



THE COMPARATIVE ANALYSIS OF EPIDURAL ANALGESIA VERSUS INTRAMUSCULAR DICLOFENAC SODIUM ON POST-OPERATIVE RESPIRATORY FUNCTION AFTER NON-LAPAROSCOPIC ABDOMINAL SURGERY

Anaesthesiology

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ABSTRACT

Context: Patients undergoing non-laparoscopic abdominal surgery have impaired respiratory function postoperatively resulting in increased postoperative pulmonary complications.

Aims: To evaluate respiratory function postoperatively with epidural analgesia versus intramuscular diclofenac sodium for postoperative pain relief in patients undergoing non-laparoscopic abdominal surgery.

Material and Methods: Patients who underwent non-laparoscopic abdominal surgeries, were divided randomly into two groups - Group 1 (n = 30): receiving general anaesthesia (GA) with lumbar epidural analgesia for postoperative analgesia and Group 2 (n = 30): receiving GA with intermittent intramuscular diclofenac sodium for postoperative analgesia. Pulmonary Function tests (PFTs) were performed preoperatively and at 04 hours, 12 hours and 24 hours postoperatively and recordings analysed.

Results: There was a decrease in PFTs postoperatively in both Group A and Group B compared to preoperative values. The Vital Capacity (VC) measured after 04 hours, 12 hours and 24 hours in Group A was 2.38+/-0.47, 2.30+/-0.49 and 2.40+/-0.49 liters respectively and in Group B was 1.96+/-0.40, 1.92+/-0.41 and 1.99+/-0.41 liters respectively (P < 0.05). The PEFr measured after 04 hours, 12 hours and 24 hours in Group A was 3.21+/-0.67, 3.13+/-0.67 and 3.23+/-0.67 liters/sec respectively and in Group B was 2.76+/-0.68, 2.73+/-0.69 and 2.78+/-0.70 liters/sec respectively (P < 0.05).

Conclusions: Administration of epidural analgesia as compared to intramuscular NSAIDs for postoperative analgesia helps to preserve respiratory function better after non-laparoscopic abdominal surgeries.

KEYWORDS

Pulmonary Function Tests, Epidural Analgesia, Non Steroidal Anti-inflammatory Drugs

INTRODUCTION

Post-operative pain, apart from the psychological trauma, affects the physiology of the respiratory system, cardiovascular system as well as the neuroendocrine system. Patients undergoing upper abdominal and thoracic surgical procedures show marked ventilatory compromise after surgery resulting in increased respiratory rate, increased post operative hypoxemia and decreased tidal volume (TV), vital capacity (VC), Forced Expiratory Volume in first second (FEV1) and Forced Vital Capacity (FVC) and peak expiratory flow rate (PEFR). This has been rationalized as pain related neural reflex producing increased tone in abdominal muscles during expiration.^[1] This marked ventilatory compromise due to post-operative pain increases the incidence of post-operative pulmonary complications, which are a major cause of morbidity and mortality in the post-operative period. Despite advances in technology and availability of various drugs, techniques for post-operative analgesia, which favorably improve post operative respiratory function, continues to evolve.

Intramuscular Non-steroidal anti-inflammatory drugs (NSAID) like diclofenac sodium has been routinely used in the management of post-operative pain. This has the benefit of producing acceptable analgesic and anti-inflammatory action, and is devoid of the adverse effect of opioids such as respiratory depression. Epidural analgesia (EA) has gained widespread acceptance for providing postoperative pain relief. Various studies have shown epidural analgesia to be superior for postoperative analgesia as compared to intramuscular opioids or NSAIDs.^[2] EA may be superior mode of pain relief, but being more invasive procedure, requires superior technical expertise. If the procedure has not been carried out with due diligence, likely to have wide range of complications ranging from mild to life threatening such as post-dural puncture headache, nerve compression, cord compression, total spinal anaesthesia and haemodynamic derangement etc. The fear of complication limits widespread use in our country. However, newer, evidencebased outcome data show that the benefits of epidural analgesia are not as significant as previously believed. There are some benefits in a decrease in the incidence of cardiovascular and pulmonary complications, but these benefits are

probably limited to highrisk patients undergoing major abdominal or thoracic surgery who receive thoracic epidural analgesia with local anaesthetic drugs only.^[3]

