Observational Study on Patients' Satisfaction During Epidural Anaesthesia, Without Breakthrough Pain, in Patients scheduled for Orthopaedic Surgery

ABSTRACT

Introduction*:* This study was undertaken to determine the level of patients' satisfaction after epidural anaesthesia, without breakthrough pain, in patients scheduled for orthopaedic surgery. Epidural block is one of the regional anaesthesia that can be used in orthopeadic cases with prolonged duration of surgery.

Aim and objectives: To study the intraoperative pain outcome and patients' satisfaction during epidural anaesthesia with top up doses without breakthrough pain.

Methods:A prospective study of patients who underwent orthopaedic procedures under epidural block in the operating rooms of Ekiti State University Teaching Hospital, was carried out. Post-operatively, a proforma was filled for each of the participants to score their satisfaction on a Numerical Rating Scale regarding pain and discomfort during and after epidural anaesthesia and surgery. Other adverse reactions were documented. Patients' satisfaction score was also documented.

Results:A total of 103 patients, with age ranging from 25 to 60 years, were recruited. Majority (102/99%) of the patients had their data well documented while remaining (1/0.9%) patient was excluded from the study for poor documentation. In all, satisfaction with epidural anaesthesia administration was observed in (95/93.1%) whereas (7/6.9%) patients were dissatisfied. Factors associated with dissatisfaction were prolonged onset time (2/1.9%) patients. Breakthrough pain in (1/0.9%) patients. Post-operative nausea and vomiting (PONV) was observed in 1 (0.9%) patient. In addition, (92/90.2%) patients would opt for epidural anaesthesia in future for similar surgery, if situation demands for it, 10 (9.8%) patients would not.

Conclusion: The patients receiving epidural anaesthesia, without breakthrough pain, for orthopaedic surgery demonstrated a high rate of patients' satisfaction.

Keywords: Epidural, anaesthesia, patient satisfaction, orthopaedic surgery

Comment [rk1]: Paragraph needs to be reframed with basic introduction to pain

Comment [rk2]: Specify primary and secondary objective
Aims not clear

Comment [rk3]: Drugs used in epidural to be mentioned

Comment [rk4]: It will be good if depicted in the statistical values.
Intraoperative pain outcome which is the primary objective is not mentioned.
And also to mention this in Conclusion

INTRODUCTION

The choice of regional anaesthesia for any surgery may be tasky and this may depend on myriad of factors.[1,2,3,4] These include the purpose for the surgery, duration of the surgery, urgency of surgery, and surgeons' as well as anaesthetists' preferred method.[1,2] Based on surgeons' ~~desire~~ and the position for surgery, anaesthetists always prefer the regional block that is safe and most comfortable for the patients.[5] The advantages of regional anaesthesia include awake patients, avoidance of the use of multiple drugs, and avoidance of the risks of general anaesthesia. ~~Recently, regional anaesthesia has been popularized and gained international prominence.~~

However, complications occurring during or after anaesthesia as well as discomfort from the procedure, position, and neuraxial block might compel patients to prefer general anaesthesia.[2] Based on our knowledge, we do not have many articles on patients' satisfaction during epidural anaesthesiawithout breakthrough pain. There is no study on prevention of breakthrough pain during top up doses of bupivacaine epidural anaesthesia. Breakthrough pain is the pain that patients experience when the initial bolus of bupivacaine has worn off. It can also occur when each of the subsequent top up doses of bupivacaine has worn off. ~~After about one hour of the initial dose, patients begin to feel pain. P~~atients will continue to feel pain until a top up dose is given to alleviate the pain. The pain that patients complain about before a top up dose of bupivacaine is given, is known as breakthrough pain.~~Sometimes, it may be severe that the surgeons have to stop the operation for top up doses to be given before they continue with the surgery.~~

This study is designed to determine the patients satisfaction during epidural anaesthesia without breakthrough pain and to popularize its benefits amongst patients.

