A PROSPECTIVE RANDOMISED STUDY COMPARING POSTOPERATIVE OUTCOME AFTER REGIONAL OR GENERAL ANESTHESIA FOR INCISIONAL HERNIA SURGERY IN OBESE PATIENTS.

A PROSPECTIVE RANDOMISED STUDY COMPARING POSTOPERATIVE OUTCOME AFTER REGIONAL OR GENERAL ANESTHESIA FOR INCISIONAL HERNIA SURGERY IN OBESE PATIENTS.

A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQIREMENT OF THE **DR. M.G .R MEDICAL UNIVERSITY TAMILNADU, CHENNAI** FOR THE DEGREE OF **M.D.(Anesthesiology – Branch-X)** TO BE HELD IN MARCH 2009.

CERTIFICATE

This is to certify that the dissertation entitled "**A PROSPECTIVE RANDOMISED STUDY COMPARING POSTOPERATIVE OUTCOME AFTER REGIONAL OR GENERAL ANESTHESIA FOR INCISIONAL HERNIA SURGERY IN OBESE PATIENTS "** is the bonafide work by **Dr. Dibyendu Khan**, in the partial fulfillment of the requirement for the M.D. Degree (Anesthesiology –Branch-X) of the Tamil Nadu Dr. M.G.R Medical University, Chennai, to be held in March 2009.

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The project titled " A PROSPECTIVE RANDOMISED STUDY COMPARING POSTOPERATIVE OUTCOME AFTER REGIONAL OR GENERAL ANAESTHESIA FOR INCISIONAL HERNIA SURGERY IN OBESE PATIENTS" has been reviewed by the Institutional Review Board of the Christian Medical College which considered its objective, study design, human research participants protection and budget. This study has been approved for conduct at the Christian Medical College, Vellore under the direction of Dr. Dibyendu Khan.

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TABLE OF CONTENTS

AIM

To test the efficacy and evaluate the impact of epidural anesthesia and postoperative epidural analgesia on postoperative outcomes in obese patients undergoing incisional hernia surgery.

INTRODUCTION

Incisional hernia is the most frequent postoperative complication following abdominal surgery. The cumulative incidence has remained constant despite several attempts to improve laparotomy closure. Surgical closure technique, individual, biological and patient dependent risk factors play a key role. Recent advances in anesthesia techniques, adequate prevention and treatment of infection during surgery, and the use of new suture materials though have reduced the incidence of incisional hernia. Nevertheless, incisional hernia still occurs in 0.5% to 11% of all laparotomies performed. It has been estimated that about half of incisional hernias will develop within 3 months of the initial abdominal procedure. Surgical repair may be established by open or laparoscopic approaches. Some of the well-known factors affecting recurrence rates are obesity, large incision size, preoperative presence of mesh and postoperative wound infection.Incisional hernia surgery is considered as a major abdominal procedure and can be performed under general anesthesia , regional anesthesia or both combined together.Any surgery is associated with stress responses and this contribute to various organ dysfunctions . Pain relief may be a powerful technique to modify surgical stress response . It has been assumed that sufficient pain relief will improve the surgical outcome and there is a common consensus that optimal pain relief is a prerequisite for early postoperative recovery.[12]The effect of epidural anesthesia and analgesia on high risk patients coming for major abdominal surgery has been studied in mid 1980_s by Yeager and colleagues on 53 patients, which has shown significant improvement in postoperative outcome.[1,8] Multimodal analgesia programs have shown to decrease hospital stay and improve postoperative recovery. The most commonly used pain-relieving techniques for major abdominal surgeries are patient controlled analgesia with opioids ,non-steroidal anti-inflammatory drugs and epidural analgesic techniques. Evidence suggests that epidural local anesthetic or local anesthetic-opioid techniques are the most effective in providing dynamic pain relief, after major surgical procedures. The duration of epidural local anesthetic analgesia is important , atleast 24 hours

and preferably 48 hours. The MASTER (Multicentre Australian Study of Epidural Anesthesia) RCT investigated the influence of perioperative epidural analgesia on outcome in 888 patients undergoing major abdominal surgery in between 1995 and 2001 from 25 hospitals in six countries.[1] These patients were considered high risk because of the presence of one or more important co-morbidities. In comparison with a control group who received intravenous(IV) opioid analgesia, they found no difference in mortality or in the incidence of major morbidity with the exception of the incidence of respiratory failure. However, postoperative analgesia was found to be clinically superior on the basis of pain visual analog scores (VAS) in patients randomized to the epidural group. In the epidural group, mean pain VAS with coughing was 30% less than in the control group in the first 24 hours after surgery and 20% less for the remaining 48 hours.

A systemic overview was conducted by Rodgers and colleagues in year 2000 of 141 available randomized controlled trials, including 9559 patients till January 1997. It showed that the use of epidural and spinal block resulted in a statistically and clinically significant reduction in morbidity and mortality after surgery.[3]

REVIEW OF LITERATURE

Incisional hernia

An incisional hernia arising after open or laparoscopic operation is defined as a bulge visible and palpable when the patient is standing, elicited by physical activity such as exercise or coughing, and disappearing after stopping the activity. 10–15% of laparotomy incisions are estimated to eventually develop hernias. 60% of patients with incisional hernias do not have any symptoms. Physical examination of the patient supine and relaxed usually reveals the hernia. As part of palpation, the hernia protrusion is examined with regards to it's consistency, reducibility, size and its anatomical relationship to the anterior abdominal wall. Occasionally, palpation may reveal multiple incisional hernias within a scar with fascial bridges in between (latticed hernia). Ultrasound examination is a useful diagnostic test and will often discover other impalpable defects, especially in patients who are obese. A CT scan is more efficient and accurate in defining the defect and the contents of an irreducible sac. It also enables the visualization of internal hernial sac structures and the entire abdominal wall as well as it's relationship to intra-abdominal organs. The European Hernia Society, classifies incisional hernia based on site, size, recurrence, reducibility, and symptoms.[39]

Treatment options

As for all elective surgery, the abdominal wall should be free of signs of inflammation or infection. Ideally at least six months should have elapsed between the initial intervention that led to incisional hernia or relapse and the planned repair, in order to allow the recovery of the abdominal wall.

The surgeon can choose from a number of treatment options, which fall into two principal categories:

- conventional suture technique
- open or laparoscopic mesh technique.

Suture technique

Traditional defect repair using continuous or interrupted suture technique is almost abandoned. Relapse rates of more than 50% are quoted for the suture technique, depending on length of follow-up. Results for Mayo fascia duplication are little better. Conventional suture techniques should now be reserved for selected indications such as the presence of significant co morbidity, repairs involving bowel, and small trocar.

Mesh technique

Mesh material was first used for incisional hernia repair more than 50 years ago. In the first years following its introduction it was used primarily for defect bridging. The possibility of using mesh for abdominal wall reinforcement was first described in the 1970s by French surgeons, Chevrel, Rives, and Stoppa. Depending on the positioning of the mesh prosthesis, epifascial mesh reinforcement is known as the onlay technique and retro muscular mesh reinforcement as the sublay technique .An advantage of abdominal wall reinforcement is that it permits the reconstruction of the abdominal wall as an anatomical functional unit. The onlay technique reinforces the fascial suture by placing a mesh over the fascia. This requires extensive epifascial preparation to ensure sufficient blanketing of the fascial suture. The onlay technique is problematic in incisional hernias where the fascial defect extends to bony structures such as the xiphoid process or the symphysis pubis. Relapse rates of between 6 and 17% have been reported in the literature for this technique.

In sublay technique the mesh is positioned in the retro muscular space posterior to the rectus abdominis muscle. This technique has relapse rates of between 2 and 12% and is presently the "gold standard" for incisional hernia surgery.

In laparoscopic incisional hernia repair (Lap-IPOM) the mesh prosthesis is placed after adequate

preparation from the inside onto the fascial defect. The mesh is used for bridging the defect. Since the majority of the tension rests on the fixation points of the mesh, local pain is frequently reported especially in the early postoperative phase.[39]

Anesthesia Techniques for Incisional Hernia Surgery

Incisional hernia mesh repair can be performed under general anesthesia combined with epidural analgesia or parentral opioids for postoperative analgesia. Combined spinal epidural (CSE) by combining subarachnoid blockade and epidural analgesia can be considered as a pure regional anesthetic technique.

Anesthetic considerations in Obesity

Obesity is an excessive accumulation of body fat to the extent that health may be impaired. Clinically defined as a Body Mass Index (BMI: weight in kilograms divided by the square of height in metres) = 30 kg/m^2. Asians generally have a higher percentage of body fat than Caucasians of the same age, sex and BMI. Excessive abdominal or visceral fat is defined as the waist circumference more than 102 cm in men or more than 88 cm in women, is associated with a high risk of morbidity and mortality. Recently World Health Organization (2000) proposed reclassification of overweight for adult Asians BMI more than 23kg/m^2 and for obesity more than 25kg/m^2.[16]

The physiologic and pathophysiologic consequences of obesity in different systems affect anesthesia during major abdominal surgery.

Cardiovascular System:

Cardiac output rises about 0.1 liter/min for each 1 kg addition in weight. Stroke volume is elevated since total blood volume increases to perfuse the added body fat. Increased cardiac output combined with normal peripheral vascular resistance leads to systemic hypertension. A 3 - 4 mm Hg increase in

systolic pressure and a 2 mm Hg increase in diastolic arterial pressure can be expected for every 10 kg of weight gained. This increase in blood volume and cardiac output eventually produce dilational cardiac hypertrophy. Left ventricular dysfunction is often present. Even normotensive patients have increased pre-load, after-load, mean pulmonary artery pressure (PAP) and an elevation in right and left ventricular stroke work. Obese patients are often not physically active and may appear asymptomatic even with significant cardiovascular disease. Right heart failure is common in older patients.[30]

Pulmonary System:

Adipose tissue is metabolically active in obese patients. Oxygen (O_2) consumption and Carbon dioxide (CO_2) production rise with increasing weight. The work of breathing is increased since more energy must be expended to carry the additional body mass, while respiratory muscle performance is impaired. The fatty chest and abdominal walls reduce chest wall compliance. Mass loading of the thoracic and abdominal chest walls causes abnormalities in lung volumes and gas exchange. Morbid obesity(MO) is associated with reductions in expiratory reserve volume, forced vital capacity, forced expiratory volume, functional residual capacity, and maximum voluntary ventilation .Reductions in functional residual capacity fall below closing capacity during normal ventilation, which leads to significant intrapulmonary shunting of blood flow past underventilated or collapsed alveoli. There are further reductions in functional residual capacity in the supine position and following anesthetic induction and neuromuscular blockade. Continued perfusion of non-ventilated alveoli results in a partial pressure of arterial oxygen (PaO_2), lower than predicted for similar aged non-obese patients. All these changes are directly proportional to increasing BMI. Younger obese patients have increased ventilatory response to hypoxia. An arterial blood sample usually shows alveolar hyperventilation partial pressure of arterial carbon dioxide ($PaCO_2$ 30–35 mm Hg) and relative hypoxemia (PaO_2 70-90 mm Hg) on room air. With increasing age sensitivity to CO_2 decreases, $PaCO_2$ rises and PaO_2 falls. Many patients maintain normal PaCO2 during the day but have CO_2 retention, sleep disturbances, intermittent airway obstruction with

hypoxemia, pulmonary hypertension and cardiac arrhythmia's at night. Obstructive sleep apnea (OSA) syndrome is characterized by frequent episodes of apnea (more than 10 sec cessation of airflow despite continuous respiratory effort against a closed airway) and hypopnea (50% reduction in airflow or reduction associated with a decrease of saturation more than 4%). Patients may not be aware of these symptoms. A definitive diagnosis can only be confirmed by polysomnography in a sleep laboratory. Because of fragmented sleep patterns, patients may complain of daytime sleepiness and headaches. Chronic OSA leads to secondary polycythemia, hypoxemia, hypercapnia; and increase the risk of cardiac and cerebral vascular disease. OSA patients can be difficult to mask ventilate, and their tracheas can be difficult to intubate. OSA patients requiring nasal continuous positive airway pressure (N-CPAP) at home should use it in the PACU. Under general anesthesia after induction there is further deterioration of altered functional residual capacity - closing capacity relationship increasing the right to left shunt. Obese patients undergoing upper abdominal surgery under general anesthesia have a higher chance of postoperative pulmonary complications like hypoxia, atelectasis, impaired cough reflex.[28]

Preoxygenation is important because arterial oxygen saturation rapidly declines during anesthetic induction in obese patients. Two common preinduction techniques to denitrogenate the lungs include at least 3 to 5 minutes of mask ventilation of 100% oxygen or five vital capacity breaths of 100% oxygen. A tight-fitting mask is needed so as to not entrain room air and dilute the inspired oxygen. A recent study indicated that preoxygenation could be more effective if Morbid obese patients simply were tilted head-up. Administration of 100% oxygen by facemask in the 25 degree head-up position achieved a 23% higher oxygen tension, allowing nearly a minute of extra time after induction before clinically significant desaturation occurred.[31]

Gelman and colleagues in 1980 in Birmingham, Alabama showed epidural analgesia was associated with differences in arteriovenous oxygen content (17%), and oxygen consumption (20%), compared with values observed when 38 morbidly obese patients undergoing gastric bypass recieved morphine

intravenously postoperatively. .

In 1975 Fox *et al*. found in 110 obese patients receiving epidural analgesia for weight-reducing surgery in Canada had higher PaO_2 than patients receiving general anesthesia, though the difference was not significant.

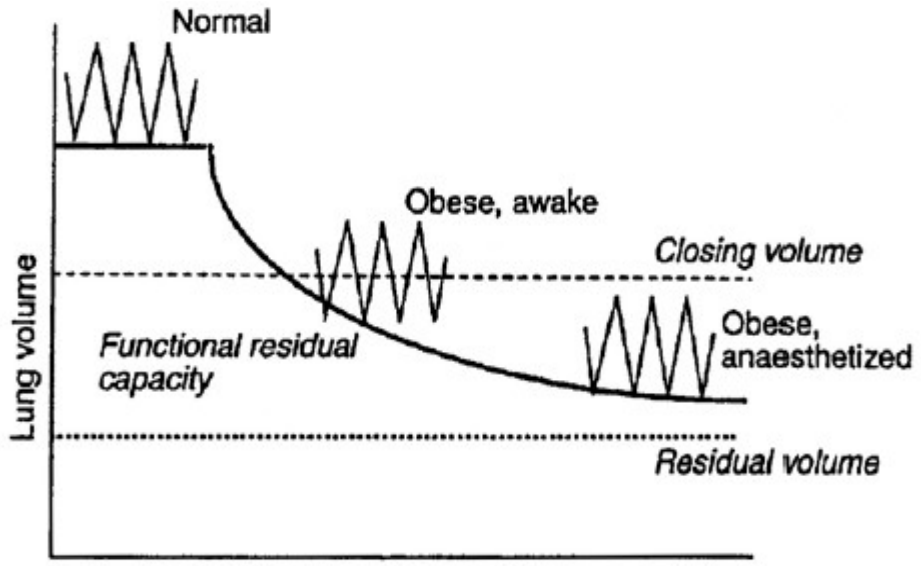


Figure. 1.

Schematic representation of the effects of severe obesity on functional residual capacity.
Under normal circumstances, the functional residual capacity (and therefore the tidal excursion) is clear of the closing volume of the lungs.
Both anesthesia and obesity are associated with a reduction in functional residual capacity, resulting in airway closure and ventilation/perfusion mismatching during normal tidal ventilation.

