Original Research Article

Comparison between Patient-Controlled Epidural Analgesia and Continuous Epidural Infusion for Pain Relief after Gynaecological Surgery

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Abstract

This prospective, randomised study compared the effectiveness of patient controlled epidural analgesia (PCEA) versus continuous epidural infusion (CEI) in providing pain relief post gynaecological surgery. Sixty six ASA I or II patients planned for gynaecological surgery via Pfannensteil incision under combined spinal epidural anaesthesia were recruited. They were randomised into two groups: Group A patients received PCEA while Group B patients received CEI. In the recovery area, both groups received an epidural combination of levobupivacaine 0.1% and fentanyl 2 µg/ml. Group A patients were allowed demand bolus doses of 5 ml with a 20 minute lockout interval, while Group B patients had their epidural infusion initiated at 6 ml/hour with increments as required to a maximum of 12 ml/hour. Pain score and degree of motor blockade was assessed hourly in the first four hours and subsequently at four hourly intervals. Side effects were recorded at four-hourly interval. The total amount of analgesia, number of anaesthetic interventions and patient satisfaction was assessed 24 hours, postoperatively. There was no significant difference in pain score, total amount of analgesia, number of anaesthetic interventions and patient satisfaction. The degree of motor blockade and side effects were comparable between the groups. In conclusion, PCEA was comparable to CEI for pain relief after gynaecological surgery.

Keywords: Patient controlled analgesia, epidural analgesia, postoperative pain, pain relief, gynaecological surgery

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Introduction

Epidural techniques were first introduced in the 1980's (1). It is popular for labour analgesia and a commonly used, safe and effective technique of providing pain relief after thoracic, major abdominal, orthopaedic and paediatric surgery (2,3,4,5,6). Potential life-threatening postoperative complications may be the result of serious psychological effects and distress caused by unrelieved postoperative pain. Studies have shown that postoperative analgesia using an epidural infusion provided excellent pain relief without the side effects associated with parenteral administration of opioids (1,4,5,6).

Drugs administered via an epidural catheter may be given via intermittent epidural bolus doses by trained personnel, continuous epidural infusion (CEI), delivered by an infusion pump or via patient-controlled epidural analgesia (PCEA) with or without a background infusion (3). PCEA enables the patient to titrate the analgesic agent according to their requirement, while minimizing medication-related side-effects (2). It results in the use of lower amounts

of drugs and less anaesthetic intervention, while giving greater patient satisfaction and analgesia comparable to CEI for a variety of surgical procedures (7). In addition to the quality of analgesia, the lower total dose of local anaesthetic in patients on PCEA resulted in less motor block (7,8).The lower anaesthetic dose however did not consistently minimize side effects such as hypotension, nausea, vomiting or pruritus (2). Most of the studies comparing different epidural administration techniques and dosages focussed on labour analgesia and other types of abdominal surgery but there are paucity of studies on gynaecological surgery (5,9). Thus, the present study was carried out to compare PCEA and CEI in terms of adequacy of pain relief in patients undergoing gynaecological surgery.

Materials and Methods

This prospective, randomised study carried out following institutional ethics approval. Sixty-six ASA I or II women aged between 18-75 years, planned for elective gynaecological surgery via Pfannenstiel's incision, under combined spinal-epidural (CSE) anaesthesia were recruited. Patients with cognitive impairment or documented psychologic impairment, history of allergy or contraindications to any of the study medications, or to central neuraxial block were excluded.

During the preoperative visit, patients were assessed and offered the CSE technique for intraoperative anaesthesia and postoperative pain relief. Written informed consent was obtained and they were randomised into two groups using computer generated random numbers, where Group A patients received PCEA and Group B patients received CEI. Patients in Group A were taught on the use of PCEA and both groups were briefed on the pain score using the verbal numerical rating scale (VNRS) ranging from 0 to 10, (0 = no pain, 1 to 4 = mild, 5 to 6 = moderate, 7 to 10 = severe pain). Pain scores were assessed with patients at rest. All patients were fasted for at least 8 hours prior to surgery and premedicated with oral midazolam 3.75 mg or 7.5 mg based on age and body weight on the night before and when called to the operation theatre.

