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RESEARCH ARTICLE

A COMPARATIVE STUDY OF EFFECT OF DEXMEDETOMIDINE AND DEXAMETHASONE AS AN ADJUVANT TO 0.2% ROPIVACAINE FOR ULTRASOUND GUIDED TRANSVERSUS ABDOMINIS PLANE BLOCK FOR INFRAUMBILICAL SURGERIES”

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Abstract

Background: The relief of pain and suffering is, and always has been, one of the primary concerns of mankind and one of the prime factors that has influenced the course of history of medicine. Transversus abdominis plane (TAP) block is a regional anaesthetic technique which blocks the abdominal neural afferents by introducing local anaesthetic into the neuro-fascial plane between the internal oblique and the transversus abdominis muscle.

Aim: To compare the efficacy of Dexmedetomidine and dexamethasone as an adjuvant to 0.2% ropivacaine in ultrasound guided transverses abdominis plane block in infra umbilical surgeries in terms of,

1. Time to initial postoperative pain.
2. Time to initial rescue analgesia.
3. Quality of block..
4. Total postop analgesic consumption.
5. Patient satisfaction with regard to pain relief.
6. Post-operative nausea and vomiting.

Materials And Methods: We included 80 patients of age between 18-60 years of American Society of Anesthesiologists status (ASA) I and II scheduled for elective infraumbilical surgeries in our study. We randomly allotted these patients into two groups namely Group A and Group B of each. Patients in Group A Patients who received transversus abdominis plane block with - 18ml Ropivacaine 0.2%+ 2 ml Dexamethasone 8mg. Patients in Group B received transversus abdominis plane block with-18ml Ropivacaine 0.2%+ 2 ml Dexmedetomidine .This TAP block was given soon after the surgery is completed. The duration of block and regression of sensory block, time for rescue analgesia, degree of sedation, hemodynamic parameters, post operative analgesia and adverse effects were noted.

Result: The two groups were comparable on the basis of duration of surgery, site of surgery, ASA and BMI. Heart rates and mean arterial pressure were compared and it was found to be significantly lower in group B compared to group A until initial 5 hours. In our study we

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found that the visual analogue score at rest and on coughing between groups A and B was statistically insignificant. However, the time to first rescue analgesia (330 mins vs 240 mins) and total analgesic consumption in the 24 hours period post operatively was significantly lesser for group A compared to group B. Ramsey sedation score was significantly higher in group B compared to group A until 8 hours post operatively. Nausea and vomiting in 3 cases of group A, and 2 cases in group B. No other significant side effects were noted.

Conclusion: USG-guided TAP block is an effective and safe adjunct for postoperative analgesia in infra umbilical surgeries. Addition of dexamethasone as an adjuvant prolongs the duration and reduces postoperative analgesic requirement in patients significantly more than dexmedetomidine whereas dexamethasone provides better control of the heart rate and mean arterial pressure.

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Introduction:-

“It is the duty of the anesthesiologist to study the wellbeing of the patient as well as the convenience of the surgeon”
-Ralph Waters

Definition for pain is “an unpleasant sensory or emotional experience associated with either actual damage or potential tissue damage or described in terms of such damage”^[1] by International Association For The Study Of Pain (IASP).

Elective infra umbilical surgeries is one of the most common surgical procedures we encounter. Various modalities like general anaesthesia, spinal anaesthesia, and regional anaesthesia techniques are practiced based on the experiences or as is tradition in a particular OT setup. Like in any other surgery the management of post operative pain and other post operative complications following an infra umbilical surgery can pose challenges for the practicing anesthesiologist and surgeon. In a case of infra umbilical surgeries, pain following surgery is of maximum intensity in the initial 24 hours following procedure as well as during coughing, standing and initial mobilization. According to the latest guidelines by working group (PROSPECT) regional nerve block technique is strongly recommended as a component of post operative multimodal pain management after an infra umbilical surgery.²

The relief of pain and suffering is, and always has been, one of the primary concerns of mankind and one of the prime factors that has influenced the course of history of medicine. Acute pain is an unpleasant sensory and affective experience normally associated with injury. It arises from activation of the peripheral nervous system and emerges from complex higher-level processing.²

Perioperative pain is arguably the most common clinical problem which not only gives the patients an unpleasant experience but also is associated with hemodynamic stress responses and undesired outcomes.

Poorly controlled pain is associated with a variety of detrimental acute as well as chronic effects.⁴ The attenuation of perioperative pathophysiology that occurs during surgery through reduction of nociceptive input to the CNS and optimization of perioperative analgesia may decrease complications and facilitate recovery during immediate post operative period and after discharge from the hospital. Post-operative consequences of pain include, distress, confusion, post operative development of hypercoagulability, neuroendocrine stress response leading to development of cardiac complications, paralytic ileus, inadequate cough and pulmonary complications all of which result in prolonged hospital stay and increase morbidity and mortality.⁴

Provision of effective perioperative analgesia is of key importance in patients. With adequate peri-operative analgesia, the magnitude of the neuro-endocrine stress response, postoperative pulmonary complications and the incidence of myocardial ischemia can be decreased.⁵

Several options are available for the management of peri operative pain including systemic analgesics (opioid and non-opioid) and regional (neuraxial, and peripheral) techniques. Individualized assessment of risks and benefits of different treatment modalities helps us optimize the post operative regimen for each patient.¹

Opioid analgesics such as morphine, fentanyl, sufentanyl, nalbuphine have been one of the cornerstones for pain management exerting their analgesic effects mainly through μ receptors in the CNS. Their analgesic efficacy is however limited by the development of tolerance as well as opioid related side effects such as nausea vomiting, sedation, respiratory depression.⁶

NSAID's are a group of analgesics that mainly act through inhibition of cyclooxygenase and prostaglandin synthesis. They are used commonly to alleviate mild to moderate pain and also as adjuncts to opioids in severe pain forming an important component of multi-modal analgesia by reducing the dose requirement of opioids.⁷

They are however not without side effects which include peri operative renal dysfunction, reduction in haemostasis, gastro intestinal bleeding, delayed bone healing. Gabapentinoids, tramadol, ketamine etc. are other drugs used for managing peri operative pain.⁶

Local anaesthetic instillation of wounds through subcutaneous planes also provides analgesia without much of side effects⁶

Regional anesthesia has been frequently used as a modality for the management of post operative pain in surgical patients.⁷ The transversus abdominis plane block is a peripheral nerve block technique to attain analgesia from the skin to parietal peritoneum. Transversus abdominis plane block is a regional anaesthetic technique which blocks the abdominal neural afferents by introducing local anaesthetic into the neuro-fascial plane between the internal oblique and the transversus abdominis muscle. This TAP plane is infiltrated with local anesthetics to target the T7–T12 intercostal nerves, the ilioinguinal, iliohypogastric, and the lateral cutaneous branches of the dorsal rami of L1–L3. Despite a relatively low risk of complications and a high success rate using modern techniques, TAP blocks continue to be overwhelmingly underutilized.⁸

However, the use of local anaesthetic agents in TAP block limits duration of analgesia. In order to circumvent that limitation, peripheral nerve catheters that offer continuously delivery of local anesthetics have been proposed as an efficient method of postoperative analgesia. Nevertheless, peripheral nerve catheters are costly and can be cumbersome to manage.⁹ Another method to increase the duration of peripheral nerve blocks is the addition of adjuvants to the local anaesthetic such as, steroids, alpha agonists, opioids, and ketamine to name a few.

Dexamethasone is a systemic glucocorticoid commonly used to reduce postoperative nausea/vomiting pain and to improve quality of recovery after surgery.¹⁰ Recently, several studies have examined the use of dexamethasone in order to prolong analgesic duration of peripheral nerve blocks with variable results.

Alpha-2 adrenergic receptor agonists have been the focus of interest for their sedative, analgesic, perioperative sympatholytic and cardiovascular stabilizing effects with reduced anaesthetic requirements. Dexmedetomidine, a potent α_2 adrenoceptor agonist, is approximately eight-times more selective towards the α_2 adrenoceptor than clonidine which has both analgesic and sedative properties¹¹. It has been used as an adjuvant during regional and local anaesthesia¹¹. Several studies have shown efficacy of adding dexmedetomidine to local anaesthetic procedures, such as subarachnoid, epidural, and caudal injections.

There are studies showing evidence of improved post operative analgesia with addition of adjuvants such as dexmedetomidine or dexamethasone in comparison with plane local anesthesia in terms of time to rescue analgesia and the overall quantity of analgesic used post operatively thereby avoiding their potentially harmful side effects.¹¹

However, there are very few studies comparing dexamethasone and dexmedetomidine as adjuvants to bupivacaine in TAP blocks are few and hence the need for our study.

Aims and Objectives:-

The primary aim of this study is

To compare the efficacy of Dexmedetomidine and dexamethasone as an adjuvant to 0.2% ropivacaine in ultrasound guided transverses abdominis plane block in infra umbilical surgeries in terms of,

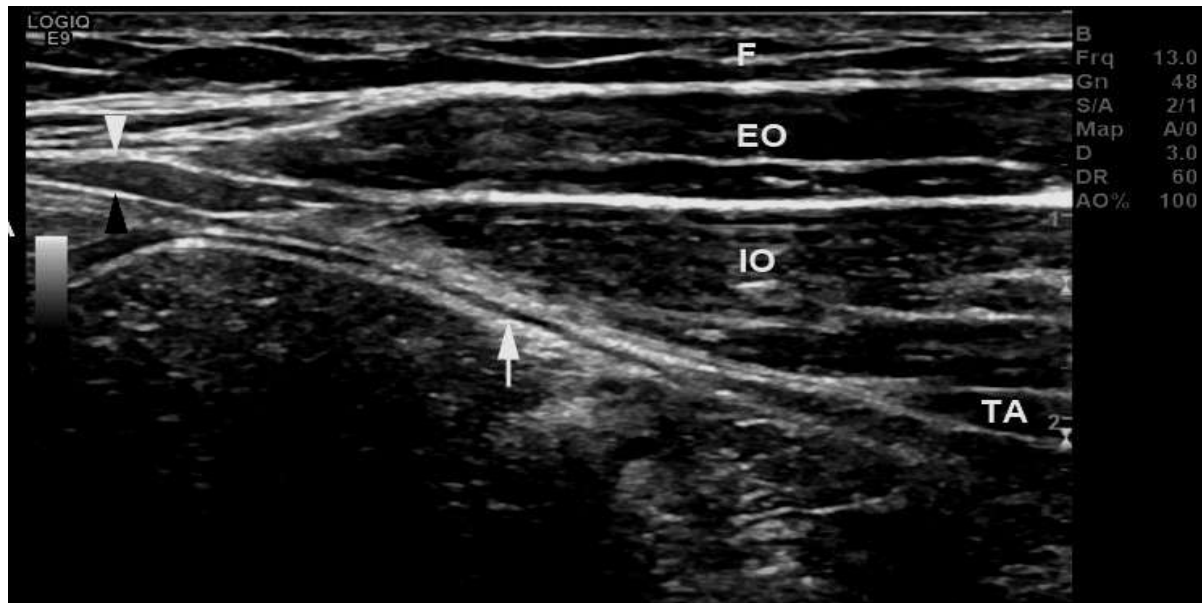
1. Duration of time to initial postoperative pain after the block.
2. Time to initial rescue analgesia.
3. Quality of block.
4. Total postoperative analgesic consumption.
5. Patient satisfaction with regard to pain relief.
6. Post-operative nausea and vomiting.

Anatomy Of Anterior Abdominal Wall

The anterior abdominal wall extends from the xiphisternum, right and left costal margins above, to the anterior part of the iliac crest, fold of the groin, pubic tubercle, pubic crest and symphysis pubis below, and is separated from the posterior abdominal wall by downward prolongation of mid axillary line.

The abdominal wall is a layered structure, consisting of skin, superficial fascia, subcutaneous fat, the muscle layer, the transversalis fascia and a layer of extra-peritoneal fat.

The skin is echogenic. The subcutaneous fat is usually hypoechoic. The muscles reveal medium-level echoes with a lamellar pattern of the muscle fibers. Real-time USG can reliably assess the changes in the thickness of the abdominal muscles, when they contract.



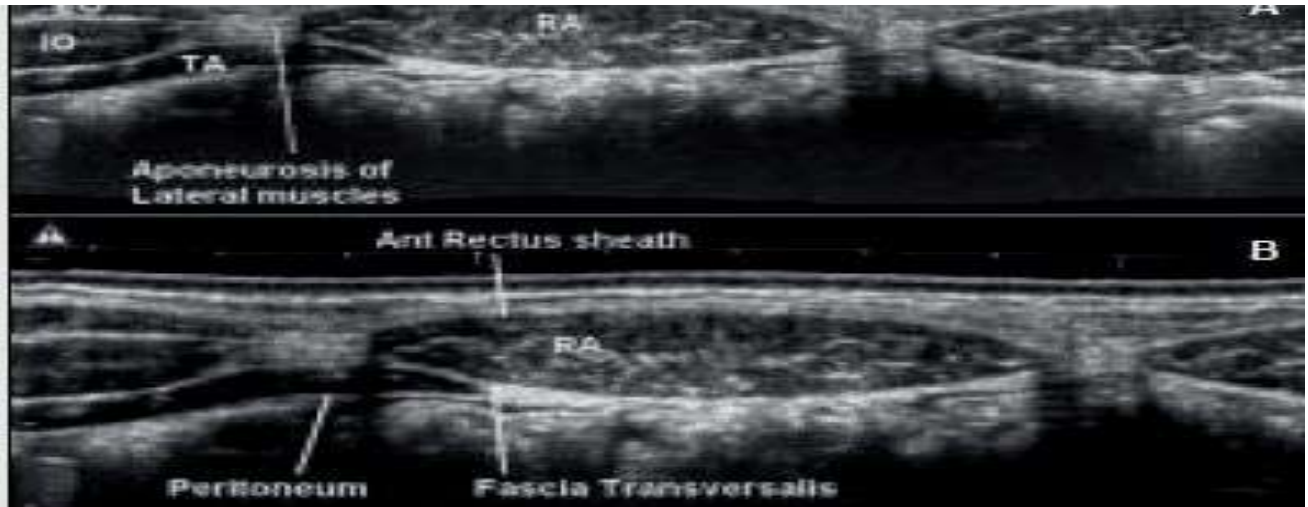


Figure 1:- Layers of the abdominal wall as seen on high frequency ultrasound. Fat (F); external oblique muscle (EO); internal oblique muscle (IO); transversus abdominis muscle (TA); rectus abdominis (RA); peritoneum (arrow); aponeurosis of external oblique (white arrowhead) and anterior part of the aponeurosis of internal oblique contributing to the rectus sheath (black arrowhead).

Skin:

It is thinner and more sensitive. It consists of 2 parts, an outer epidermis which is non-vascular and an inner dermis which is highly vascular and presents a rich blood supply. The skin presents a median longitudinal groove overlying the linea alba, and a curved groove on each side with convexity directed laterally which corresponds with lateral border of rectus abdominis muscle.

Superficial Fascia

It is a single layer in the anterior abdominal wall till the line joining the two anterior superior iliac spines. Beyond this line it splits into 2 layers- superficial layer of Camper and deep layer of Scarp. Fascia of Camper is continuous with subcutaneous fat of adjoining areas; over the scrotum the fatty tissue is replaced by Dartos muscle. Fascia of Scarpa is made of elastic fibrous tissue and is attached in the midline to the linea alba and is continued in front of symphysis pubis as the fundiform ligament of penis. Following structures are found in between these two layers: superficial, epigastric, external pudendal and circumflex iliac vessels and superficial inguinal lymph nodes.

External Oblique Muscle

It takes its origin as eight fleshy slips from the outer surfaces and lower border of the lower eight ribs. The upper four slips interdigitate with serratus anterior and lower four slips with Latissimus dorsi. Posterior fibers get inserted into the anterior half outer lip of iliac crest. The remaining fibers pass downwards and forwards and medially and end in a broad aponeurosis that passes in front of the rectus abdominis forming the anterior wall of the rectus sheath and is inserted into linea alba. The lower border is thickened and folded backwards to form the inguinal ligament.

Internal Oblique Muscle

It is also known as obliquus internus abdominis. It takes its origin from the lateral 2/3rd of upper surface of the inguinal ligament. Also arises from intermediate lip of the ventral segment of the iliac crest and from the fusion of anterior and middle layers of the thoracolumbar fascia at the lateral border of quadratus lumborum. Insertion-inguinal fibers pass upwards and medially forming anterior wall of the inguinal canal, then arch backwards forming the roof and finally turn downwards and medially and become aponeurotic. The aponeurosis of the internal oblique forms the conjoint tendon after blending with similar aponeurosis of the transversus muscle and is inserted into the pubic crest. The most posterior fibers pass vertically upwards and are inserted to the lower border of lower 3 or 4 ribs and their costal cartilages.

Transversus Abdominis Muscle

It is named so because most of its fibers are horizontal. Origin- from the lateral 1/3rd of upper surface of lingual ligament, anterior 2/3rd of inner lip of iliac crest, thoraco lumbar fascia at the lateral border of quadratus lumborum,

inner surface of lower six ribs and their costal cartilages. Insertion- inguinal fibers arch backwards forming the roof of inguinal canal and turn medially to become aponeurotic and form the conjoint tendon and are inserted into pubic crest. The remaining fibers end in an aponeurosis which is narrow towards the xiphoid process and wide at the umbilical region. It is inserted into the linea alba. The upper 3/4th reaches linea alba forming the posterior wall of the rectus sheath and the lower 1/4th reaches forming the anterior wall of rectus sheath. Nerve supply- ventral rami of lower six thoracic nerves and first lumbar nerve.

Fascia Transversalis

It is an areolar membrane, which lines the inner surface of the transversus muscle and forms an endo- abdominal fascia. Traced in front, it is continuous with similar fascia of the opposite side. Behind, it is continuous with the renal fascia along the lateral border of kidney. Above, it is continuous with ill-defined sub diaphragmatic fascia. Below, it is well defined and it is attached to the inner lip of iliac crest, posterior margin of inguinal ligament and to pectin pubis and pubic crest. The thickened lower part of fascia transversalis forms the ilio- pubic tract which extends from anterior superior iliac spine to the pubis.

Extra- Peritoneal Tissue.

It is composed of fibro-areolar and fatty tissue and is traversed by following structures; medial to deep inguinal ring- inferior epigastric artery before it pierces the fascia transversalis. Obliterated umbilical artery, passing towards the umbilicus, median umbilical extending from the apex of the urinary bladder to the umbilicus.

Parietal Peritoneum

Between and around these folds, the peritoneum presents six.

A pair of supra vesical fossae between medial and median umbilical folds.

1. A pair of medial inguinal fossae between medial and lateral umbilical folds.
2. A pair of lateral inguinal fossae outside the lateral umbilical folds.
3. C Below the umbilicus it presents with five folds-
4. Median umbilical fold containing median umbilical ligament.
5. A pair of medial umbilical folds each containing obliterated umbilical artery.
6. A pair of lateral umbilical folds each containing inferior epigastric artery.

