**Comparison between thoracic epidural and systemic opioid analgesia on lung mechanics in obese patients in major gynecological procedures**

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**Abstract**

**BACKGROUND:** The study was done to compare the effects of thoracic epidural analgesia versus systemic opioid analgesia on lung mechanics in obese patients undergoing major gynecological procedures(abdominal hysterectomy, ovarian cyst, ovarian mass and abdominal explorations) We evaluated their analgesic efficacy over the first 12 postoperative hours after gynaecological surgeries , in a randomized, single-blind, clinical trial in 60 Patients divided into two equal groups , 30 patients in each group .

**METHODS:** Sixty Patients were randomized into two equal groups , 30 patients in each group Group I received general anaesthesia in combination with intravenous opioids, Group II received general anaesthesia in combination with thoracic epidural anaesthesia. General anaesthesia was induced with fentanyl 1-2 mcg/kg and propofol 1–3 mg/kg followed by rocuronium 0.6 mg/kg . Each patient was assessed for pulmonary function tests (PFTs) ,pethidine consumption, visual analogue pain scale (VAS) at rest and on movement, vital signs and presence of complications (nausea, vomiting, sedation and pruritis) postoperatively by a blinded investigator in the postanesthesia care unit (PACU) and at 1 , 3, 6, and12h postoperatively.

**RESULTS:** Group II patients showed signiﬁcantly increased postoperative PFTs values compared with group I patients at 1,3 and 6 hours**,**the postoperative analgesia is more effective with group **II** than group **I** , ( Epidural > systemic opioid) and the postoperative consumption of pethidine in epidural group is lower than in opioid group. Asregard complications during the study in all groups , complications as nausea , vomiting , pruritis and sedation were recorded which were more in systemic opioid than epidural .

**CONCLUSION:** Particularly for obese patients, Epidural anesthesia and postoperative epidural analgesia improve the postoperative respiratory function, compared with general anesthesia and systemic analgesia and reduce postoperative pain in obese patients undergoing major gynecological procedures.

**Keywords**:Thoracic epidural , opioids, lung mechanics,obesity, gynecological.

**INTRODUCTION :**

Obesity is becoming a serious problem because its prevalence is increasing and it is well known now that, there is a significant negative correlation between lung mechanics and obesity. The severely obese patients have varying degrees of intrinsic reduction of expiratory flow rates and lung volumes.1 They are predisposed to postoperative atelectasis, ineffective clearing of respiratory secretions, and other pulmonary complications. Abdominal surgeries lead to severe pain that is associated with changes in respiratory mechanics, shallow breathing and impaired ability to cough. Epidural anesthesia for perioperative analgesia would reduce the magnitude of postoperative deterioration in lung function in obese -more than in non obese patients compared with systemic opioid. Despite some controversies, many anaesthetists consider perioperative epidural anaesthesia (EDA) as an important part of a multimodal approach to improving patient outcome and analgesia rather than relying solely on systemic opioid administration.2

**PATIENTS AND METHODS:**

After obtaining approval by the Benha university Hospital Ethics Committee, and written informed consent from the patient, we studied 60 ASA physical status I–II patients scheduled for elective major gynecological surgeries (abdominal hysterectomy, ovarian cyst, ovarian mass and abdominal explorations ) in a randomized, single-blind, clinical trial. We excluded patients who were pregnant , history of relevant drug allergy, Age < 20 years old or > 60 years old,Coagulopathy ,End stage obstructive or restrictive pulmonary disease . Patients were randomly allocated into two equal groups (Group I) (n=30) patients received general anaesthesia in combination with intravenous opioids.

(Group II) (n= 30) patients received general anaesthesia in combination with thoracic epidural anaesthesia.

