesia compared to the dexamethasone group and also reduced the total opioid dose in the postoperative period.

Rao et al.[12] studied Nalbuphine and Dexmedetomidine as adjuvants to Ropivacaine in ultrasound-guided erector spinae plane block for video-assisted thoracoscopic lobectomy. Involving 102 patients, the study compared Ropivacaine (RC), Ropivacaine with Dexmedetomidine (RD), and Ropivacaine with Nalbuphine (RN). RD and RN groups had significantly lower visual analogue scale scores, rescue analgesia rates, and postoperative pain compared to RC ($P < 0.0001$). Postoperative opioid consumption was also lower in the Nalbuphine group (50.4 ± 15.4 vs. 61.3 ± 14.1, $P = 0.0004$).compared to dexmedetomidine group our study results similar to this study total opioid consumption is decreased in nalbuphine group compared to dexamethasone group.

AhmedHIetal.[13] compared dexmedetomidine and dexamethasone as adjuvants to levobupivacaine in erector spinae plane blocks for modified radical mastectomy. Involving 90 patients, they found that dexmedetomidine provided longer analgesia, reduced intraoperative fentanyl, and decreased postoperative morphine use compared to dexamethasone.

In the current study, the postoperative analgesic efficacy of Nalbuphine versus Dexamethasone with Levobupivacaine in ultrasound-guided erector spinae plane block was compared. There were no statistical differences in age or gender between the two groups. The duration of analgesia was significantly longer in the Nalbuphine group, and no notable side effects were observed.

Conclusion:

We concluded that Nalbuphine is superior in prolonging duration of analgesia and reducing opioid consumption perioperatively compared to dexamethasone

References:

1. Kotemane NC, Gopinath N, Vaja R. Analgesic techniques following thoracic surgery: a survey of United Kingdom practice. *Eur J Anaesthesiol* 2010;27:897-9. 10.109 7/EJA. 0b013 e32833d 1259.
2. Schlondorff D. Renal complications of nonsteroidalantiinflammatory drugs. *Kidney Int.* 1993;44:643–53.
3. Benyamin R, Trescot AM, Datta S, Buenaventura R, Adlaka R, Sehgal N, et al. Opioid complications and side effects. *PainPhysician.* 2008;11:105–20.
4. Baidya DK, Khanna P, Maitra S. Analgesic efficacy and safety of thoracic paravertebral and epidural analgesia for thoracic surgery:A systematic review and meta-analysis. *Interact CardioVascThorac Surg.* 2014;18:626–35.
5. Forero M, Adhikary SD, Lopez H, Tsui C, Chin KJ. The erector spinae plane block:A Novel analgesic technique in thoracic neuropathic pain. *Reg Anesth Pain Med.* 2016;41:621–7.
6. De la Cuadra-Fontaine JC, Concha M, Vuletin F, et al. Continuous Erector Spinae Plane block for thoracic surgery in a pediatric patient. *Paediatr Anaesth* 2018;28:74-75. 10.1111/pan.13277.

7. Paladini G, Musella G, Farris G, et al. Erector spinae plane block to enhance recovery after thoracoscopic lung lobectomy in infants. *Minerva Anestesiol* 2019. [Epub ahead of print]. 10.23736/S0375-9393.19.13880-1.
8. Jain K, Jaiswal V, Puri A. Erector spinae plane block:Relatively new block on horizon with a wide spectrum of application - A case series. *Indian J Anaesth.* 2018;62:809–13.
9. Schmidt W, Tam S, Shotzberger G, Smith D, Clark R, Vernier V. Nalbuphine. Drug and Alcohol Dependence. 1985;14(3-4):339-362.
10. Narver H. Nalbuphine, a non-controlled opioid analgesic, and its potential use in research mice. Lab Animal. 2015;44(3):106-110.
11. Peng X, Knapp B, Bidlack J, Neumeyer J. Pharmacological Properties of Bivalent Ligands Containing Butorphan Linked to Nalbuphine, Naltrexone, and Naloxone at μ, δ, and κ Opioid Receptors. Journal of Medicinal Chemistry. 2007;50(9):2254-2258
12. Rao J, Gao Z, Qiu G, Gao P, Wang Q, Zhong W, Wang Y, Li Y. Nalbuphine and dexmedetomidine as adjuvants to ropivacaine in ultrasound-guided erector spinae plane block for video-assisted thoracoscopic lobectomy surgery: A randomized, double-blind, placebo-controlled trial. Medicine (Baltimore). 2021 Aug 13;100(32):e26962. doi: 10.1097/ MD. 000 0 000000026962. PMID: 34397949; PMCID: PMC8360433.
13. Ahmed HI, Ali AR, El Emam NH, Magdy M, Gamal RM. Dexmedetomidine vs dexamethasone as adjuvants to levobupivacaine in ultrasound-guided erector spinae plane block for patients undergoing modified radical mastectomy: a randomized double-blind study. Anaesth. pain intensive care 2022;27(1):65−72.