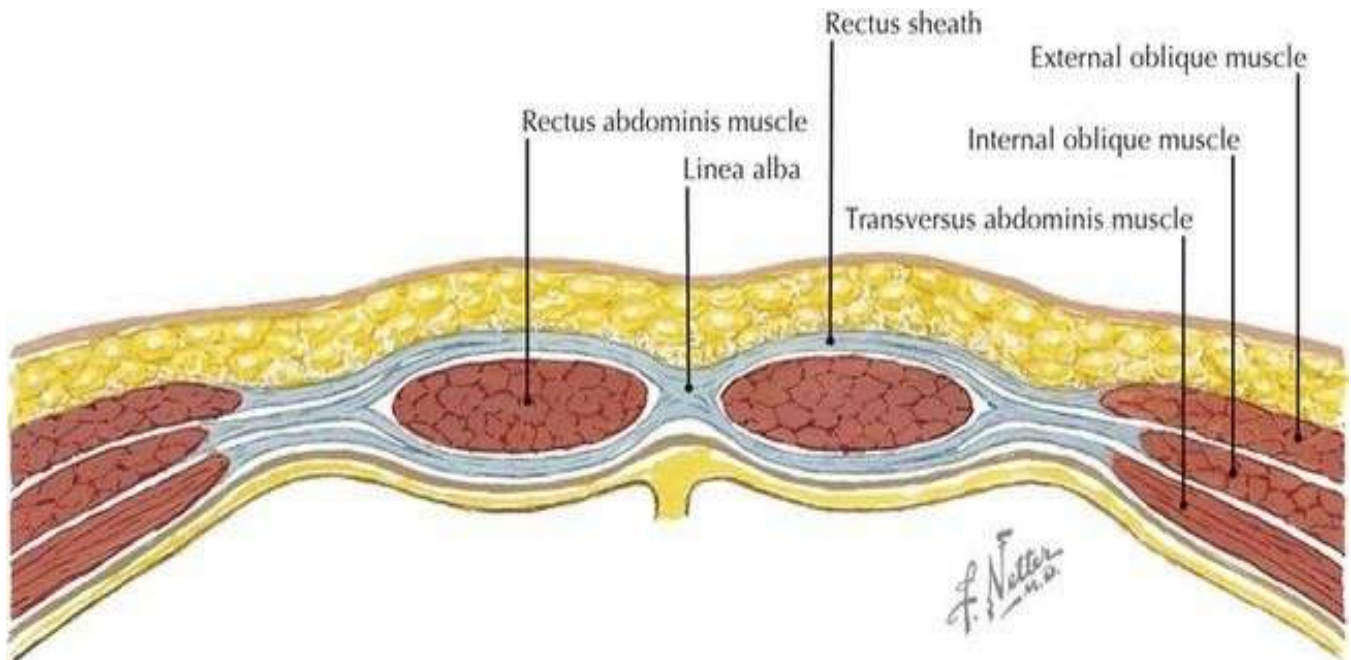


Figure 2:- Layers of Anterior Abdominal Wall ⁽⁴²⁾

A number of nerves run to the muscles and skin of the abdomen:

Thoracoabdominal nerves:

Five pairs of thoracoabdominal nerves continue from the 7th through 11th intercostal nerves. They run between the layers of abdominal muscles to innervate the muscles of the anterolateral abdominal wall. Anterior and lateral and cutaneous branches provide nerve supply to the skin.⁴¹⁻⁴⁴

Subcostal nerves:

These nerves stem from the anterior rami of the 12th thoracic spinal nerves. They run just inferior to the 12th ribs and down to below the umbilicus. Subcostal nerves innervate the abdominal wall muscles and the skin via cutaneous branches between the iliac crests and the umbilicus⁴¹⁻⁴⁴

Iliohypogastric nerves:

The iliohypogastric nerves stem from the anterior rami of the 1st lumbar spinal nerves and form branches that run below the subcostal nerves to the lower part of the abdominal wall. They innervate the skin over the iliac crests, inguinal regions, and hypogastric regions. They also give nerve supply to the internal oblique and transversus abdominis muscles.⁴¹⁻⁴⁴

Ilioinguinal nerves:

These nerves stem from the anterior rami of the 1st lumbar spinal nerves. They run between the layers of abdominal muscle and down to the inguinal canal. They innervate the scrotal skin in men and labia majora in women, the area over the pubic bone, and the medial portions of the thigh. They also innervate the internal oblique and transversus abdominis muscles.⁴¹⁻⁴⁴

Lateral cutaneous nerves of the thigh:

These nerves run from the 2nd and 3rd lumbar spinal nerves inferiorly on the iliacus muscles to the thighs. They supply the skin on the anterolateral parts of the thighs.⁴¹

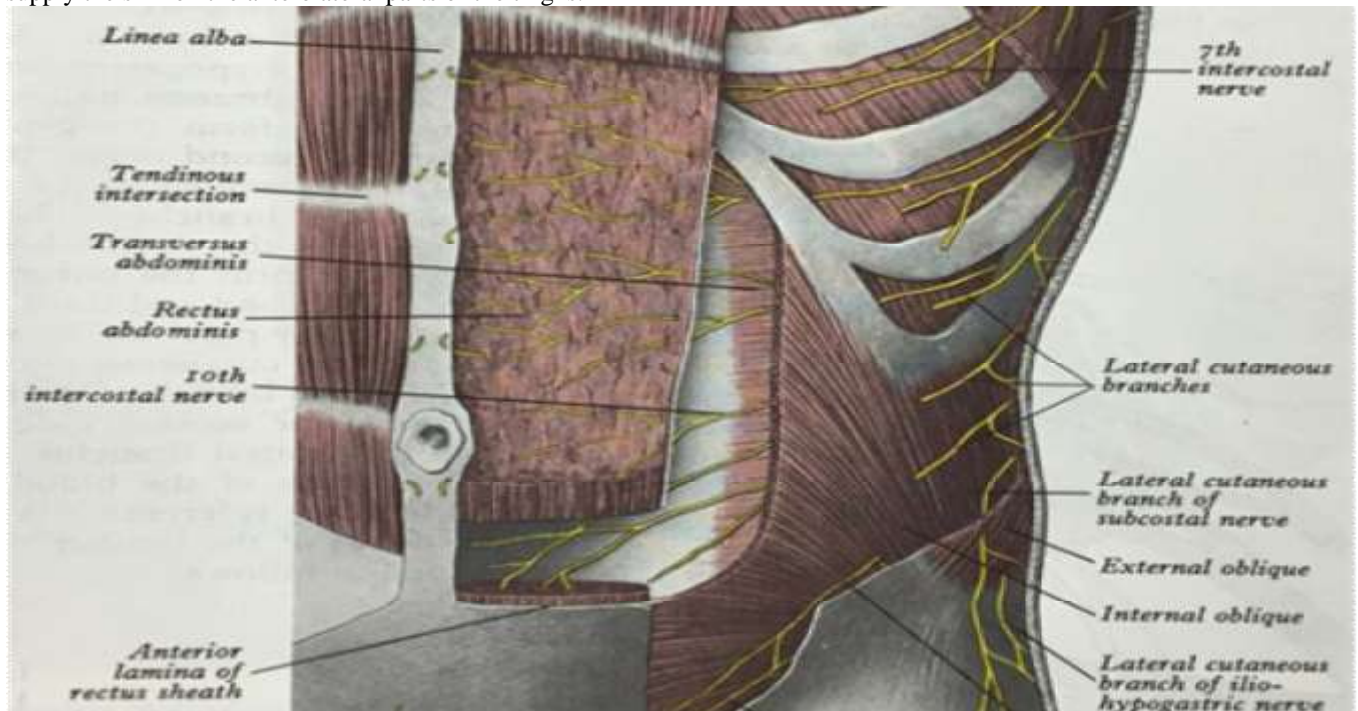


Figure 3:- Innervation of the abdomen.

The Tap Block

The TAP block is a safe peripheral nerve block with rare complications which include risk of bleeding, perforating abdominal organs or a failed block due to injecting the local anaesthetic in the wrong anatomical site. The TAP block provides enhanced pain control by blocking the peripheral nerves that provide sensory supply to the anterior abdominal wall from level T9-L1. The TAP is the fascial layer between the internal oblique and the transversus

abdominis muscles. It exists as a continuous plane located at any point on the abdomen where the two innermost muscle layers exist.⁴³

An ultrasound guided technique is better than the landmark technique as deposition of the local anesthetic agent is done by visualization of the correct plane.⁴⁴

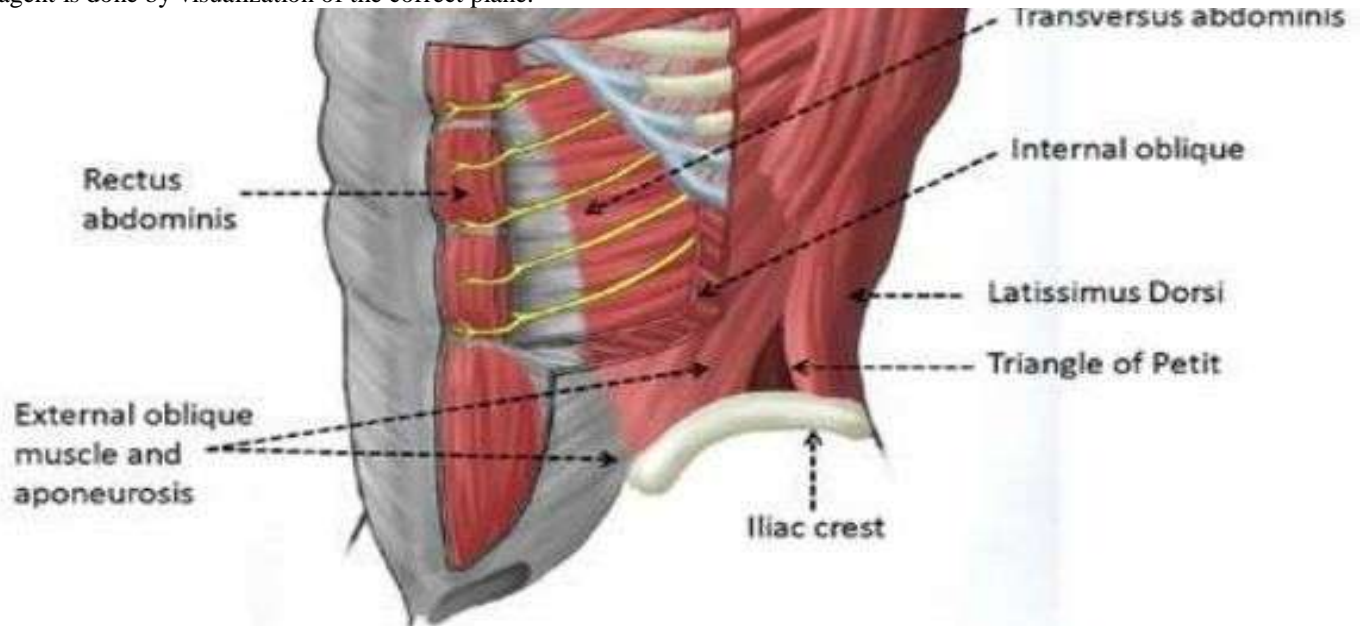


Figure 4:- Lumbar Triangle of Petit Between External Oblique Muscle and Latissimusdorsi. CM: costal margin, IC: iliac crest.

Anterior rami of thoracolumbar nerves that innervate the anterior abdominal wall pass through this plane as small, but well-defined neurovascular bundles.

Rozen et al. described an extensive fascial layer, nonadherent to the deep surface of the internal oblique that bind down the nerves on its deep surface, superficial to the transversus abdominis muscle. There is a fascial sheath between the internal oblique and transversus abdominis muscles⁴³. The nerves lie deep to this fascia. Nerves of T6-T9 enter the TAP medial to the anterior axillary line. T6 enters the TAP just lateral to the linea alba, and T7-T9 at progressively increasing distances from the linea alba. Nerves running in the TAP lateral to the anterior axillary line, on the other hand, originate from segmental nerves T9-L1. There is extensive branching and communication of the segmental nerves in the TAP. In particular the T9-L1 branches form a so-called "**TAP plexus**"⁴⁴ that runs with the deep circumflex iliac artery.

The transversus abdominis is the deepest layer, and below is the peritoneum. The skin, muscles, and peritoneum of the anterior abdominal wall are innervated by the lower 6 thoracic nerves and the first intercostals nerve. At the costal margin, thoracic nerves 7 to 11 leave their intercostals spaces and enter the neurovascular plane of the abdominal wall between transversus abdominis and internal oblique. Running across the surface of the transversus abdominis muscle and aponeurosis are the lower intercostals, subcostal, and iliohypogastric nerves.

Advantages.

Simple and effective analgesic technique,

1. Appropriate for surgical procedures where parietal pain is a significant component of postoperative pain.
2. It can be performed when neuroaxial blocks are contraindicated, □ It provides an alternative analgesic solution in that setting.

Disadvantages

1. Bilateral block is required in most surgical procedures,
2. The duration of the block may be limited to a few hours and could be too short to guarantee a pain-free postoperative course.

Indication Of Tap

Bilateral TAP blocks to provide effective postoperative analgesia in abdominal, gynecologic, or urologic surgery involving the T6 to L1 distribution like the following

1. Large and small bowel resection,
2. Caesarean delivery,
3. Abdominal hysterectomy,
4. Open appendectomy
5. Laparoscopic cholecystectomy
6. Abdominal and inguinal hernia repair,
7. Nephrectomy
8. Abdominoplasty with/without flank liposuction, and
9. Iliac crest bone graft

Absolute Contraindications⁵⁰

1. Infection at the site of injection,
2. Patient refusal or inability to cooperate, and
3. Allergy to local anesthetics

Complications**Local Anesthetic Toxicity**

To date, there are no published reports in the English language of local anesthetic toxicity following TAP blocks. **Griffiths et al.** reported a mean peak plasma ropivacaine level of 2.54 ± 0.75 mcg/mL using a total dose of 3 mg/kg to perform bilateral TAP blocks⁵¹

Organ Injury

Case reports of liver lacerations caused by right-sided TAP blocks can also be found in the literature.

There are two cases of liver trauma following TAP block in the literature **Farooq and Carey⁵²** described a liver laceration of an enlarged liver after a landmark-based TAP block **Lancaster and Chadwick** also reported a liver laceration after ultrasound-guided TAP block, which was likely as a result of failure to adequately visualize the needle during the procedure.⁵³

Block Technique

The aim of a TAP block is to deposit local anesthetic in the plane between the internal oblique and transversus abdominis muscles targeting the spinal nerves in this plane. The innervation to abdominal skin, muscles and parietal peritoneum will be interrupted. If surgery traverses the peritoneal cavity, dull visceral pain (from spasm or inflammation following surgical insult) will still be experienced. The block can be performed blind or using the ultrasound.

In the modern day guided blocks under the imaging guidance are used, the most commonly used imaging modality for guided blocks is the ultrasound. The below image gives an anatomical image of the structures encountered during a guided block.

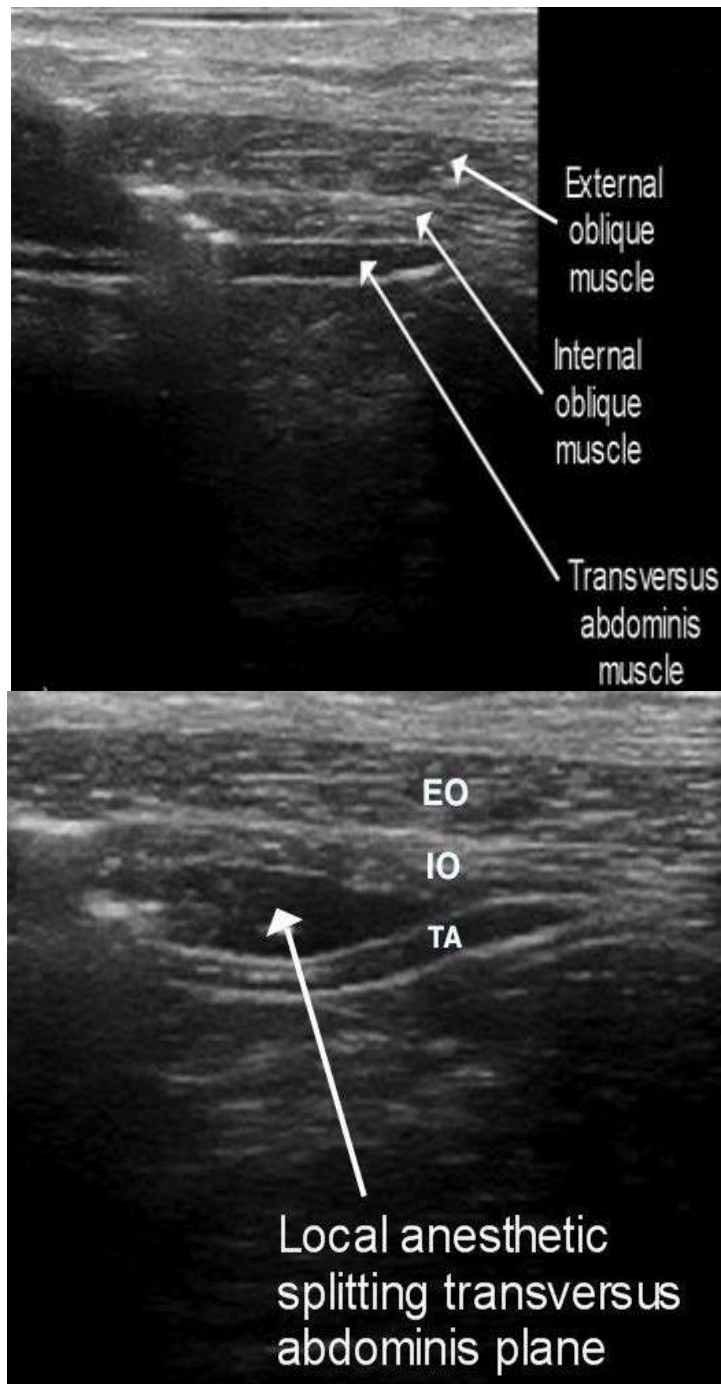


Figure 5:- Guided TAP needle tip lies between the internal oblique and transversus abdominis muscles.

Types Of Tap Block

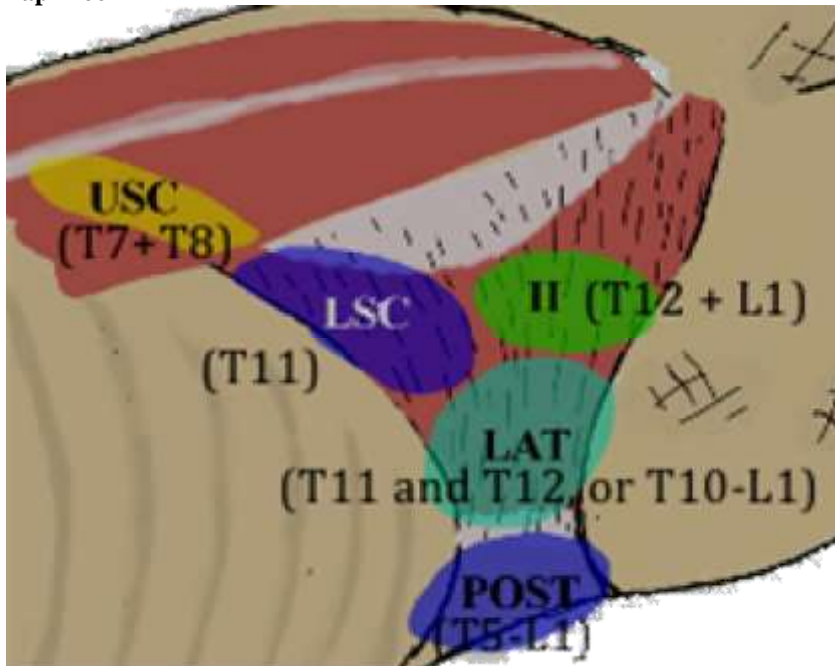


Figure 6:- Various tap block and their main area of sensory block.

<p>Subcostal TAP or Upper Intercostal TAP</p> <p>Upper subcostal TAP = Injection is deep to the rectus</p> <p>Lower subcostal TAP = Injection is lateral to rectus</p>	<p>Bilateral dual, BD-TAP or Four-Quadrant TAP</p> <p>Bilateral upper and lower TAP blocks to cover all four anatomical quadrants of the anterior abdominal wall</p>
<p>Lateral TAP = Injection is midway between the costal margin and iliac crest on the anterior to midaxillary line</p> <p>Posterior TAP = Injection is in the TAP in the area of the Triangle of Petit (6), antero-lateral border of quadratus lumborum (9), or 1-2cm anterior to the thoracolumbar fascia (10)</p>	
<p>Ilio-inguinal TAP = Injection is near the iliac crest lateral to the anterior superior iliac spine</p>	<p>All these techniques can be administered as a single bolus, or provide continuous analgesia by the placement of a catheter to infuse local anaesthetic</p>

Figure 7:- Various Tap Block and their Site of Infiltration.

Ultrasound-Guided Tap Block (Posterior Approach):

With the patient in the supine position, the ultrasound probe is placed in a transverse plane between the lower costal margin and the iliac crest in the midaxillary line (Figure 4). The needle is advanced using in-plane technique with an

anteromedial to posterolateral direction. The needle is advanced between the aponeurosis of the internal oblique and transversus abdominis muscles. With intermittent aspiration, the local anaesthetic is deposited and seen as a hypo echoic shadow pushing the 2 layers apart. Visualizing hypo echoic spread, with the fascial layer above and the muscle layer below, ensures proper deposition. Needle is repositioned until local is seen to spread within the plane, separating the fascia between the muscles. This approach is used in our study.

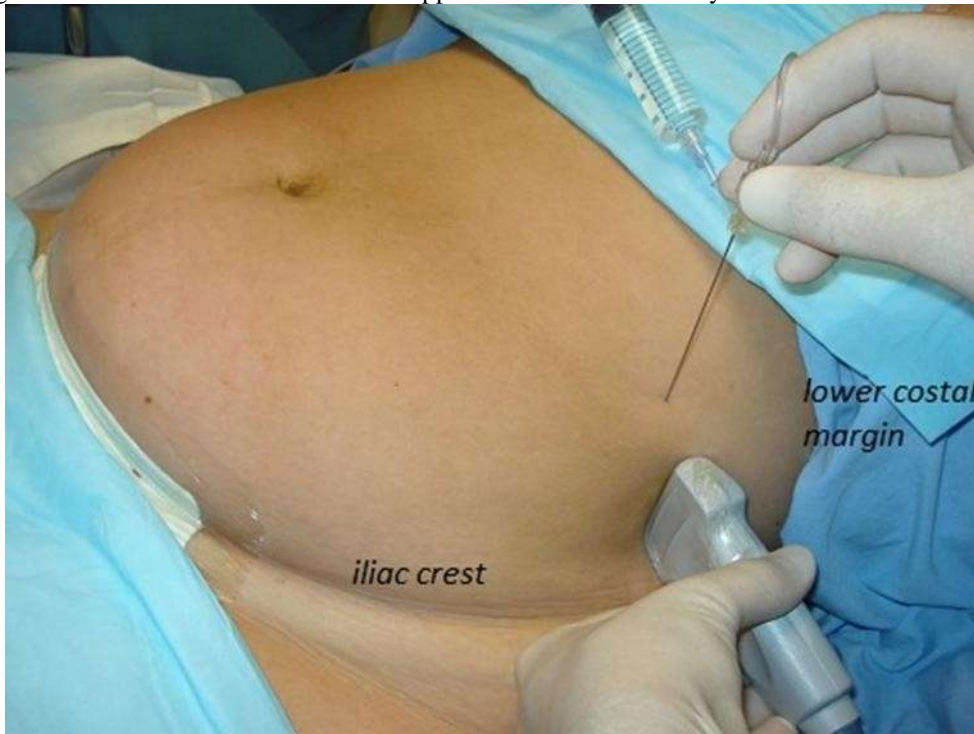


Figure 8:- Ultrasound Transducer Position and In-Plane Needle Technique for Posterior Approach TAP Block.

