

Failure rate of labor epidural: An observational study among different levels of trainee anesthesiologists in a university hospital of a developing country

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Abstract

Context: Frequent use of labor epidural has also led to a corresponding increase in failed epidural analgesia (FEA).

Aims: This study aims to identify the overall rate of FEA and evaluate its association with trainee anesthesiologist at different years/levels of anesthesia residency training.

Settings and Design: Prospective observational study was conducted for one year in the labor room suit of a university hospital.

Methods and Material: After university ethics committee approval, full-term parturient receiving labor epidurals and consenting for the study were included. FEA was identified by the presence of one or more set criteria of failure including; pain of numeric rating scale of >4 at 45 minutes after epidural placement, accidental dural puncture, need to re-site the epidural, abandoning the procedure, and maternal dissatisfaction with labor pain relief.

Statistical Analysis Used: A binary logistic regression was used to assess the association between failure rate of labor epidural and grades of anesthesiologists. Odds ratio (OR) and 95% confidence interval (CI) were reported. *P* value ≤ 0.05 was considered significant.

Results: Out of 500 women included, 76 (15.2%) had FEA, which was significantly high in 2nd and 3rd year residents compared to 5th year and above level anesthesiologists [OR = 2.08; 95% CI: 1.17 to 3.67; *P* = 0.012]. Failure rate was also high but insignificant in 4th year residents compared to senior level anesthesiologists [OR = 1.78; 95%CI: 0.89 to 3.53; *P* = 0.098].

Conclusions: The incidence of FEA is comparable to those quoted in literature from developed countries and shows association to experience and year of training of anesthesia residents.

Keywords: Failure rate, labor epidural, anesthesia training, trainee resident

Introduction

Epidural analgesia is widely used as an effective analgesic option for laboring women.^[1] Nevertheless, its frequent use in obstetrical pain management has also led to a corresponding increase in the failed epidural analgesia (FEA) especially in a university-based hospital where residents are trained to perform labor epidurals.^[1] Researchers have investigated the learning

curve experienced by anesthesia trainees for epidural insertion and have reported an increased failure rate for junior trainees compared to their more experienced peers in an obstetric setting.^[1,2] However, other studies have shown no effect of the level of provider experience on the failure rate and therefore the role of operator experience remains controversial.^[3-6]

There is no widely accepted definition of epidural failure in literature, which has led to a variable failure rate ranging from

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8% to 23%.^[7-10] Thangamuthu *et al.*,^[11] using Delphi process, have devised a definition of failure that includes the presence of any one or more of endpoint including inadequate pain relief at 45 min after placement, accidental dural puncture (ADP), re-siting or abandonment of the procedure, and patient's dissatisfaction at follow-up.

Good clinical practice recommends that every healthcare institution measures their practice and benchmark it against standards and take remedial measures if standards are not met.^[12] We in our literature search were unable to find any data from developing countries addressing the failure rate of epidural and the impact of different levels of anesthesiologists on the failure rate. Using the definition of labor epidural failure from the study of Thangamuthu *et al.*,^[11] this study aims to find the failure rate of labor epidural analgesia in a tertiary care hospital of a developing country and see the impact of the operator from different levels/years of the anesthesia training program on the failure rate. This study hypothesizes that the incidence of FEA is negatively correlated with the experience of an anesthesiologist, as the incidence increases with junior trainees compared to their more experienced peers instituting epidural.

The objectives of this study were to identify the overall failure rate of labor epidural in the institution where this study is conducted and to evaluate its association with different levels of trainee anesthesiologists performing the epidural. The failure rate was identified by the presence of one or more of the following criteria, including 1) inadequate pain relief 45 minutes after placement 2) ADP 3) re-siting or abandonment of procedure, and 4) patients' dissatisfaction with labor epidural pain relief at follow-up.