In this study, two techniques of post operative analgesia were compared in patients undergoing non-laparoscopic abdominal surgery for their beneficial effect on post-operative respiratory function. Post-operative respiratory function was evaluated preoperatively as well as postoperatively using Pulmonary Function Tests (PFT) with a spirometer, after either epidural analgesia or intramuscular diclofenac sodium, for postoperative analgesia, after non-laparoscopic abdominal surgery.

MATERIAL & METHODS

Patients in the age group of 18 years to 60 years of both sexes and in ASA I or II, scheduled for non-laparoscopic major abdominal surgeries without extensive surgical incision such as hysterectomies, appendicectomies, epigastric hernias and open cholecystectomies were included in the study. Permission of the hospital ethical committee was taken for this prospective, open labeled, interventional comparative study and informed consent was taken from the patients included in the study. Patients with deformity of the spine, abnormalities of chest wall, coagulation abnormalities and sepsis were excluded from the study.

Pre-operative PFT assessment was done in all patients in a 30 degree head up position with Schiller SP1™ (Schiller India) spirometer. After a detailed demonstration of the correct use of the spirometer, the patient's VC, FVC, FEV1 and PEFr was recorded. Three PFTs were performed in each patient and the best-recorded measurements were used for analysis. Sixty patients undergoing non-laparoscopic major abdominal surgery were randomly allocated into two groups of thirty each. All patients were randomly divided into two groups by drawing any one of the two labeled cards (Groups A and B) from a sealed opaque envelope. Patients in Group A were given epidural analgesic for post-operative pain relief. Patients in Group B were given intramuscular sodium diclofenac for post-operative pain relief.

All patients were premedicated with Glycopyrrolate 0.2 mg IV, Midazolam 1mg IV, Morphine 0.1 mg/kg IV and Ondansetron 4 mg IV. Patients in Group A were then placed in left lateral position and under aseptic precautions 18 G Touhy needle was inserted into L3-4 or L2-3 epidural space using loss of resistance technique to air. A 20G epidural catheter was inserted into the epidural space 5 cm beyond the needle tip and was fixed to the skin. A test dose of 0.3 ml of 2% Lignocaine with Adrenaline was then administered and intravascular placement and subarachnoid placement of epidural catheter tip was ruled out. The patients were then administered general anesthesia (GA). Induction of anesthesia was carried out with Thiopentone sodium 5 mg/kg IV and trachea was intubated with use of muscle relaxant Atracurium at 0.5 mg/kg. Vital parameter monitoring was carried out with electrocardiography, non-invasive blood pressure, pulse oximetry and end-tidal capnography. Anaesthesia was maintained with inhalational anaesthetic agents and intermittent administration of non-depolarizing muscle relaxants.

Duration of surgeries ranged from approximately from 60 minutes to 180 minutes, and patients were maintained on inhalational agent Sevoflurane and intermittent muscle relaxation with Atracurium 0.1 mg/kg. Towards the end of surgery, during closure of the peritoneum of patients in Group A, a total of 15 ml of 0.25% bupivacaine with 50 g fentanyl was injected, in repeated boluses of 5 ml, into the epidural catheter, after confirming negative aspiration of cerebrospinal fluid or blood and watching for hemodynamic instability. This was repeated every 12 hourly in the post-operative period, in boluses of 5 ml and watching for hemodynamic instability. In patients in Group B, 75 mg diclofenac sodium was given intramuscularly at the same time period of closure of peritoneum and was repeated every 8 hourly in the post-operative period.