Comment [rk5]: Entire introduction part needs to be modified

Comment [rk6]: Reframe the sentences, Not giving appropriate meaning

Comment [rk7]: Redefine Breakthrough pain

METHODS

This is a prospective study of patients' satisfaction during epidural anaesthesia for orthopaedic surgery. The study was carried out over 7 year period. The research was carried out in Ekiti State University Teaching Hospital, Nigeria between January, 2013 and December, 2019 in main theatre of the institution. The tertiary institution is a referral centresub serving Edo, Delta, Ekiti and part of Ondo State. The hospital is State Government owned and manages majority of high risk patients coming from primary, secondary and even other tertiary health care centres, in these catchment areas.

Comment [rk8]: Doesn't match the primary objectives mentioned in abstract

Comment [rk9]: Is the study registered in the traial registries?

After ethical clearance for the study was obtained from the Research and Ethics Committee of the institution, a total of 103 patients scheduled for orthopaedic surgery under epidural anaesthesia were recruited for the study. Before induction of epidural block, patients' characteristics and previous history of anaesthesia were recorded.

All the recruited patients had epidural anaesthesia with initial bolus of 15 to 20 ml of 0.5% plain bupivacaine and a top up dose of 5ml at exactly 45 minutes after the initial bolus. The second, third or fourth top up dose would also be given exactly 45 minutes after the last top up dose. The aim was to avoid breakthrough pain that usually occurs before top up dose is given. ~~This, we thought, might not allow patients to complain about any pain before top up dose was given~~. The pain and the level of patients' satisfaction were assessed on a 1-10 Numerical Rating Scale.
Intra-operative and post operative complications such as breakthrough pain, nausea and vomiting, back pain, hypotension, bradycardia, and inadequate anaesthesia/analgesia were recorded. Post-operatively, data detailing patients' satisfaction score were documented. Statistical analyses were performed using Statistical product and service solutions (SPSS) Software (Version 26.0, SPSS Inc., IL, USA).

Comment [rk10]: Mention full drug name and concentration

Comment [rk11]: 1)Wasn't pain scores assessed before giving the drug
2) reference for 45 mins

Comment [rk12]: Cannot be a complication

Comment [rk13]: Reference?

RESULTS

A total of 103 patients scheduled for elective lower limb orthopaedic surgery were studied. Majority (102/99%) of the patients had their data well documented regarding this choice of regional anaesthesiawhile remaining (1/0.9%) patient was excluded from the study for poor documentation. One patient was excluded from the study for poor documentation.Majority of the patients (83/81.4%) were male while (26/25.5%) were female. Patients aged between 25 and 60 years according to Table 1. Majority of the patients (88/86.3%) were ASA1 whereas (14/13.7%) patients were ASA II. According to Table 2, majority of the patients (91/89.2) had one form of pain or the other before the institution of epidural block. Only one patient complained of pain as shown in Table 3. In all, satisfaction with epidural anaesthesia administration, was observed in (95/93.1%) whereas (7/6.9%) patients were dissatisfied. Factors associated with dissatisfaction were breakthrough pain during surgery in (1/0.9%) patient. Prolonged onset time in (2/1.9%) patients. Post-operative nausea and vomiting (PONV) was observed in 1 (0.9%) patient. In addition, (92/90.2%) patients would opt for epidural anaesthesia in future for similar surgery, if situation demands for it, 10 (9.8%) patients would not.