In the operating theatre, an IV drip was established. Baseline electrocardiograph (ECG), non invasive blood pressure (NIBP) and pulse oximetry (SpO_2) were documented and subsequently monitored at regular intervals. The L3-4 or L4-5 intervertebral space was identified and the skin was infiltrated with 3 to 5 ml of lignocaine 2%. CSE was performed under aseptic technique using the loss of resistance technique to saline. Two and half millilitre of heavy bupivacaine 0.5% with fentanyl 25 µg (total volume of 3 ml) was given intrathecally. The epidural catheter was placed 3-5 cm in the epidural space and the level of blockade was assessed for adequacy of surgical anaesthesia. Intraoperatively, bolus doses of 3-5 ml of levobupivacaine 0.5% and fentanyl 5 µg/ml were given (up to a maximum levobupivacaine dose of 3 mg/kg body weight over 4 hours) as necessary.

In the recovery area, Group A patients received PCEA levobupivacaine 0.1% and fentanyl 2 µg/ml, with a demand dose of 5 ml and a lockout interval of 20 minutes, without background infusion delivered via the Omnifuse™ PCA (Smiths Medical MD, Inc.) syringe pump. Group B patients received CEI consisting of levobupivacaine 0.1% and fentanyl 2 µg/ml commenced at 6 ml/hour via the Perfusor™ (B. Braun, USA) syringe pump. Pain score, motor blockade (using the Modified Bromage Score where 0 = no motor block, 1= unable to raise straight leg, 2 = unable to flex knee, 3 = unable to flex ankle) and side effects such as pruritus, nausea and vomiting were assessed and documented by the attending nurse after a 30 minute stay in the recovery area postoperatively (time 0). In case of inadequate pain relief, rescue analgesia was given accordingly. In Group A patients, 5 ml of epidural bolus (levobupivacaine 0.1% and fentanyl 2 µg/ml) was given for moderate pain. The maximum volume of epidural bolus allowed was 20 ml per hour. For Group B patients, 5 ml of epidural bolus (levobupivacaine 0.1% and fentanyl 2 µg/ml) was given and the infusion rate was increased by 2 ml to a maximum of 12 ml per hour for moderate pain. In both groups, if these measures had been implemented and failed, IV pethidine 50 mg was administered as rescue treatment. Nausea and vomiting was treated accordingly. IV metoclopramide 10 mg was administered if the nausea score was 2 and above (0 = no nausea, 1 = no nausea at rest, mild nausea on movement, 2 = intermittent nausea at rest, moderate nausea on movement, 3 = continuous nausea at rest, severe nausea on movement) and IV granisetron 1 mg was administered if there was any episode of vomiting.

In the ward, pain and degree of motor blockade were assessed by the ward nurses; hourly for the first four hours followed by four hourly intervals, up to 24 hours postoperatively. Oral tablet etoricoxib 120 mg daily was prescribed 8 hours postoperatively for both groups in addition to the epidural analgesic. The patients were monitored at four hourly intervals for side effects such as pruritus, nausea and vomiting and treated as per standard protocol. If there was no alleviation of pain after anaesthetic intervention, or the occurrence of side effects due to the epidural warranted discontinuation of the postoperative analgesic technique, the epidural

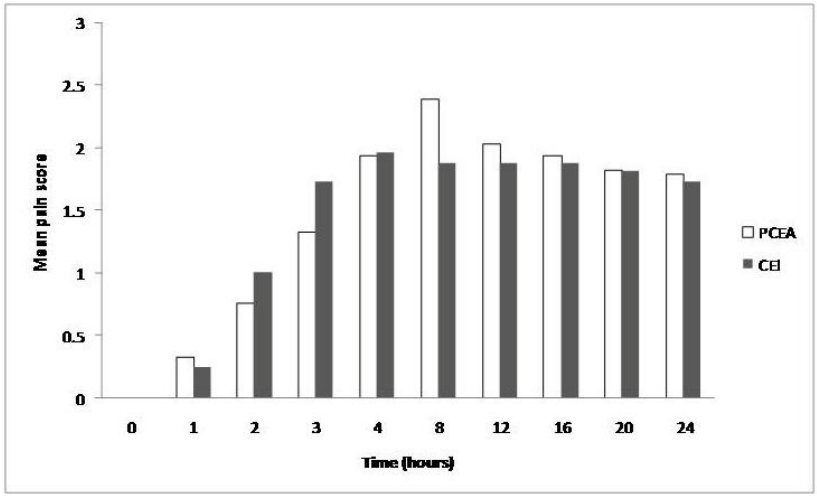

Figure 1: Mean pain score over twenty four hours postoperatively.