Gastrointestinal Systems:

It was once believed that these patients were at greater risk for acid aspiration because of increased in-

tra-abdominal pressure, high incidence of GERD (gastroesophageal reflux disease), hiatus hernia, and increased gastric volume with low gastric fluid pH. Recent work has challenged this belief. There were no differences in gastric volume or pH between lean and moderately obese surgical patients. Obese patients without symptoms of GERD have relatively normal gastro-esophageal sphincter tone and may have faster gastric emptying time. Patients at particular risk for gastric aspiration may be those with diabetes and gastroparesis. Non-alcoholic steatohepatitis (NASH), with or without liver dysfunction, is seen in 90% of patients. General anesthesia may predispose patients to aspiration of gastroesophageal contents based on depression or loss of protective reflexes during induction and emergence from anesthesia. Many consider morbid obese patients to be at increased risk for aspiration as a result of gastroesophageal reflux. The risk of developing the acid aspiration syndrome is increased with low pH of gastric contents or increased gastric volume.[30]

Airway Managemennt

Mask ventilation can be difficult when cricoid pressure is applied to Morbid obese patients.[18]A BMI more than 26kg/m^2 results in a three-fold increase in the incidence of difficult ventilation via mask and a 3 to 10-fold increase in the incidence of difficult tracheal intubation.[32,33,34,35] Oxygen desaturation during apnea in morbidly obese patients is 65% more rapid when compared to non-obese patients. [36]The finding of a Mallampatti class III or IV airway on visual exam, a thyromental distance less than 6 cm, a mouth opening less than 4 cm, and a positive past history of difficult intubation were the most significant predictors of laryngoscopy grade III and IV.[37] The presence of the classic “buffalohump” at the back of the neck and upper shoulders would portend difficult positioning into the optimal sniffing position. Positioning with the head, neck and shoulders elevated in the head elevated laryngoscopy position (HELP) “stacked” or “ramped” facilitates direct laryngoscopy.[40] The results of the assessment

may lead the anesthetist to choose alternate intubation techniques such as awake fiberoptic, intubating LMA and supraglottic airway devices. In Morbid obese patient with anticipated difficult airway, Mallampati 3 or 4 and neck circumference greater than 40 cm, an awake, fiberoptic intubation is the technique of choice. However, recent studies have described the highly successful use of intubating laryngeal mask airway. In Morbid obese patients, successful tracheal intubation was achieved 96% of the time with this device at first attempt.[37]

Premedication may affect the activity of the respiratory muscles. Benzodiazepines have a spinally mediated muscle relaxant effect that can affect the respiratory muscles, so premedication could affect respiration. Obese patients might be more affected by these agents because they have a greater work of breathing.[38]

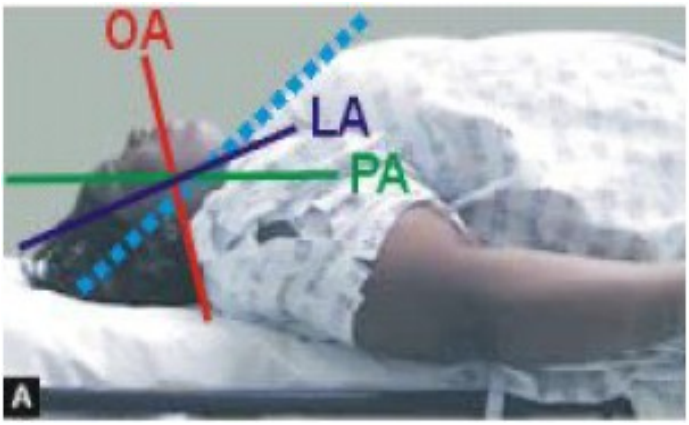


Figure.2. **Obese patient positioning for laryngoscopy**

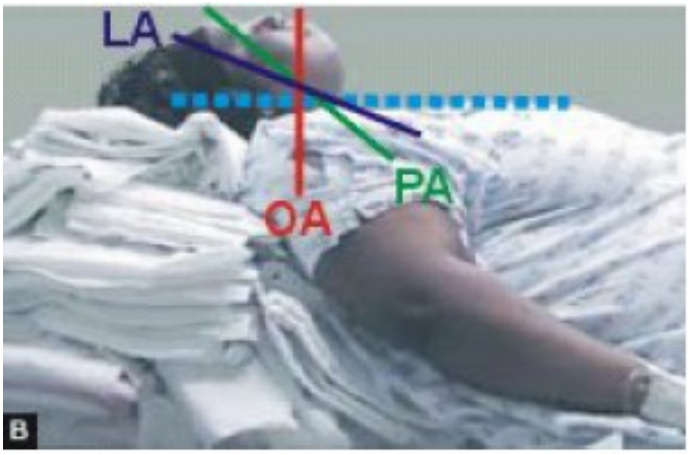


Figure .3. HELP (Head elevated laryngoscopy position ("stacked"or "ramped")

Post operative considerations in obese individuals

Position and Oxygenation: The semi-recumbent position and reverse trendelenburg maximize

oxygenation by increasing FRC. The Morbid obese hemodynamically stable patient should have their airway extubated with their upper body elevated 30^0-45^0,and be transferred in that same position. Postoperative mechanical ventilation is rarely needed, especially following laparoscopy. However, general anesthesia in these patients results in a significant postoperative atelectasis. Patients can become hypoxemic if O_2 is with held. Restoration of normal pulmonary function after abdominal surgery may take days. For patients with OSA(obstructive sleep apnea)N-CPAP (non invasive CPAP) should be considered in the PACU. Patients who fail to respond to N-CPAP may do better with bi-level positive airway pressure (BiPAP). BiPAP combines pressure support ventilation and PEEP via nasal mask allowing alveolar recruitment during inspiration and prevents alveolar collapse during expiration.

Hemodynamic Problems: In obese individuals a significant decrease in left ventricular function may occur in the immediate postoperative period. Patients receiving regional anesthetic technique are closely monitored and IV fluid boluses along with vasopressors are given when indicated.

Anti-thrombosis: Thromboembolism is a major cause of mortality. Immobilization can lead to deep vein thrombosis. Risk of thrombosis is increased due to greater blood volume and relative polycythemia.

Anticoagulation or other prophylaxis measures, such as an inferior vena cava filter, are used when indicated.

Analgesia: Opioid epidural analgesia, alone or combined with local anesthetics, is preferred after major abdominal surgery and laparoscopy. Since local anesthetic is usually infiltrated into the port sites during laparoscopy, incision pain in the PACU is minimal. Opioid patient-controlled analgesia dosed on IBW (Ideal body weight) is satisfactory for laparoscopic procedures. The insufflated CO2 used for the surgical pneumoperitoneum causes pain, which is not alleviated by analgesics. Despite attempts at warming and humidifying CO2, abdominal discomfort is common following laparoscopy. Large doses of any opioid should always be avoided following surgery. Non-opioid analgesics should be instituted early. NSAIDs are helpful, but should be discontinued after several days to avoid potential gastric

ulceration.

Cinical effects of Epidural Anesthesia and Analgesia

Cardiovascular system:

Administration of epidural local anesthetics or opioids during intraoperative and postoperative period provides better analgesia , suppresses the stress response to surgery and reduces incidence of myocardial ischemia and dysrhythmias when compared with systemic opioids. Regional anesthesia-analgesia may provide many cardiovascular benefits by diminishing the stress response, attenuating postoperative hypercoagulability, and providing a favorable redistribution of coronary blood flow. Tuman *et al* in 1991 conducted a prospective randomized study in 80 patients with atherosclerotic vascular disease ,to examine the interaction of epidural anesthesia, coagulation status, and outcome after lower extremity revascularization. He suggested that postoperative epidural analgesia may be associated with a reduction in cardiac morbidity, similarly to the findings of Yeager in 1987.There are no definitive conclusions concerning the effect of regional anesthesia-analgesia on outcomes, although the effects of epidural analgesia on cardiac morbidity are controversial.[8]

Pulmonary function :

There is significant decrease in respiratory function after upper abdominal and thoracic surgery under general anesthesia. As a result of inadequate analgesia there is an increase in upper abdominal,

intercostal muscle tone and spinal reflex inhibition of diaphragmatic function.

Jayr and colleagues in 1993, included 153 patients undergoing major abdominal surgery in France. The impact of epidural bupivacaine and opioids was compared with parenteral opioids on pulmonary complications which were evaluated according to clinical complications, chest radiographs, arterial blood gas analysis, and pulmonary function tests. While Yeager and colleagues in 1980 observed benefit from epidural analgesia, mostly for high-risk patients like obese patients undergoing major abdominal surgery. However Jayr study showed adequate patient comfort from pain, but epidural analgesia did not decrease the incidence of postoperative pulmonary complications.

Von Ungern-Sternberg et al. in Switzerland prospectively included 84 adult female patients scheduled for midline laparotomy for extensive abdominal gynaecological procedures from year 2000. Perioperative spirometry, as measures of pulmonary function (forced expiratory volume in 1 second, forced vital capacity, peak expiratory flow rate) was compared between the groups of patients who received epidural analgesia and parenteral opioids. He concluded that epidural analgesia should be considered in obese patients undergoing midline laparotomy to improve postoperative spirometry.[46]

Gastrointestinal system:

Transient postoperative ileus is common after abdominal surgery under general anesthesia and may be caused by several factors, including an increase sympathetic efferent outflow from pain or stress response, postoperative use of opioids for analgesia, and spinal reflex inhibition of gastrointestinal motility. Use of regional anesthesia-analgesia facilitates recovery of postoperative gastrointestinal functions and is associated with an earlier fulfillment of discharge criteria. Randomized trials in 1993 by Jayr *et al* in France on 153 patients , have demonstrated that the use of epidural opioids with a local anesthetic-based regimen is associated with significantly early return of gastrointestinal function after major abdominal surgery , compared to patients who received parenteral opioids.

Similar outcome was demonstrated by Carli *et al* on 64 adult patients undergoing elective colorectal

surgery between 1998 and 2000 from two hospitals within McGill university health centre,Montreal,Canada.

Coagulation system :

A hypercoagulable state occurs after surgery under general anesthesia and may be attenuated with use of regional anesthesia. Although the etiology of this hypercoagulable state is uncertain, possible mechanisms include potentiation by the stress response, endothelial damage with tissue factor activation, and synergism with inflammation. Postoperative hypercoagulability may lead to vaso-occlusive and thromboembolic events, such as deep venous thrombosis, pulmonary embolism, and vascular graft failure, and may contribute to more postoperative morbidity.

Tuman *et al* in 1991 conducted a prospective randomized study in 80 patients with atherosclerotic vascular disease ,to examine the effects of epidural anesthesia and analgesia on coagulation status, and outcome after lower extremity revascularization. Similarly Modig *et al* in 1983 demonstrated role of extradural and of general anesthesia in fibrinolysis and coagulation after total hip replacement in 30 patients .

Compared with general anesthesia, use of regional anesthesia is associated with a significant decrease in hypercoagulable-related events, especially after orthopaedic and vascular surgery..Continuation of postoperative regional analgesia with local anesthetics may also contribute to a decreased incidence of deep vein thrombosis.

Mobilization and hospital stay:

The effects of epidural analgesia on postoperative mobilization have been investigated only sporadically ,usually with a negative result. It appeared that the improved pain relief given by epidural analgesic techniques has no significant effect on hospital stay. These findings differ from the demonstrated positive effects in some procedures on paralytic ileus, pulmonary, cardiac and

thromboembolic outcomes after the use of epidural analgesia. It was emphasized that hospital stay may be a poor outcome measure as it depends on many factors other than pain relief (eg. use of drains, catheters, traditions, restrictions and reimbursement policy).

Recently Carli *et al* demonstrated positive impact of epidural analgesia on out-of-bed mobilization ,on 64 adult patients undergoing elective colorectal surgery between 1998 and 2000 from two hospitals within McGill university health centre,Montreal,Canada.

Central Neuraxial Blockade

History:

The first neuraxial block was performed in Heidelberg, eight months after the demonstration of local anesthetic properties of cocaine by Koller. James Leonard Corning a neurologist injected cocaine in dogs and in patients to relieve chronic pain. Quincke observed that dural sac ,described by Domenico Cotugno in 1787 could be punctured by inserting needle between the lumbar spinous processes. On august 15,1898,August Bier used Quincke's method of entering the intrathecal space and injected cocaine to produce operative anesthesia in six patients, the first real spinal anesthesia.[13]In the same year Matas in New Orleans and Tuffier in France also reported use of cocaine spinal anesthesia as did Tait and Caglieri in SanFracisco in 1900. The first phase in the history of spinal anesthesia used only cocaine from 1899 to 1905.[14] By the next century procaine was synthesized by Einhorn in 1904, Heinrich Braun used procaine for operative spinal anesthesia in 1905. Clinicians like Babock,Koster,Labat,and Pitkin suggested the causes of hypotension during spinal anesthesia and how to manage it. Baker in 1907 first reported hyperbaric and hypobaric procaine solutions by adding glucose and alcohol respectively. [14]

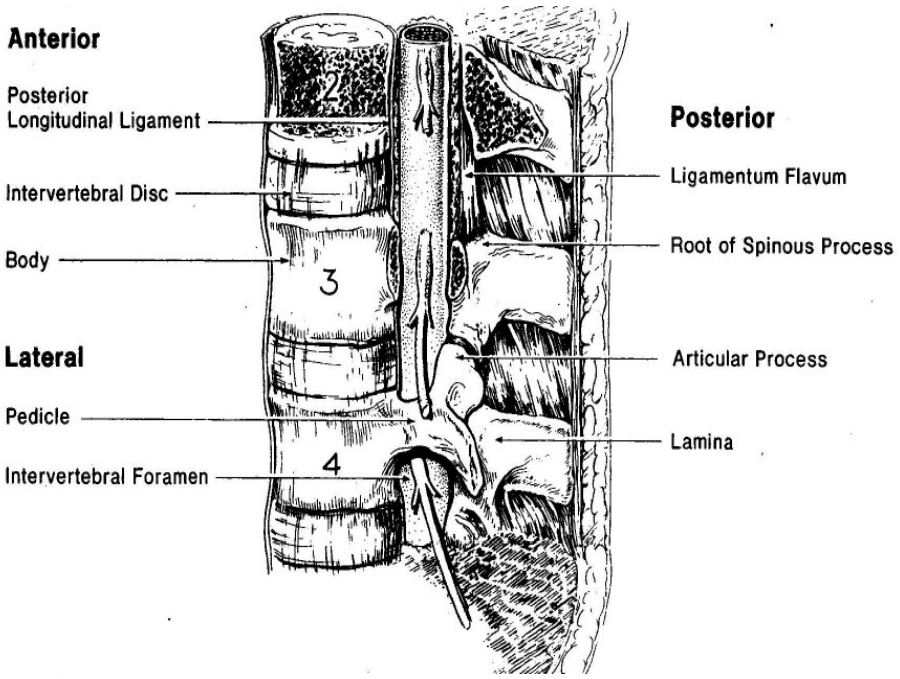
Epidural anesthesia is a central neuraxial block technique with many applications. The epidural space was first described by Corning in 1901.The first epidural injection was by caudal route by Sicard and Cathelin in 1901.[17] Sicard described "loss of resistance" technique for locating epidural space in 1921.In the same year Fidel Pages first used epidural anesthesia and described midline approach to

lumbar epidural analgesia[18].In 1945 Tuohy introduced the epidural needle and used a catheter for lumbar epidural analgesia which is still most commonly used[19].The idea of combined spinal–epidural analgesia (CSEA) originated in 1937 by Soresi to reduce the dosage of local anesthetic[22].

Anatomy:

The epidural space surrounds the spinal meninges and extends from the foramen magnum to the sacral hiatus ,which is covered by sacrococcygeal ligament. It is bounded anteriorly by the posterior longitudinal ligament, posteriorly by the ligamenta flava and the periosteum of the laminae and laterally by the pedicles of the spinal column and the intervertebral foramina containing their neural elements.The space communicates freely with the paravertebral space through the intervertebral foramina.The anterior epidural space is very narrow because of the proximity of dura and anterior surface of vertebral canal.The epidural space contains loose areolar connective tissue, semiliquid fat, lymphatics, arteries, an extensive internal vertebral venous plexus of Batson,and the nerve roots. The epidural space is widest posteriorly and varies with the vertebral canal ,ranging from 1-1.5mm at C5 , 2.5 - 3mm at T6 and 5 to 6mm at the level of L2 [14].