Comment [rk14]: Has to be rewritten

Comment [rk15]: Repeated

Comment [rk16]: Split the results and write 2 or 3 sentences below the each result table

Table 1: Basic characteristics of the patients

Parameters	Number	Percentages
Age		
25-40	76	74.5
41-60	26	25.5
ASA Status		
ASA I	88	86.3
ASA II	14	13.7
Sex		
Male	83	81.4
Female	19	18.6
Education		
Primary	21	20.6
Secondary	43	41.1
Tertiary	38	37.3

Table 2: Assessment of pain before administration of epidural anaesthesia

Parameter	**Number**	**Percentages**
No pain (0)	11	**10.8**
Mild pain (1-3)	**59**	**57.8**
Moderate pain (4-6)	**20**	**19.6**
Severe pain (7-10)	**12**	**11.8**

Comment [rk17]: Mean and standard deviation values to be mentioned

Table3: Assessment of pain during epidural anaesthesia

Comment [rk18]: Doesn't make sense Please mention the statistics in detail

Parameter	Number	Percentage
No pain (0)	0	0.0
Mild pain (1-3)	1	0.9
Moderate pain (4-6)	0	0.0
Severe pain (7-10)	0	0.0

Table 4:Level of patients' satisfaction without breakthrough pain

Level of satisfaction	Number	percentages
No satisfaction (0)	**2**	**2.0**
Mild satisfaction (1-3)	**5**	**4.9**
Moderate satisfaction (4-6)	**4**	**3.9**
Excellent satisfaction (7-10)	**91**	**89.2**

Table 5: Factors associated with patients' dissatisfaction

Factors	Number	Percentages
Breakthrough pain	1	0.9
Prolonged onset time	2	1.9
PONV	1	0.9
Option for future epidural		
Those who embrace it	92	90.2
Those who are against it	10	9.8

DISCUSSION

Comment [rk19]: Will be reviewed later once results section is corrected
Needs major changes
Need to add recent articles for reference and compare with them

Epidural anaesthesia is performed by injecting large amounts of local anaesthetic agent into the epidural space.[5] Spinal anaesthesia is easy to perform and provides excellent operating conditions for caesarean section. Compared with general anaesthesia, epidural anaesthesia has lower rates of venous thromboembolism, haemodynamic shift, the need for immediate post-operative analgesia, sympathetic responses to surgical stimulation along with few other life-threatening complications.[2,6]

Although most studies report high satisfaction levelfor post operativeepidural anaesthesia, the satisfaction rate for intraoperative epidural anaesthesia, without breakthrough pain, had not been well studied.[1,2,6,7]. To carry out this our study, trained personnel, who were not directly involved in that patient's care, were assigned to perform the survey.

Intra operative pain is one of the major concerns amongst care givers and in surgical patients. Researchers have carried out some studies in order to find out different methods that can be used to assess patient satisfaction with postoperative pain management and associated factors [1,2,3,4,5].

Patient's satisfaction in pain management is one of the variables that can affect the outcomes of health care services, but it could be difficult to achieve by a single specific intervention [8, 9]. In the past, lack of complications and routine check of blood pressure, pulse rates and oxygen saturation were the measure used to assess clinical condition and clinical success in the patients. Recently, the primary and secondary outcome measures as reported by the patients are now the accurate barometer used to gauge the level of pain relief and satisfaction in them.

Untreated breakthrough pain may have an effect in the clinical and psychological status of the patients. In addition, it creates a burden to health institutions by increasing patients' aversion to epidural anaesthesia.

Despite different methods of postoperative pain control have been provided to surgical patients, there had been lack of evidence that examined patients' satisfaction with the quality of intraoperative pain management in this study area. Therefore, we aimed to assess the level of patients' satisfaction and identify ways in which breakthrough pain could be avoided in patients having epidural anaesthesia.

Based on our knowledge, we do not have many articles on patients' satisfaction during epidural without breakthrough pain. There is no study on prevention of breakthrough pain during top up doses of bupivacaine epidural anaesthesia. Breakthruogh pain is the pain that patients experience when the initial bolus of bupivacaine has worn off. It can also occur when each of the subsequent top up

doses of bupivacaine has worn off. After about one hour of the initial dose, patients begin to feel pain. Patients will continue to feel pain until a top up dose is given to alleviate the pain. In this our study, we made sure that patients did not have breakthrough pain. We set out to prevent this by giving bupivacaine every 45 minutes after checking patients' blood pressure and heart rates.