Randomization was done by online program which used to generate random number list. Patient randomization numbers were concealed in opaque envelops which were opened by the study investigator. The staff providing postoperative care were blinded to group assignment. All Patients were asked to fast 8 hours before operation. Intravenous cannula was inserted and the patients were premedicated with midazolam (0.01-0.02) mg/kg IV (30 minutes) preoperatively while patients lying on semi setting position on oxygen mask.on admission to the operating room, routine monitors were connected and baseline measurements were recorded then an Arterial cannula was inserted in the radial artery of nondominant hand under local anesthesia after doing modified Allen's test .

Technique of thoracic epidural :-

The patient was in the sitting position and supported by an attendant . A standard regional anesthesia tray was prepared with the following equipment:

* Sterile towels and 4"x4" gauze packs
* 20-mL syringes with local anesthetic .
* Sterile gloves, marking pen, and surface electrode
* One 1½" 25-gauge needle for skin infiltration
* An 18 gauge 8 cm epidural needle (Perifix.B.BRAUN Melsungen AG) .

Before induction of general anesthesia epidural block was initiated, the patient was positioned by sitting supported by an attendant on the edge of the operating bed with legs on a stool, leaning forward with arms crossed. Following patient positioning, the skin of the back was prepared with an iodine-containing sterilizing solution. The back was draped in a sterile fashion, as we followed full sterile precautions, including gown, mask and gloves, then the thoracic interspace (T8-T9) or (T9-T10) was identified. Low thoracic approach was chosen to spare block of intercostals muscles and affection of pulmonary functions would be minimized. Mid line approach was chosen (because some of patients were obese and Paramedian approach would be difficult) and a skin wheal of local anesthetic (5ml lidocaine 2%) was produced using a 25 gauge needle atthe midpoint between the two adjacent vertebrae to anesthetize the potential tract of the epidural needle. An 18 gauge Tuohy epidural needle (Perifix.B.BRAUN Melsungen AG)was inserted and directed through the dermis into the interspinous ligament which was verified by firm resistance, at this point, the needle trocar was removed and a glass syringe filled with air was connected, then advancing the needle was done by two handed grip on the syringe and needle with continuous firm pressure on the hub as the needle moves forward, till loss of resistance was elicited. Epidural catheter(B. Braun) was threaded through the needle, the needle was removed and the catheter was adjusted to keep 4 cm in the epidural space. A test dose of 4ml of 2% plain lidocaine with 1:200,00 epinephrine(0.005 mg/ml) was injected to rule out subarachnoid or IV placement of the catheter.At least 15 min before surgery, a loading dose of bupivacaine 0.5%(8ml) and 100µg fentanyl were injected in the epidural catheter and we waited until establishment of analgesia was evidenced by diminished sensation to pin prick. Further bolus injections of bupivacaine 0.5% were sensation to pin prick. Further bolus injections of bupivacaine 0.5% were given according to clinical needs (heart rate, arterial blood pressure, pupil size and sweating). In both groups, general anaesthesia was induced with propofol 2 mg and fentanyl 1-2 µg/kg IV Tracheal intubation was facilitated by rocuronium 0.6 mg/kg iv, Anaesthesia was maintained with Sevofluorane 2% Increments of Esmeron were given to maintain muscle relaxation when ever needed in a dose of (0.5 mg/kg). Analgesia was maintained intraoperativly using Fentanyl and repeated doses were given according to clinical signs (heart rate, arterial blood pressure, pupil size and sweating), but not within one hour of the estimated end of the surgery to achieve rapid recovery. Ventilation was controlled using lean body weight used to calculate a tidal volume of 8-10 ml/kg with a respiratory rate, which avoids excessive hyper- or hypo-capnea (usually 10-14 breaths/minute). neostigmine ( 0.04-0.08)mg/kg together with atropine (0.01-0.02)mg/kg , were given as needed when extubation criteria were found as well as recovery of consciousness (eye opening on demand), protective airway reflexes and adequate spontaneous ventilation.