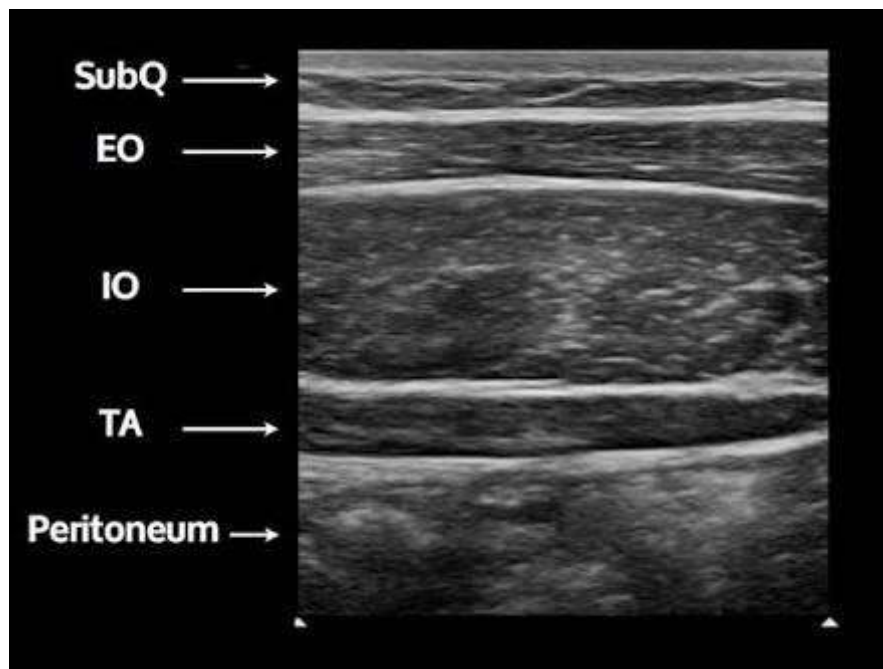


Figure 9:- Ultrasound image of muscles of anterior abdominal wall. [Sub Q: subcutaneous tissue; EO: External oblique; IO: Internal oblique; TA: Transversus abdominis].

Ultrasound Guided Tap Block (Subcostal Approach)

This should be performed if analgesia of the abdominal wall above the umbilicus is required.

The ultrasound transducer should be placed under the costal margin, close to the midline, and the upper portion of the rectus muscle is identified. In the midline of the subcostal region the transversus abdominis muscle can be seen deep to the rectus abdominis muscle, unlike near the umbilicus where it is seen only lateral to the rectus muscle.

Insert the needle at the medial end of the transducer to obtain an in-plane view. Use a long regional block needle for a single-shot technique or a Tuohy needle if a catheter is to be placed as for a continuous technique. Once the tip of the needle is placed between the posterior rectus sheath and superficial border of transversus abdominis, inject a small amount of local anaesthetic (after aspiration). Up to 20ml of local anaesthetic may be needed to fill the transversus abdominis plane.

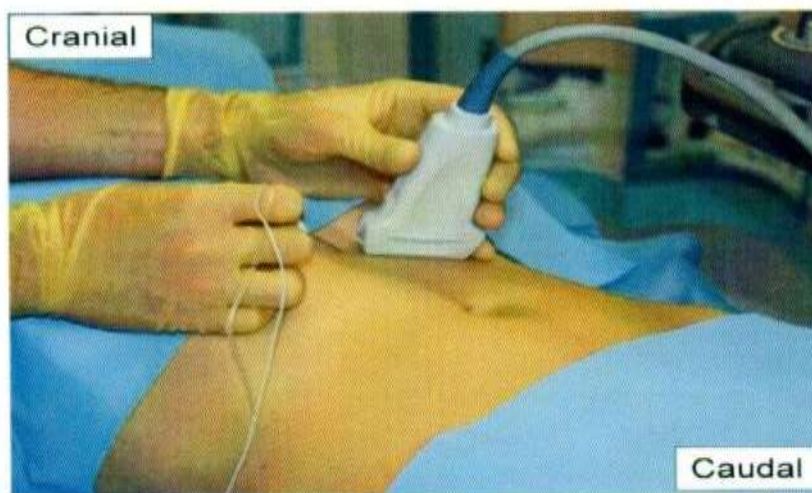


Figure 10:- Showing the ultrasound transducer position and in-plane needle technique for the oblique subcostal TAP block on the left side of the patient.

Pharmacological Review

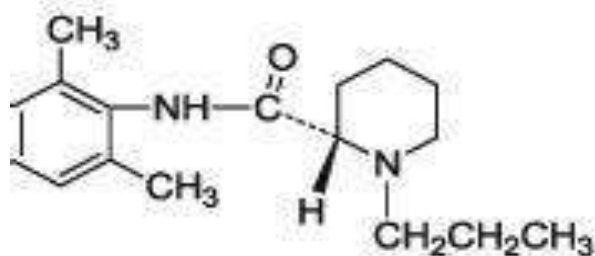
Pharmacology Of Ropivacaine

Ropivacaine is a new aminoamide local anaesthetic. One of the pipercoloxylidides, introduced in 1992 .

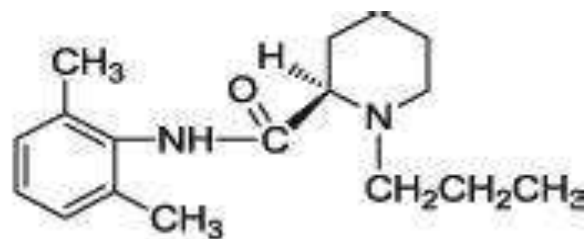
It is a single "S" enantiomer with an enantiometric purity of 99.5%.

Chemical Name:

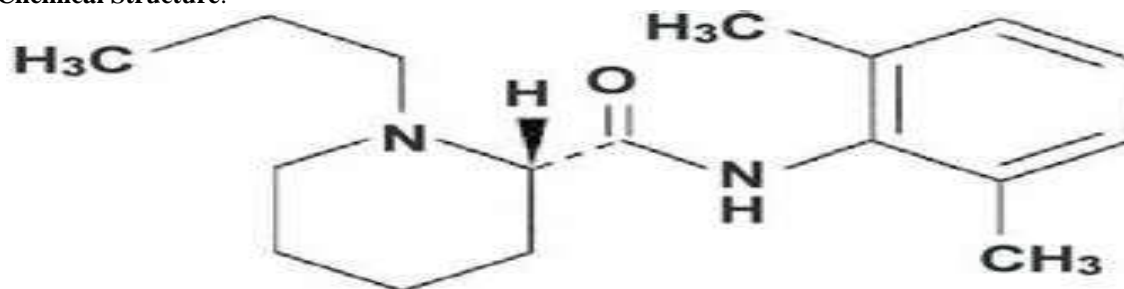
(S)-N-(2,6-dimethylphenyl)-1-propylpiperidine-2-carboxamide



S(-)-Ropivacaine



R(+)-Ropivacaine

Chemical Structure:

Molecular formula : C₁₇H₂₆N₂O

Molecular weight: 274.41

Physicochemical Profile

Molecular weight (base)- 274
 pKa (25°C) -8.1
 Lipid solubility - 6.1
 Plasma protein binding -94%
 Water partition coefficient -2.9

Pharmacokinetics:

In terms of lipid solubility , it is 2-3 times less than bupivacaine When compared to Bupivacaine, Ropivacaine has a smaller volume of distribution, greater clearance, and shorter elimination half-life. It undergoes hepatic biotransformation by cytochrome P450 and only a minor proportion is excreted unchanged in urine.

Pharmacokinetic Profile :

Volume of distribution - 59±7 litres

Clearance -0.82±0.16 l/min

Elimination half life -111± 62 min.

Metabolism- It is rapidly cleared from plasma and it is extensively metabolised by cytochrome P450 to 2''6''-pipercoloxylidide[PPX], 3''-OH ropivacaine and 4''-OH ropivacaine. 28

USES: -Peripheral nerve blocks

-Central neuraxial blocks

-Infiltration anaesthesia

Advantages Of Ropivacaine :

The stereospecificity of s-ropivacaine decreases cardiotoxicity. Both Bupivacaine and Ropivacaine molecules have chiral centers. Commercial bupivacaine is a 50:50 racemic mixture of the S- and R-enantiomers. R-enantiomer has greater affinity at voltage-gated sodium channels and confers greater cardiotoxicity Also Compared to the S-enantiomer, R-bupivacaine binds three times more firmly to the sodium channel, and unbinds 4.4 times as slowly.It is also more arrhythmogenic, and slows ventricular conduction 4.6 times as much as S-bupivacaine. But Ropivacaine is manufactured as the pure S- enantiomer ,so it has decreased cardiotoxicity.

Negative Inotropy:

Compared to bupivacaine, Ropivacaine has a smaller direct negative inotropic and arrhythmogenic effect. In a study where the effect of bupivacaine and ropivacaine on multiple electrophysiologic parameters in isolated Purkinje fiber-ventricular 29 muscle were measured ,it showed that bupivacaine produced much more depression of cardiac excitability and conduction. In addition, bupivacaine induced electrophysiological alterations can make re-entrant type ventricular arrhythmias more likely.Some other studies suggest that direct myocardial toxicity of ropivacaine is about half that of bupivacaine.

Reduced CNS Toxicity:

Convulsions are less likely with ropivacaine and produce only mild CNS effects like light headedness, tinnitus, tongue numbness. If convulsions occur, they are of shorter duration than produced by bupivacaine and resuscitation is almost always effective if started immediately. PREPARATIONS AVAILABLE: 0.5% Ropivacaine in 10 ml and 20 ml ampoules 0.75% Ropivacaine in 4, 10 and 20 ml ampoules. 1% Ropivacaine in 10 ml ampoule Recommended Safe Dose: 3.5mg/kg

Drug Interaction

Drugs like theophylline and imipramine are found to increase the dose of Ropivacaine via competitive inhibition as these drugs are also metabolised by CYP1A2. Ropivacaine should be used in caution with other amide type local anaesthetics as the toxic effects of these drugs are additive.

Pharmacology Of Dexmedetomidine

Dexmedetomidine, the d-enantiomer of medetomidine primary compound. It belongs to the imidazole subclass of α_2 receptor agonists. It has more selectivity towards α_2 agonist of about 1600 greater selectivity for the α_2 receptor when compared with that of α_1 receptor. This drug was first introduced into the clinical practice in the year 1999 and the FDA has permitted its use only for sedation in patients in intensive care unit who are mechanically ventilated. Hence it is now being used off-label outside of the ICU in various settings, including sedation and also as an adjunct to analgesia in the operating room, sedation in procedure units.

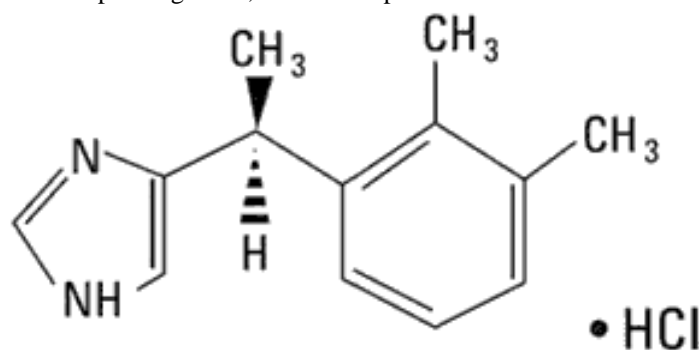


Figure 10:- Chemical Structure Of Dexmedetomidine.

Image source: internet.

Mechanism Of Action

Alpha2 adrenoceptors are membrane-spanning G proteins. The three subtypes of α_2 adrenergic receptors in humans are α_2A , α_2B , and α_2C . The α_2A receptors being distributed mainly in the periphery, likewise α_2B and α_2C receptors are primarily distributed in spinal cord and brain.

Postsynaptic α_2 receptors in the peripheral blood vessels produce vasoconstriction, whereas α_2 receptors located in the presynaptic region inhibit the release of norepinephrine, potentially attenuating the vasoconstriction. These receptors also contribute in the sympatholytic, sedation, and antinociceptive effects of α_2 receptors.

Pharmacokinetics

Dexmedetomidine intravenously causes rapidly distribution in the body and metabolized primarily in the liver and excreted in urine and feces. Dexmedetomidine is 94% protein bound. The half-life of dexmedetomidine for elimination is approximately 2 hours. The context-sensitive half-life following continuous infusion for about 8 hours is approximately 4 minutes to 250 minutes. Volume of distribution is 118 liters. Clearance is estimated to be approximately 39litres/ hour.

Effects On The Central Nervous System**Sedation**

Dexmedetomidine has the sedative and hypnotic effects by its action on the alpha 2 receptors that are located in locus ceruleus by acting through the endogenous sleep-promoting pathways hence mimics the normal sleep with no respiratory depression.

Analgesia

Analgesia produced by dexmedetomidine is complex and the mechanism of which is not clearly known. The primary site of action for analgesia is thought to be spinal cord. It can cause analgesia both when injected either in intrathecal or epidural space.

Respiratory System

When dexmedetomidine is given at doses required to produce significant sedation it reduces minute ventilation, but the response to increase in carbon dioxide concentration is preserved. Ventilatory changes caused by dexmedetomidine is identical to the changes that appear during normal sleep.

Effects on the Cardiovascular System

There is bradycardia, decreased force of contractility and also decrease in cardiac output. Rapid intravenous bolus dose is shown to have biphasic response. Rapid injection in a dose of 2 µg/kg causes a brief rise in the blood pressure and a decrease in the heart rate from the base line value, this is due to the stimulation of peripheral alpha 2 receptors that causes vasoconstriction. After 15 minutes the heart rate came back to the baseline level, and blood pressure gradually declined to approximately 15% below baseline by 1 hour.

Uses

Uses of dexmedetomidine is mainly for sedation in ICU patients who are mechanically ventilated and for weaning patients.

In operation theatre it is used for premedication and also as sole anaesthetic for monitored anaesthesia care.

As an adjuvant with local anaesthetic drugs in peripheral nerve block, epidural and spinal anaesthesia.

Intensive care unit

Dexmedetomidine has several advantages while sedating postoperative patients in intensive care units over other sedatives like opioids and propofol. It has opioid sparing effect and thus reduces their adverse effects like respiratory depression, nausea, vomiting and pruritis. PaO₂/FiO₂ ratio was higher significantly and heart rate was slower. As it provides good sedation with less respiratory depression it is also used while weaning patients from the ventilator.

Anaesthesia

Dexmedetomidine is used for premedication agent as it suppresses the hemodynamic response to intubation also reduces the requirements of induction agents, volatile anaesthetics and opioids. Its special use in Hypotensive anaesthesia especially in major bleeding surgeries like head and neck surgery, neurosurgery, spine surgery. Also used in ophthalmic cases as it has its effect on reducing the intraocular pressure. Reducing stress response to surgery by decreasing catecholamine secretion. In patients who are morbidly obese, dexmedetomidine have shown the narcotic-sparing effect in the intraoperative and postoperative period after bariatric surgery. Perioperative requirements for analgesic and sedations are reduced significantly.

Dexmedetomidine has been evident in the treatment of withdrawal effects of narcotics, benzodiazepines, alcohol, and other recreational drugs.

Dosage and administration:

In adults, dexmedetomidine is administered at a loading dose of 1 µg/kg as infusion over a period of ten minutes intravenously, then with a maintenance dose of 0.2 to 0.7 µg/kg/hr. diluted in 0.9 % normal saline for infusion. For infusion lasting upto 24hrs dexmedetomidine is the recommended drug.

Adverse effects:

The adverse effects include transient hypertension due to its biphasic action, hypotension, bradycardia, atrial fibrillation, conduction blockade, sinus tachycardia, sinus arrest, ventricular tachycardia, myocardial infarction, agitation, confusion, delirium, hallucination.

Dexamethasone**Pharmacology Of Dexamethasone**

Dexamethasone is a synthetic corticosteroid exhibiting both anti-inflammatory and immuno-suppressant properties. The anti-inflammatory potency of dexamethasone has been estimated as 25x that of hydrocortisone. It has little mineralocorticoid activity.

Pharmacokinetics

Dexamethasone is readily absorbed after oral administration achieving peak plasma concentrations after one hour. Binding to plasma proteins is less than for most other corticosteroids. The biological half-life is approximately 190 minutes. Dexamethasone penetrates tissue and cerebrospinal fluid. Elimination occurs via metabolism and renal excretion.

Indications

Dexamethasone is indicated for replacement therapy in secondary adrenal insufficiency arising from insufficient corticotrophin secretion. It is not indicated for primary adrenal insufficiency states, such as Addison's disease or after adrenalectomy⁷⁰. In such cases hydrocortisone and fludrocortisone in combination is more appropriate.

Dexamethasone is also indicated for allergic disorders such as bronchial asthma and allergic skin reactions, blood disorders such as leukemia, thrombocytopenia and hemolytic anemia's, selected collagen and rheumatic disorders (only rarely in rheumatoid arthritis), gastrointestinal disorders such as inflammatory bowel disease, connective tissue disorders such as arteritis, systemic lupus erythematosus (but not scleroderma), some skin diseases such as pemphigus, oedema, some eye disorders, certain neoplastic disorders such as cerebral neoplasm, secondary hypercalcemia, and acute leukemia in children.

It used to prevent neonatal respiratory distress syndrome and in the diagnosis of Cushing's syndrome.

Role of dexamethasone as an adjuvant to local anaesthetic agents

It prolongs analgesia with local anaesthetic drugs in peripheral nerve blocks by inducing vasoconstriction and reducing the absorption of local anaesthetic. It may also lead to increased activity of inhibitory potassium channels on nociceptive c fibers, which results in reduction of their activity prolonging sensory as well as motor blockade by reducing transmission in these fibers.⁸⁷

Dosage and administration

The dose of dexamethasone varies according to the condition being treated. The tablets are for oral administration in a dose of 4mg-20mg daily. The duration of therapy is dependent on the clinical response of the patient and as soon as improvement is indicated, the dosage should be adjusted to the minimum required to maintain the desired response. Withdrawal of dexamethasone at completion of treatment should be gradual.

Contraindications

Hypersensitivity to any ingredient
Systemic infections unless specific anti-infective therapy is given
Live virus immunization

Review Of Literature:-

Hebbard PD, Barrington MJ, Vasey C. 2010[11] He gave descriptive anatomy of Ultrasound-guided continuous oblique subcostal transversus abdominis plane blockade and clinical technique. Recently, ultrasound-guided transversus abdominis plane blockade for abdominal wall analgesia has been described, and it involves injection of local anesthetic into the transversus abdominis plane. The posterior approach involves injection of local anesthetic in the lateral abdominal wall between the costal margin and the iliac crest and is suitable for postoperative analgesia after surgery below the umbilicus. The subcostal approach is suitable after abdominal surgery in the periumbilical region. The subcostal block can be modified, and the needle can be introduced along the oblique subcostal line from the xyphoid process toward the anterior part of the iliac crest. A catheter can be placed along the oblique subcostal line in the transversus abdominis plane for continuous infusion of local anesthetic. Multimodal analgesia and intravenous opioid are used in addition because visceral pain is not blocked. Continuous oblique subcostal

transversus abdominis plane block is a new technique and requires both a detailed knowledge of sonographic anatomy and technical skill for it to be successful.

Singh et al. in 2011 demonstrated that bilateral TAP blocks in addition to non-invasive positive pressure ventilation was effective in the management of a 74-year-old patient with impending respiratory failure resulting from excessive pain and narcosis following emergency laparotomy

Bhavna et al.⁴⁰ conducted study in 2012 on fifty women to undergo bilateral TAP block with ropivacaine 0.5 % (n=25) versus placebo (n=25). Each patient was assessed postoperatively by a blinded investigator for morphine usage, average pain score, nausea, vomiting, pruritus, drowsiness and satisfaction with pain relief.

Postoperative morphine requirements up to 24 hours was significantly reduced (median 18.0mg) compared with placebo group (median 33 mg). Patients in TAP group reported lower visual analog scale scores than patients in the placebo group. Fewer patients required anti-emetics in the TAP group.

Priya Sharma et al.⁴¹ in 2013 conducted a study on sixty patients (mean age 36.2 ± 9.6 years) of either sex of ASA grade 1 or 2 who underwent major gynaecological or surgical operation. These patients were randomized either to receive standard care, including patient-controlled tramadol analgesia (n = 30), or to undergo TAP block (n = 30) in addition to standard care. After completion of surgery, 20 ml of 0.375% levobupivacaine was deposited into the transversus abdominis neurofascial plane via the bilateral lumbar triangle of Petit. Each patient was assessed in the post anaesthesia care unit and at 2, 4, 6, 12, 24, and 48 hours postoperatively. The TAP block reduced visual analog scale pain scores at most (2, 4, 6, 12, 24 h), but not at all time (36, 48 h) points assessed. Patients undergoing TAP block had reduced tramadol requirement in 24 h (210.05 ± 20.5 vs. 320.05 ± 10.6 ; $P < 0.01$) and 48 h (508.25 ± 20.6 vs. 550.25 ± 20.6 ; $P < 0.01$), and a longer time to the first PCA tramadol request (in minutes), compared to the control group (178.5 ± 45.6 vs. 23.5 ± 3.8 ; $P < 0.001$).