Subarachnoid space is bounded internally by the piamater and externally by arachnoidmater, which is attached to dura and ends at S2. The space is filled with cerebrospinal fluid and contains numerous arachnoid trabeculae. The space has three divisions: cranial(surrounding brain),spinal (surrounding spinal cord), and root(surrounding dorsal and ventral spinal nerve roots) [14]



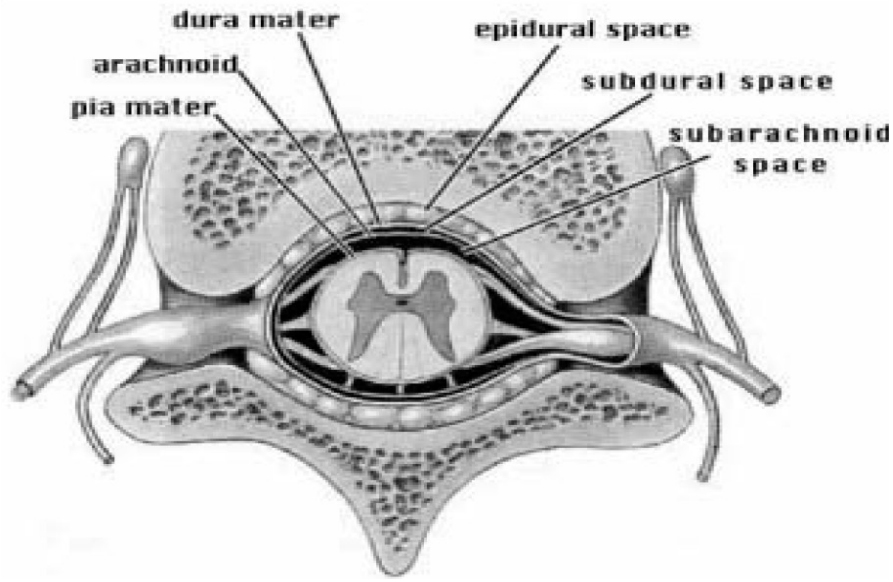


Figure .4. EPIDURAL SPACE ANATOMY

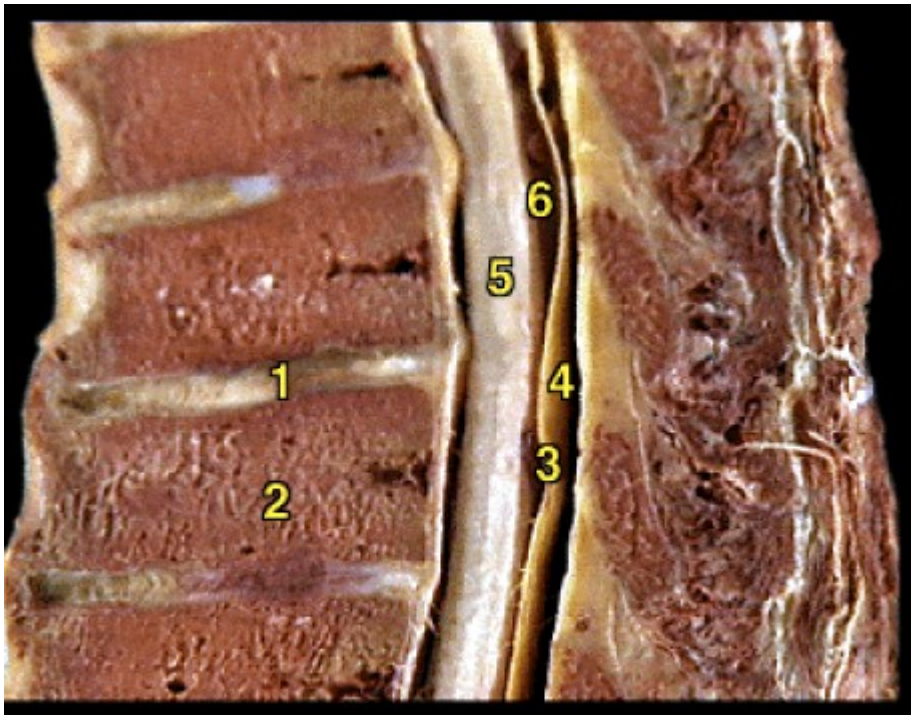


FIG.5. EPIDURAL SPACE ANATOMY

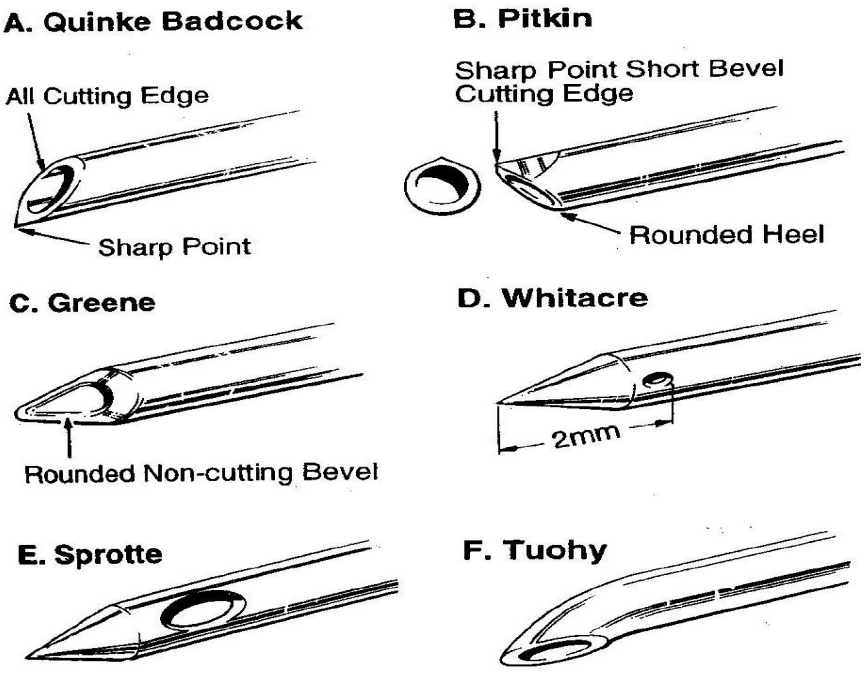
1. - intervertebal disc 2. - vertebral body 3.- duramater

4. - epidural space 5.- spinal cord 6.- subdural space

Spinal Needles:

The history of the design of spinal needle starts from the first used by J.Leonard Corning in 1885 to the modern needles available in market.From the time August Bier used Quincke needle to perform spinal anesthesia ,postdural puncture headache(PDPH) has been a common complication.Since then different modifications of the spinal needle tip have been made to various conditions.Spinal needles fall into two main categories : those that cut the dura and those designed to spread dural fibres[20].The former include

traditional Quincke-Babcock needle and the later contain Whitacre and Sprotte needles.With use of Quincke needles the incidence and severity of PDPH is directly related to the needle size (similar may occur with Whitacre and Sprotte).Quincke needle has diamond type bevel, sharp, most widely used,cheap and if 27 gauge(G), the incidence of PDPH is low. Whitacre is noncutting, with solid conical tipped 'pencil point', first described in 1951 by Hart and Whitacre. commonly available as 25G [23]. Sprotte first described 22 and 24 G needles in 1987 which has a solid ogival tip and longer sideport than Whitackre. It is used for other blocks besides spinal though failure rate is higher. Pitkin had devised 20G or 22G needle,the tip had short ,sharp bevel ground off to a taper of 45^0,resulting in rounded ,blunted bevel heel. The realization in 1920s that cutting of dural fibres caused increased. incidence of PDPH resulted in the design of Greene needle. In 1923,Herbert Merton Greene introduced needle sized 20G and 26G, the point was rounded ,noncuting bevel of medium length with fitted stylet. [23]



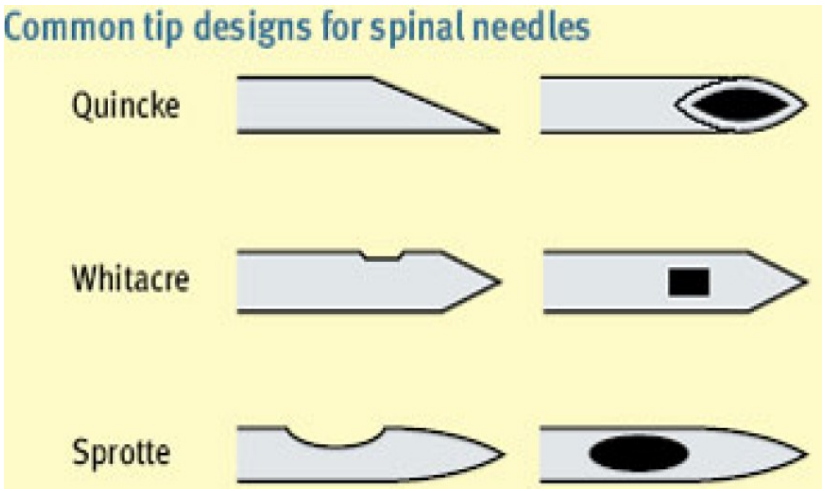


Figure .6. SPINAL NEEDLES

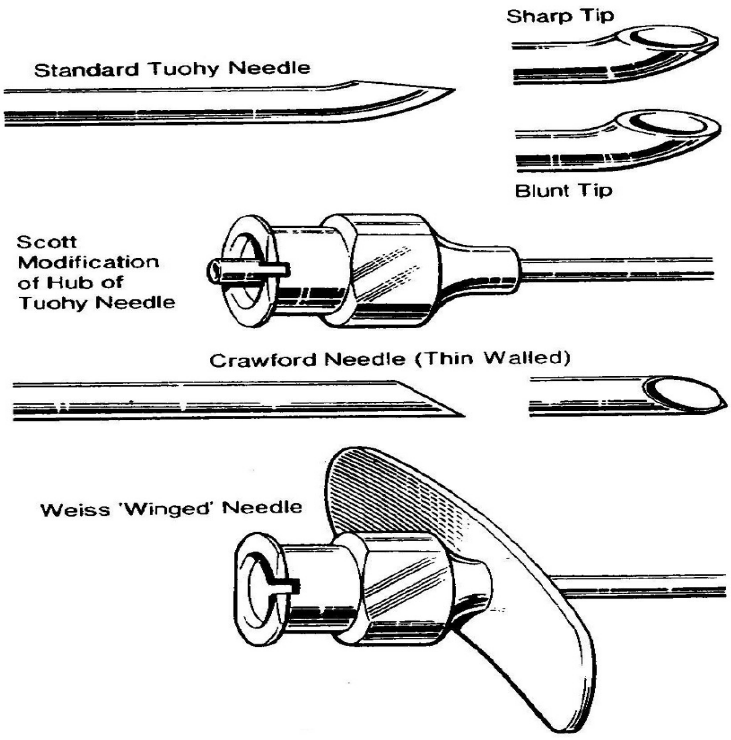
Epidural Needles and Catheters :

As for spinal analgesia , a close fitting removable stylet is essential for epidural anesthesia, to prevent

plugging of needle tip with skin and failure to recognize loss of resistance.[14] in 1944 ,Tuohy ,used 15G Barker needle through which no.4 ureteric silk catheter was passed into subarachnoid space.[19] A Seattle dentist Huber RL invented hypodermic needle with a long sharp curved tip to lessen the pain on injection.[25] Tuohy recognized this curved tip (Huber point) would facilitate placement of epidural catheter and designed Tuohy epidural needle in 1945.[19] Charles E.Flower in 1950 modified Tuohy-Huber needle by making sharp needle dull and introduced a sharp stylet to facilitate skin perforation [26].in 1954 Hustead introduced epidural needle with heel to bevel distance less than 27mm with a rounded heel to reduce danger of catheter trapping if it had to be withdrawn. Weiss introduced metal wings to the hub of the epidural needle and practiced hanging drop method for locating epidural space.In 1987, Sprotte introduced pencil point epidural needle with olive shaped side hole,to minimize tissue trauma.Crawford introduced a thin walled needle often used for the paramedian,"paraspinous "(lateral)approach which has "front end " orifice more likely to penetrate tissues than in standard Tuohy needles used now regularly for epidural anesthesia .[26]

Other needles like large Cheng and Crawley needles and the fine 22G Wagner needle are less commonly used since they have little advantage over standard needles.

The first indwelling catheter to be used for continous epidural anesthesia was silk 3.5French(F) to 4F ureteric catheters.Lacquered silk catheters had to be boiled rather than autoclaved and made sterilization difficult with incidence of infection.Flowers in 1949 described use of plastic catheters.Recently nylon,Teflon,polyurethane and silicone materials are being used.Teflon catheters were found to kink and lead to breakages in the wall.Bromage has summarized ideal characteristics of epidural catheter as which should have biochemical inertness,low coefficient of friction,high tensile strength, maneuverable rigidity, kink resistance, atraumatic tip,depth indicator and ,radiopacity. A stylet is not recommended ,since it increases risk of trauma to blood vessels and nerve roots.[26]



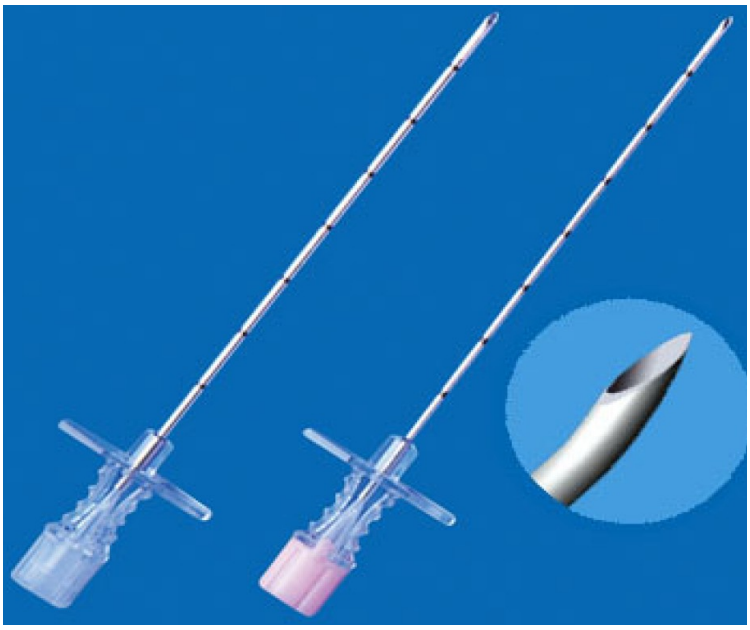


FIG.7. EPIDURAL NEEDLES

Combined Spinal Epidural Anesthesia(CSEA)

The idea of combined combined spinal epidural technique was to reduce some of the disadvantages of spinal and epidural anesthesia while preserving advantages of both. Four main varieties of CSEA are present which are :

1. **Single Needle –Single interspace method** – Soresi was the first surgeon to report the technique,which he called “episubdural”, inserting a fine needle into the epidural space ,and after injecting local anesthetic ,pushing the needle in to the subarachnoid space to administer further local anesthetic.

2. **Double Needle Double Interspace method**- This method was first used by Curelarn in 1979 in Romania.Insertion of an epidural catheter at one interspace followed by spinal injection at a separate ,usually adjacent interspace. Brownridge used this technique in cesarean section in 1981.In a modification both the spinal and epidural needles were inserted in same interspace.

3. **Double Needle –Single Interspace method**-Coates used this technique for orthopaedic surgery in 1982,for caesarean section in 1984 and also for labour pain few years later.