**Postoperative pain management**:

In group 1:- Basic analgesia was achieved using pethidine(1mg/kg) every 8hr intramuscular to obtain adequate analgesia and pain score 20 mm while coughing

In group II:- Basic analgesia was achieved using a continuous epidural infusion of bupivacaine (0.125%) with fentanyl (2µg/ml) through the epidural catheter and the infusion rate was adjusted to obtain a sensory level of T5 (ranged 5-10 ml/h) and adequate analgesia.

In both groups, If additional analgesia was needed it was achieved by pethedine (0.5mg/kg).Adequate analgesia was defined as pain score less than 20 mm while coughing, which was assessed on the 100 mm visual analogue scale,where zero represented no pain while 100mm indicated the worst possible pain or dyspnea.

**Spirometry**

1. Spirometry was standardized with each patient in a 30 head-up position using an automated flow-sensing spirometer (spirolab ΙΙΙ Ver 4.3,Italy). At the pre-anaesthetic visit, a baseline spirometry measurement was taken based on American Thoracic Society/European Respiratory Society, 2005 recommendations (ATS/ERS) with all subjects in a sitting position. If at all possible, at least three and up to a maximum of eight forced expiratory maneuvers were performed in an effort to meet the American Thoracic Society standards. Spirometric measurements taken were:Vital capacity(VC), Forced Vital Capacity(FVC), Forced Expiratory Volume in 1 second(FEV1),and Peak Expiratory Flow(PEF). Spirometric assessments were repeated at 1,3,6, 12 hours postoperative. As soon as the patients were free from pain during coughing.

**Parameters of assessment:-**

The primary outcome was Pulmonary function tests: Vital capacity(VC), ForcedVital Capacity(FVC), Forced Expiratory Volume in 1 second(FEV1),and Peak Expiratory Flow(PEF), all these parameters were taken preoperative as a base line, 1,3,6 and 12 hours postoperative.

Secondary outcome measures included visual analogue score (VAS) recorded postoperative at 0, 0.5,1,3,6 and 12 hours,total dose of post operative pethidine requirements,and side effects related to narcotics, epidural and major surgical procedures.

Statistical analyses were performed using a standard statistical program (SPSS version 16). Quantitative data was presented as mean ± Standard deviation, Qualitative data was presented as numbers and percentages, Quantitative data was analyzed by using unpaired student t-test, Qualitative data was analyzed by using Chi-square test and Z test, P – Value < 0.05 was considered statistically significant, P – Value < 0.01 was considered statistically highly significant.

**RESULTS:** Sixty patients were entered into the study undergoing elective gynecological surgeries, 30 patients were randomized to receive general anaesthesia in combination with intravenous opioids. 30 patients were randomized to receive general anaesthesia in combination thoracic epidural anaesthesia.

On comparing the two groups as regard demographic data (table 1) shows that there was no significant difference among the two studied groups . In the two groups as regard (Vital Capacity) (table 2) shows that there was statistically insignificant value at preoperative period and statistically significant decrease at (1, 3 and 6hours) postoperatively in the opioid group.

Comparing the two groups as regard FVC (figure 1) show that there was statistically insignificant value at preoperative period and statistically significant decrease at (1, 3 and 6hours) postoperatively in the opioid group. On comparing the two groups as regard (FEV1) (table 3) shows that there was statistically insignificant value preoperatively and statistically significant decrease at (1, 3 and 6hours) postoperatively in the opioid group.

As regard (PEFR) , the two groups (figure2) there was statistically insignificant value preoperatively and statistically significant decrease at (1, 3 and 6hours) postoperatively in the opioid group. On comparing the two groups as regard (post operative analgesic requirements) (table 4) shows that there was statistically significant increase in analgesic requirement in opioid group postoperative.