ReymiMarseela, Abdul Jalil et al.2013[20] Compared the effectiveness of ropivacaine 0.5% versus ropivacaine 0.2% for transabdominal plane block in providing postoperative analgesia after appendectomy. Fifty-six patients with American Society of Anesthesiologists physical status I or II, aged 18 years and above, undergoing 43 appendectomy were recruited in this prospective, randomized, double blind study. They divided the groups into two: Group A patients who received 0.5 mL/kg of ropivacaine 0.5% and Group B patients who received 0.5 mL/kg of ropivacaine 0.2% via TAP block under ultrasound guidance. Postoperative pain was assessed using the visual analog scale upon arrival at the recovery room in the operating theatre, just prior to being discharged to the ward, and at 6hours, 12hours, 18 hours, and 24 hours postoperatively to compare the effectiveness of analgesia Intraoperatively, patients in Group B required a significantly greater amount of additional intravenous fentanyl than those in Group A. There were no significant statistical differences in pain scores at rest and on movement at all assessment times as well as in the dose of 24- hour intravenous morphine consumption given via patient-controlled analgesia postoperatively between the two groups. The effectiveness of two different concentrations of ropivacaine (0.5% versus 0.2%) given via TAP block was comparable in providing postoperative analgesia for patients undergoing appendectomy

Chee Kean Chen, Peter Chee Seong Tan, VuiEngPhui, and Shu Ching Teo. 2013 Forty adult patients undergoing laparoscopic cholecystectomy under standard general anesthesia, were randomly assigned for either bilateral OSTAP block using 1.5 mg/kg ropivacaine on each side (n = 20) or IV morphine 0.1 mg/kg (n = 20). The intra-operative pulse rate, 44 systolic and diastolic blood pressure and mean arterial blood pressure were monitored every five minutes. Repetitive boluses of IV fentanyl 0.5 µg/kg were given as rescue analgesia when any of the above - mentioned parameters rose more than 15% from the baseline values. Time to extubation was documented. Additional boluses of IV morphine 0.05 mg/kg were administered in the recovery room if the recorded visual analogue score (VAS) was more than 4. Nausea and vomiting score, as well as sedation score were recorded. The morphine group required more rescue fentanyl as compared to the OSTAP block group but the difference was not significant statistically. Time to extubation was significantly shorter in the OSTAP block group (mean [SD] 10.4 [2.60] vs 12.4 [2.54] min; $P = 0.021$). Both methods provided excellent analgesia and did not differ in postoperative morphine requirements. No between-group differences in sedation score and incidence of nausea and vomiting were demonstrated.

Li K, Li L, Gao M, et al. 2015 [15]

Aim of the study is “application of ultrasound-guided subcostal transversus abdominis plane block in gastric cancer patients undergoing open gastrectomy”.

To observe intraoperative and postoperative analgesic effect of ultrasound-guided subcostal transversus abdominis plane (TAP) block in gastric cancer patients undergoing open gastrectomy.: Forty patients with gastric cancer underwent open gastrectomy were randomly assigned into groups R and S. All patients received ultrasound-guided subcostal bilateral TAP under general anesthesia, and then were injected with 40 ml of 0.375% ropivacaine (group R) or equivalent amount of normal saline (group S). The surgery was performed in 30 min following the blocking. Intraoperatively, BIS value was maintained between 45 and 65. Patient-controlled intravenous analgesia pump was properly connected after the operation. Intraoperative changes in systolic blood pressure (SBP), diastolic blood pressure (DBP) and heart rate (HR) were observed and the dosage of sufentanil and alternative drugs was closely monitored during the surgery. Visual analogue scale (VAS) scores and related surgical complications were recorded at 2, 4, 6, 12, 24 and 48 h following the 46 operation. Results: The SBP, DBP and HR changes in the group R were significantly decreased compared with those in the group S (all $P < 0.05$). No TAP puncture-induced adverse reaction was observed in both groups. Conclusion: Ultrasound-guided subcostal transversus abdominis plane block has the advantages of accurate localization and high success rate. Clinical application of this technique in open gastrectomy can significantly decrease intraoperative and postoperative dosage of analgesics and exert desirable analgesic effect.

Mukherjee A, Guhabiswas R, Kshirsagar S, Rupert E. 2016[17] An observational case series study involving thirty patients was conducted after obtaining hospital ethical committee permission. Patients who underwent consecutive laparoscopic cholecystectomy and which were subsequently converted to open technique due to technical difficulty and/or anatomical variations were administered ultrasound-guided oblique subcostal TAP blockade for post-operative analgesia after the procedure. The profound analgesic coverage of oblique subcostal TAP block within first 24 post-operative hours shows its effectiveness as post-operative analgesic measure for upper abdominal surgery.

Mitesh D. Falia*, Prasad Kulkarnin 2016 in their research study they evaluated and compared the efficacy of dexamethasone and clonidine as an adjunct to bupivacaine in transversus abdominis plane block in patients undergoing lower segment caesarean section

In their study they had total 104 patients aged 20 to 60 years belonging to ASA grade I and II undergoing lower segment caesarian section surgeries with randomly allocated two groups, TAP-D (n=54) received 0.25% Bupivacaine with Dexamethasone 4mg and those in group TAP-C (n=50) received 0.25% Bupivacaine with Clonidine 75mcg as TAP block at the end of surgery. The postoperative pain was evaluated by visual analog scale (VAS) for pain scoring at every 2 hours for 12 hours postoperatively. Subjective assessment of duration of analgesia was done.

The average duration of analgesia with TAP block for the overall study population was 316.15 minutes. The average VAS score in patients who received TAP with dexamethasone was 1.50 which is significantly lower than those who received clonidine (1.95) (P value-0.0001). Further the duration of analgesia was 151 minutes longer in the first group who received dexamethasone TAP. In majority of the patients (84%) who received clonidine TAP, the analgesia persisted for 2-4 hours. While in patients who received dexamethasone addition, the analgesia persisted for 6-8 hours in 37%.

Hence the study concluded that TAP block is a safe and effective way of relieving postoperative pain in LSCS patients and addition of dexamethasone to bupivacaine significantly enhances its effect in terms of block quality and analgesia duration. TAP block has opioid-sparing effects, reduces antiemetic use and improves overall patient satisfaction with pain relief. In addition to the advantages of a TAP block, supplementation of dexamethasone to bupivacaine significantly increases the duration of analgesia. An early requirement of rescue analgesia arose in the clonidine addition group, while those in the other group could sustain the TAP block for more hours.

Women undergoing LSCS present a unique set of problems to the anaesthetist and require optimal pain management. Thus, TAP block becomes an important component of multimodal analgesia for post LSCS pain relief and dexamethasone is indeed a safe and effective adjunct that prolongs the duration of the block.

Vyas M, Deepshika D, Patel KB. Addition of dexmedetomidine to bupivacaine in USG guided transversus abdominis plane block potentiates post-operative pain relief among Lower Abdominal Surgeries. *Int J Sci Res.* 2017;6(9):360–62.

Kumar VS, Cheran K, Chaitanya K. Comparison of dexmedetomidine with bupivacaine and bupivacaine alone for post-operative analgesia in ultrasound guided transversus abdominis plane block in patients undergoing Lower Abdominal Surgeries. *Int J Curr Med Pharm Res.* 2017;

Robert wegner et al, UT Health. (2017) A total of 82 patients undergoing inguinal hernia repair or spermatocelectomy were enrolled in the study, of which 41 patients received TAP block with ropivacaine with saline, and the other 41 received ropivacaine with dexamethasone immediately following surgery. Both the proceduralist (resident) and the patient were blinded to the solution used. Visual analog pain scores (0 – 10) were obtained pre-block and immediately post block. endpoint was visual analog pain score at 12 hours, with 24 and 48-hour pain scores as the secondary endpoints. Study showed significant prolongation of TAP blocks with ropivacaine when 8 mg dexamethasone was added.

Prannal Bansal, Dinesh Soodin 2018 in their comparative study of effect of Dexmedetomidine as an Adjuvant to Ropivacaine in Ultrasound-guided Transversus Abdominis Plane Block for Post-operative Pain Relief in Cesarean Section.

Forty American Society of Anesthesiology grade I or II patients undergoing C-section were enrolled in this randomized, controlled, double-blind study. Twenty patients each were allocated to two groups receiving bilateral TAP block. Test group received TAP block with 3 mg/kg of ropivacaine with 50 µg of dexmedetomidine. Control group received TAP block with 3 mg/kg of ropivacaine. Patient demographics, time to initial reporting of pain, time to first rescue analgesia, quality of block, and side effects were recorded.

Time to initial onset of pain (6.6 vs. 5.03 h; P = 0.01) and time to first rescue analgesia (7.8 vs. 6.47 h; P = 0.03) were significantly longer in the test group compared with control group. The two groups were similar in demographics and quality of block. No significant difference in side effects was noted between the two groups.

The final inference of their study was that : Addition of dexmedetomidine to ropivacaine for TAP block in patients undergoing C-section prolonged the time to initial onset of pain and time to first rescue analgesia.

Uma Datt Sharma, Prateek, HimaniTakin 2018 a double blinded study was conducted which was aimed to evaluate and compare the effect of addition of dexamethasone to ropivacaine on post-operative analgesia in ultrasonography-guided transversus abdominis plane block for inguinal hernia repair

The study discusses the effects of addition of dexamethasone to ropivacaine in USG-guided TAP block for inguinal hernia repair. Following inguinal hernia repair the use of regional anaesthesia along with conventional oral and IV analgesics have resulted in improved outcomes. 0.5% ropivacaine was used in this study instead of 0.25% as it provides denser analgesia as observed in various previous studies. Addition of dexamethasone to local anaesthetics as an adjuvant increased the duration of TAP block (RD vs. RS; 547.50 [530,530] min vs. RS 387.50 [370,400] min, respectively). The increase in the duration was similar to the previous studies.[13] Dexamethasone exerts its analgesic action by inhibiting transmission and neural discharge in nociceptive C-fibres. Hence, the duration of anaesthesia is prolonged due to dexamethasone additive action.[14] Steroids prolongs analgesia when administered as adjuvant in regional blocks but the results have been variable depending on the dosage of dexamethasone, local anaesthetic and its concentration and site of block. Duration of prolongation of analgesia with dexamethasone is highly variable with few studies suggesting analgesia up to 20–24 h while others suggest only up to 12–16 h as observed in this study.[8,15,16] Furthermore, it has also been found that dexamethasone at doses more than 0.1 mg/kg is an effective adjunct in multimodal strategies to reduce post-operative pain and opioid consumption after surgery.[17,18]

Considering the fact that doses 8 mg dexamethasone was used as an adjuvant with ropivacaine. Addition of dexamethasone to ropivacaine in TAP block resulted in significant reduction of tramadol consumption (RD vs. RS; [223.33 ± 56.83 mg] vs. [293.33 ± 25.71 mg], respectively). This was found to be associated with decreased side effects. Decreased nausea and vomiting associated with dexamethasone can be explained due to various reasons such

as anti-inflammatory effect, direct central action at the solitary tract nucleus, interaction with the neurotransmitter serotonin, and receptor proteins tachykinin NK1 and NK2 and alpha-adrenaline maintaining the normal physiological functions of organs and systems, regulation of the hypothalamic–pituitary–adrenal axis, reducing pain and the concomitant use of opioids, which in turn reduces opioid-related nausea and vomiting.[21]

From this study they came to the conclusion that the addition of dexamethasone to ropivacaine in USG-guided TAP block significantly prolongs the duration of post-operative analgesia.

Jitender Thakur1 , Bharti Gupta1*, Amit Gupta2 , Ravinder Kumar Verma1 , Anita Verma1 , Payal Shah3 in2019 the study carried out on 1200 ASA 1 and 2 patients planned for LSCS surgery. Aim of this study was to evaluate the efficacy of dexmedetomidine and dexamethasone as an adjunct to bupivacaine in ultrasound guided TAP block for postoperative analgesia in patients of caesarean section.

Zhaojun qin et al, BMC, (2019), One hundred and twenty-five patients undergoing laparoscopic gynaecological surgery were included in this prospective and randomized double-blind study. Patients received general anaesthesia with or without a total of 60ml of 0.2% ropivacaine in combination with low (0.25µg/kg), medium (0.50µg/kg) or high dose (1.0µg/kg) of dexmedetomidine for the four-quadrant transversus abdominis plane block (n=25). The addition of dexmedetomidine at the dose of 0.5µg/kg into ropivacaine for ultrasound-guided transversus abdominis plane block is the optimal dose to inhibit stress response with limited impact on blood pressure and heart rate in patients undergoing laparoscopy gynaecological surgery.

Priyanka Agarwall ,PurvashreeDeshmukh2 ,ChaitanyaKamat3 ,RaviKerur4 ,MeghanaHanagandi5 , GuruprasadShetty6 in 2019 the study carried out for total of 60femalepatients,scheduled for open lower abdominal surgery under general anesthesia, were recruited into two Groups :Ropivacaine (R)and Ropivacaine and Dexmedetomidine (RD).Group R received USG-guided TAP block with 30ml of 0.2% Ropivacaine and saline. Group RD received USG -guided TAP block with 30ml of 0.2% Ropivacaine and 0.5mcg/kg of Dexmedetomidine. .Post-operative pain scores, sedation score, time to first rescue analgesic ,and total opioid requirement in first 24hours, were calculated.

The difference between the duration of time to first rescue analgesic ,between two groups, was statistically significant($p=0.018$). Further ,it was observed that the VAS scoring was lower in group RD as compared to Group R ,the time intervals .The RD Group showed a significant difference between Modified Wilsons sedation score at first hour in both the groups, $p<0.05$.

From there study they concluded that the analgesic efficacy of Dexmedetomidine with 0.2% Ropivacaine in TAP block showed a positive result when compared to 0.2% Ropivacaine alone .The analgesic efficacy of Dexmedetomidine with 0.2% Ropivacaine was more pronounced when compared to the 0.2% Ropivacaine individually in TAP block procedure during Lower Abdominal Gynecological Surgeries.

Methodology:-

Study Design

Double blinded randomized case control study.

Study Setting

This study is conducted at the Department of Anesthesiology, Al Ameen Medical College Hospital, Vijayapura, Karnataka, under Rajiv Gandhi University of Health Sciences, Bangalore, Karnataka

Study Period

The collection of data was done from NOVEMBER 2020 to NOVEMBER 2022.

Study Population

Prospective randomised double-blind study would be conducted on 80 adult patients of ASA grade I & II in the age group of 18 to 70 years of either sex, posted for infraumbilical surgeries after taking informed written consent.

Patients were randomly divided on an alternative basis into 2 groups of 40 each.

Group-A: Patients receiving 20ml of 0.2% ropivacaine with 50mcg (0.5ml) / 0.5mcg/kg of Dexmedetomidine.

Group-B: Patients receiving 20ml of 0.2% ropivacaine with 8mg (2ml) of dexamethasone

Inclusion Criteria:

1. Patients willing to give informed consent according to annexure 1.
2. All patients belonging to age group 18-70 years weight 40-70 kg
3. ASA grade I and grade II patients.
4. Patients undergoing elective/emergency infraumbilical surgeries under spinal or general anaesthesia.
5. Patients who can understand and rate their pain on visual analogue scale (VAS scale of 0-10) were eligible for the study.

Exclusion Criteria:

1. Patients who were unwilling to participate in the study.
2. Patients who could not provide informed or written consent.
3. Patients with ASA Grade >2
4. Patients who had any complications with spinal or general anaesthesia both intra or post operatively.
5. Patients who has a history of anaphylaxis with ropivacaine or Dexmedetomidine or dexamethasone use.
6. Patients who has a history of drug abuse.
7. Unable to understand VAS score.
8. Patients with coagulation disorders or on anticoagulant therapy
9. Patients with medical complications like anaemia, heart diseases, severe hypovolemia, shock, septicaemia and neurological defects.

Sample Size Estimation

Total sample size =80

80 patients (40 per group) are required to have a 90% chance of detecting, as significant at the 5% level, an increase in the mean duration of analgesia (minutes) from 300.2 in the group I to 400 in the experimental group II. (reference article Thakur J et al 2019).

Calculation based on the formula: $n = f(\alpha/2, \beta) \times 2 \times \sigma^2 / (\mu_1 - \mu_2)^2$

where μ_1 and μ_2 are the mean outcome in the control and experimental group respectively, σ is the standard deviation

All characteristics will be summarized descriptively. For continuous variables, the summary statistics of N, mean, standard deviation (SD) will be used. For categorical data, the number and percentage will be used in the data summaries and data will be analyzed by Chi square test for association, comparison of means using t test, ANOVA, and diagrammatic presentation. Other suitable methods of analysis also will be used as per need

The subscript “c” are the degrees of freedom. “O” is observed value and E is expected value. $C = (\text{number of rows}-1) * (\text{number of columns}-1)$

The difference of the means of analysis variables between two independent groups was tested by unpaired t test.

The t statistic to test whether the means are different can be calculated by below mentioned formula

$$t = \frac{(\bar{x}_1 - \bar{x}_2) - (\mu_1 - \mu_2)}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}}$$

where \bar{x}_1 = mean of sample 1

\bar{x}_2 = mean of sample 2

n_1 = number of subjects in sample 1

n_2 = number of subjects in sample 2

$$s_1^2 = \text{variance of sample 1} = \frac{\sum(x_1 - \bar{x}_1)^2}{n_1}$$

$$s_2^2 = \text{variance of sample 2} = \frac{\sum(x_2 - \bar{x}_2)^2}{n_2}$$

With the p-value was < 0.05 the results were considered to be statistically significant otherwise it is not statistically significant. Here the Data were analyzed by using SPSS software v.23(IBM Statistics, Chicago, USA) and Microsoft office 2007.

Methods Of Collection Of Data:-

1. This study included 80 patients presented to the Department of Anaesthesiology, Al Ameen Medical College, Vijayapura
2. Informed/ written consent was obtained from the patients.
3. Proper history was obtained, and a clinical examination was performed.
4. All details were recorded in the proforma.

Preoperative Preparation:

The routine preoperative assessment of patient was done, initial hemodynamic parameters were noted. Intravenous line started preoperatively. Then closed cover technique was used to randomly allocate the patients into two groups of 40 each .

While preparing the operating room appropriate equipment for airway management and emergency drugs were kept ready before hand.

Procedure

1. The patients selected based on those satisfying the inclusion criteria and gave a written informed consent underwent the following
2. A detailed history and complete clinical examination of patients was done to rule out the exclusion criteria. Routine investigations like blood grouping, hemoglobin, blood urea and creatinine, coagulation test, and blood sugar was done. ECG whenever indicated was taken to rule out the presence of any cardiac disease. Preoperative pulse rate, respiratory rate, blood pressure values noted. Written and informed consent was taken prior to scheduled operation.
3. Detailed preanesthetic check-up including anticipation of difficult airway was done and patients were counselled regarding general anaesthesia, transversus abdominis plane block and visual analogue scale which is a line graded from 0-10, where 0=no pain and 10=the worst pain imaginable.
4. Patients involved in the study will be premedicated with Tablet Ranitidine 150mg and Tablet Alprazolam 0.5mg night prior to the surgery. Patient kept nil per oral 6 hr before surgery. In the pre-operative room, baseline readings of heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure , oxygen saturation and end tidal carbon dioxide are measured . Consent was checked. Monitors such as Non-invasive blood pressure with right sized BP cuff, Pulse oximetry, Electrocardiography, was connected. Airway equipment's like oral airways, laryngeal mask airway size 3 and 4, different sized laryngoscope blades and cuffed endotracheal tubes, difficult airway cart and emergency drugs were kept ready.

On arrival to the anesthetic room, patient was connected to pulse oximeter, NIBP and ECG. An average of three recordings would be considered as baseline recording. Intravenous line would be secured and stable

vitals ensured. General anesthesia is standardized for all patients in the two groups. All patients were premedicated with intravenous midazolam 0.02mg/kg half an hour before the surgery.

Intra operative analgesia established with fentanyl 2mcg/kg. Induction with propofol 2mg/kg. After ensuring bag mask ventilation, neuromuscular blockade was achieved with vecuronium 0.1mg/kg and, endotracheal intubation was performed 3 minutes later with cuffed ET tube. The ET tube was connected to circle breathing system and appropriate placement was determined by chest wall movement, auscultation of breath sounds, capnograph and lack of gastric insufflation (determined by epigastric auscultation).

TAP block is administered after the completion of surgery both in patients undergoing spinal and general anesthesia. The anesthesiologist, performing the TAP block and assessment of the block, was blinded to the group of study solution. The study solution would be prepared by another anesthesiologist who will not be involved in the clinical care of the patient.

Reversal with 0.05mg/kg neostigmine and 0.01mg/kg glycopyrrolate. Trachea was extubated after extubation criteria is met and shifted to post operative care for monitoring.