catheter was removed and other modes of analgesia was implemented. At the end of the study, total analgesic requirement, number of anaesthetic interventions and patient satisfaction were assessed. Based on a study by Collis et al. (1999) (10), 33 patients were required in each group to obtain a study power of 0.9 with an α-value of 0.05, taking into consideration a 20% drop-out rate. Statistical analysis was done using the IBM Statistical Package for Social Science statistics 19^{TM} (SPSS, Chicago, IL). The general linear model was used for analysis of VNRS. Chi-square was used to analyse categorical data such as race, ASA status, type of procedure and patients' satisfaction, while t-test was used for age and amount of analgesic used. A p-value of less than 0.05 was considered to be statistically significant.

Results

Sixty six women were recruited for this study. There were no statistical differences with respect to age, weight, race, ASA status and surgical procedure in both groups as showed in Table 1.

The bar graph (Fig. 1) showed no statistical difference in mean pain scores ($p > 0.05$) in both groups at each study interval. All the patients had only mild pain over the 24 hour postoperative period.

The total analgesic required over 24 hours was greater, though not statistically significant in Group B (Table 2). Generally, all patients were satisfied with the APS technique that they received and would recommend it to others.

Eight patients (24.2%) in Group A and seven patients (21.1%) in Group B required rescue analgesia (Table 3).

Table 1: Demographic data and types of procedures. Values are expressed as mean ± SD, or number (percentage) where appropriate.

	Group A (N=33)	**Group B (N=33)**
Race		
Malay	22 (66.7)	24 (72.7)
Chinese	8 (24.2)	8 (24.3)
Indian	2 (6.1)	1 (3.0)
Others	1 (3.0)	0 (0)
ASA		
I	25 (75.8)	26 (78.8)
II	8 (24.2)	7 (21.2)
Age (years)	43.0 ± 9.1	38.7 ± 12.0
Weight (kg)	59.2 ± 14.9	58.0 ± 11.7
Procedure		
Myomectomy	9 (27.3)	10 (30.3)
Hysterectomy	16 (48.5)	10 (30.3)
Cystectomy	5 (15.2)	11 (33.3)
Evisceration	3 (9.0)	2 (6.1)

None of the patients required more than two anaesthestic interventions. In the first hour postoperatively, none of the patients from either group required rescue analgesia. Majority of patients, seven from each group, required rescue analgesia between 4 to 6 hours, postoperatively. None of the patients in Group A and B required rescue analgesia after 18 and 8 hours, respectively.

All patients had complete motor block at time 0 in the recovery area. At the 8th hour of assessment, all patients in Group B had complete motor recovery and this was seen at the 12th hour for all patients in Group A (Table 4). The difference in Bromage scores between

Table 2: Total analgesic required within 24 hours postoperative and patient satisfaction. Values expressed as mean ± SD or number (percentage), where appropriate.

	Group A (N=33)	Group B (N=33)	p Value
Total analgesic required (ml)	156.3 ± 51.6	170.9 ± 30.1	0.164
Patient satisfaction excellent/good/ satisfactory/not satisfactory	3/26/4/0	6/27/0/0	0.078
Recommendation to others	33 (100)	33 (100)	

Table 3: Frequency of rescue analgesia over 24 hours postoperatively. Values expressed as number (percentage).

No. of Rescue	Group A (N=33)	Group B (N=33)	p value
0	25 (75.8)	26 (78.9)	0.922
1	4 (12.1)	4 (12.1)	
2	4 (12.1)	3 (9.0)	
3	0	0	
> 3	0	0	

the two groups was not statistically significant at all points of assessment.

The incidence of pruritus observed within the 24-hour postoperative period was higher but not statistically significant in Group B patients (21.2%) as compared to Group A patients (9.1%). In contrast, the incidence of nausea was higher in Group A (45.4%) as compared to Group B (12.1%). However, this was also not statistically significant. None of the patients in Group B vomited while 12.1% of patients in Group A had vomiting. All patients who experienced vomiting, received treatment with IV granisetron 1 mg.