On completion of surgery, neuromuscular blockade was reversed with neostigmine and trachea was extubated. The patients were shifted to the post-operative ward for further monitoring. PFT recordings were repeated at 4 hours, 12 hours and 24 hours post-operatively. Post-operatively, all patients were monitored for adequate analgesia and were administered Paracetamol 1 gm IV as a rescue analgesic if the patient complained of pain and the Visual Analogue Scale (VAS) for pain was more than 4.

Adequate hydration was provided during intra-operatively and post operatively in all the patients. There was marginal transient decrease of blood pressure (mean arterial pressure 60 to 70 mm Hg) in 9 of the 30 patients of group one, which was managed with intermittent doses of vasopressors such as phenylephrine or ephedrine. In two patients, intraoperative and post operative epidural analgesia were abandoned, because in one case the epidural catheter was found to be blocked and in the other, there was intravenous migration of catheter tip, diagnosed by aspiration of blood. Both the cases were excluded from the study and pain relief was achieved with intramuscular diclofenac sodium. Two extra cases were recruited to achieve the sample size of 30 in Group A.

STATISTICAL ANALYSIS:

Data was analysed using SPSS Version 20 statistical software package, chi square tests were applied for categorical variables. Data are expressed in terms of mean \pm SD. *P* value was reported at the 95% confidence interval and *P* value less than 0.05 was considered significant. G*Power 3.1 free-to-use software was used for sample size calculation. Sample size was calculated based on literature search for variation in studied data. The sample size was calculated using difference in means of PEFR at 48 hours postoperatively of 57.1 L/min and difference in Standard Deviation of 7.3 L/min.^[4] With an alpha error at 5% and power at 80%, the required sample size was 25 per group, and 30 patients per group were included in the study.

RESULTS

Demographic profiles of patients such as age, sex, and height distribution were similar in the two groups. The mean weight in kgs in Group A was 68.23 \pm 2.25 and in Group B was 55.03 \pm 3.07, which was significantly different in the two groups [Table 1] The VC was measured at 04 hours, 12 hours and 24 hours postoperatively and compared to the preoperative values. In both Group A and Group B, there was a fall in the VC post operatively as measured at 04 hours, 12 hours and 24 hours as compared to the pre-operative values. The VC preoperatively in Group A was 3.49 \pm 0.68 liters and the VC preoperatively in Group B was 3.57 \pm 0.69 liters. The VC measured

after 04 hours, 12 hours and 24 hours in Group A were 2.38 \pm 0.47, 2.30 \pm 0.49 and 2.40 \pm 0.49 liters respectively. The VC measured after 04 hours, 12 hours and 24 hours in Group B were 1.96 \pm 0.40, 1.92 \pm 0.41 and 1.99 \pm 0.41 liters respectively. There was no significant difference in preoperative VC between the two groups (*P* =0.687). However, there was a significant difference in post-operative VC between patients of Group A and Group B at 04 hours, 12 hours and at 24 hours (*P* <0.05) [Table 2].

The FVC was measured at 04 hours, 12 hours and 24 hours postoperatively and compared to the preoperative values. The FVC preoperatively in Group A was 3.06 \pm 0.58 liters and in Group B was 3.13 \pm 0.61 liters. The FVC measured after 04 hours, 12 hours and 24 hours in Group A were 2.05 \pm 0.30, 1.99 \pm 0.41 and 2.07 \pm 0.42 liters respectively. The FVC measured after 04 hours, 12 hours and 24 hours in Group B were 1.72 \pm 0.34, 1.69 \pm 0.34 and 1.73 \pm 0.34 liters respectively. There was no significant difference in preoperative FVC between the two groups (*P* =0.682). However, there was a significant difference in post-operative FVC between patients of Group A and Group B at 04 hours, 12 hours and at 24 hours (*P* <0.05) [Table 3].