1. For spinal anesthesia, skin infiltration was done with 2% lidocaine by creating a small wheal, 25G Quincke's needle was introduced at the L3/4 interspace in the midline by identifying tuffier's line. The free flow of CSF is confirmed after the puncture of duramater, the complete solution was injected. Then patients were repositioned to lie supine immediately after the injection and the time of injection was noted.
2. TAP block is administered after the completion of surgery both in patients undergoing spinal anesthesia. The anesthesiologist, performing the TAP block and assessment of the block, was blinded to the group of study solution. The study solution would be prepared by another anesthesiologist who will not be involved in the clinical care of the patient
3. After scrubbing and wearing sterile gloves, the skin was painted with Povidine iodine solution three times and then with spirit. Sterile hole towel was draped over the appropriate side of the abdomen where block is to be given.
4. Under aseptic conditions the study solution was injected with 21G Stimuplex-A 10cm needle into the transverses abdominis plane between internal oblique and transverses abdominis using ultrasound guidance with sonosite HD 11 XE high frequency transducer 8-13 mega Hz..
5. Intraoperative hypotension was defined as 20% decrease in blood pressure and was treated with intravenous fluids, intravenous boluses of Injection mephentermine 6mg.
6. Intraoperative bradycardia was defined as 20% decrease from the basal heart rate and treated with Injection Atropine 0.6mg iv.

All surgical interventions were performed by the same surgical team.

In the post operative period VAS score was measured every half an hour for first 6 hours and then every 2nd hourly for upto 24hr. rescue analgesia, inj diclofenac 75mg slow IV was given when VAS score >4. Nausea and vomiting was recorded using a categorical scoring system (0 = none, 1 = nausea, 2 = retching, 3 = vomiting) at 1,2,4,8,12,18,24 hr. Intravenous ondansetron 4mg was offered for any patient with a score 1 or more. Hemodynamic variables such as Heart rate, systolic blood pressure, diastolic blood pressure, MAP were recorded every 10 mins for first hour and hourly thereafter upto 24hr. Post operative Sedation Score at 1,2,4,8,12,18,24 hr using Ramsey sedation scale¹⁰³

Rescue analgesia –

The doses of analgesia consumed after the operation, first time of requesting analgesia, frequency of administration and the total dose consumed by the patient during the 24 hours post operatively were recorded in all groups.

Group-A: Patients receiving 20ml of 0.2% ropivacaine with 50mcg (0.5ml) / 0.5mcg/kg of Dexmedetomidine.
Group-B: Patients receiving 20ml of 0.2% ropivacaine with 8mg (2ml) of dexamethasone.

The following parameters were noted.

Haemodynamic Parameter :-

Pulse rate.

a) Blood pressure- Systolic Diastolic and Mean.

2. Respiratory Parameter:-

- a. Saturation.
- b. Respiration rate.

3. Adverse Effects: -

- a. Nausea.
- b. Vomiting.
- c. Pruritis.
- d. Hypotension.
- e. Bradycardia.
- f. Respiratory depression.
- g. Urinary retention.

4. Assessment Of Post Operative Analgesia

- a) Pain intensity assessed by Visual Analogue Scale.
- b) Time required for first rescue analgesia.

5. Sedation

- a) Levels assessed by modified Ramsay sedation score

Degree of sedation assessed by Ramsay Sedation Score (RSS)

1. Anxious and Agitated.
2. Cooperative, oriented, tranquil
3. Responds only to verbal commands
4. Asleep with brisk response to light stimulation
5. Asleep with sluggish response to light stimulation
6. Asleep without response to light stimulation

Hypotension was noted when the MAP fell less than 20% from basal blood pressure and this is treated by increasing the infusion rate of IV fluids and or injecting vasopressors like Inj. Ephedrine or mephentermine in incremental dosage of 6mg.

Bradycardia was noted when the heart rate fell below 20% from basal heart rate and was treated with intravenous atropine 0.02mg/kg body weight.

If Respiratory depression was noted if $SpO_2 < 90\%$. It was managed with oxygen supplementation either with Hudson mask or nasal prongs and intubation and IPPV .

Any discomfort like nausea, vomiting, shivering, pruritis were noted.

Vomiting was managed with Inj. Ondansetron 4mg intravenously. After the completion of surgery, patient was shifted to post anaesthesia care unit for further monitoring

Duration Of Analgesia

The duration of analgesia was noted as the interval between the time of administration of TAP block to the first requirement of rescue analgesics when the patient complaints of pain in the postoperative period.

Observation and Analysis:-

The 80 patients allotted in both the groups completed the study with no exclusions. Thorough Inter group analysis was done and the results were as follows. The data's that were collected were analyzed by chi square test and results obtained in the form of range, mean and standard deviation. The 'p' value, that is probability value of less than 0.05 considered statistically significant. The demographic data includes age, sex, heart rate, systolic and diastolic blood

pressure and oxygen saturation at different intervals and the side effects between the patients of these two groups were comparable.

Table 1:- Distribution Of Age Between Study Group.

The two groups were compared in terms of demographic variables such as age, and gender. Table 1 and figure 1 shows the age distribution across two groups. There was no significant difference amongst the two groups in terms of age with P value 0.0530.

Table 1:- Comparison of Group A and Group B with age groups.

Age groups	Group A	%	Group B	%	Total	%
20-29yrs	20	50.00	12	30.00	32	40.00
30-39yrs	12	30.00	9	22.50	21	26.25
40-49yrs	3	7.50	11	27.50	14	17.50
>=50yrs	5	12.50	8	20.00	13	16.25
Total	40	100.00	40	100.00	80	100.00
Chi-square=7.6920, p=0.0530						

Figure 1:- Comparison of Group A and Group B with age groups.

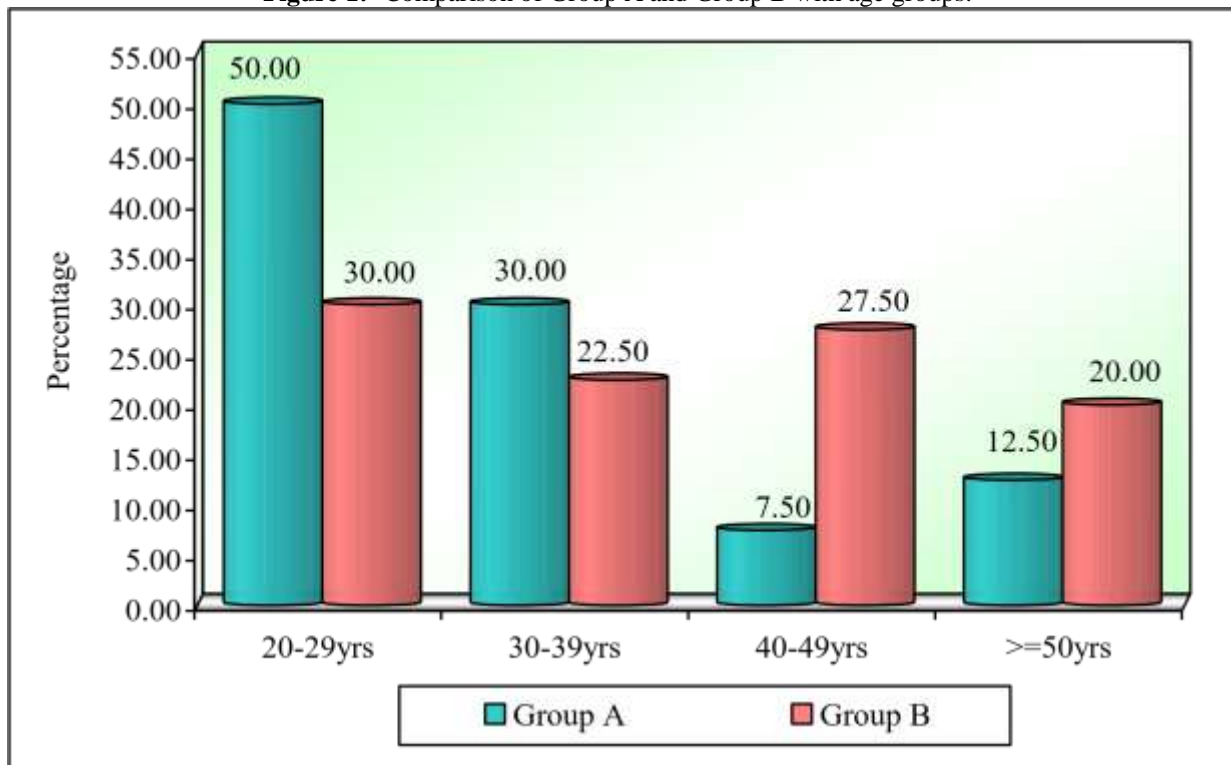


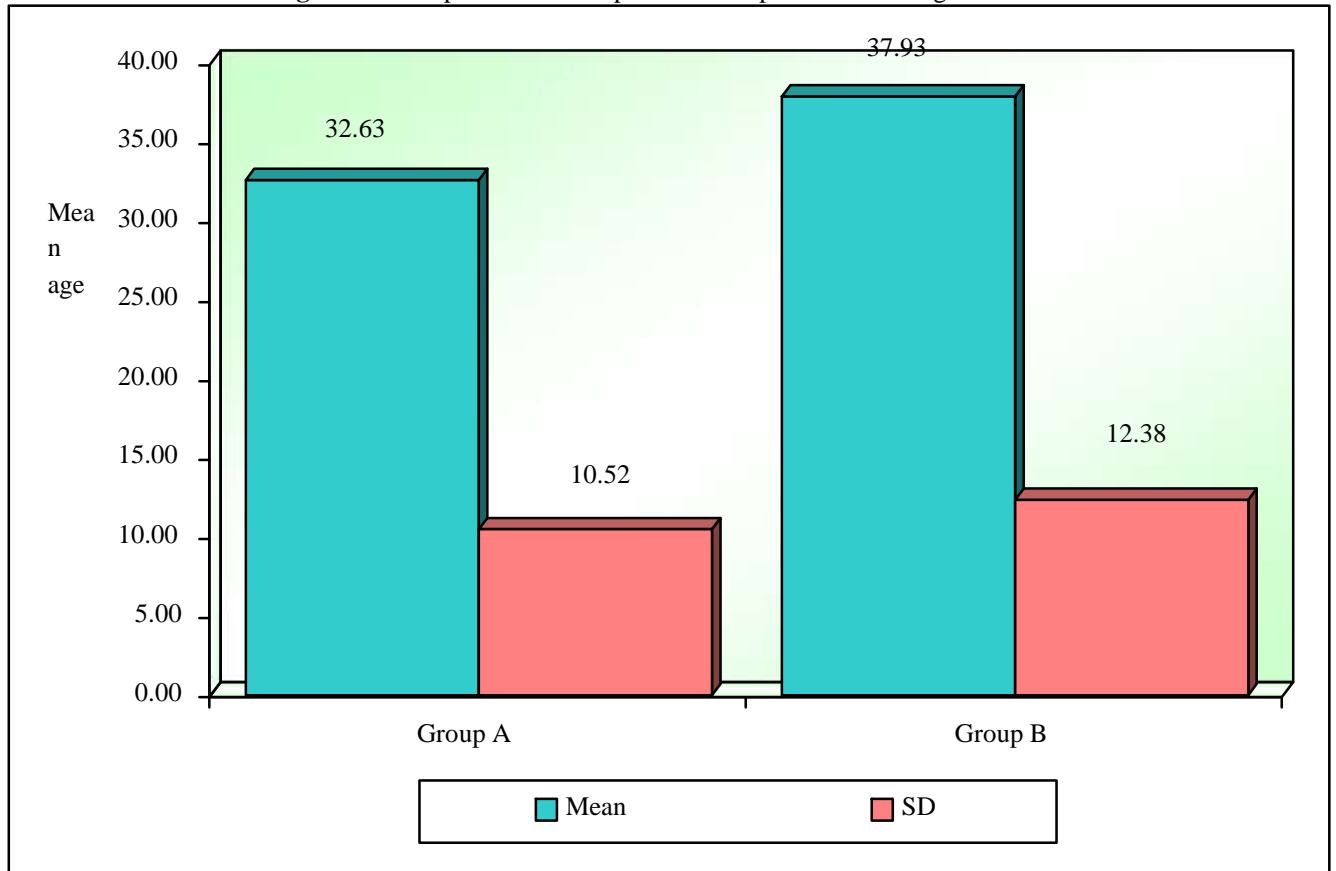
Table 2:- Comparison of Group A and Group B with mean age by independent t test.

Groups	n	Mean	SD	SE	t-value	P-value
Group A	40	32.63	10.52	1.66	-2.0634	0.0424*
Group B	40	37.93	12.38	1.96		
Total	80	35.28	11.72	1.31		

*p<0.05

There was significant difference amongst the two groups in terms of mean age with P value 0.0424 (p<0.05) and mean age was found to be 35.28 years as seen in table 2.

Figure 2:- Comparison of Group A and Group B with mean age.



Gender Distribution

Table 3:- Comparison of Group A and Group B with gender.

Gender	Group A	%	Group B	%	Total	%
Male	21	52.50	20	50.00	41	51.25
Female	19	47.50	20	50.00	39	48.75
Total	40	100.00	40	100.00	80	100.00
Chi-square=0.0500, p=0.8230						

There was no definite statistical gender preponderance observed in our study population. Both the groups were distributed in near equal proportion as shown in table 3

Figure 3:- Comparison of Group A and Group B with gender.

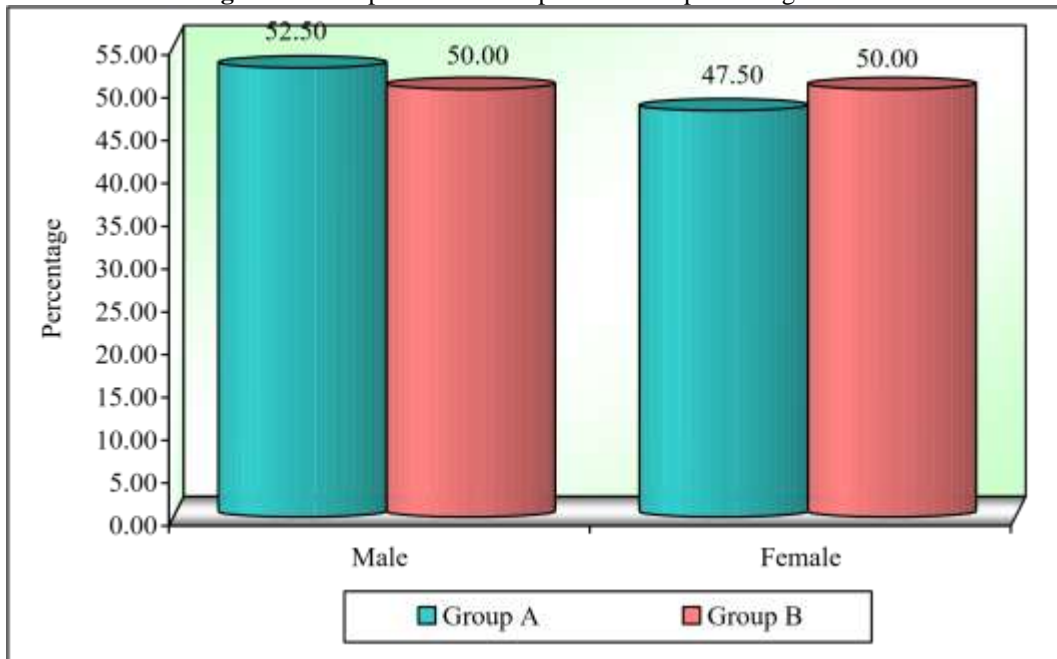


Table 4:- Comparison of Group A and Group B with ASA scores.

ASA scores	Group A	%	Group B	%	Total	%
Score 1	21	52.50	26	65.00	47	58.75
Score 2	19	47.50	14	35.00	33	41.25
Total	40	100.00	40	100.00	80	100.00
Chi-square=1.2890, p=0.2560						

There was no significant statistical difference amongst the two groups in terms of ASA scoring as seen in table no 4 with P value 0.2560.

Figure 4:- Comparison of Group A and Group B with ASA scores.

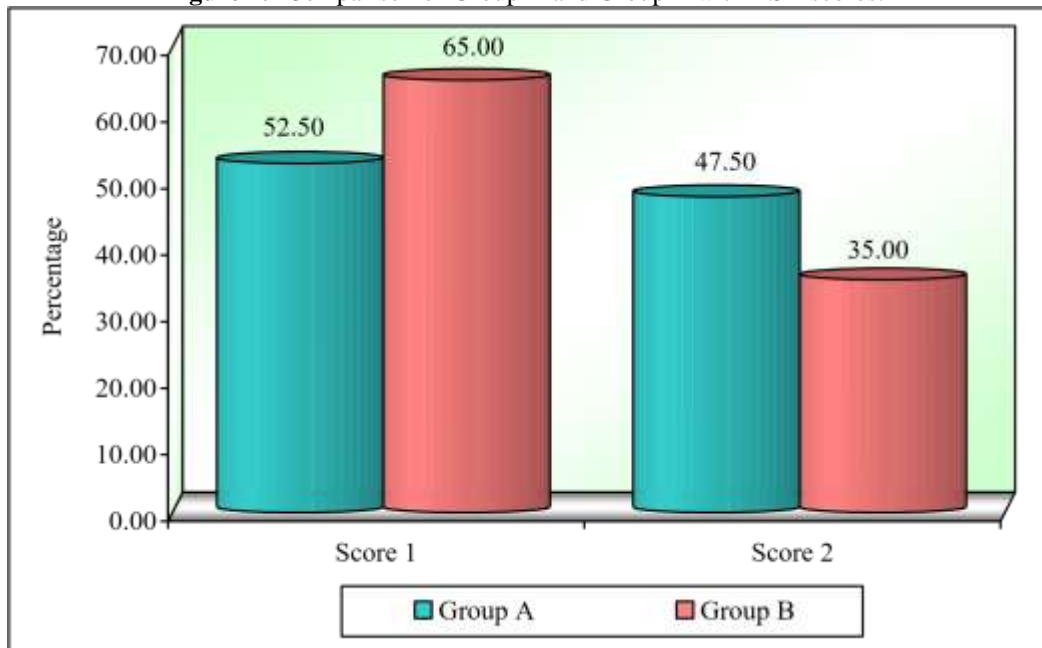


Table 5:- Comparison of Group A and Group B with Types of surgery.

Types of surgery	Group A	%	Group B	%	Total	%
Cholecystectomy	7	17.50	6	15.00	13	16.25
Appendicectomy	8	20.00	11	27.50	19	23.75
Hernioplasty	12	30.00	15	37.50	27	33.75
LSCS	12	30.00	6	15.00	18	22.50
Hysterectomy	1	2.50	2	5.00	3	3.75
Total	40	100.00	40	100.00	80	100.00
Chi-square=3.2170, p=0.5220						

There was no significant statistical difference amongst the two groups in terms of type of surgery in table no 5 with P value 0.5220.

Figure 5:- Comparison of Group A and Group B with Types of surgery.

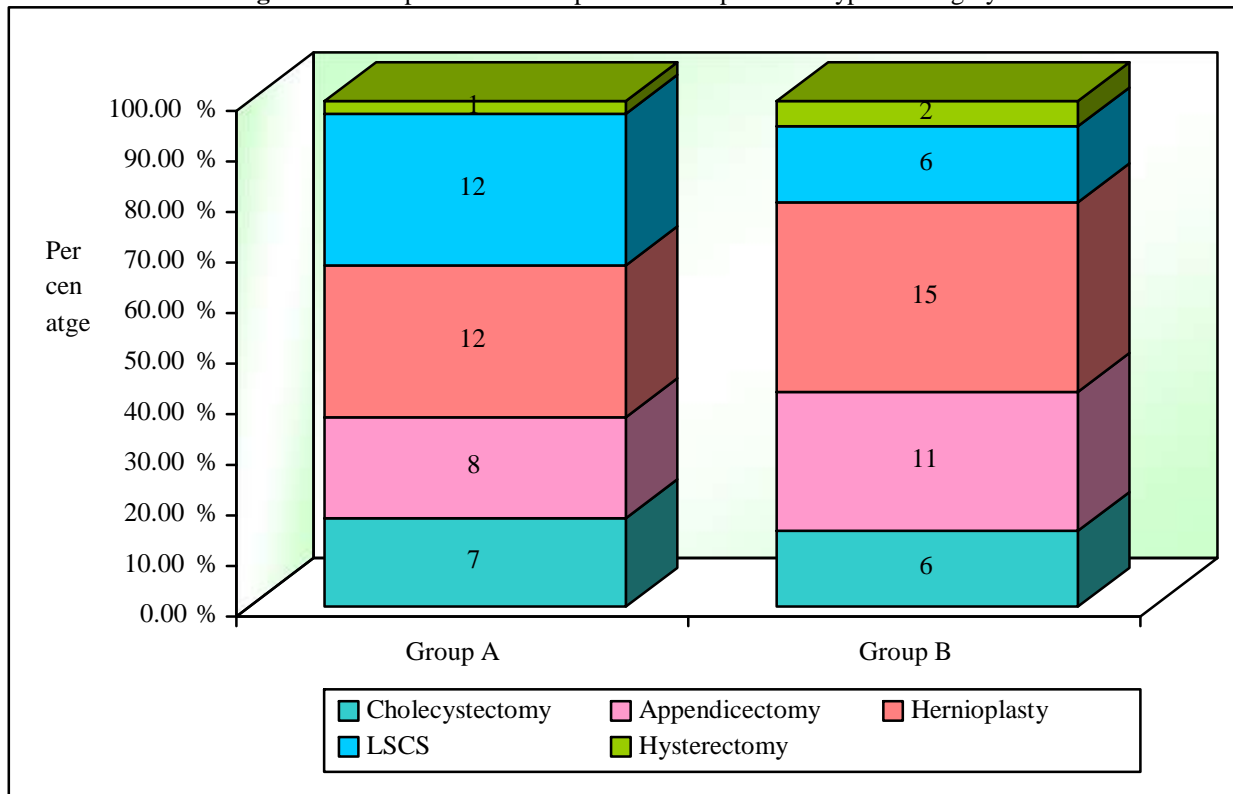


Table 6:- Comparison of Group A and Group B with heart rate at different treatment time points by independent t test.