Methods

After approval from the hospital ethics review committee, this prospective observational study was conducted for 1 year from 1st July 2017 to 30th June 2018, in the labor room suite of a tertiary care University Hospital of a developing county. This 800-bedded hospital has a dedicated obstetric unit having an annual delivery rate between 2500 and 3000, with an established 24 hours epidural service.

During the study period, all consecutive patients requesting for labor epidural and fulfilling the inclusion criteria were approached for written informed consent. These patients were explained the purpose and procedure of the study and only after written informed consent, patients were enrolled in the study. Inclusion criteria were full-term parturient over 18 years of age with established labor and requesting for labor epidural

analgesia. Patients with previous back surgery or any other contraindication for labor epidural, having chronic pain, on any pain medications, not consenting to be a part of the study, having psychiatric problems and inability to understand and communicate or requiring cesarean section within 45 minutes of epidural placement were excluded from the study.

The outcome of the study was to determine the rate of FEA and to identify the effect of level of trainee anesthesiologist performing the epidural on failure rate by the presence of one or more of the criteria including inadequate pain relief 45 minutes after placement, ADP, re-siting or abandonment of procedure and patients' dissatisfaction with labor epidural pain relief at follow-up visit. Data were collected by designated trained data collector and labor room nurses on a predesigned data collection form, [Appendix 1] and included pain score by numeric rating scale (NRS) with '0' considered as no pain and '10' considered as worst imaginable pain. NRS was recorded before insertion of epidural, then at 15 minutes, 45 minutes and then at 2, 4 and 6 hours either by the research assistant or labor room nurse who were not the part of the study.

Other data included patients' demographics including age, weight, height, gestational age, cervical dilatation at the time of epidural placement, number of attempts at epidural insertion, and anatomical grade of the parturient spine. Anatomical grading of the spine was assessed by the anesthesiologists performing the epidural and graded according to the following scale:^[4] grade 1 = spinous processes visible, grade 2 = spinous processes easily palpable but not visible, grade 3 = spinous processes not seen or easily palpable but interspace palpable and grade 4 = spinous process and interspace neither visible nor palpable.

To identify the effect of the level of trainee anesthesiologists on failure rate, anesthesiologists were grouped according to the year of training: year 2-3, year 4, and year 5 and above (fellows, senior trainees, and consultants). The anesthesia-training program in the institution where the study was conducted is a five-year residency program and one-year obstetric anesthesia fellowship program. Trainee residents from years 2 to 5 are assigned obstetric anesthesia rotation, once during their junior years (2nd and 3rd year) and another in senior years (4th and 5th year) of the residency program. Consultant is physically available in the labor room suit from 8:00 to 17:00 hours and in the premises of the hospital from 17:00 to 8:00 hours. Junior residents have full supervision either by the consultant or fellow and senior residents have either full or partial supervision. All residents are allowed two attempts at epidural insertion, after which it is taken over by the fellow or consultant. Epidurals after 17:00 hours are performed by senior residents/fellow with partial supervision by consultants who are available in

the premises of the hospital. In cases of anticipated difficult epidural, it is performed by the consultants/fellows or by senior residents under complete supervision of the consultant.

All labor epidurals were instituted according to the set protocol of the department in the sitting or lateral position by a 16-gauge Tuohy needle (Portex, Smith Medical, Hythe, United Kingdom). Analgesia was established using 0.125% bupivacaine (Bupivacaine Hydrochloride, Lahore Chemical Pharmaceutical, and Pakistan) in a titrated bolus dose of 10-15 ml for the establishment of labor epidural. Subsequent analgesia was maintained by using 0.1% bupivacaine by an infusion pump at a titrated rate of 10-15 ml per hour infusion. Block was assessed to achieve a decrease in NRS to <4 and if labor pains were not relieved within 45 minutes after this initial bolus administration and the start of continuous infusion of local anesthetics, epidural was assigned in the category of failed labor epidural. The patient is managed by the midwife/nurse and they regularly take the patient's vital and record NRS for pain score. As labor is a dynamic process and as labor progresses, the patient might require additional dose any time during labor. Therefore, according to department protocol, any patient complaining of pain with NRS >4 any time during labor are provided with additional boluses by the anesthesiologists.