Patients' satisfaction after anaesthesia as an important outcome of hospital care was studied by Myles et al.[1] They analysedanaesthetic database to identify potentially modifiable factors associated with dissatisfaction. At the time of analysis, their database contained information on 10 811 in-patients interviewed on the first day after operation. The major subjective outcome measure was patient satisfaction.
They also measured other predetermined outcomes, such as nausea, vomiting, pain and complications. They found that overall level of satisfaction was high (96.8%); 246 (2.3%) patients were 'somewhat dissatisfied' and 97 (0.9%) were 'dissatisfied' with their anaesthetic care. After adjustment for patient and surgical factors, there was a strong relation between patient dissatisfaction. Several factors associated with dissatisfaction may be preventable or better treated. Most satisfaction studies of anesthesia reported high levels of satisfaction [1,7,8] . Epidural analgesia is effective with low rate of adverse effects.[1,5]
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Songthamwatet al.[2] and other studies have shown that patients receiving epidural analgesic techniques generally had lower VAS pain scores and a higher level of satisfaction.[(9,10,11,12,13] According to their results, high level of
overall satisfaction of epidural analgesia was rated (satisfaction score greater than 7, 90.5%), and it was found comparable to other studies[14,15] Furthermore,
apart from mild postoperative pain, the factors favored satisfaction in their study was the duration of indwelling epidural catheter. Leaving the left epidural catheter
in situ may cause patients discomfort and produce numbness from local anesthetic agents. Therefore, they might prefer a shorter period of indwelling epidural
catheter. Regarding the difference in current clinical practices for epidural analgesia, the technique of epidural pain management in their study was not a significant factor.

According to our study, a total of 103 patients scheduled for elective lower limb orthopaedic surgery were studied. Majority (102/99%) of the patients had their data well documented regarding this choice of regional anaesthesia. One patient was excluded from the study for poor documentation. Majority of the patients (83/81.4%) were male while (26/25.5%) were female. Majority of the patients (88/86.3%) were ASA1 whereas (14/13.7%) patients were ASA II. Majority of the patients (91/89.2) had one form of pain or the other before the institution of epidural block. Only one patient complained of pain mild pain intraoperatively. This patient felt a breakthrough pain because the caregiver failed to give the first top up dose at 45 minutes to the same patient. An act of omission that made the patient to feel pain before a first top up dose was given. Satisfaction with epidural anaesthesia administration was observed in (95/93.1%) whereas (7/6.9%) patients were

dissatisfied. This study shows that breakthrough pain could be avoided in patients undergoing epidural anaesthesia.These are in keeping with other studies that epidural anaesthesia is good in managing both intraoperative and postoperative pain.[15,16,17] Factors associated with dissatisfaction were breakthrough pain during surgery in (1/0.9%) patient. Prolonged onset time in (2/1.9%) patients. Post-operative nausea and vomiting (PONV) was observed in 1 (0.9%) patient. In addition, (92/90.2%) patients would opt for epidural anaesthesia in future for similar surgery, if situation demands for it, 10 (9.8%) patients would not.

LIMITATION

Our study is limited by unavailability of researches in this area of study. There was no previous research on patients' satisfaction during epidural anaesthesia with top up doses without breakthrough pain. The study is still open for further comparative researches. And a much larger population may be needed to detect any level of significance.

CONCLUSION

The results of our study show that breakthrough pain can be highly alleviated by the application of epidural anaesthesia with repeat administration of the drug every 45 minutes. The satisfaction of patients is very high. Although the study was designed to administer drug to patients every 45 minutes, the incidence of complications such as hypotension, headache, nausea and vomiting is low. We conclude that epidural anaesthesia can be given to patients without patients experiencing breakthrough pain in-btween different top up doses. Although, this is an observational study, a comparative study is necessary in order to draw significant conclusions about the association of the effectiveness of epidural anaesthesia with or without breakthrough pain.

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Comment [rk20]: Recent refernces are required
Vancouver style

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