Treatment time points	Group A		Group B		Mean Difference	t-value	p-value
	Mean	Std.Dev	Mean	Std.Dev			
1 minute	74.18	11.19	60.63	16.65	13.55	4.2716	0.0001*
5 minute	77.93	11.40	73.85	12.73	4.08	1.5081	0.1356
10 minute	75.55	12.34	75.10	11.28	0.45	0.1702	0.8653
15 minute	73.18	13.43	77.18	8.23	-4.00	-1.6063	0.1122
30 minute	79.70	10.92	75.55	12.73	4.15	1.5647	0.1217

*p<0.05

Comparison between heart rates for the initial 1min shows statistically significant difference between the two groups (p=0.0001). However, heart rates values from 5 min to 30 mins showed no statistically significant

difference between the two groups. Graph 6 shows that the heart rate is significantly lower in group B compared to group A. The mean heart rate for group B was least with 60.63 beats per minute in comparison to group A with 74.18 beats per minute.

Figure 6:- Comparison of Group A and Group B with heart rate at different treatment time points.

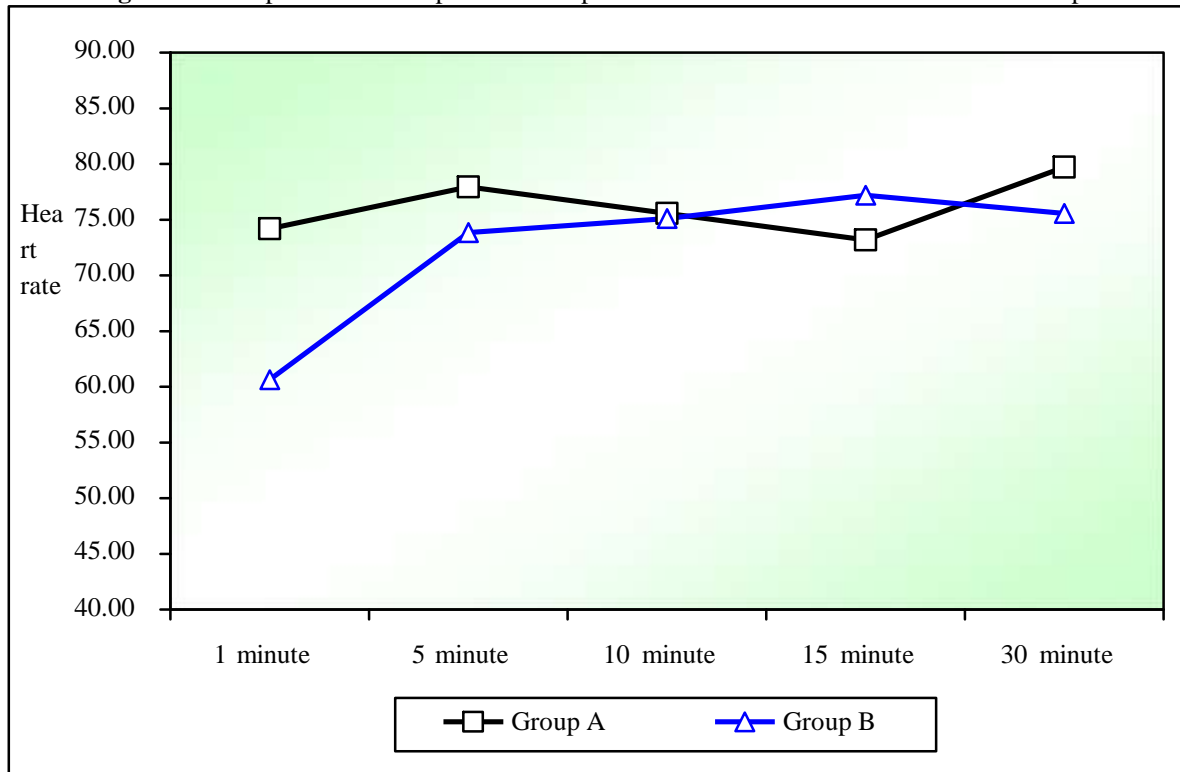


Table 7:- Comparison of Group A and Group B with SBP at different treatment time points by independent t test.

Treatment time points	Group A		Group B		Mean Difference	t-value	p-value
	Mean	Std.Dev	Mean	Std.Dev			
5 minute	116.15	6.38	118.25	5.42	-2.10	-1.5861	0.1168
10 minute	113.28	11.08	115.73	6.86	-2.45	-1.1890	0.2381
15 minute	118.13	5.54	116.78	5.82	1.35	1.0632	0.2910
30 minute	117.73	6.08	116.48	6.32	1.25	0.9011	0.3703

Comparison between the systolic blood pressure from 5 min to 30 minutes shows no statistically significant difference between the two groups.

Table 7:- Comparison of Group A and Group B with SBP at different treatment time points.

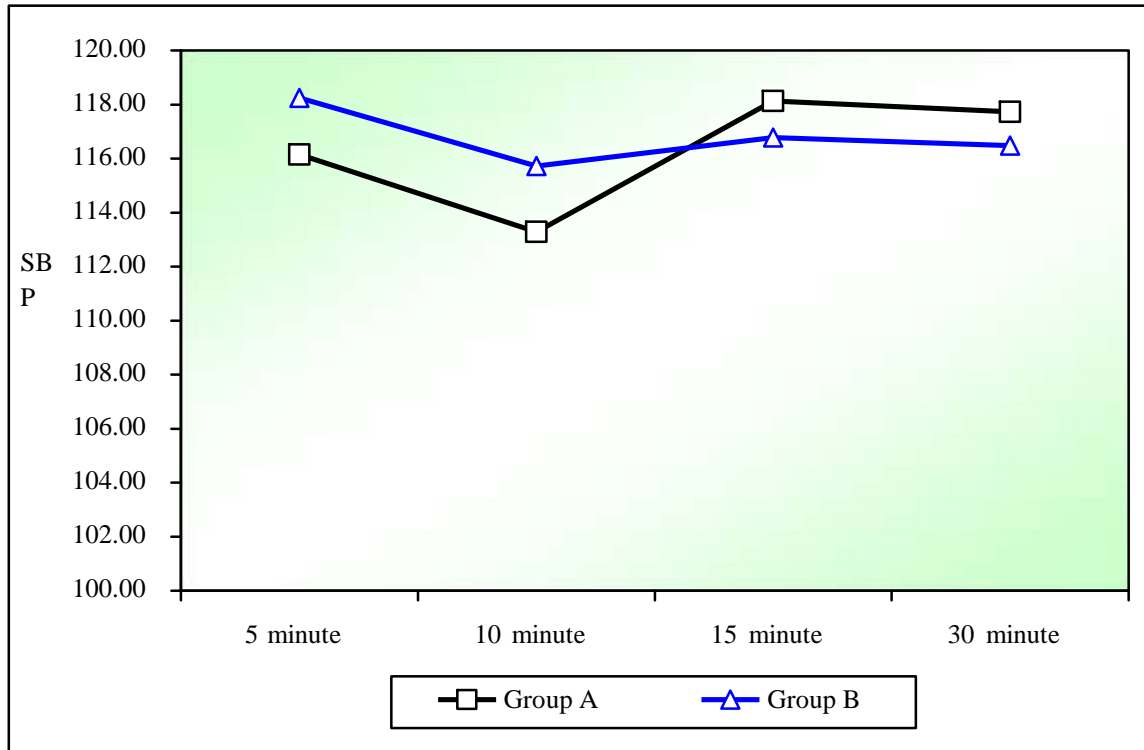


Table 8:- Comparison of Group A and Group B with DBP at different treatment time points by independent t test.

Treatment time points	Group A		Group B		Mean Difference	t-value	p-value
	Mean	Std.Dev	Mean	Std.Dev			
1 minute	76.20	6.84	74.20	6.45	2.00	1.3451	0.1825
5 minute	74.98	11.86	98.40	1.17	-23.43	-12.4321	0.0001*
10 minute	74.30	6.82	83.10	14.10	-8.80	-3.5541	0.0006*
15 minute	76.58	9.64	76.20	6.60	0.38	0.2029	0.8397
30 minute	73.95	9.24	95.95	7.73	-22.00	-11.5521	0.0001*

*p<0.05

Comparison between the diastolic blood pressure at 5 min, 10 min and 30 min shows statistically significant difference between the two groups (p<0.05). However, heart rates values from 1 min and 50 mins showed no statistically significant difference between the two groups. Graph 6 shows that the diastolic blood pressure is significantly lower in group A compared to group B. The mean heart rate for group A was least with 74.98 mmHg at 5 min and 74.30 at 10 min and 73.95 at 30 min in comparison to group B.

Figure 8:- Comparison of Group A and Group B with DBP at different treatment time points.

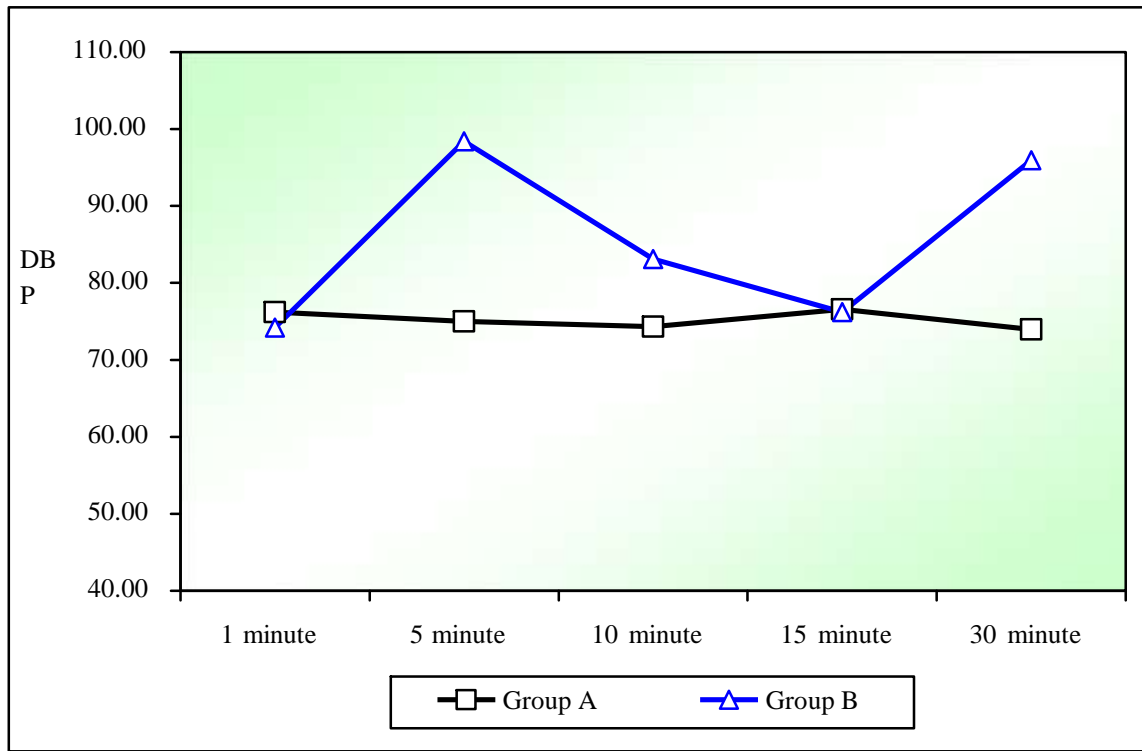


Table 9:- Comparison of Group A and Group B with SPO2 at different treatment time points by independent t test.

Treatment time points	Group A		Group B		Mean Difference	t-value	p-value
	Mean	Std.Dev	Mean	Std.Dev			
1 minute	98.35	1.03	98.15	1.05	0.20	0.8609	0.3919
5 minute	98.45	1.22	98.28	1.01	0.17	0.6987	0.4868
10 minute	98.40	1.03	98.20	1.07	0.20	0.8518	0.3969
15 minute	98.50	0.99	98.15	1.05	0.35	1.5350	0.1288
30 minute	98.25	1.13	98.78	1.31	-0.53	-1.9213	0.0583

Table 9 and Figure 9 shows Comparison between the oxygen saturation from 1 min to 30 minutes shows no statistically significant difference between the two groups.

Figure 9:- Comparison of Group A and Group B with SPO2 at different treatment time points.

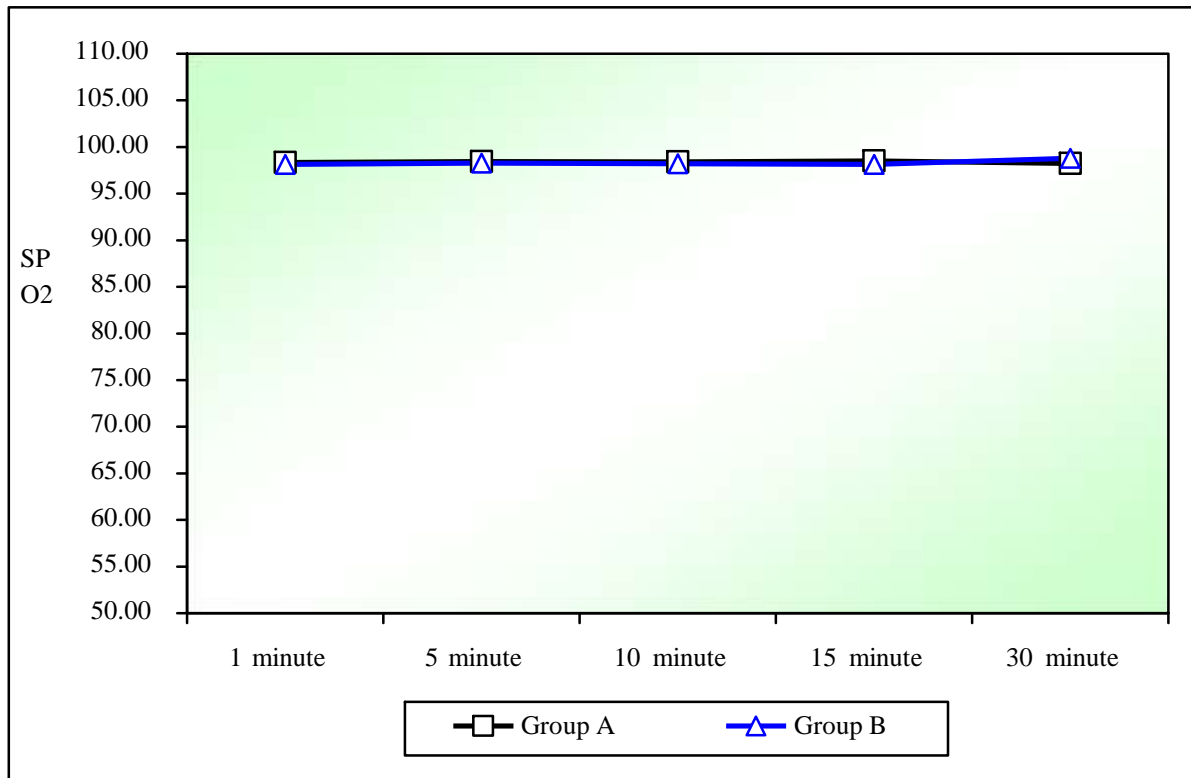


Table 10:- Comparison of Group A and Group B with Pain scores at post operative timings by MannWhitney U test.

Post operative timings	Group A			Group B			U-value	Z-value	p-value
	Mean	SD	Median	Mean	SD	Median			
30th min	1.0	0.2	1.0	1.0	0.0	1.0	780.00	0.1876	0.8512
2 nd hr	1.0	0.2	1.0	1.1	0.3	1.0	760.00	-0.3801	0.7039
4 th hr	2.0	0.2	2.0	2.2	0.5	2.0	648.00	-1.4578	0.1449
6 th hr	2.1	0.5	2.0	2.0	0.2	2.0	683.50	1.1162	0.2643
12 th hr	3.6	0.5	4.0	3.5	0.5	4.0	720.00	0.7650	0.4443
16 th hr	3.5	0.5	3.5	3.7	0.5	4.0	660.00	-1.3423	0.1795
24 th hr	1.0	0.0	1.0	1.1	0.4	1.0	760.00	-0.3801	0.7039

Table 10 and Figure 10 shows comparison between the pain scores from 30 min to 24 minutes shows no statistically significant difference between the two groups.

Figure 10:- Comparison of Group A and Group B with Pain scores at post operative timings.

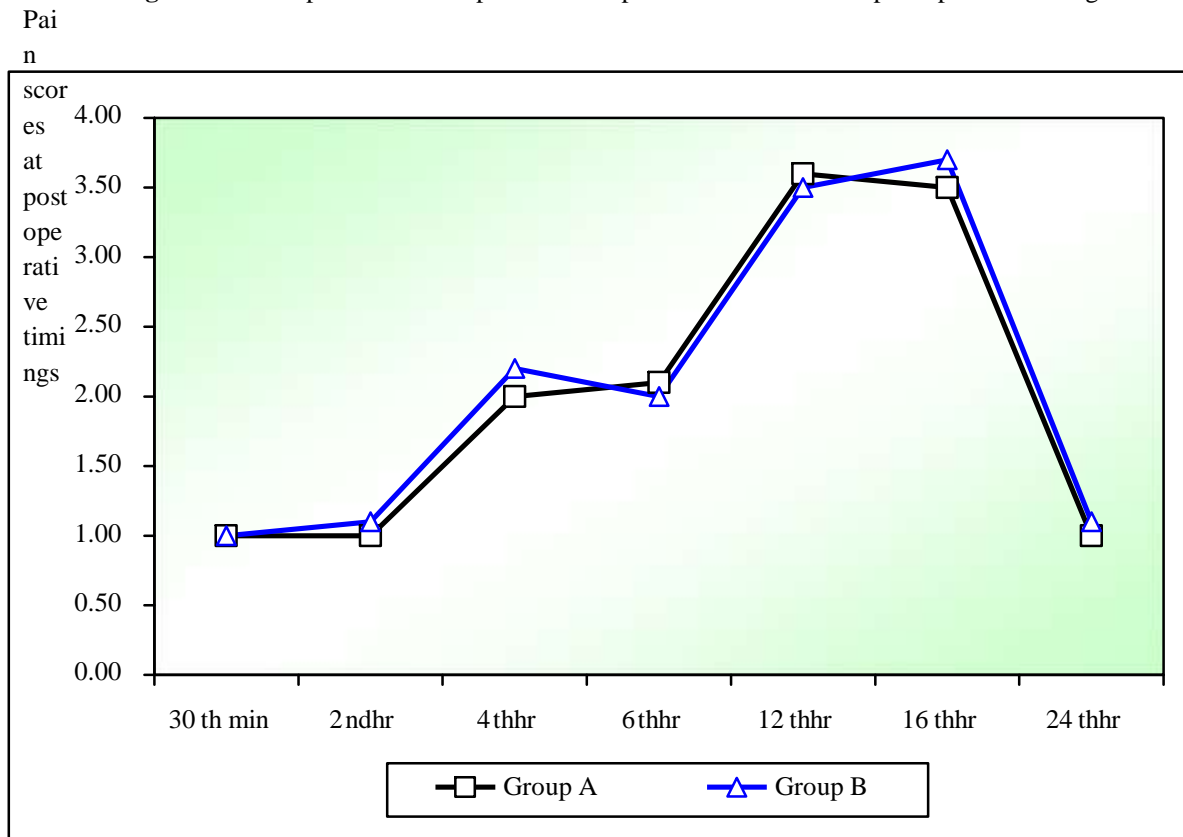


Table 11:- Comparison of Group A and Group B with Pain scores at time of observations (AM/PM) by Mann-Whitney U test.

Times of observations	Group A			Group B			U-value	Z-value	p-value
	Mean	SD	Median	Mean	SD	Median			
1st hr AM	1.0	0.0	1.0	1.0	0.0	1.0	800.00	0.0048	0.9962
2nd hr AM	0.0	0.0	0.0	0.0	0.0	0.0	800.00	0.0048	0.9962
4th hr AM	1.2	0.4	1.0	1.0	0.0	1.0	660.00	1.3423	0.1795
6th hr PM	2.7	0.6	3.0	2.4	0.5	2.0	577.50	2.1362	0.0327*
12th hr PM	3.3	0.8	3.0	3.2	0.8	3.0	721.50	0.7506	0.4529
16th hr PM	3.9	1.1	4.0	4.1	0.8	4.0	731.00	-0.6591	0.5098
20th hr PM	3.8	1.3	4.0	1.2	0.4	1.0	116.00	6.5770	0.0001*
24th hr PM	2.0	0.8	2.0	2.2	0.6	2.0	738.00	-0.5918	0.5540

*p<0.05

Table 11 and Figure 11 shows comparison between the pain scores at time of observation from 1sthr to 24hrs. At 6thhr and 20thhr at observation time shows statistically significant difference between the two groups.

Figure 11:- Comparison of Group A and Group B with Pain scores at time of observations (AM/PM).