4. **Needle through Needle –Single interspace method**- This uses a modified Tuohy needle with a hole(back eye) in its curve so that spinal needles passes through the back eye directly into the subarachnoid space,instead of exiting from the end of Tuohy needle.Joshi et al (1994) evaluated the CSE technique using standard 16G Tuohy needle or the modified Tuohy needle with the back eye.It was concluded that improved needle set for needle through needle technique would be one with modified Tuohy needle with the back eye and a spinal needle protruding more than 13mm beyond the Tuohy needle.

Techniques and approach to Subarachnoid blockade :

The lumbar puncture or subarachnoid block can be approached in lateral ,sitting and prone position.

Lateral decubitus position is the most popular position for the performance of spinal anesthesia as it most comfortable for the patient. In this position patient is placed on the edge of the table, the vertebral column is flexed to widen interlaminar spaces, the knees drawn up to the chest, the chin touching the chest and the head supported by a pillow.

Sitting position is used less frequently in urologic and gynecologic surgeries and facilitates lumbar puncture in obese patients.The patient sits on the table with neck and back flexed again to provide maximum opening of interspinous spaces.

Prone position is used for hypobaric technique for procedures on rectum, sacrum,and lower vertebral column.The patient is placed on his abdomen on operating table to avoid repositioning after induction of spinal anesthesia.The technique is most easily accomplished if lumbar curve is extended by flexion of table or by placing a pillow under patient's abdomen.[14]

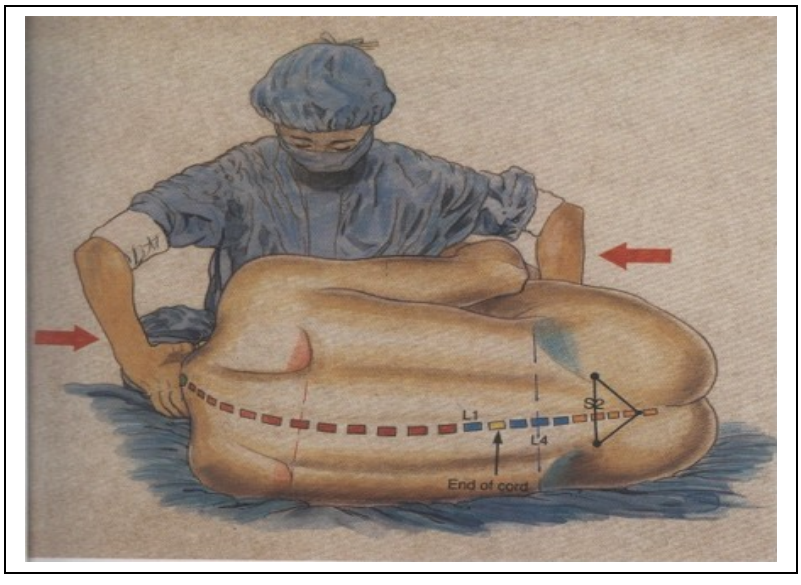


Figure .8. LATERAL DECUBITUS

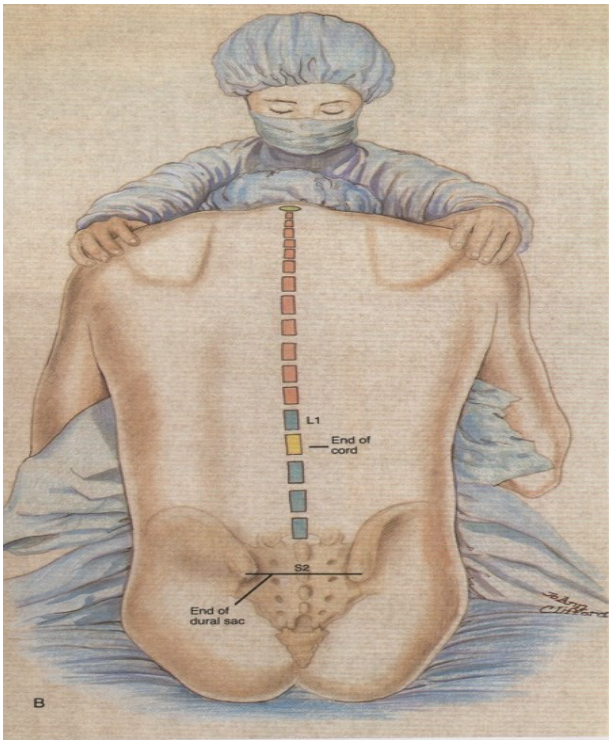


Figure. 9 **SITTING POSITION**

Midline Approach : This approach in lateral position is most popular. The spinal needle is inserted through the same puncture in the skin that was used to perform the intracutaneous wheal and subcutaneous infiltration. The bevel of the spinal needle should be directed laterally so that dural fibers that run longitudinally are spread rather than transected. After traversing the skin and subcutaneous tissues ,the needle is advanced in a slightly cephalad direction with the long axis of the vertebral column. There is a characteristic change in resistance as the needle traverses the ligamentum flavum and the dura arachnoid. The stylet is removed and CSF allowed to appear at the hub of the needle before injecting local anesthetic agent with the syringe.

Paramedian(Lateral) Approach : This approach is useful when degenerative changes are encountered in the interspinous structures especially in elderly patients and when ideal positioning of patient cannot be achieved ,owing to pain(lower limb fractures).The patient is placed in flexed lateral

decubitus position, and a skin wheal raised 1.5 cm lateral to the midline directly opposite the cephalad tip of spinous process. The direction of the spinal needle is at angle of about 15^0 to 20^0 with the midline and slightly cephalad. There is a characteristic “feel” encountered as the needle passes through the ligamentum flavum and dura arachnoid. At this point the needle is not further advanced and the stylet withdrawn to allow CSF to appear at the hub of the needle before injecting local anesthetic agent with the syringe.

If periosteum rather than subarachnoid space encountered, the needle should be redirected slightly cephalad, thus walked off the laminae into the interspace.

Taylor Approach : This is a special paramedian approach to enter L5 interspace (the largest interlaminar space).Used originally for urologic procedures and subsequently for surgeries in pelvis and perineum. The patient is placed in lateral position and a 12cm spinal needle is inserted through a skin wheal made 1cm medial and 1cm caudad to lowest part of the posterior-superior iliac spine.The needle is directed medially and cephalad at an angle of 55^0 into the subarachnoid space.

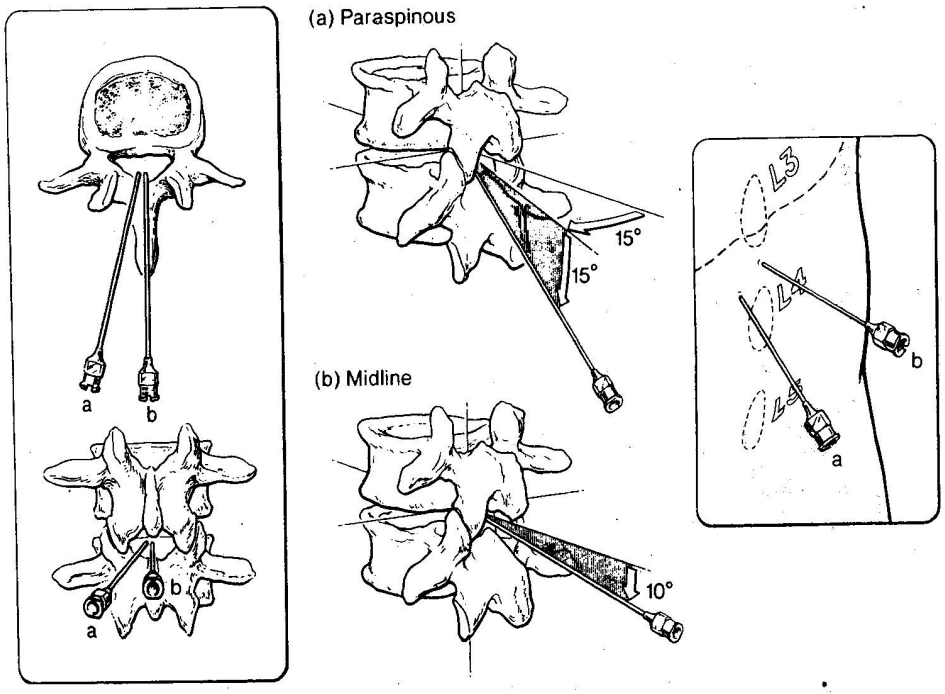


Figure. 10 SPINAL APPROACH

Techniques and approach to identify the epidural space:

The epidural space is located by a midline or paramedian approach with the patient either sitting or any of the lateral position.

Midline Technique: This technique involves needle insertion in midline. After infiltrating skin and interspinous region of the desired level. Theinterspinous space is selected by Labat's technique..The needle is inserted closer to the superior spinous process with slight upward angle. Loss of resistance technique with saline in the "testing" syringe is used to identify the chosen space. After confirmation of epidural space, catheter is inserted 3 to 5 cm inside the space .

Paraspinous (Paramedian) Techniques : It is a useful alternative technique. After infiltration of skin

in lumbar region 1 to 1.5 cm lateral to caudad tip of inferior spinous process of the chosen interspace. A 9 to 10cm 22G spinal needle is used to infiltrate perpendicular to skin beside the spinous process, which permits the depth of the lamina to be determined before epidural needle is inserted. In most patients 18G epidural needle is inserted beside the spinous process and angled upward at 45^0 to long axis of spine and angled towards the midline 10^0 to 15^0 .

In thoracic region the epidural needle is inserted 1cm lateral to spinous process above the intended level of entry and angled 55^0 to60^0 to long axis of spine.[26]

The following maneuvers help to identify epidural space :[27]

1.Sudden loss of resistance to advancing needle as it leaves the dense ligamentum flavum.

2.Sicard and Dogliotti suggested sudden ease of injection of air or liquid from a syringe attached to a needle. If the point is in the ligamentum flavum ,the plunger rebounds, if it is in the space, the plunger can be pushed easily.

3.Gutierrez's sign which shows withdrawal of hanging drop of saline on the hub of needle. It is useful and reliable in thoracic than lumbar region.

4.Odom's indicator in which a glass tube with fine bore containing saline and an air bubble is attached to the hub of needle.

5. Recent advances in imaging the epidural space uses Ultrasound, Fluoroscopy, CT scan and Epiduroscopy.

Technique in Obese patients :

In obese patients the bony landmarks are impalpable, in this situation it is helpful to carry the epidural block with the patient sitting. After skin infiltration with local anesthetic agent, a 5cm 22G needle is used to infiltrate the deeper tissues in the region, where the spinous processes are judged to lie. The needle is used to gently probe the underlying spine. Each time the needle touches bone, the depth is noted and the needle is systematically redirected medially or laterally until the space is located.

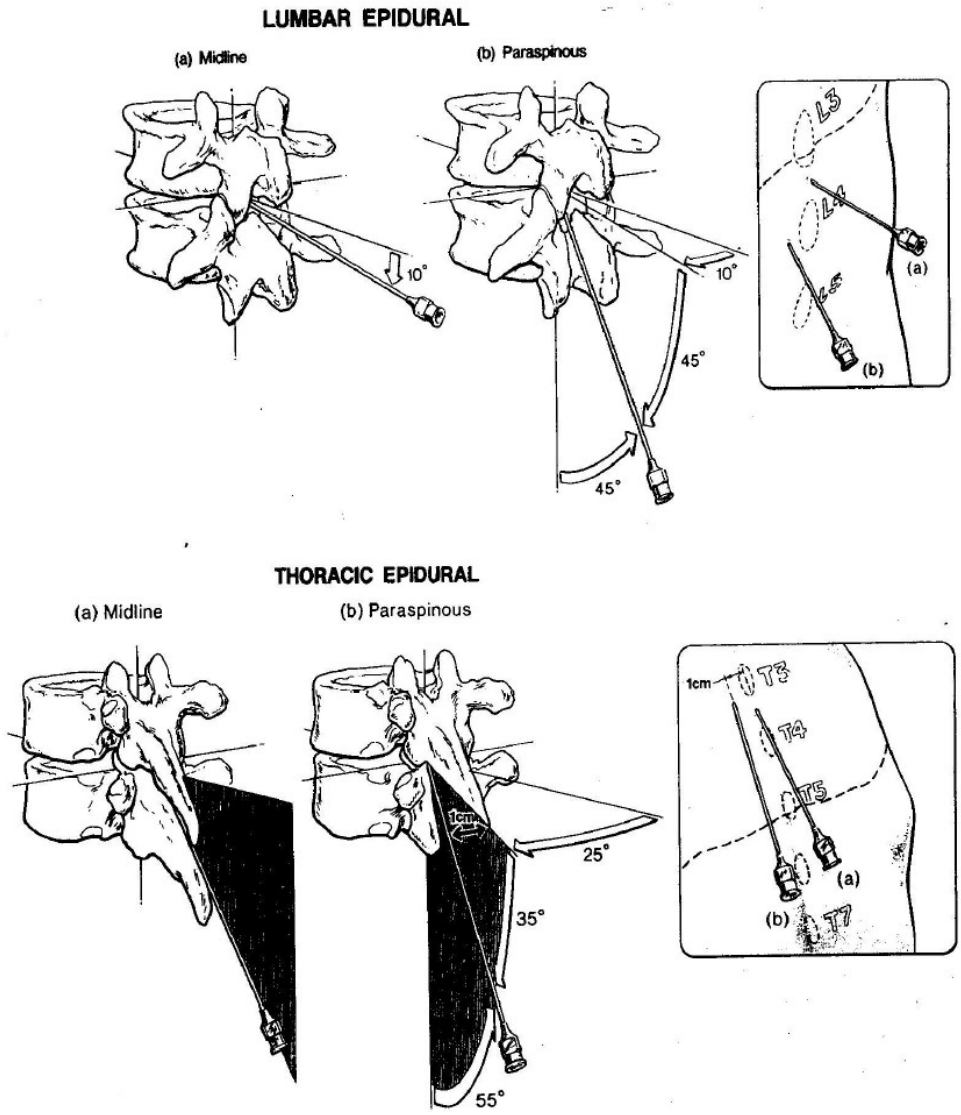


Figure.11. EPIDURAL APPROACH

Mechanism of central neuraxial blockade:

Local anesthetics prevent both the generation & conduction of nerve action potentials. Their main site of action is the nerve cell membrane, where they effectively block the sodium channels. As anesthetic action progresses the threshold for excitability is increased and when these two effects are sufficiently well developed, conduction in the nerve is blocked.

In subarachnoid blockade, the local anesthetic once injected intrathecally, gets absorbed by nerve rootlets and result in the desired effect. Local anesthetic acts on the nerve roots in the epidural space and produces reversible blockade by preventing the passage of sodium ions through nerve membrane. Another mechanism for neural blockade assumes that local anesthetic passes through the dura and arachnoid mater to reach the spinal cord itself.

Opioids in central neuraxial blockade:

Opioids block the transmission of pain by binding to the presynaptic and postsynaptic receptors in the dorsal horn of spinal cord (Rexed laminae I, II, V),brainstem nuclei, periventricular gray matter and medial thalamus. When administered in the epidural space opioids reach the receptor sites by penetrating the dura and through the cerebrospinal fluid to the dorsal horn.

Factors Affecting central neuraxial blockade:

The major factors affecting are the site of injection, dosage of local anesthetic, baricity of local anesthetic solution and posture of the patient. The minor factors are age, height, weight, direction of needle and rate of injection.

Complications and Side Effects:

Hypotension, urinary retention, pruritus and transient neurological injuries are the minor complications

and the major complications are total spinal, epidural haematoma, epidural abscess, severe respiratory depression and arachnoiditis.