The FEV1 preoperatively in Group A was 2.40 \pm 0.44 liters and in Group B was 2.50 \pm 0.51 liters. The FEV1 measured after 04 hours, 12 hours and 24 hours in Group A were 1.54 \pm 0.30, 1.49 \pm 0.32 and 1.56 \pm 0.32 liters respectively. The FEV1 measured after 04 hours, 12 hours and 24 hours in Group B were 1.37 \pm 0.30, 1.35 \pm 0.31 and 1.39 \pm 0.31 liters respectively. There was no significant difference in preoperative FEV1 between the two groups (*P* =0.399). However, there was a significant difference in post-operative FEV1 between patients of Group A and Group B at 04 hours, 12 hours and at 24 hours (*P* <0.05) [Table 4].

The PEFR preoperatively in Group A was 4.90 \pm 0.97 liters/sec and in Group B was 5.35 \pm 1.22 liters/sec. The PEFR measured after 04 hours, 12 hours and 24 hours in Group A were 3.21 \pm 0.67, 3.13 \pm 0.67 and 3.23 \pm 0.67 liters/sec respectively. The PEFR measured after 04 hours, 12 hours and 24 hours in Group B were 2.76 \pm 0.68, 2.73 \pm 0.69 and 2.78 \pm 0.70 liters/sec respectively. There was no significant difference in preoperative PEFR between the two groups (*P* =0.114). However, there was a significant difference in post-operative PEFR between patients of Group A and Group B at 04 hours, 12 hours and at 24 hours (*P* <0.05) [Table 5].

DISCUSSION

Surgical incision in non-laparoscopic abdominal surgeries, GA and EA independently affect respiratory function in the post-operative period.^[5] Abdominal surgery and surgical incision has a detrimental effect on respiratory function by functional disruption of inter-costal or abdominal muscles, thus impairing their effectiveness during respiration. Surgical incision also has a detrimental effect on respiratory function because of postoperative pain, which may cause voluntary limitation of chest expansion.

Epidural analgesia, apart from providing postoperative pain relief, affects the respiratory system in several ways. The associated motor blockade due to epidural local anaesthetic drugs can hinder the inspiratory expansion resulting in likely decrease in the functional residual capacity (FRC).^[6] However, in a meta-analysis, neuraxial blockade was found to be beneficial in terms of reducing overall mortality, pneumonia and respiratory failure in comparison to GA.^[7] In another study, patients undergoing gastroplasty for weight reduction were compared for the effects of intramuscular and epidural morphine given for post-operative pain relief. There was a lower incidence of post-operative pulmonary complication in patient receiving epidural morphine (13%) as compared to patients receiving intramuscular morphine (40%).^[8]

NSAIDs are a class of heterogeneous drugs with analgesic, anti-inflammatory properties with mechanism of action by inhibition of prostaglandin synthesis. Administration of intramuscular NSAIDs such as diclofenac sodium intra-operatively for post-operative pain relief is not known to have any adverse effect on respiratory function by its central action or by action on respiratory muscles.^[9] Though diclofenac sodium has potential for adverse effects such as gastrointestinal mucosal damage and renal tubular and platelet dysfunction, it is an effective post operative analgesic for non-laparoscopic abdominal surgeries.^[10]

In the study, baseline PFT values were determined, before patient was taken for administration of anaesthesia and surgical procedure. There was no significant difference in baseline PFTs in the two groups, in spite of the significant difference in mean weight in kgs in the two groups. This may be attributed to comparable lean body weight of patients in the two groups, resulting in similar baseline PFTs. However there was a significant difference in spirometry recordings were repeated at 4 hours, 12 hours and 24 hours postoperatively to determine the changes in respiratory function among two groups of patients who were undergoing non-laparoscopic abdominal surgeries under GA. There was a decrease in VC, FVC, FEV1 and PEFR postoperatively in both the groups but the decrease in PFTs in diclofenac group was much more as compared to epidural analgesia group, and this difference was statistically significant.