By comparing the two groups as regard visual analogue score(VAS) (figure 3) show that there was statistically significant decrease at (0, 0.5,1 and 3hours) in the epidural group postoperatively. Also comparing the two groups as regard (Complications) (table 5) shows that there was statistically insignificant value among the two studied groups

**Discussion:**

Obese patients undergoing major abdominal surgeries were anesthetized in the past, by general anesthesia alone in spite of the associated adverse effects of general anesthesia on these already compromised patients. Despite some controversies, many anesthetists consider perioperative epidural anesthesia (EDA) as an important part of the multimodal approach for improving patient outcome and analgesia rather than relying solely on systemic opioid administration. This may be particularly important for obese patients undergoing major surgeries, In our study a comparison was made between the effect of thoracic epidural analgesia and systemic opioids on the perioperative lung mechanics on obese patients undergoing major gynecological procedures and Patients were divided into two equal groups

**group I**: received general anesthesia in combination with intravenous opioids.

**group II:** received general anesthesia in combination with low thoracic epidural anesthesia.

In the present study the results of ***demographic data*** were nearly the same in all groups and are of no significance or concern to our study

In the present study ***pulmonary function tests*** *(VC,FVC,FEV1and PEFR )* were decreased in both epidural and opioid groups from base line data in the whole readings and shifted towards base line at 12 hours, and there was significant decrease in the opioid than the epidural group. The (VC) showed nearly the same values of both epidural and opioid groups preoperatively and a significant decrease in the whole postoperative period (1, 2,3hs) then non significant decrease (6 and12hs) this was the same in (FVC, FEV1, PEFR). The FEV1/FVC was not significally different among the two groups as both FEV1 and FVC decreased. The better effect of thoracic epidural on pulmonary function over the systemic opioid group can be explained by the better postoperative analgesia, decreased incidence of atelectasis compared with systemic opioids also the rapid recovery allowing patients to sigh and cough and due to respiratory depression and a decrease in all respiratory functions caused by systemic opioids. Our study was also in agreement with ***Zerrin and Mert*** who reported that, reduction in functional residual capacity (FRC) after abdominal and thoracic surgeries is a well known change with general anesthesia and adequate analgesia is not only a contributing factor to prevent respiratory complications, but other factors like preservation of diaphragmatic function, early extubation must be considered.

The results were in agreement with ***von Ungern- Stenberg et el*** in a similar study found that, thoracic EDA had less influence on spirometric measurements, even though initiation of EDA may have accounted for some degree of muscle relaxation as shown by changes in dynamic rather than static spirometric measurements of respiratory function. They found that the decrease in FVC and FEV1 after initiation of EDA was mainly attributable to change of position, since baseline measurements performed in the sitting position were compared with subsequent measurements in the supine position. they also reported that, during forced expiration (e.g. spirometry), the principal expiratory muscles are those of the abdominal wall and, to a lesser extent, the internal intercostal muscles so EDA with sensory levels extending from approximately T4 to L1 is likely to be accompanied by some degree of muscle paralysis, even if low concentrations of local anesthetics were used, and is more likely to block the muscles of the abdominal wall (innervation T6–L1) than the diaphragm (C3–C5) or the intercostal muscles (T1–T11). This blockade of abdominal muscles because of lowthoracic EDA is reflected by a reduction of the dynamic parameters PEFR and MEF25–75, which depend more on active exhalation, but is without significant changes in comparatively static spirometric measurements.

In contrast a study done by ***de Leon-Casasola et al*** showed no improvement in pulmonary outcome with the use of TEA by that, however these studies consisted mostly of healthy low-risk patients and did not control postoperative analgesia, and/or lacked sufficient statistical power**.**, Also in the present study, ***VAS*** was significally lower in the epidural group than the opioid group from (0h to 12hs postoperatively) this was also confirmed by *patient satisfaction score* that, showed significally higher values in the epidural groups (45.044 ± 8.9) versus (35.73 ±7.48) in opioid group. This could be explained by the quality of analgesia and the reduced pulmonary functions complications caused superiorly by epidural anesthesia over systemic opioids.