Satisfaction score as how satisfied the patient was with the epidural procedure and its effects on her labor pains was recorded by the research assistant 12 hours after the delivery by a five-point satisfaction score:^[13] 1) Perfect: patient did not experience any pain at all, 2) Very satisfied: helped relieve most of her pains, 3) Satisfied: the epidural relieved major pains, but she still experienced minor pains, 4) Not satisfied: the epidural helped a bit only, 5) Poor: the epidural did not help at all. Scores 1 to 3 were taken as patients satisfied with labor epidural analgesia and scores 4 to 5 were taken as patients unsatisfied with labor epidural analgesia.

Statistical analysis

Data were analyzed by statistical packages for social science version 19 (SPSS Inc., Chicago, IL). It was observed that some studies reported an 8% to 23% epidural failure rate.^[7-10] The sample size of 492 patients (approximate = 500) was included to estimate the expected epidural failure rate within a 2.5% margin of error on the basis of an 8% epidural failure rate. The outcome variable of the study was the failure rate of labor epidural as per defined criteria and the exposure variable was grades of anesthesiologists. The central tendency of the quantitative point estimates were reported as mean and standard deviation and qualitative point estimates were as frequency and percentage. A binary logistic regression was used to assess the association between the failure rate of labor epidural and grades of anesthesiologists. Odds

ratio (OR) and 95% confidence interval (CI) were reported. P value ≤ 0.05 was considered significant.

Results

In this prospective study from 1st July 2017 to 30th June 2018, complete data were collected on 500 patients. During the study period of 12 months, a total of 529 epidurals were performed, out of them, 519 patients fulfilled our inclusion criteria. These eligible patients were approached for the written informed consent, 9 declined to give consent and 10 patients were dropped out due to incomplete data entry. Patients' demographics, number of attempts at epidural, anatomical finding of spine, cervical dilatation, and level of anesthesiologists performing labor epidural are shown in Table 1.

Seventy-six (15.2%) labor epidurals were deemed to have failed due to the presence of at least one of the failure criteria. There were 53.95% (41/76) patients in whom labor epidural failed due to the presence of one criteria of failure, 42.11% (32/76) had a combination of two criteria of failure, and 3.95% (3/76) patients had a combination of three criteria of failure. The commonest was the combination of pain score >4 at 45 minutes and poor satisfaction at follow-up visit in 29 (40.8%) patients. There were 8 (11.3%) patients who had NRS >4 at 45 minutes but did not report epidural as unsatisfactory and 21 (29.6%) patients who reported labor epidural analgesia as unsatisfactory but did not have NRS >4 at 45 minutes.

Table 1: Patients' demographics, number of attempts at epidural, anatomical finding of spine, cervical dilatation and level of anesthesiologists performing labor epidural

Variables	Point Estimate
Age (Years)	28.11 \pm 4.02
Gestational Age (Weeks)	38.17 \pm 1.38
Weight (Kg)	73.77 \pm 12.26
Height (cm)	158.74 \pm 19.49
BMI (kg/m ²)	29.59 \pm 5.11
Number of attempts at epidural insertion	
1	398 (79.6%)
2	68 (13.6%)
3	24 (4.8%)
4	10 (2%)
Anatomical finding of Spine	
Grade 1	41 (8.2%)
Grade 2	344 (68.8%)
Grade 3	98 (19.6%)
Grade 4	17 (3.4%)
Cervical dilatation at the time of epidural insertion (unit)	3.38 \pm 1.00
Level of Anesthesiologist	
2 nd or 3 rd Years	190 (38%)
4 th Years	99 (19.8%)
5 th years and above	211 (42.2%)