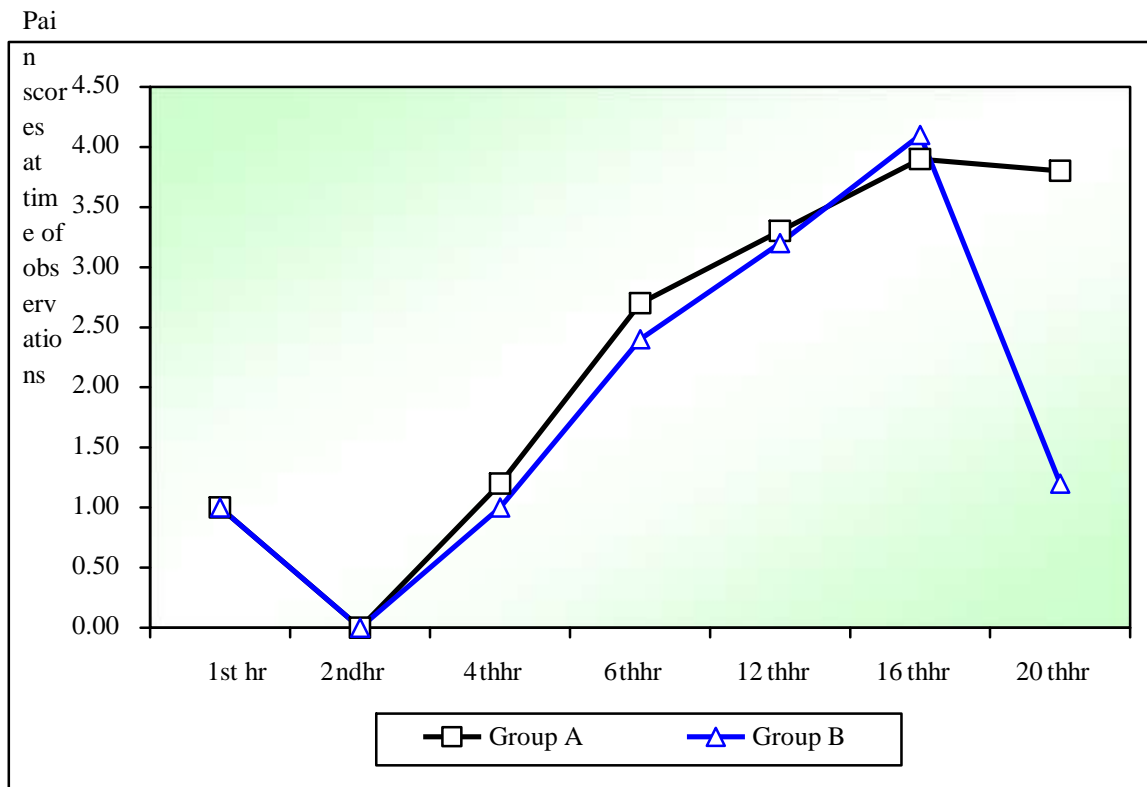


Table 12:- Comparison of Group A and Group B with Pain scores at rests by Mann-Whitney U test.

Rest times	Group A			Group B			U-value	Z-value	p-value
	Mean	SD	Median	Mean	SD	Median			
At 2nd hr	0.0	0.0	0.0	0.0	0.0	0.0	800.00	0.0048	0.9962
At 4th hr	1.2	0.4	1.0	1.0	0.0	1.0	660.00	1.3423	0.1795
At 6th hr	2.7	0.6	3.0	2.4	0.5	2.0	577.50	2.1362	0.0327
At 12th hr	3.3	0.8	3.0	3.2	0.8	3.0	721.50	0.7506	0.4529
At 16th hr	3.9	1.1	4.0	4.1	0.8	4.0	731.00	-0.6591	0.5098
At 20th hr	3.8	1.3	4.0	1.2	0.4	1.0	116.00	6.5770	0.0001*
At 24th hr	2.0	0.8	2.0	2.2	0.6	2.0	738.00	-0.5918	0.5540

*p<0.05

Table 12 and Figure 12 shows comparison between the pain scores at rest from 2nd hr to 24hrs. At 20thhr at rest shows statistically significant difference between the two groups.

Figure 12:- Comparison of Group A and Group B with Pain scores at rests.

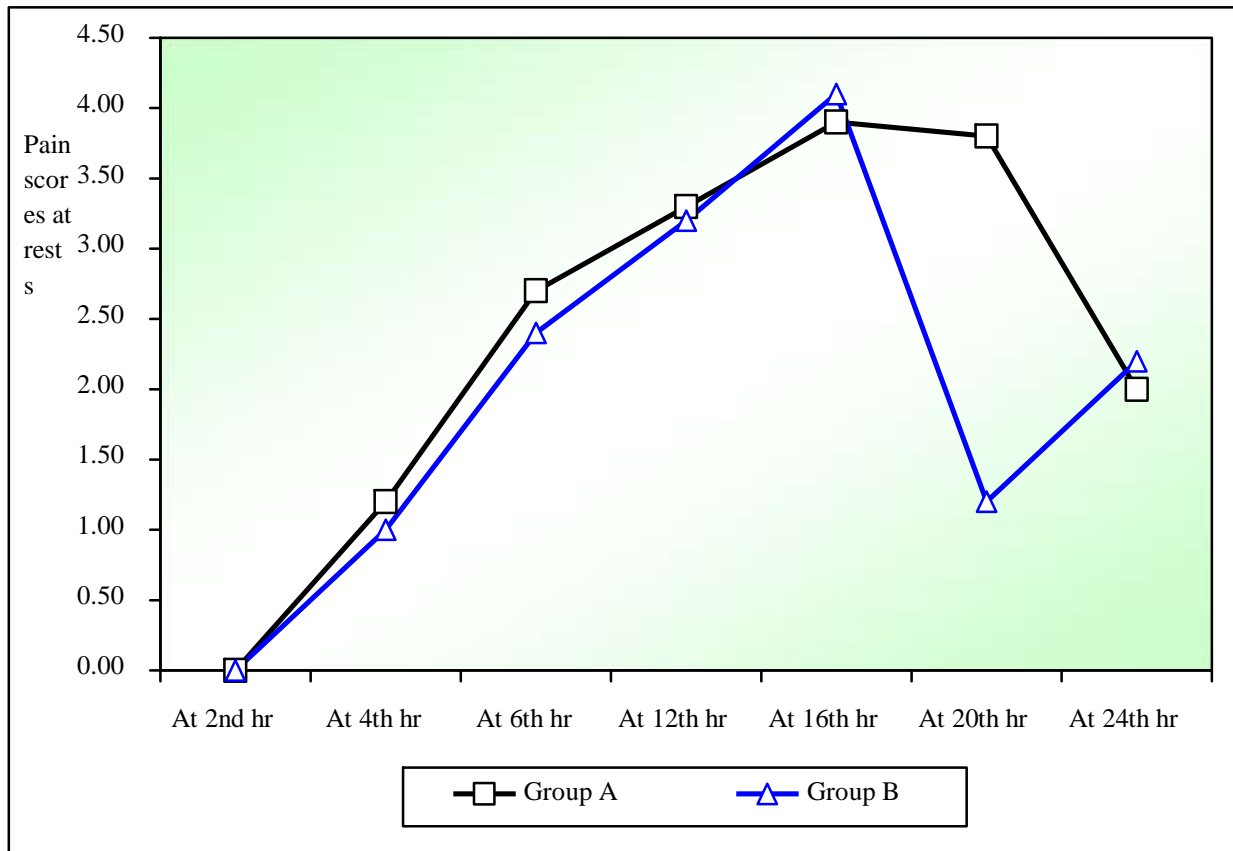


Table 13:- Comparison of Group A and Group B with presence of coughing.

Time points	Group A	%	Group B	%	Total	%	p-value
2 nd hr	0	0.00	1	2.50	1	2.50	0.3140
4 th hr	3	7.50	1	2.50	4	10.00	0.3050
6 th hr	1	2.50	3	7.50	4	10.00	0.5560
12 th hr	2	5.00	1	2.50	3	7.50	0.6440
16 th hr	3	7.50	2	5.00	5	12.50	0.3050
20 th hr	1	2.50	3	7.50	4	10.00	0.3050
24 th hr	4	10.00	2	5.00	6	15.00	0.3960

Table 13 and Figure 13 shows comparison between the pain scores on coughing from 2sthr to 24hrs shows no statistically significant difference between the two groups.

Figure 13:- Comparison of Group A and Group B with present status of coughing.

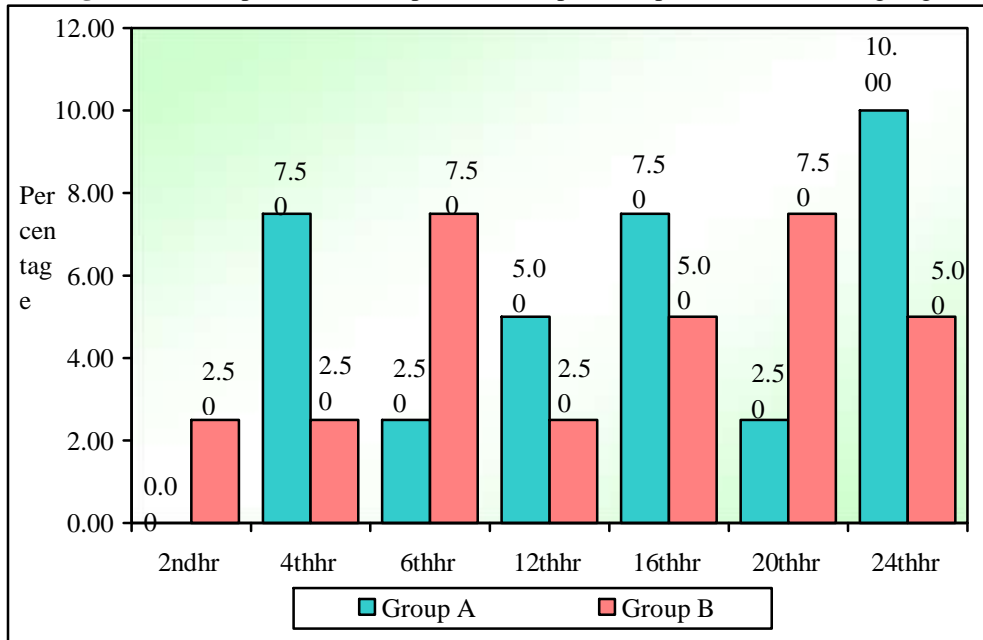


Table 14:- Comparison of Group A and Group B with present status of Nausea.

Time points	Group A	%	Group B	%	Total	%	p-value
30 min	1	2.50	1	2.50	2	5.00	1.0000
2 nd hr	0	0.00	0	0.00	0	0.00	1.0000
4 th hr	1	2.50	1	2.50	2	5.00	1.0000
6 th hr	1	2.50	1	2.50	2	5.00	1.0000

Table 14 and Figure 14 shows comparison between the side effects like nausea from 30 min to 6thhrs shows no statistically significant difference between the two groups.

Figure 14:- Comparison of Group A and Group B with present status of Nausea.

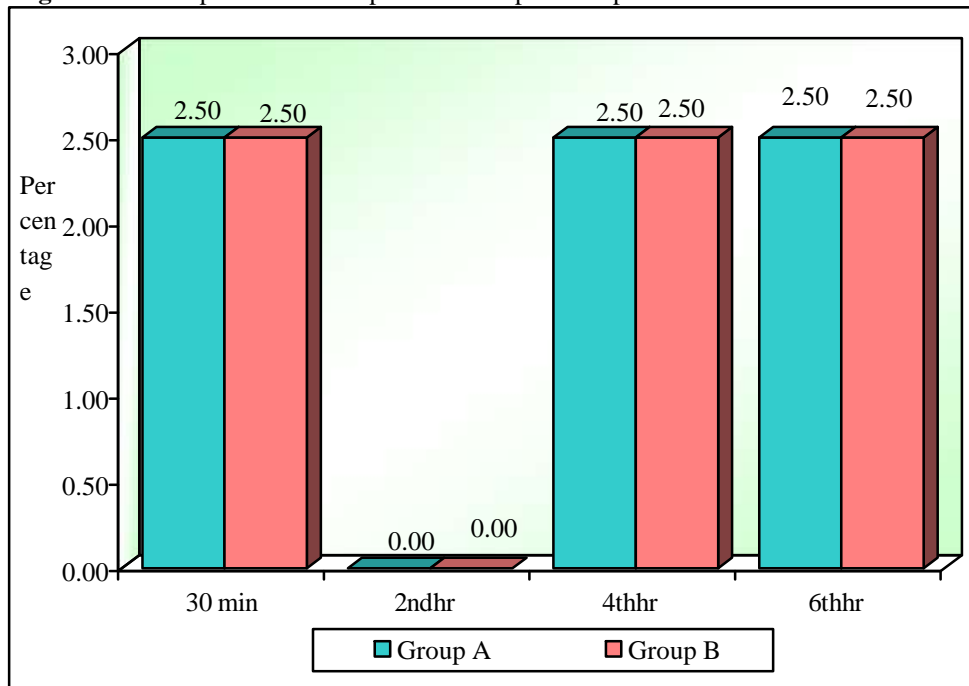


Table 15:- Comparison of Group A and Group B with present status of vomiting.

Time points	Group A	%	Group B	%	Total	%	p-value
30 min	2	5.00	2	5.00	4	10.00	1.0000
2 nd hr	2	5.00	2	5.00	4	10.00	1.0000
4 th hr	1	2.50	2	5.00	3	7.50	0.5560
6 th hr	0	0.00	0	0.00	0	0.00	1.0000

Table 15 and Figure 15 shows comparison between the side effects like vomiting from 30 min to 6thhrs shows no statistically significant difference between the two groups.

Figure 15:- Comparison of Group A and Group B with present status of vomiting.

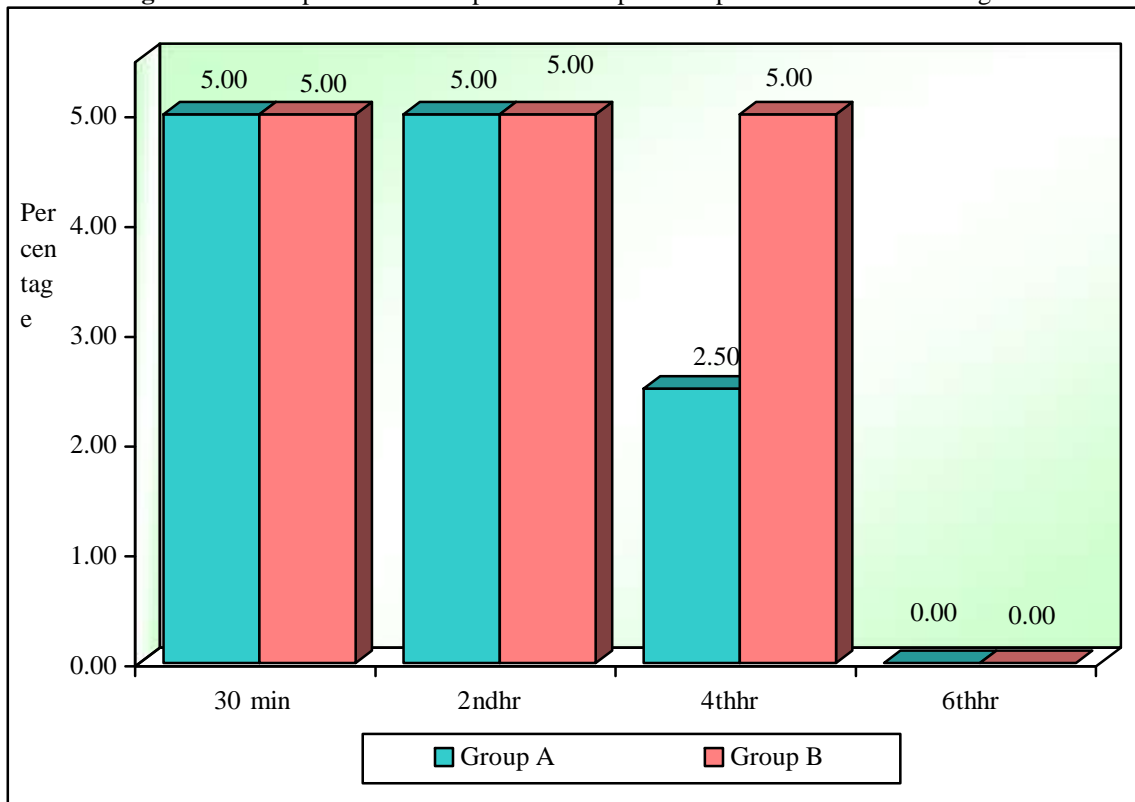


Table 16:- Comparison of Group A and Group B with present status of other side effects .

Time points	Group A	%	Group B	%	Total	%	p-value
30 min	1	2.50	1	2.50	1	2.50	1.0000
2 nd hr	1	2.50	1	2.50	1	2.50	1.0000
4 th hr	1	2.50	1	2.50	1	2.50	0.5560
6 th hr	1	2.50	1	2.50	1	2.50	1.0000

Table 15 and Figure 16 shows comparison between the other side effects from 30 min to 6thhrs shows no statistically significant difference between the two groups.

Figure 16: Comparison of Group A and Group B with present status of other side effects

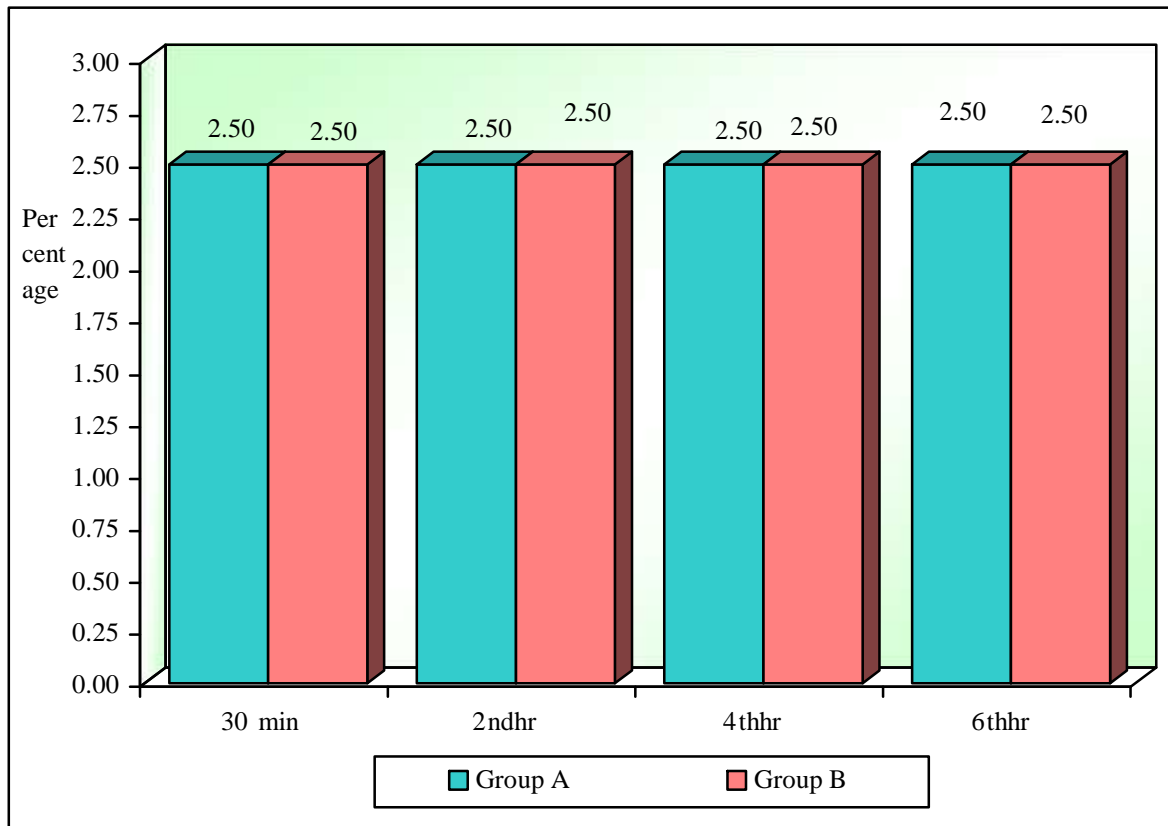


Table 17:- Comparison of Group A and Group B with mean post operative timings of rescue analgesia by independent t test.

Groups	n	Mean	SD	SE	t-value	P-value
Group A	40	6.50	0.93	0.15 0.21 0.17	-7.5365	0.0001*
Group B	40	8.43	1.32			
Total	80	7.46	1.49			

*p<0.05

Table 17 and Figure 17 shows comparison between the mean post operative timings of rescue analgesia which shows statistically significant difference between the two groups with p value <0.05.

Figure 17:- Comparison of Group A and Group B with mean post operative timings of rescue analgesia.