This was in agreement with a systemic review done by ***(Pergialiotis et al.,2016)***who found that Patient controlled epidural analgesia seems to be superior to traditional patient controlled intravenous analgesia during the postoperative management of gynecologic oncology patients They also reported that the need for morphine-equivalents was more frequent among patients of the PCA group and for postoperative days 1 and 2 respectively. This was confirmed by ***Zerrin and Mert*** 2007 who reported that, dynamic analgesia, rapid mobilization and blunted stress response with TEA performed alone or combined with general anesthesia, is not only the method of choice for postoperative analgesia in many operations but also obtains a large number of other, non-analgesic advantageous effects as the synergistic effect of local anesthetic and opioids combination is well known and it provides better analgesia during activity. The use of combination may reduce the dose related adverse effects of either agent alone and Epidural anesthesia is particularly effective at providing dynamic analgesia, early mobilization and rapid functional recovery.

Our results doesn’t go with ***(Moawad and Mokbel 2014)*** who do acomparative study between Fentanyl–bupivacaine patient controlled epidural analgesia versus fentanyl patient controlled intravenous analgesia as Postoperative analgesia after major abdominal surgery, they found that In the first hour postoperatively, the NPRS for pain score in PCIA group was significantly less than pain score in PCEA group because of the rapid onset of intravenous fentanyl than epidural fentanyl–bupivacaine combination. There are two possible explanations for this. The peak effect of intravenous fentanyl occurs 2–5 min after intravenous bolus administration, whereas the analgesic onset of fentanyl after epidural administration is delayed for 10–20 min . This delay may be explained by the time taken for fentanyl to traverse the dura and cerebrospinal fluid and bind to opiate receptors in the neuraxis of the spinal cord. An alternative explanation may be the analgesic effects of epidural fentanyl appear largely mediated by systemic absorption.

As regard*,* ***The total post operative analgesic requirement,*** *the total analgesic requirement* postoperatively was (197 ±24.5 mg) in opioid group versus (60.12 ±16.2 mg) in epidural group for the whole(12hs) postoperatively and this because of the effectiveness of thoracic epidural anesthesia on pain relieve so there was no need of extra added opioid analgesia so, the consumption was lower. In our study only two patients of the epidural group needed extra added systemic opioids.

This was in agreement with ***(Von Ungern- Stenberg et al.,2005)***who did a study on 84 patients having midline laparotomy they were divided into two equal groups one received TEA and the other received systemic opioids they found that, there was a significant difference between the two groups as regard intraoperative analgesics. As the fentanyl dose was (300µg) in the epidural group versus (600µg) in the opioid group and postoperative analgesic requirement was (3.6mg) versus (0.7mg) in the epidural group.

In our study, ***side effects*** were not significant among both epidural and opioid groups. This is due to the fact that both groups received opioids whether epidurally or systemically. This is in agreement with ***Parris*** in a similar study comparing epidural and systemic opioids.In our study ***vomiting*** was (7) in the opioid versus (3) in the epidural group. ***Pruritis*** was (5) in the opioid versus (2) in the epidural group. ***Sedation*** was (2) in the opioid versus (0) in the epidural group. This is due to the fact that, both groups received opioids whether intravenously or epidurally but the effect of opioids was more but not significantly evident in the systemic opioid group.

**Limitations of our study** are one of the possible shortcomings of our study; the study did not include a placebo control group and the study limited assessment of postoperative analgesia to the first 12 postoperative hours.

**We conclude** that obesity is an important risk factor for perioperative impairment of spirometric measurements in patients undergoing major gynecological surgeries. the severity of postoperative lung volume reduction measured by spirometry was reduced by the presence of EDA and postoperative restoration of lung volumes was signiﬁcantly quicker. So we recommend that, whenever possible epidural analgesic techniques should be adopted in the obese patients particularly if undergoing major abdominal surgeries to improve postoperative pulmonary functions.

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