Discussion

Epidural analgesia is a well established technique for postoperative pain management (11).Various ways of epidural drug administration with a variety of drug combination regimes have come into practice. The best regime should be that which is most effective in terms of analgesic quality and cost, with the least possible side effects.

This study demonstrated that both PCEA and CEI provided efficient postoperative pain relief (mean pain score ≤ 2) without significant side effects. There was no significant difference in pain scores between both groups and this was consistent with that found in Standl's study (2003) in patients post median laparotomy for gynaecological surgery (5). Similarly, Ferrante et al. (1994) studied four regimes of epidural labour analgesia; CEI, PCEA, PCEA + 3 ml/hour background infusion and PCEA + 6 ml/hour background infusion and found that all four regimes resulted in comparable pain scores (12). However, the presence of a background infusion has shown inconsistent results. A study by Nightingale et al. (2007) in patients post colonic resection, reported lower pain scores in PCEA with background infusion compared to CEI (9). This difference between Ferrante's and Nightingale's studies may be attributed to the use of different concentrations and varying infusion rates of bupivacaine and fentanyl, and the different patient population studied. We found that there was no significant difference between the groups in terms of amount of analgesia used after 24 hours, number of anaesthetic interventions and patient satisfaction. However, Standl et al. reported a lower total analgesic amount used in the PCEA group but no difference in the requirement of intravenous rescue medication (5). In our study, the continuous infusion was started at a lower rate (6 ml/hour) and titrated to demand as compared to Standl's fixed rate of 10 ml/hour, for comparable age groups in both studies. The higher infusion rate used in Standl's study may have resulted in the significant difference between the two groups in terms of total analgesic dose.

There are not many studies which compare PCEA without background infusion and CEI for postoperative pain relief. Most incorporate a background infusion to the PCEA regime. Ferrante's study in epidural labour analgesia found that the PCEA groups, with or without background infusion, required significantly lower amounts of bupivacaine compared to the CEI group (12). Nightingale's study in post colonic resection patients also found higher cumulative analgesic and number of epidural interventions in the CEI group compared with that in the group with PCEA with background infusion (9). Additionally, patients in the PCEA group were more satisfied with the technique of postoperative pain relief than those in the CEI group.

The modified Bromage score was used to assess the degree of motor blockade in our study. Postoperative motor blockade in our study was possibly due to the residual effects of CSE anaesthesia. Although the CEI group regained full motor function as early as 8 hours postoperatively, the difference between the groups was not statistically significant. All patients regained full motor function at the 12th hour of assessment. Ferrante who also graded motor function using the

Table 4: Modified Bromage Score

	Time (Hours)	Group A (N = 33)	Group B (N = 33)	p value
Modified Bromage Score 0/1/2/3	0	0/0/0/33	0/0/0/33	0.170
	1	0/2/3/28	0/2/2/27	
	2	2/12/5/14	2/17/6/8	
	3	12/9/6/6	16/11/3/3	
	4	22/6/3/2	25/6/0/2	
	8	31/2/0/0	33/0/0/0	
	12	33/0/0/0	33/0/0/0	
	16	33/0/0/0	33/0/0/0	
	20	33/0/0/0	33/0/0/0	
	24	33/0/0/0	33/0/0/0	

Bromage score found that none of the patients had Grade 3 motor blockade and there was no statistical difference amongst the study groups (12). In our study, Grade 3 motor blockades in patients was most probably due to the spinal component of the CSE which produced denser motor blockade compared to that in Ferrante's study in which the patients were given epidural analgesia alone.

The incidence of pruritus, nausea and vomiting was 9.1%, 45.4% and 12.1% respectively in the PCEA group while the CEI group on other hand recorded incidences of 21.1%, 12.2% and 0%, respectively. However, these differences between the groups were not significant. The incidence of these side effects was also not significantly different between the PCEA and CEI groups in Standl's study (5).

One limitation to this study was the fact that we did not take into account the duration and complexity of the surgery which may influence postoperative pain. Reduced intraoperative time, elimination of unnecessary soft tissue manipulation and meticulous surgical techniques are essential for postoperative pain reduction (13). Another limitation which could lead to bias in interpretation of results may be the lack of an independent observer.

Further studies comparing CEI and PCEA with different methods of administration and drug combinations might be helpful to ascertain the optimum regime for postoperative pain relief.

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