Contraindications:

Absolute contraindications

- Patient refusal
- Coagulopathy. Clotting abnormalities may lead to the development of a large haematoma leading to spinal cord compression.
- Therapeutic anticoagulation.
- Skin infection at injection site leads to serious complications such as meningitis or epidural abscess.
- Raised intracranial pressure. accidental dural puncture in a patient with raised ICP may lead to brainstem herniation (coning).
- Hypovolaemia. The peripheral vasodilatation produced by central neuraxial blockade, in combination with uncorrected hypovolaemia, may cause profound circulatory collapse.

Relative contraindications

- Pre-existing neurological disorders, such as multiple sclerosis, may be a contraindication.
- Fixed cardiac output states. aortic stenosis, hypertrophic obstructive cardiomyopathy (HOCM), mitral stenosis and complete heart block are relative contraindications. Patients with these cardiovascular abnormalities are unable to increase their cardiac output in response to the peripheral vasodilatation caused by epidural blockade.
- Anatomical abnormalities like kypho-scoliosis of vertebral column may make the placement of an epidural technically impossible.
- Prophylactic low dose heparin
- Sepsis

MATERIAL AND METHODS

The aim of the study was to test the efficacy and evaluate the impact of epidural anesthesia and analgesia on postoperative outcomes in obese patients undergoing incisional hernia surgery.

After obtaining institutional review board approval and written informed consent, an open randomized controlled trial was conducted on 60 patients scheduled for elective incisional hernia surgery.

Sample size:

The sample size was calculated as 30 in each group based on Franco Carli *et al* study[41]

A sample size of 30 was calculated in each group with 80% power to detect a difference of 2.2 in the means of Visual Analogue Scale the primary outcome ,assuming the common standard deviation of 2.7, and the test to be performed at 5% significance level (two-sided).

Formula for calculation :

$$n > \frac{2(z_{1-\alpha/2} + z_{1-\beta})^2 \sigma^2}{\Delta^2}$$

Where n = calculated sample size ;

Za- type 1 error ,normal value= 1.96

Z 1-b power of the study = 1.28

sigma – standard deviation ,average value of the two groups

delta - difference between the mean values in the two groups

$$n = \frac{(1.98 + 1.28)2 * 2 * 7.24}{4.8} = 30 \text{ (approx)}$$

In this open trial, patients undergoing elective incisional hernia surgery was randomized either to

receive general anesthesia with subcutaneous morphine for postoperative analgesia (control group) or spinal anesthesia with postoperative epidural analgesia with bupivacaine and fentanyl (regional group).

Inclusion criteria*:*

1. Patients aged between 18 and 60 years.

2. American Society Anesthesia class I, II. (ASA Risk categorization)

3. Scheduled for incisional hernia as elective planned surgery.

4. Calculated Body Mass Index(BMI) more than 25.

Exclusion criteria*:*

1. Pediatric and geriatric age group.

2. Pregnancy.

3. Known allergy to any anesthetic agent.

4.Scheduled for emergency surgery.

5.Contraindications to regional anesthetic technique.

6.Failure in performing the anesthetic technique.

Consent

Consent for either anesthetic technique was taken in the pre anesthetic clinic(PAC).The risk and benefits of either anesthetic techniques were explained.

Group Allocation and Randomization

Patients were block randomized (6-8) into two groups. Randomization were done using a computer generated list by a person not included in the study and allocation to the two arms were concealed using serially numbered opaque envelopes.

Management protocols:

All patients were premedicated with diazepam(0.1-0.2 mg/kg) and metoclopramide (0.25 mg/kg) orally an hour before surgery. In both groups

after intra-venous access was secured, a infusion of crystalloid was commenced. Pulseoximetry, heart rate, noninvasive blood pressure and electrocardiogram was monitored during the procedure. All patients received prophylactic antibiotics immediately before surgery.

Group 1(control or general anesthesia)

Patients in this group were given IV morphine(0.1mg/kg) prior to anesthesia with sodium thiopental (3-5mg/kg) IV and fentanyl (1-2 mcg/kg) IV. Anesthesia was augmented with isoflurane (1%-2%),oxygen and nitrous oxide. Endotracheal intubation was facilitated with vecuronium (0.1- 0.2 mg/kg) IV and lungs were mechanically ventilated to end-tidal CO_2 30– 35 mm Hg. If indicated endotracheal intubation was accomplished using succinylcholine (1.0- 1.5 mg/kg) or “awake“ under topical anesthesia using fiberoptic bronchoscopy. During the operation mean arterial pressure, heart rate, Spo_2 and $ETCO_2$ were recorded at five minutes intervals Maintenance anesthesia consisted of N_2O 70% with oxygen and end-tidal isoflurane 0.5%-1.0%. Intravenous Morphine was given as needed to maintain hemodynamic variables within 30% of baseline values. Patients who became hemodynamically unstable intraoperatively were switched over to air and oxygen 50%, end-tidal isoflurane 1.0% - 1.5% and vasopressors like ephedrine 6mg intravenous boluses. Vecuronium IV was given during surgery as needed for muscle relaxation. At the end of surgery ,muscle relaxation was

reversed by combination of neostigmine (0.04-0.08 mg/kg and glycopyrrolate (0.2-0.4 mg). Patients were extubated and transferred to post anesthesia care unit (PACU) and monitored until they met the recovery criteria of wakefulness and hemodynamic stability.

Group 2(combined spinal epidural or regional anesthesia)

Patients in this group received subarachnoid block at the lumbar level for intraoperative anesthesia along with lumbar or thoracic epidural anesthesia for postoperative analgesia in the sitting position. The epidural space was identified with a 18-gauge Tuohy needle after local infiltration of skin and muscle with 2-3 ml of 2% lignocaine in the respective interspace by using the loss-of-resistance to air technique. A 20g catheter was threaded through the needle and 5cm of catheter was passed into the epidural space After confirmation of epidural space and negative aspiration for blood and CSF through the catheter, the epidural catheter and filter were firmly taped to the patient's back. A test dose containing 3ml of 2% lignocaine with adrenaline 1:200000 was injected through the epidural catheter. Then,a 25 gauge Whitacre spinal needle was inserted either at L3-L4 or L4-L5 interspace, after local infiltration. Once free flow of CSF was noted 15 mg of 0.5% bupivacaine in 8.5% dextrose solution with 25 mcg fentanyl was injected over 15 seconds under continous monitoring of pulseoximetry ,heartrate and noninvasive blood pressure. While performing the epidural block if an accidental "wet" or "bloody" tap occured, another attempt was tried in a space higher or lower. The sensory level of epidural block was assessed by loss of sensation to temperature using ice. The modified Bromage

motor score (0 = able to move hip, knee and ankle; 1 =unable to move hip, able to move knee and ankle; 2 = unable to move hip and knee, able to move ankle; 3=unable to move hip, knee and ankle) was assessed after subarachnoid injection. Surgery was allowed to commence as soon as the sensory block height reached T4-T6 dermatome. Intraoperatively mean arterial pressure, heart rate, SpO_2 were recorded at five minute intervals. If the duration of surgery was more than 2 hrs, infusion of 0.25% bupivacaine was started and the rate was titrated based on the hemodynamic parameters. At the end of the surgery, an epidural infusion of 0.1% bupivacaine with 2µg /ml fentanyl was started at a rate between 3-10ml/hr and continued for upto 48 hours postoperatively. Patients remained in the PACU and were monitored until they met the recovery criteria like,hemodynamic stability and the ability to move their lower limbs.

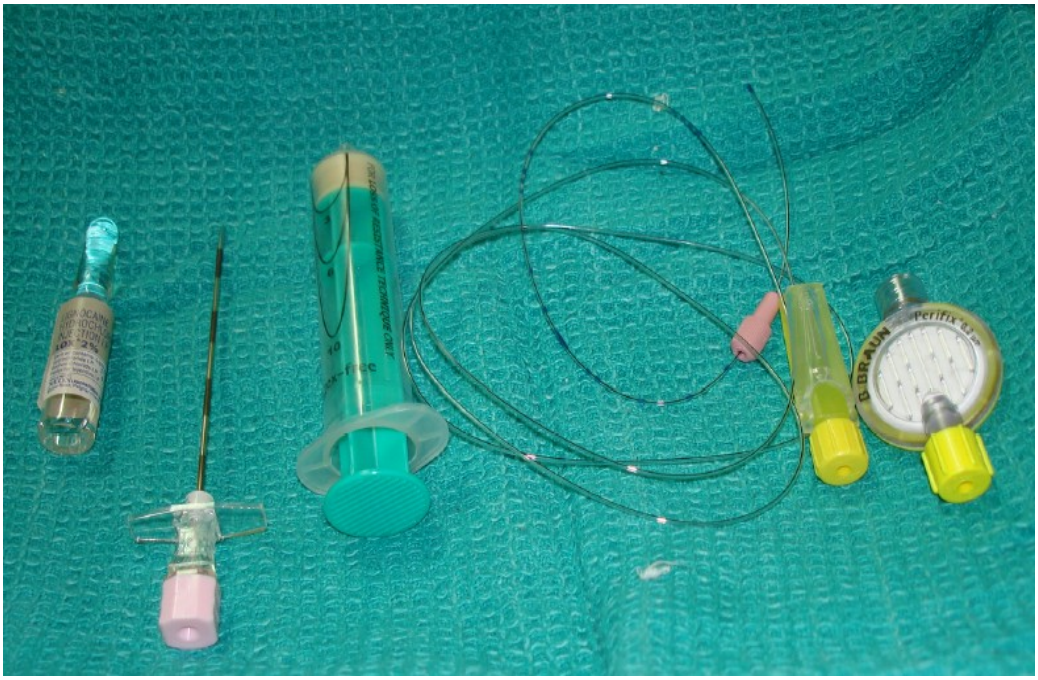


FIG.12. EPIDURAL KIT

18 gauge Tuohy needle, stylet , plastic syringe to confirm the epidural space and 20 gauge catheter attached to microfilter was

used for the study.

Postopeartive period :

Patients in **group 1** received subcutaneous morphine (0.1 mg/kg) through a 24 gauge cannula fixed on the anterior chest wall in the subcutaneous plane. Subcutaneous morphine was administered every 4-6 hourly, the dose and frequency were adjusted according to the patient's weight and pain score. In the ward analgesic requirement were evaluated by the nurses using the visual analog scale (VAS) and patient's who complained of pain irrespective of VAS, received the rescue analgesic, injection

Pethidine 1mg/kg intramuscularly. There was no use of other drugs available like nonsteroidal anti-inflammatory as rescue analgesic in the study.

Patients in **group 2** received continous epidural infusion of 0.1% bupivacaine with 2mcg/ml fentanyl at a rate between 3-10ml/hr. Hemodynamic variables in the post operative period were maintained within 30% of baseline values.

The segmental sensory and autonomic levels of epidural block were assessed on day1 and 2 postoperatively by the acute pain service team using a cotton wisp and ice. The infusion was adjusted to maintain a sensory block exclusively in the dermatomes of the surgical site. The quality of pain relief was assessed using a visual analog scale VAS(0–10 cm; where 0 represented no pain and 10, the worst imaginable pain). If VAS was greater than 5, the rate of infusion was increased to a maximum of 15 ml/h and rescue analgesic injection of Pethidine 1mg/kg was administered by the intramuscular route.

Follow up:

In the immediate postoperative period the heartrate, oxygen saturation, systolic and diastolic noninvasive blood pressure were recorded every 10 min for the first half hour. If the patient complained of pain, nausea or actually vomited,a positive response was noted. In addition, the severity of pain was assessed for all patients using 10cm visual analogue scales (VAS) (where 0 represented no pain and 10 the worst imaginable pain). Patients were encouraged to place a spot on the scale that best represented their pain. If patients required analgesia, they received injection morphine 2mg intravenously in increments until pain scores decreased to 2 or less. All administration of analgesics, antiemetic, first episode of vomiting, retching, nausea and total length of PACU stay were recorded. Injection ondansetron 100 mcg per kg IV, was given as antiemetic and was repeated after 30 min when nausea persisted.

Over the next 24 hours , VAS scores at rest and after coughing , sedation score and occurrence of nausea and vomiting , was documented by the acute pain service team. The time to requirement of

rescue analgesia and other variables like urinary retention ,recovery of bowel function ,length of hospital stay ,time to mobilization, patient's and surgeon's satisfaction were recorded.

Sedation score was recorded as

1 – not arousable

2 – arousable but sleeping

3 – awake

Statistical analysis:

All the study variables are described using either mean with standard deviations or absolute numbers with frequency percentages as appropriate.

Baseline comparisons between the two study groups are made.

Comparisons for quantitative variables are made using Student's t-test and chi-square test was used for categorical variables.

A p value of less than 0.05 was considered statistically significant.

The data were coded and entered into Microsoft Excel computer programme and analysed using software STATA,VERSION 8.

RESULTS

A total of 62 patients were assessed for eligibility. Among them, 2 patients were excluded from the study because one of them did not satisfy the inclusion criteria and one patient refused to participate in the study. 60 patients were enrolled and randomized to two groups of 30.

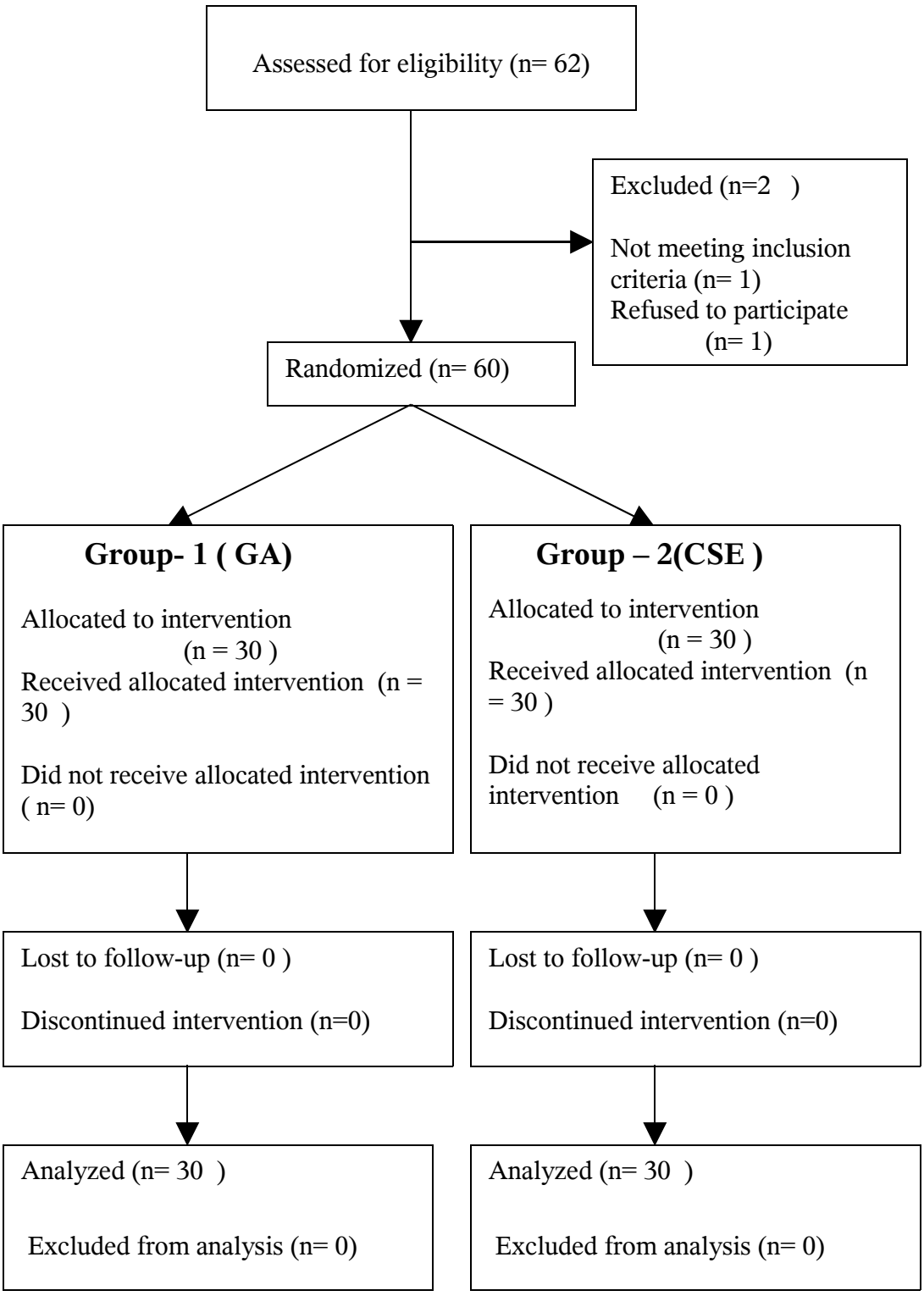


Table 1: Demographic data

	Group 1 (Control) **n=30**	**Group 2 (CSE)** **n=30**
Age (Years)		
Mean	44.6 ± 10.2	43.3 ± 9.9
Range	23-60	24- 60
Sex		
Male	10	2
Female	20	28
Body Weight (Kg)		
Mean	67.7 ± 11.5	68.7 ± 11.4
Range	55 - 89	55- 95
Height (cm)		
Mean	155.4 ± 6.6	155.5 ± 7.1
Range	140 - 171	145 - 170
BMI (kg/m2)		
Range	25.3 - 31.2	25.1 – 34.2
ASA Risk (in no.)		
Gr I	14	12
Gr II	16	18

Table 1 shows the demographic data of the sixty patients selected randomly , posted for incisional hernia surgery in our hospital main theatre complex.