In spite of studies showing that lumbar epidural analgesia is associated with some degree of muscle weakness due to blockade of motor nerves supplying lower abdominal muscles (T_{10} - L_1), there was consistent improvement of respiratory function in comparison to intramuscular administration of diclofenac sodium. All the parameters of post-operative respiratory function such as VC, FVC, FEV1 and PEFR remained significantly below the pre-operative level in both the groups, but there was consistent significant improvement of respiratory function post-operatively in epidural group in comparison to intramuscular diclofenac sodium group. Though there is likely chance of blockade of lower abdominal muscles (T_{10} - L_1), the improved respiratory function can be explained by the sparing of diaphragm muscle (C_3 - C_5) and intercostal muscles (T_1 - T_{10}) in lumbar EA. Blockade of abdominal muscles allows, comparative free movement of diaphragm with less resistance for movement, contributing to better respiratory function parameters in comparison to diclofenac group.

Dynamic respiratory function parameters such as FVC, FEV1 and PEFR depend upon forceful exhalation, with expiratory effort likely to be adversely influenced by weakness of expiratory muscles due to epidural analgesia. The improved dynamic respiratory parameters in epidural analgesia seen in our study in comparison to diclofenac can only be explained due to effective pain relief, which overrides any muscle weakness.

CONCLUSION

The post-operative respiratory function is adversely affected following non-laparoscopic abdominal surgery under GA, irrespective of techniques used for postoperative analgesia. There is better preservation of respiratory function (VC, FVC, FEV1 and PEFR) post-operatively, when lumbar epidural analgesia is used in comparison to intramuscular diclofenac sodium for postoperative pain relief. Thus, it can be concluded that administration of epidural analgesia as compared to intramuscular NSAIDs for postoperative pain relief helps to preserve respiratory function better and minimizes post-operative pulmonary complications after non-laparoscopic abdominal surgeries.

Table 1 : Demographic profile

Characteristics	Group A Mean +/- SD	Group B Mean +/- SD	'P' Value
Age (in years)	45.37+/-15.27	38.53+/-14.33	0.078
Weight (in kgs)	68.23+/-2.25	55.03+/-3.07	0.782
Height (in cms)	165.07+/-7.84	164.50+/-08.07	0.001
Male	23 (76.6%)	22 (73.3%)	-
Female	07 (23.3%)	08 (26.6%)	-

Table 2 : Comparison of Vital Capacity (in Liters)

	Group A Mean +/- SD	Group B Mean +/- SD	't' value	'P' Value
Pre-operative	3.49+/-0.68	3.57+/-0.69	-0.405	0.687
At 04 Hours	2.38+/-0.47	1.96+/-0.40	3.734	0.001
At 12 Hours	2.30+/-0.49	1.92+/-0.41	3.184	0.002
At 24 Hours	2.40+/-0.49	1.99+/-0.41	3.524	0.001

Table 3: Comparison of FVC (in Liters)

	Group A Mean +/- SD	Group B Mean +/- SD	't' value	'p' Value
Pre-operative	3.06+/-0.58	3.13+/-0.61	-0.411	0.682
At 04 Hours	2.05+/-0.30	1.72+/-0.34	3.422	0.001
At 12 Hours	1.99+/-0.41	1.69+/-0.34	3.343	0.004
At 24 Hours	2.07+/-0.42	1.73+/-0.34	3.322	0.001

Table 4 : Comparison of FEV1 (in Liters)

	Group A Mean +/- SD	Group B Mean +/- SD	't' value	'p' Value
Pre-operative	2.40+/-0.44	2.50+/-0.51	-0.850	0.399
At 04 Hours	1.54+/-0.30	1.37+/-0.30	2.209	0.031
At 12 Hours	1.49+/-0.32	1.35+/-0.31	2.174	0.041
At 24 Hours	1.56+/-0.32	1.39+/-0.31	2.045	0.045

Table 5 : Comparison of PEFR (In Liters/sec)

	Group A Mean +/- SD	Group B Mean +/- SD	't' value	'p' Value
Pre-operative	4.90+/-0.97	5.35+/-1.22	-1.603	0.114
At 04 Hours	3.21+/-0.67	2.76+/-0.68	2.566	0.013
At 12 Hours	3.13+/-0.67	2.73+/-0.69	2.280	0.026
At 24 Hours	3.23+/-0.67	2.78+/-0.70	2.556	0.013

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