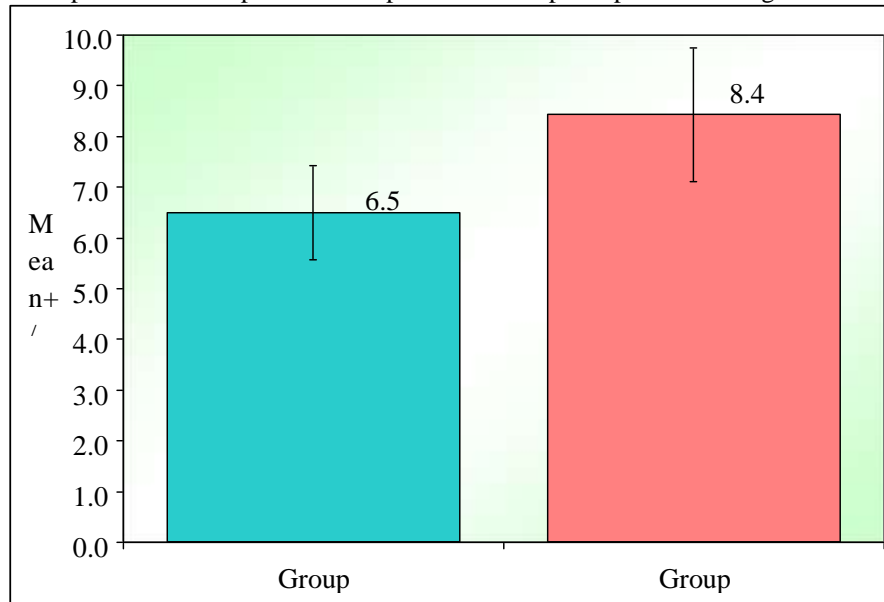


Table 18:- Comparison of Group A and Group B with mean time of analgesia of rescue analgesia by independent t test.

Groups	n	Mean	SD	SE	t-value	P-value
Group A	40	6.30	1.54	0.24	-7.5088	0.0001*
Group B	40	8.95	1.62	0.26		
Total	80	7.63	2.06	0.23		

*p<0.05

Table 18 and Figure 18 shows comparison between the mean time of rescue analgesia which shows statistically significant difference between the two groups with p value <0.05.

Figure 18:- Comparison of Group A and Group B with mean time of analgesia of rescue analgesia.

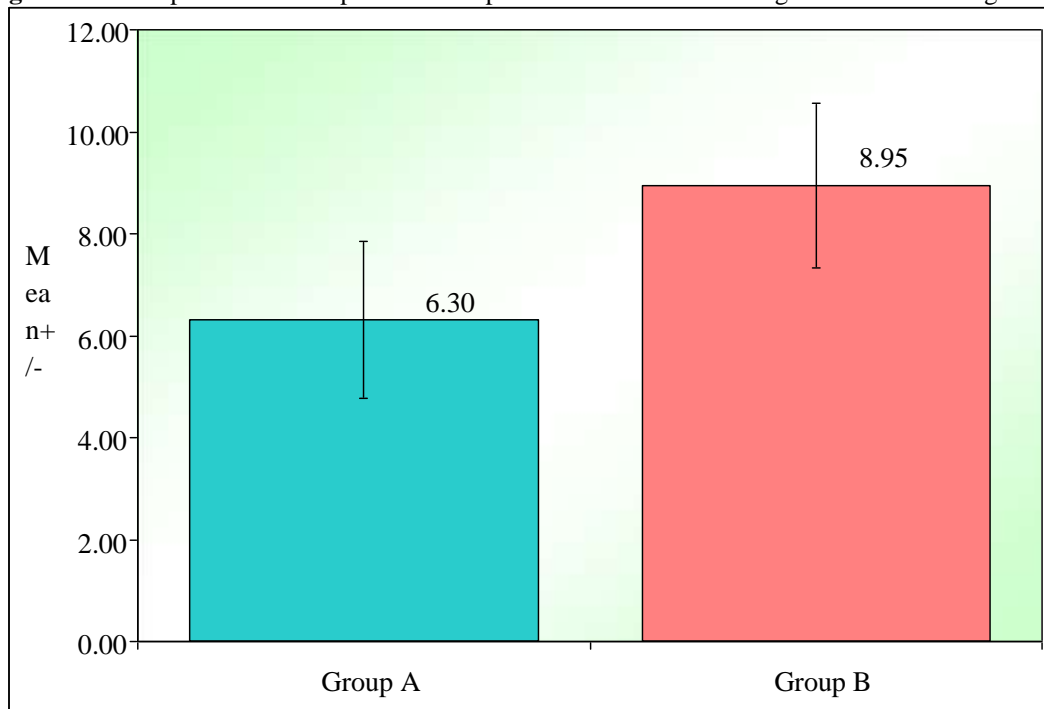
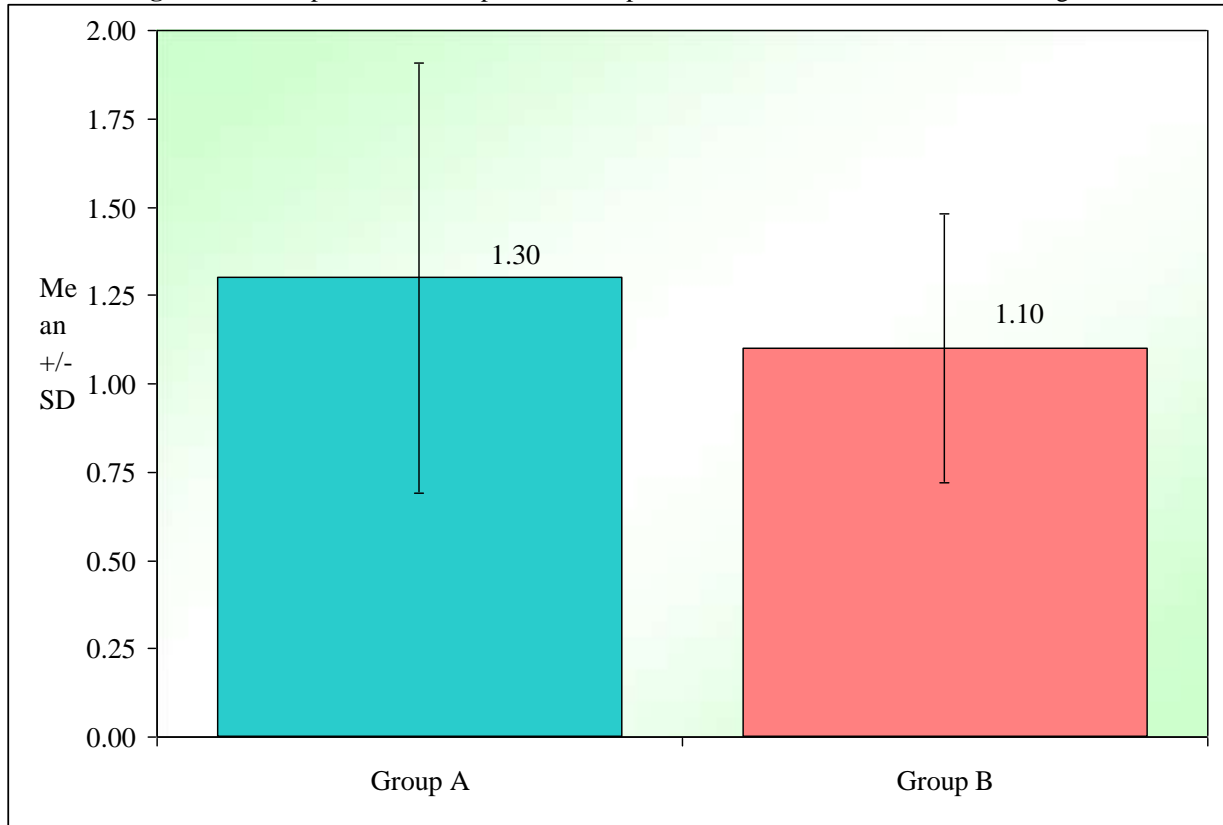


Table 19:- Comparison of Group A and Group B with mean total doses of rescue analgesia by independent t test.

Groups	n	Mean	SD	SE	t-value	P-value
Group A	40	1.30	0.61	0.10	1.7664	0.0812
Group B	40	1.10	0.38	0.06		
Total	80	1.20	0.51	0.06		

Table 19 and Figure 19 shows comparison between the mean total dose of rescue analgesia which shows no statistically significant difference between both the groups .

Figure 19:- Comparison of Group A and Group B with mean total doses of rescue analgesia.**Discussion:-**

This prospective, randomized, double-blinded study carried out at Al Ameen Medical College, Hospital and Research Centre, Vijayapura, from April 2021 to December 2022 80 patients aged 18-70 years of ASA- 1 and 2 who were scheduled to undergo infra umbilical surgeries under spinal anaesthesia and general anaesthesia were the study population. The selected sample size was allocated into groups of 40 each by simple randomization. All the patients were premedicated with injection ondansetron 0.5mg/kg and injection ranitidine 75mg and were preloaded with 15-20ml/kg of ringer lactate. All patients baseline data of vital parameters like, pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, oxygen saturation, temperature, random blood sugar and were noted. All patients were monitored intraoperatively using standard anaesthesia monitors. At the end of the procedure ultrasound guided TAP block was performed. The local anaesthetic under study were injected in the TAP plane and duration of analgesia and hemodynamic parameters, pain scores and time for first rescue analgesia was recorded every 15minutes for initial one hour and then at 2, 4, 8, 10, 12, 14, 16, 24hours.

In our study, 2 groups were comparable with respect to age, sex and ASA status. However, the average or mean age in group A is 32.63, group B is 37.93. The difference between the mean age in two groups was moderately significant statistically (p=0.0424) by independent t test.

The two groups were also compared with respect to gender, ASA scores and type of surgeries. However the percentage of group A was 52.50 of males and 47.50 of females. The percentage of males in group B is 50% which was same as females. The mean showed no significant statistical difference between the two groups.

There was no significant statistically significant difference between the two groups with respect to ASA grading and type of surgery.

In our study, the hemodynamic parameters which includes heart rate, systolic and diastolic blood pressure and oxygen saturation were measured at baseline and at intervals as mentioned above.

The pulse rate was comparable in all two groups. The mean pulse rate in group A was 74.18bpm at 1 minute of time, in group B was 60.63bpm which was statistically significant with $p = 0.0001 (< 0.05)$. but the later values of heart rate at 5min, 10 min, 15 min, and 30 min were not statistically significant.

After TAP Block the mean systolic blood pressure was comparable in both the groups. The mean systolic blood pressure in group A was 116.15, 113.28, 118.13 and 117.73 mmHg at 5 min, 10 min, 15 min and 30 min respectively. group B was 118.25, 115.73, 116.78, 116.48mmHg at 5 min, 10 min, 15 min and 30 min respectively which was statistically insignificant.

The mean diastolic blood pressure was comparable in both the groups. The mean diastolic blood pressure in group A was 76.20, 74.98, 74.30, 76.58, 73.95 mmHg at 1min, 5 min, 10 min, 15 min and 30 min respectively. group B was 118.25, 115.73, 116.78, 116.48mmHg at 5 min, 10 min, 15 min and 30 min respectively.

This is statistically significant except for first 5 min and 10 mins and at 30 min.

The heart rate and diastolic blood pressure in group A was lower up to 30 min than in group B, showing dexamethasone provided superior hemodynamic stability with respect to heart rate and diastolic blood pressure in comparison to dexmedetomidine. Although, the p-values for hemodynamic variables under study have for been found to be statistically significant ($p < 0.001$), the heart rate and blood pressure in both the study groups were comparable with their respective baseline values throughout the study period.

A study conducted by Bhattacharjee. et al. on 90 adult female patient of ASA1 or 2 undergoing TAH by lower abdominal transverse incision under general anaesthesia, showed that TAP block prevents hemodynamic responses to surgical stimuli in perioperative period and provides effective postoperative analgesia⁴⁴.

Both the groups showed no statistically significant change with respect to oxygen saturation.

When the groups were compared on the basis of pain at different intervals of time (group A vs B at 2nd hour, MD 0.0/P value 0.9962; at 4th hours MD -0.0/P 0.1795; 12th hour MD -0.3/P value 0.4592; 24th hour MD -4.0/p value 0.5098; 24th hour MD -2.0/p value 0.5540) and pain on coughing at various intervals, showed no statistically significant. Similar results were noted by Hisham et al¹⁷ with dexamethasone as adjuvant to TAP block, where in the VAS score was significantly lower in the 24 hours post operatively.

But the pain scores at 6th hour and 20th hour showed statistical significance between the two groups with the p value of 0.0327 and 0.0001 respectively. This statistical difference between the two groups may be due to various degree of visceral handling during abdominal surgeries and type of surgeries eg; superficial surgeries like hernia which is extra peritoneal surgery. And the difference in pain thresholds in different individuals.

Minor side effects like nausea which was seen in 3 cases in group B and one in group A. vomiting was seen in 5 cases in group A and 11 cases in Group B.

There was no significant difference between 2 groups in terms of nausea and vomiting score. This may be due to the small sample size of 40 per group in our study. None of the patients required treatment with atropine for bradycardia during the study period. No major adverse effects were noted during the study.

We found a significantly lower VAS in group A at all time intervals until rescue analgesia was administered to the patient. Almarakbi et al in their study with dexmedetomidine found a significantly higher VAS score both at rest as well as on coughing for 8 hours in the post-operative period. we also noted significantly longer time for first rescue analgesia as well as significantly lesser consumption of opioids in the 24 hour period post operatively in group A than in group B (P value 0.001) which are comparable to the results achieved by Almarakbi et al.³⁶ Aksu R et al¹¹⁸ and Almarakbi et al³⁶ have also concluded in their study that use of dexmedetomidine as adjuvants in TAP block significantly reduced the 24 hours post-operative opioid consumption. However, in a study by A. Ramya Parameswari et al¹¹¹ 24 hours of morphine consumption (7.72 ± 7.33 mg in control group I and 6.06 ± 5.20 mg in group 2 receiving dexmedetomidine; $P=0.437$) and time to first morphine requirement (182.35 ± 125.16 minutes in group I and 143.21 ± 87.28 minutes in group II; $P=0.332$) were not different between groups. On comparing the Ramsey sedation score there was a statistically significant higher score noted in group A at 1 hr, 2 hours, 4th hour and 8th hour (P value 0.001, 0.001, 0.007, 0.003 respectively). Akin S et al used dexmedetomidine 0.2 micro gram per kg an hour as adjuvant in epidural infusion for post-operative analgesia following abdominal surgeries and found a significantly higher sedation scores compared to the other group. H D Rashmi et al used dexmedetomidine 0.5 microgram per kg as adjuvant to ropivacaine 0.75% in interscalene blocks and found a significant difference in sedation scores in the drug group as compared to control group.¹¹⁴ Almarakbi et al found no significant difference in sedation scores when dexmedetomidine was used as adjuvant in TAP block.³⁶ This may be explained by the dose (0.5 microgram/kg) of dexmedetomidine that was used which was lesser than in our case. M J Lee et al also found no significant difference in sedation scores when dexmedetomidine was used as adjuvant in brachial block by axillary approach.¹¹⁰ However, patients in this study underwent upper limb surgeries with only brachial block and not supplemented with general anaesthesia as in our study.

Hence, with significantly lesser heart rate, longer time to first analgesia, lesser post-operative opioid consumption and significantly lower VAS scores and better sedation score in the post-operative period use of dexmedetomidine as an adjuvant is more efficacious compared to plain dexamethasone.

When comparing group, A to group B, a statistically significant lower heart rate was seen in group B until 30 min. Exceptions to this were values at 1 mins, which could be probably due to intraoperative events with manipulation at sites other than the areas covered by block. In a study by MJ Lee et al when dexamethasone and dexmedetomidine were used as adjuvants there was bradycardia in just one patient. There is a dearth of studies comparing the two drugs in terms of heart rate and hemodynamic variation when used as adjuvants for TAP block in literature. when group A and group B were compared in our study, group B had a significantly longer time for first rescue analgesia. Variable results are noted with other researchers in this aspect. M J Lee et al found no difference in the onset of action (15.2 mins in dexamethasone vs 13.8 mins in dexmedetomidine) and duration of blockade (715.1 ± 286.3 mins in dexamethasone vs 781.1 ± 257.5 in dexmedetomidine group) when the two drugs were compared as adjuvants in brachial block. Yasser et al concluded in their study that dexmedetomidine prolonged the duration of analgesia more than dexamethasone.¹¹⁷ Finally, there is a statistically significant lesser consumption of opioid in group A compared to group B with P value 0.001. Hence the 24 hours opioid equivalent dose is also significantly lesser in group A compared to group B. There is lack of literature comparing the two drugs as adjuvants to nerve blocks in terms of total 24-hour analgesic consumption.

Group A also had significantly lesser consumption of opioid in the 24 hours post operatively compared to group B.

But the total opioid consumption between the two groups showed no statistical significance.

From the above observations we can conclude that dexamethasone when used as an adjuvant prolonged the time to rescue analgesia more than dexmedetomidine.

Summary

The study was a prospective randomized, double blind control study conducted on 80 patients undergoing elective infra umbilical surgeries under general anesthesia in Al Ameen Medical College

Hospital from November 2020 to November 2022 at the Department of Anaesthesia, Vijayapura, aged between 18 to 70 years and belonging to ASA class-I and class-II was randomly divided into 2 groups (n=40): Group A: Patients who received transversus abdominis plane block with - 20ml of 0.2% ropivacaine with 50mcg (0.5ml) / 0.5mcg/kg of Dexmedetomidine.

Group B Patients who received transversus abdominis plane block with - 20ml of 0.2% ropivacaine with 8mg (2ml) of dexamethasone.

The mean age across the two groups was 35.28years. Males constituted 51.25% and females of 48.75% % of the study. The groups in our study were comparable in terms of age, gender, ASA status, heart rate, systolic and diastolic blood pressure, oxygen saturation, pain scores at rest and on coughing,time for first rescue analgesia and total analgesic consumption.

In our study we found that

There was a significant variation in the mean age between the two groups. Group A had significantly lower mean age of 32.63 than group B with mean age of 37.93.

There was a significant variation in heart rate between the groups at 1 min intervals. Group B had significantly lower heart rate compared to group A .

There was a significant variation in the diastolic blood pressure between the groups at 5min, 10min , and 30 min of intervals. Group A had significantly lower diastolic blood pressure than group B with p value <0.05

The visual analogue score at rest was statistically significant between the groups. The mean time for first dose of rescue analgesia in both the groups was found to be at 6th and 20th hour which was statistically significant with p value of <0.05.

However it is observed that patients who underwent intra abdominal surgeries or visceral surgeries required rescue analgesia at 6th hour onwards compared in the patients undergoing superficial surgerieslike inguinal hernia who required rescue analgesiafrom16th hour to20th hour in both the groups.

There was a significant variation in mean post operative timings of rescue analgesia between the groups. Group A had significantly lower mean value of 6.50 compared to group B with mean value of 8.43 and with p value <0.05.

The total rescue analgesic consumption in the 24 hours post operatively was not statistically significant in both the groups.

We had only minor side effects like nausea which was seen in 3 cases in group B and none in group A. 5 cases of vomiting in group A and 11 cases in Group B.

Conclusion:-

The TAP block is an effective for multimodal postoperative analgesia in abdominal surgery. This study demonstrated that addition of dexmedetomidine or dexamethasone as an adjunct to ropivacaine for TAP block was more efficacious and addition of dexamethasone gave better post operative analgesia than dexmedetomidine with ropivacaine for postoperative pain control.

In our study we conclude by stating that,

1. There was no significant difference amongst the two groups in terms of age with P value 0.0530.
2. There was significant difference amongst the two groups in terms of mean age with P value 0.0424 (p<0.05) and mean age was found to be 35.28 years
3. There was no significant statistical difference amongst the two groups in terms of ASA scoring with P value 0.2560.
4. There was no significant statistical difference amongst the two groups in terms of type of surgery in with P value 0.5220.
5. Comparison between heart rates for the initial 1min shows statistically significant difference between the two groups (p=0.0001). However, heart rates values from 5 min to 30 mins showed no statistically significant difference between the two groups. Graph 6 shows that the heart rate is significantly lower in group B compared to group A. The mean heart rate for group B was least with 60.63 beats per minute in comparison to group A with 74.18 beats per minute.
6. Comparison between the systolic blood pressure from 5 min to 30 minutes shows no statistically significant difference between the two groups.

7. Comparison between the diastolic blood pressure at 5 min, 10 min and 30 min shows statistically significant difference between the two groups ($p < 0.05$). However, heart rates values from 1 min and 50 mins showed no statistically significant difference between the two groups. Graph 6 shows that the diastolic blood pressure is significantly lower in group A compared to group B. The mean heart rate for group A was least with 74.98 mmHg at 5 min and 74.30 at 10 min and 73.95 at 30 min in comparison to group B.
8. Comparison between the oxygen saturation from 1 min to 30 minutes shows no statistically significant difference between the two groups.
9. comparison between the pain scores at time of observation from 1sthr to 24hrs. At 6thhr and 20thhr at observation time shows statistically significant difference between the two groups
10. comparison between the pain scores at rest from 2nd hr to 24hrs. At 20thhr at rest shows statistically significant difference between the two groups.
11. comparison between the pain scores on coughing from 2sthr to 24hrs shows no statistically significant difference between the two groups.
12. Both the groups had minimal side effects.
13. comparison between the mean post operative timings of rescue analgesia which shows statistically significant difference between the two groups with p value < 0.05 .
14. comparison between the mean time of rescue analgesia which shows statistically significant difference between the two groups with p value < 0.05 .
15. comparison between the mean total dose of rescue analgesia which shows no statistically significant difference between both the groups.
16. The duration of analgesia is prolonged in dexmedetomidine group than in dexamethasone group.
17. The degree of sedation is higher with dexmedetomidine.
18. The adverse effects were minimal in dexmedetomidine group than in dexamethasone group.

Limitations of the study:

1. The pain thresholds and the pain expressions vary in different individuals and gender.
2. Pain scores between the two groups may be due to various degree of visceral handling during

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