There were no significant difference in age, sex, weight, height and body mass index distribution between the two groups.

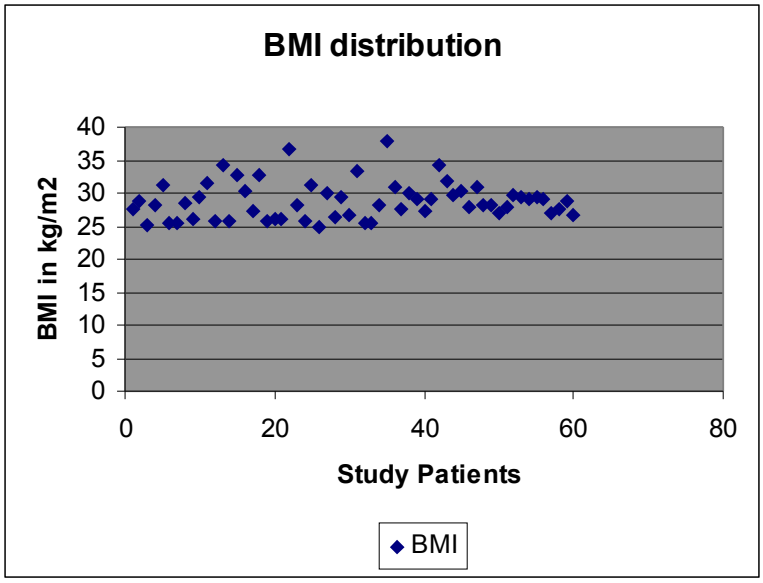


Figure .13. BMI distribution in the study patients

Figure 13 shows the distribution of BMI (body mass index) in all the sixty patients included in the study.

Table 2: Surgical variables

	Group 1 (Control) n=30	**Group 2 (CSE) n =30**

Size of Hernia		
Small (< 25cm^2)	9 (30%)	9 (30%)
Medium (26-100cm^2)	11 (36.7%)	11 (36.7%)
Large (> 100 cm^2)	10 (33.3%)	10 (33.3%)
Site of hernia		
Paraumbilical	11 (36.7%)	10 (33.3%)
Umbilical	7 (23.3%)	3 (10%)
Infraumbilical	12 (40%)	17 (56.7)
Surgery time (mins)	104 ± 27.9	105.2 ± 32.4

There were no significant difference in the size, site of hernia and surgery time distribution between the two groups. Most of the hernia were medium sized and their common site being infra umbilical.

Table 3 : Post Anesthesia Care Unit Variables

Parameters	**Group 1 (Control) n=30**	**Group 2 (CSE) n=30**	**P value**
Nausea	5(16.7%)	2 (6.7%)	0.23
Vomiting	4(13.3%)	0	0.03
Hypoxia	7(23.3%)	2 (6.7%)	0.07

Antiemetic therapy	5(16.7%)	2 (6.7%)	0.23
Analgesic requirement	9(30%)	1(3.3%)	0.006
Mean PACU time (mins)	113.5 ± 26.6	110.3 ± 29.6	0.66
Mean Pain Score (VAS)	3.5 ± 1.6	1.8 ± 1.4	<0.001

* p<0.05 Significance

ll variables are expressed in terms of number & percentage except PACU time and Pain score as mean in table 3.

In the post anesthesia care unit the incidence of vomiting(P=0.03) ,analgesic requirement(P=0.006) and the mean pain score was (P<0.001) were significantly high in control or general group. In CSE group incidence of vomiting, analgesic requirement and the mean pain score were comparatively less.

Figure 14 shows the difference in the analgesic requirement between the two groups and Figure 15 depicts the Mean Visual Analogue Pain Score in PACU.

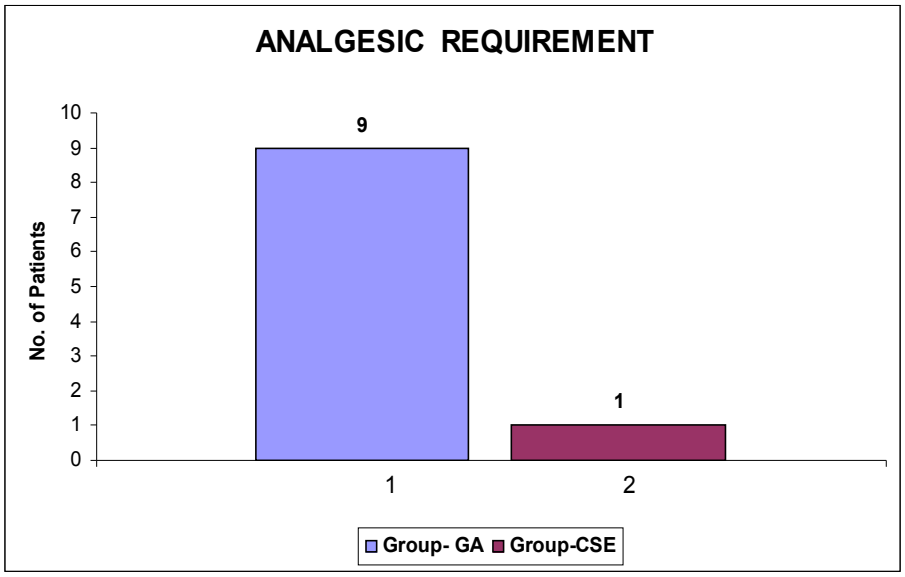


Figure.14. Analgesic Requirement in PACU

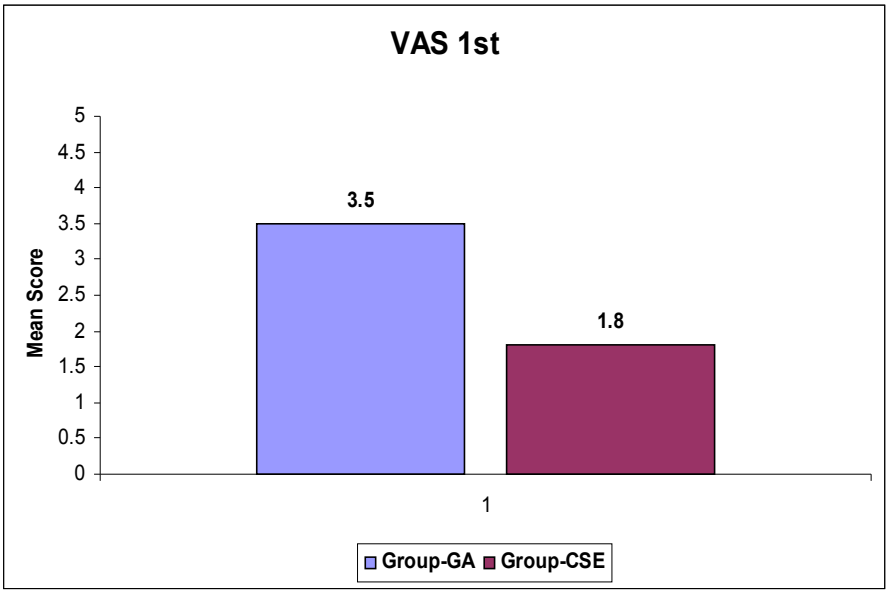


Figure.15. Mean Visual Analogue Pain Score in PACU

Table 4 : Mean Heart Rate in Post Anesthesia Care Unit (mean ± SD)

Time (in mins.)	GroupI (Control) n= 30	GroupII (CSE) n=30	Pvalue
0	77.4 ± 11.5	76.7 ± 8.2	0.77
10	77.8 ± 10.6	76.4 ± 7.9	0.58
20	77.5 ± 11.0	76.0 ± 8.1	0.55
30	77.5 ± 10.5	76.4 ± 8.3	0.64

* $p<0.05$ Significance

Table 4 depicts the heart rate changes at the various time points within the group and between the groups, measured in post anesthesia care unit.

There were no significant difference of mean heart rate measured at 10 minutes interval between the two groups.

Table 5 : Mean Blood Pressure in Post Anesthesia Care Unit

Time (in mins.)	GroupI (Control) n= 30 Sys.BP	GroupII (CSE) n=30 SysBP	P value	GroupI (Control) Diastolic BP	GroupII (CSE) Diastolic BP	P value
0	122.5±10.5	116.3±12.5	0.05	75.8 ± 7.7	69.1± 9.3	0.003
10	121.9± 10	116.3±12.2	0.05	75.4 ± 7.6	68.8±9.3	0.03
20	121.4±10.3	115.7±12.1	0.04	75.4 ± 7.5	68.7±9.1	0.002

30	121.5±10.2	115.6±11.8	0.04	74.9 ± 7.6	68.7±9.2	0.006

* p<0.05 Significance

Table 5 shows the changes in systolic and diastolic blood pressure measured in post anesthesia care unit at 10 minutes interval, immediately after the surgery. The systolic and diastolic blood pressure measured was expressed in mean ± SD, and the p value was calculated .

There were significantly decrease in both systolic and diastolic mean blood pressure measured in post anesthesia care unit in combined spinal epidural group than the control group.

The decrease in the blood pressure in combined spinal epidural group suggests the effect of regional anesthesia on the cardiovascular system.

Table 6: Sedation Score in Postoperative period(24 hour outcome)

SedationScore	**Group I (Control)** **n= 30**	**Group II (CSE)** **n=30**	**Pvalue**
1(not arousable)	0	2 (6.7%)	
2(arousable but sleeping)	24(80%)	5 (16.7%)	<0.001
3 (awake)	6 (20%)	23(76.7%)	<0.001

* p<0.05 Significance

All variables are expressed in terms of number & percentage. In CSE group there were significantly more patients awake than in control group.

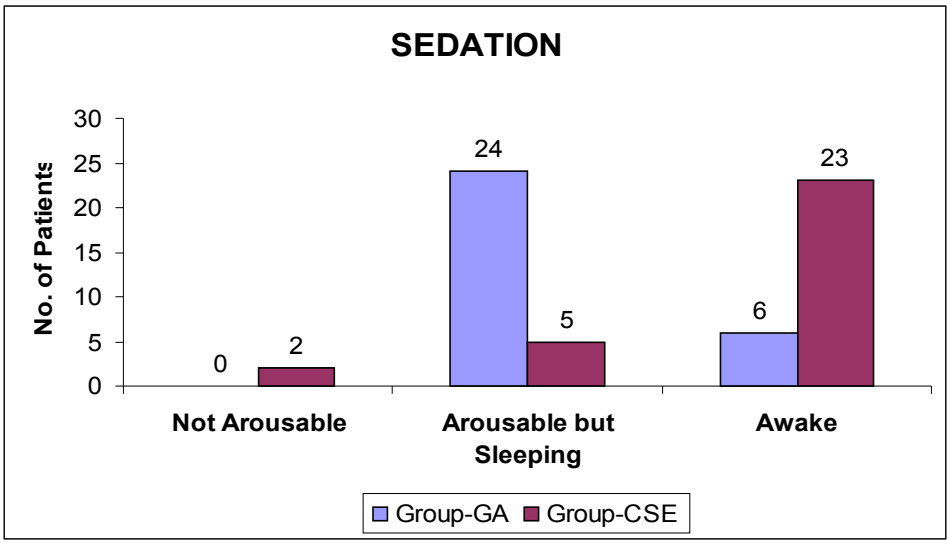


Figure. 16. Sedation Score in ward (24hour outcome)

Figure 16 shows the sedation score in the two study groups.

Sedation score was recorded as 1 – not arousable , 2 – arousable but sleeping and 3 – awake.

There were more patients awake in the combined spinal epidural group than the control group.

Table 7 : Mean Pain Score in Postoperative Period in Ward 24hour outcome. (in mean ± SD)

Visual Analogue Pain Score time	**GroupI (Control) n= 30**	**GroupII (CSE) n=30**	**Pvalue**
VAS Rest morning	3.2 ± 1.6	1.9 ± 1.2	0.003
VAS Dynamic morning	6.2 ± 1.7	4.8 ± 1.3	0.002
VAS Rest evening	3.1 ± 1.6	1.9 ± 1.3	0.003
VAS Dynamic evening	6.1 ± 1.7	4.9 ± 1.3	0.002

* $p<0.05$ Significance

Pain Score measured in ward during next 24 hours postoperatively were expressed as mean. The mean pain score at rest (P=0.003) and dynamic (P=0.002) were significantly high in control or general group both in morning and evening. In CSE group of mean pain score at rest or dynamic state in both time were less.

Figure 17 and 18 shows the differences in mean pain score measured in ward in between the two study groups. It was measured by visual analogue scale of 0 to 10 cm both at morning and evening .

The yellow bar depicts the pain score at rest and the brown bar in the graph depicts pain score after cough (dynamic pain score).

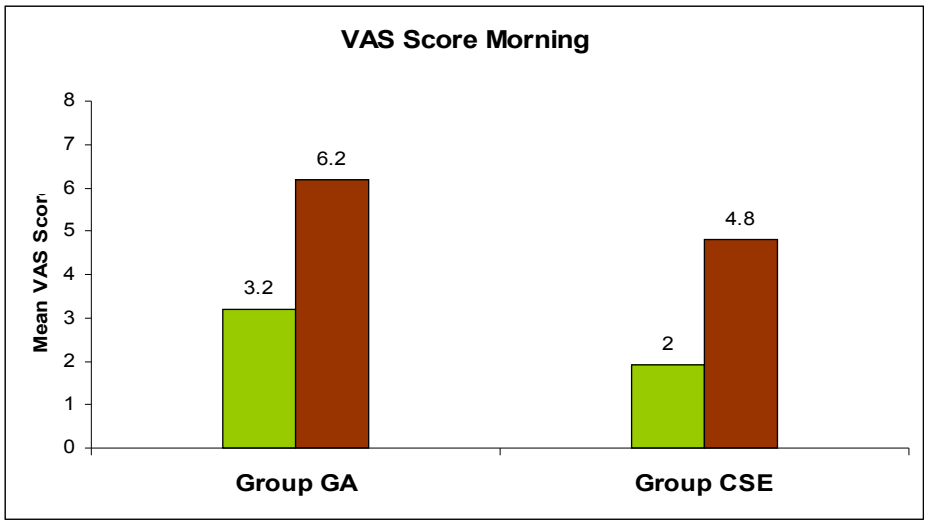


Figure. 17. Mean Pain Score in Ward at Morning

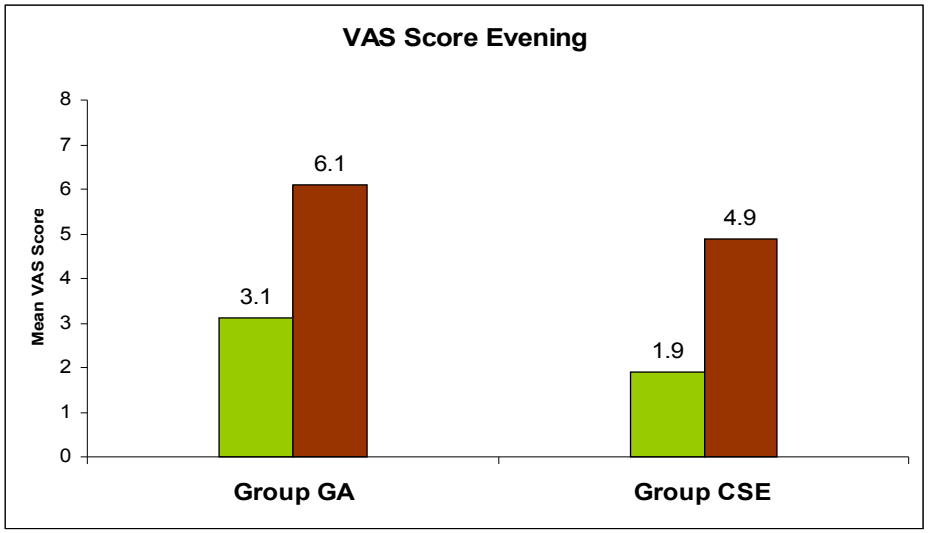


Figure. 18. Mean Pain Score in Ward at Evening

Yellow bar depicts VAS at rest .

Brown bar depicts VAS at dynamic state.

Table 8. Twenty-four-Hour (Intermediate) Postsurgical Outcomes Analgesic Requirement

Postsurgical Outcomes	**GroupI (Control) n= 30**	**GroupII (CSE) n=30**	**Pvalue**
Number of Patients Rescue Analgesic required	8 (26.7%)	2 (6.7%)	0.03
Duration of Analgesia (mean) in hours	26.76 ± (11.7)	32.80 ± (6.6)	0.02

* $p<0.05$ Significance

Rescue analgesic requirement was expressed in terms of number and percentage. Rescue analgesic

requirement was significantly in less number of patients in combined spinal epidural group (CSE) (p=0.03) than the control group. The duration of analgesia which is the time till receiving the first rescue analgesic in the ward, is measured in hours. The mean duration of analgesia calculated was found to be significantly more in CSE group.(p= 0.02).

Figure 19 shows the number of patients requiring rescue analgesic in the postoperative period in the ward.

Figure 20 demonstrates the mean duration of analgesia measured in hours in between the two groups.

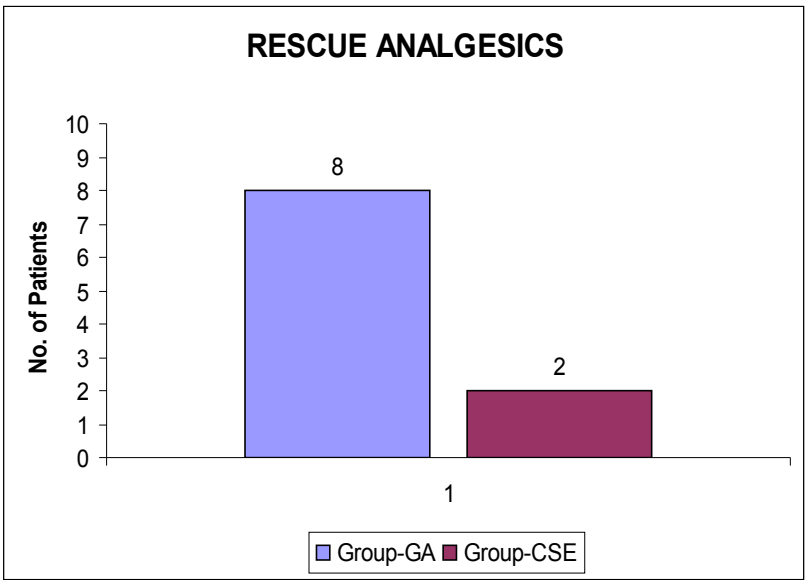


Figure. 19. Rescue Analgesic Requirement

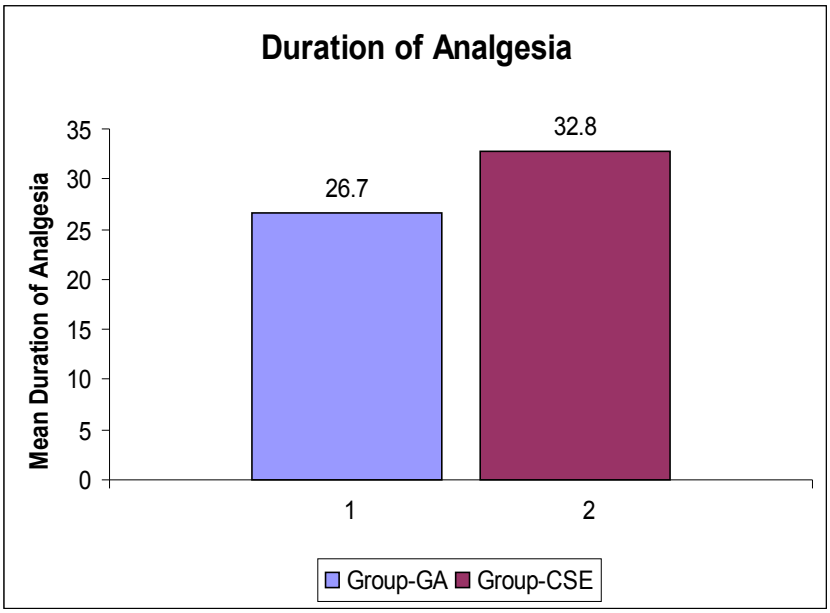


Figure. 20. Duration of Analgesia

Table 9 : Twenty-four-Hour (Intermediate) Postsurgical Outcomes

Postsurgical Outcomes	**GroupI (Control) n= 30**	**GroupII (CSE) n=30**	**Pvalue**
Nausea	14 (46.7%)	3 (10%)	0.002
Vomiting	3 (10%)	4 (13.3%)	0.68
Pruritus	4 (13.3%)	2 (6.7%)	0.38
Headache	1 (3.3%)	2 (6.7%)	0.55
Backache	0	1 (3.3%)	0.31

Time of Mobilization (mean)	28.9 ± 5.5	27 ± 4.9	0.15
Duration of Hospital Stay	Median = 4 min- 2,max - 12	Median =4 min-2, max- 8	

* $p<0.05$ Significance

Table 9 describes the intermediate outcomes assessed in the ward twenty four hours after surgery.All variables are expressed in terms of number and percentage except time of mobilization as mean. Duration of hospital stay is expressed as median with minimum and maximum values.

The incidence of nausea (P=0.002) was significantly less in Combined spinal epidural group than in control or general group.

Figure 21 shows the difference of incidence of nausea in both the groups.

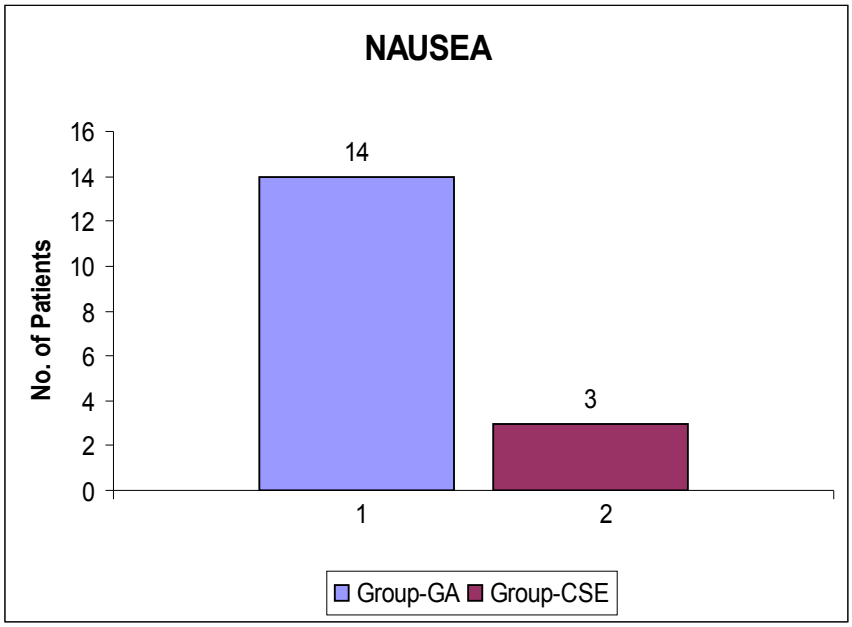


Figure.21.Incidence of Nausea in ward (24hour outcome)

Table 10 : Twenty-four-Hour (Intermediate) Postsurgical Outcomes

BOWEL RECOVERY

Postsurgical Outcomes	**GroupI (Control) n= 30**	**GroupII (CSE) n=30**	**Pvalue**
Mean Time of Passing Flatus (hrs)	26.9 ± 5.3	22.4 ± 4.1	<0.0001

Mean Time to Tolerate Sips of Fluid.(hrs)	23.8 ± 4.8	21.2 ± 4.6	0.03

* p<0.05 Significance

Table 10 shows the difference of time of bowel recovery in the two groups in the postoperative period in ward. Time of bowel recovery was calculated from the time of passing flatus and the time to tolerate sips of fluid in hours after the surgery.

The time of passing flatus ($p<0.001$) and tolerate sips of fluid ($p=0.03$) were significantly less in combined spinal epidural group than in control or general group.

Figure 22 and 23 both depicts the time of bowel recovery in both the groups.

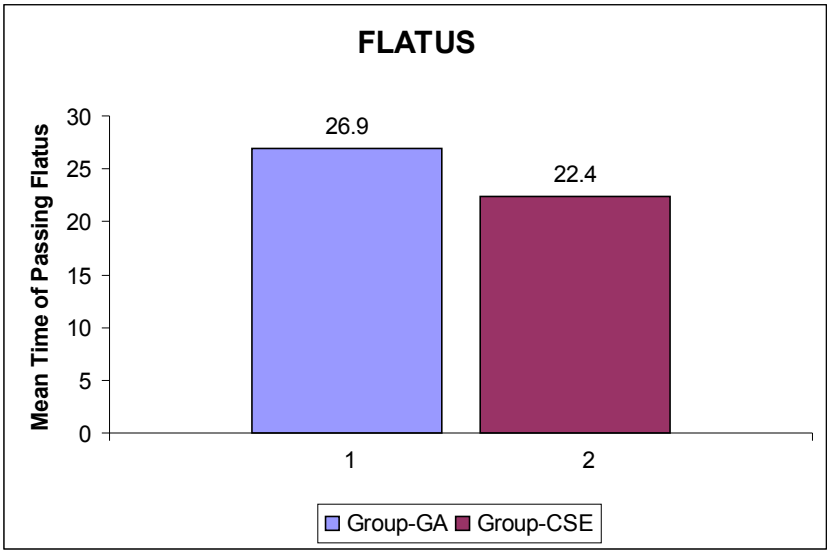


Figure .22. Time to passing Flatus in ward (24hour outcome)

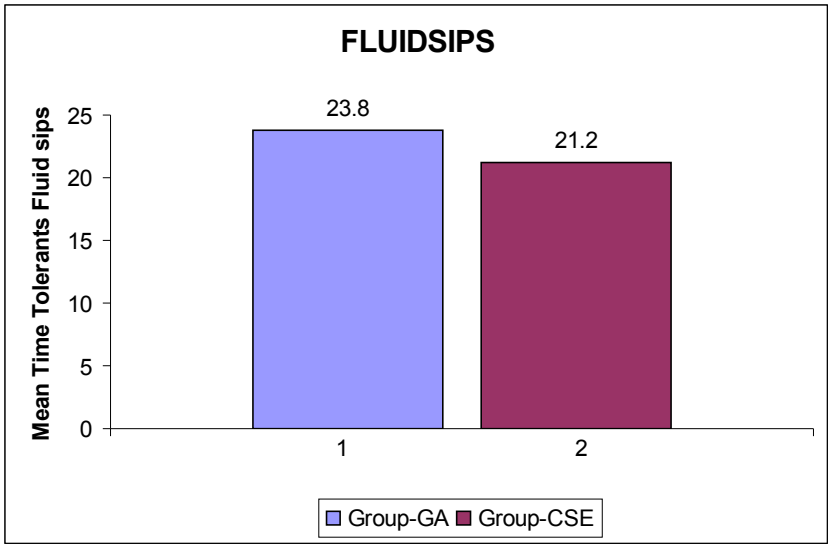


Figure. 23. Time to tolerate Fluid Sips in ward (24hour outcome

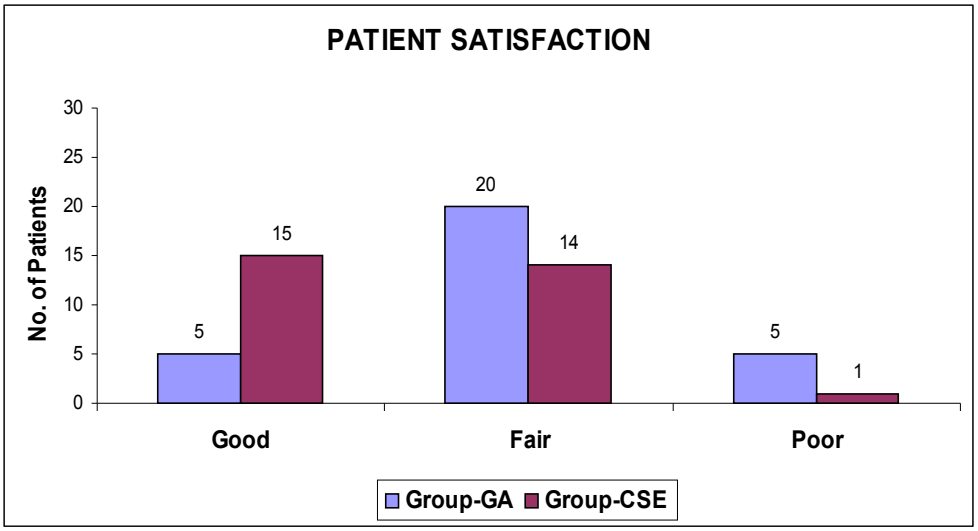


Figure. 24. Patient's Satisfaction

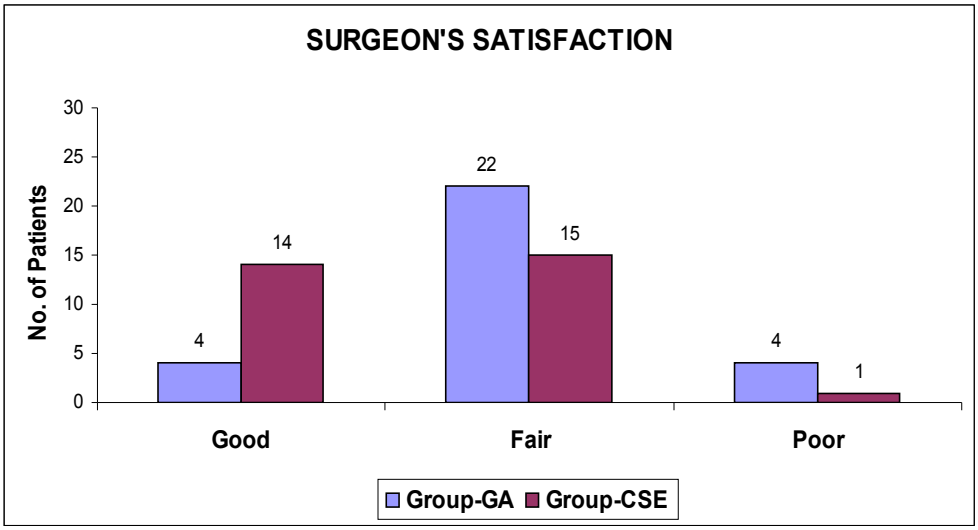


Figure. 25. Surgeon's satisfaction

Figure 24 shows the patient's satisfaction rating done after forty-eight hours in the ward on the mode of analgesia recieved by them.

The epidural pain relief was rated good by 50% (15 out of 30) of the patients, fair by 46.7% (14 out of 30) and the subcutaneous morphine pain relief was rated good by 16.7% (5 out of 30) patients and fair by 66.7% (20 out 0f 30) patients.

Figure 25 depicts the surgeon's rating on the mode of analgesia received by the patients.

The combined spinal epidural analgesia mode of pain relief was rated good by surgeons for 46.7% (14 out of 30) patients.and fair in 50%(15 out of 30) of the patients. Subcutaneous morphine pain relief was rated good for 13.3% (5 out of 30) patients and fair for 73.3% (22 out 0f 30) patients by the surgeons.

DISCUSSION

The results of this prospective randomized study showed that obese patients undergoing elective incisional hernia surgery had better postoperative outcomes with epidural analgesia compared with parenteral opiods. This was likely a result of the positive effects of epidural analgesia on postoperative pain control, gastrointestinal motility and mobilization.

Incisional hernia is the most common surgery performed in our surgical theatres and considered as a major abdominal surgery. Any surgery is associated with stress responses, which causes various organ dysfunctions.

Pain relief is a powerful technique to modify surgical stress response. It has been assumed that sufficient pain relief will improve the surgical outcome and there is a common consensus that optimal pain relief mainly dynamic, is a prerequisite for early postoperative recovery.[12]

The effect of epidural anesthesia and analgesia on fifty three high risk patients coming for major abdominal surgery has been studied in mid 1980_s by Yeager and colleagues, which has shown significant improvement in postoperative outcome.[1,8] When compared to control patients, patients who received epidural analgesia had a reduction in the overall postoperative complication rate ($P = 0.002$) .

Evidence suggests that epidural local anesthetic or local anesthetic-opioid techniques are the most effective in providing dynamic pain relief, after major surgical procedures. The duration of epidural local analgesic is important , atleast 24 hours and preferably 48 hours postoperatively.

In our study sixty obese patients were randomized either to receive general anesthesia with subcutaneous morphine for postoperative analgesia (control group) or spinal anesthesia with

postoperative epidural analgesia with bupivacaine and fentanyl (regional group). We had included patients satisfying the inclusion criteria of our study posted for elective incisional hernia surgery over the period of one year in our main theatre.

We found more patients required rescue analgesic in PACU in the control group 30% compared to regional group 3.3%.

The incidence of nausea, vomiting and hypoxia were 6.7%, 0% and 6.7% in the CSE (combined spinal epidural) group as compared to 16.6% ,13.3% and 27.7% respectively in control group, as immediate postoperative outcomes.

The lower incidence of hypoxia in the CSE group of our study supports the findings of Fox et al, where 110 obese patients receiving epidural analgesia for weight-reducing surgery in Canada had higher PaO_2 than patients receiving general anesthesia.[44]

The impact of obesity on the changes of pulmonary physiology make them prone for a higher chance of postoperative pulmonary complications like hypoxia, atelectasis, especially when undergoing abdominal surgery under general anesthesia. [28]

These results were also suggestive of the respiratory benefits of epidural analgesia as Gelman and colleagues showed in 38 morbidly obese patients undergoing gastric bypass surgery in 1980.[43]

In PACU, 30% (9 out of 30) of the patients in control group required analgesia as compared to 3.3% (1 out of 30) in CSE group. This was true as the mean pain score measured as VAS in patients who received general anesthesia and parenteral opiods was 3.5 as compared to patients who received regional technique 1.8.

The time spent in postanesthesia care unit (PACU) by either group of patients was found to be similar.

Similar to the MASTER (Multicentre Australian Study of Epidural Anesthesia) trial our study showed postoperative analgesia was found to be clinically superior on the basis of pain visual analog scores (VAS) in patients randomized to the epidural group.

The primary outcome, postoperative dynamic pain score had significant decrease ($p<0.05$) in the

regional group (mean 4.8) as compared to control group (mean 6.2). This result had supported the consensus that optimal pain relief is a prerequisite for early postoperative recovery [12] and opioid epidural analgesia, alone or combined with local anesthetics, is preferred after major abdominal surgery in obese patients.

All the patients undergoing incisional hernia surgery were routinely catheterized, and were removed after 24 to 48 hours postoperatively. The effect of epidural analgesia, urinary retention was not noticed in our patients.

The were higher incidence of patients developing pruritus in control group (13.3%) as compared to CSE group (6.7%). This was noted due to the use of parenteral opioids as the mode of postoperative analgesia, pruritus being a common side-effect .

The results showed both mean time of passing flatus (22.4 hrs) and time to tolerate sips of fluid (21.2 hrs) in CSE group were found earlier than in control group ,26.9 hours and 23.8 hours respectively. This suggests the impact of epidural analgesia on time to bowel recovery,

Transient postoperative ileus is commonly seen after abdominal surgery under general anesthesia, more in obese patients as use of larger dose of opioids required for optimal pain relief.

Randomized trials by Jayr *et al* in 1993 and Carli *et al* in 2000 have demonstrated that the use of epidural opioids with a local anesthetic-based regimen is associated with significantly early return of gastrointestinal function after abdominal surgery.[41,49]

In the study group of patients infraumbilical was the more commoner site of incisional hernia , and were medium sized ranging between $26cm^2$ -$100cm^2$.

In combined spinal epidural group there were more patients awake 76.7% than in control group where only 20% of the patients were awake.This was assessed in the surgical ward twenty-four hours after surgery.

The time to mobilization was seen similar in both the groups as it depends on many factors other than pain relief (eg. use of drains, catheters, traditions, restrictions and reimbursement policy).

The patient satisfaction was better in the Regional group which was rated good by 50% of the patients and only 16.7% of the patients for the control group. In the regional group 46.7% of the patients rated fair ,and 3.3% rated poor in the patient satisfaction.

Surgeons rated combined spinal epidural analgesia as good mode of analgesia in 46.7% of the patients and fair in 50% of the patients who received it. Subcutaneous morphine pain relief was rated good for 13.3% patients and fair for 73.3% patients in the control group by the surgeons.

CONCLUSION

Combined spinal epidural is a superior alternative technique to general anesthesia with parenteral opioids in the post operative management of incisional hernia surgery for obese patients. Combined spinal epidural technique provides better pain relief, early bowel recovery, less incidence of hypoxia and nausea and better patient satisfaction in postoperative period in obese patients.

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APPENDIX I

Information to the patient :

This information is regarding the type of anesthesia that can be given during incisional hernia surgery.

Reason for surgery :
This surgery is performed to repair the defect causing the incisional hernia.

Type of anesthesia :
This surgery can be done under general anesthesia or regional anesthesia.
General anesthesia is where you will be unconscious during the surgery and your breathing function and other organ physiology will be maintained by anesthesia machine,anasethetic drugs,and under monitoring of anesthetist.
Postoperative period you will given subcutaneous morphine intermittently throughout the day through a small cannula fixed on your chest wall.
In Regional anesthesia after injecting local anesthetic under antiseptic preparation a sterile needle is inserted in your back in the sitting or lateral position.A thin catheter is threaded through the needle and the needle is removed and catheter is firmly taped on your back. Following a test of local anesthetic , the local anesthetic solution will be injected through the catheter. This technique is done to provide post operative pain relief.The drug could cause allergic reaction and drop in blood pressure rarely, any undue reaction will be treated appropriately. In the absence of a reaction the local anesthetic solution is injected. After which another thinner needle at a site below will be inserted and further inject another drug. This drug will cause senseless and heaviness of your both lower limbs.After checking the effect of subarachnoid blockade surgeons will allowed to start. An infusion pump containing local anesthetic drug is infused through the catheter, which will give you pain relief for 2 days after the surgery. You will be asked to fill in a pain scale to help the doctor and you to decide whether the block has helped you in pain relief. Both anesthetic techniques are safe for your surgery.

Risks and benefits
However, with any procedure there are risks, side effects and the possibility of complications.General anesthesia can cause serious problems like increase in blood pressure,risk of aspiration,lung infection which if happens will be treated appropriately.The procedures itself doesn't cause much pain. Some time in regional anesthesia it may cause radiating pain in your limbs due to the catheter touching the nerve roots in epidural space .Headache alone or along with backache can be present after 2-4 days of surgery

Serious complications like respiratory arrest due to spinal injection of drug and convulsion due to drug injected into the blood vessels in the epidural space can occur which are rare and a test dose is injected to rule out such complications could occur.
However there are chances of inadequate pain relief ,in such situations S/C morphine will be injected for relief.Regional postop analgesia technique by giving drug continuously through the catheter has been recognized as a superior method of pain relief control for abdominal surgery.Evidence shows that it also enhances the recovery process and lead to wider adoption of this method and better quality of care for incisional hernia patients.

Aim of the study :
The surgery can be done under either of these anesthetic technique. I Dr.Dibyendu Khan 1st year PG student in Anesthesia department planning to study the efficacy and evaluate the impact of epidural anesthesia and postoperative epidural analgesia on postoperative outcomes.If you volunteer for this study you will receive either of these methods which will be assigned randomly. There is no cost difference in either of these methods nor any monetary benefit if you volunteer for this study.There will be a consultant senior anesthetist supervising this study and you will be monitored continuously. Your identity will be undisclosed,though your treatment records may be required to assess for the study. This is voluntary and you have the right to refuse at any stage for the study.Your care will not be affected by your decision. However if you volunteer you have to sign the following consent form.

APPENDIX I

CONSENT FORM FOR THE STUDY:

I am _____ and my hospital number is_____.

The details of this study have been explained to me. I understand that this is voluntary and I am aware of the purpose of the proposed study conducted by Dr.Dibyendu. I give my consent to be enrolled in this study.

Signature of the Patient / Guardian Signature of the Anesthetist

Name of the patient : Signature of the witness

Hospital no. : Name of the witness

Date :

APPENDIX II

INCISIONAL HERNIA STUDY PROFORMA

Name : Hospital.No : Ward : S.no :

Age : ( ) yrs IP No. : Date of surgery : / /

Sex : M / F Group : GA / RA ASA status :

Weight (kg) : Height (m) : BMI (kg/ m2):

Diagnosis : Level of Epidural : T ( ) , L( )

Size of hernia : Site of hernia : Duration of surgery :

Patient characteristics

Diabetes ( ) Smoking history ( )

Hypertension ( ) Alcohol history ( )

Renal failure ( ) Ischemic heart disease ( )

Asthma/COPD ( ) Hepatic dysfunction ( )

Thyroid disease ( )

Short-Term Recovery Outcomes in the Postanesthesia Care Unit

1.HR0 : HR10: HR20 : HR30: 2.BP0 : / BP10: / BP20: /

BP30: / 3.Nausea :( ) 4.Antiemetic given:Y / N 5.Hypoxia : ( )

6. PACU time : 8. Vomiting : ( ) 7. Analgesic given Y / N

8. Peak pain score (VAS 0-10 cms scale where 0 represents no pain and 10 - the worst pain) :

Twenty-four-Hour (Intermediate) Postsurgical Outcomes

1.Sedation : not arousable ( ), arousable but sleeping ( ), awake ( )

2.Pain VAS (at rest)Morning : Evening : (after coughing) :Morning: Evening:

3.Nausea: ( ) 4. Vomiting: ( ) 5.Pruritus : ( )

6.Urinary retention : ( ) [CBD :] 7. Headache / Backache : Y / N

8.a.Time to passing flatus (hrs after surgery): ( )
b.Tolerate sips of fluid : (hrs after surgery): ( )

9. Rescue Analgesics required : ( ) Hours after surgery : ( )

10.Time to mobilization (hrs after surgery): ( )

11.Length of hospital stay (days): ( ) Date of discharge :

12.Patient satisfaction : good ( ) fair ( ) poor ( )

13. Surgeon's satisfaction : good ( ) fair ( ) poor ( )

14. Any other complications:

KINDLY RETURN THIS FORM TO DR.DIBYENDU OR SEND TO ANESTHESIA OFFICE IF FOUND ANYWHERE

APPENDIX III

Key to master sheet

1. Sex : Male = 1 Female = 2
2. Group : General Anesthesia = 1 Regional Anesthesia = 2
3. ASA (American Society Anesthesia) class I & II grading
4. Weight in KG (kilograms)
5. Height in cms.
6. BMI (body mass index) in kg/ m^2
7. Site of hernia : 1= paraumbilical 2= umbilical 3= infraumbilical
8. Size of hernia in cm^2
9. Surgery time in hours
10. Patient's presence of any comorbid factors : 1= yes 2= no
11. HR O – heart rate at zero minute after reaching PACU
12. HR 10 - heart rate at ten minutes after reaching PACU
13. HR 20 - heart rate at twenty minutes after reaching PACU
14. HR 30 - heart rate at thirty minutes after reaching PACU
15. SysBP O- systolic blood pressure in mm Hg at zero minute in PACU
16. SysBP 10- systolic blood pressure in mm Hg at ten minutes in PACU
17. SysBP 20 - systolic blood pressure in mm Hg twenty minutes in PACU
18. SysBP30 - systolic blood pressure in mm Hg at thirty minutes in PACU
19. DiasBP0- diastolic blood pressure in mm Hg at zero minute in PACU
20. DiasBP10- diastolic blood pressure in mm Hg at ten minute in PACU
21. DiasBP20-diastolic blood pressure in mm Hg at twenty minute in PACU
22. DiasBP30- diastolic blood pressure in mm Hg at thirty minute in PACU
23. Nausea in PACU : 1= yes 2= no
24. Vomiting in PACU : 1= yes 2= no
25. Hypoxia episode in PACU : 1= yes 2= no
26. Antiemetic given in PACU : 1= yes 2= no

27. PACU time in minutes

28. Analgesic given in PACU: 1= yes 2= no

29. SedtionScore: 1-not arousable ,2- arousable but sleeping , 3 – awake.

30. VAS 1st – pain score in cm measured in PACU

31.VAS rest M- pain score in cm measured at rest in morning

32.VAS coughM - pain score in cm measured at cough in morning

33.VAS rest E- pain score in cm measured at rest in evening

34.VAScough E- pain score in cm measured at cough in evening

35. Nausea2 : episode of nausea in ward 1= yes 2= no

36.Vomit2 : episode of vomiting in ward 1= yes 2= no

37. Pruritus : in ward 1= yes 2= no

38. Headache / Backache in ward : 1= yes 2= no

39.Flatus tim= time to pass flatus in hours after surgery in ward

40. Fluid si= time to tolerate sips of fliud in hours after surgery in ward

41.Analgesic2 = rescue analgesic requirement 1= yes 2= no

42. HRs after – rescue analgesic required hours after surgery

43.Durat Anal - duration of analgesia in hours measured in ward

44.Mobile time = time to mobilization in hours after surgery.

45. Hospital stay - number of days admitted in ward postoperatively

46. . Patient satisfaction : good = 1 , fair = 2 , poor = 3

47. Surgeon's satisfaction : good = 1 , fair = 2 , poor = 3

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APPENDIX IV

Master Chart saved as separate Microsoft excel document