There were 89% (445/500) patients who were satisfied with labor epidural pain relief, out of them 37.8% ($n = 189$) patients rated their pain relief as “perfect”, 40.4% ($n = 202$) as “very satisfied”, 10.8% ($n = 54$) as ‘satisfied’. There were 11% (55/500) patients who were unsatisfied with labor epidural with 5.4% ($n = 27$) rating as “epidural helped a bit only” and 5.6% ($n = 28$) rating it as “epidural did not helped at all”. The mean NRS of this 11% of unsatisfied patients at 45 minutes, 2 h, 4 h, and 6 h was 5.11 ± 2.5 , 6.27 ± 1.69 , 6.67 ± 1.88 , and 6.50 ± 3.01 , respectively as presented in Figure 1.

There was no effect of cervical dilatation at the time of institution of labor epidural, patient’s BMI and grades of spine on the failure rate. However, number of attempts of more than one at epidural insertion was significantly higher ($P = 0.005$) for grade 3 and 4 spines.

A comparison of failure rates with failure characteristics between different grades of anesthesiologists is shown in Table 2. The failure rate of an epidural was significantly associated with the level of anesthesiologists. The failure rate of epidural was significantly high in junior-level resident (2nd or 3rd years) as compared to 5th years and above level anesthesiologists [OR = 2.08; 95%CI: 1.17 to 3.67; $P = 0.012$] similarly failure rate was also high but insignificant in 4th year residents as compared to 5th year and above level anesthesiologists [OR = 1.78; 95%CI: 0.89 to 3.53; $P = 0.098$]

Discussion

The actual incidence of FEA is hampered by the absence of uniform criteria with reported failure rates ranging from 8-23%.^[7-10] The present study, therefore, measured the

incidence of FEA according to the presence of predetermined criteria of failure, which was found to be 15.2% compared to the failure rate of 23% quoted previously by investigators using the same standardized definition.^[11] This difference in the failure rate could be the retrospective data collection on larger number of patients in the previous study,^[11] as opposed to the prospective design of this study.

This study showed that failure rate was significantly associated with the year of training of anesthesiologists performing the labor epidural. Anesthesia providers from training year 5 and above had a failure rate of 10.4%, which was significantly lower than the failure rates of anesthesia providers from junior level of training. The results are comparable to the previous study using the standardized criteria for failure rate;^[11] however, the previous study did not show any difference in the pain relief at 45 minutes of the epidural institution among different levels of anesthesiologists. In contrast, this study has shown a combination of high pain scores at 45 minutes after labor epidural institution and patient reporting unsatisfactory pain at follow-up to be highest among junior level residents. The possible explanation could be different training modules of residents and less exposure of junior level trainees to obstetric epidural as the rate of labor epidural is not more than 21% in the institution where the study is performed. A study conducted in this institution found out that the main reasons for not availing labor epidural service are lack of awareness, knowledge, and misconceptions, rather than the desire to have an unmedicated natural birth.^[14]

Pain experienced while being on labor epidural analgesia is associated with lower patient satisfaction as parturient expects minimal or no pain after receiving neuraxial anesthesia.^[15] Not surprisingly we observed that 55 patients who were unsatisfied with labor analgesia had a pain score of moderate to severe intensity at one or more times during labor. Patient satisfaction was significantly lower when the epidural was instituted with junior level residents compared to resident level 5 and above.

This study did not find any difference in the number of attempts between different levels of anesthesiologist, which is contrary to the results of the previous study showing a significantly greater number of attempts among junior anesthesia providers although the proportion of those completing central neuraxial block did not differ among different levels of anesthesiologist.^[5] The lack of difference in this study could be attributed to the fact that senior anesthesiologist performs more challenging cases like patients with difficult spines. This factor could have balanced the difference among different levels of anesthesiologist, as this study found a number of attempts to be significantly higher in patients with difficult spines (grade 3 and 4) as compared

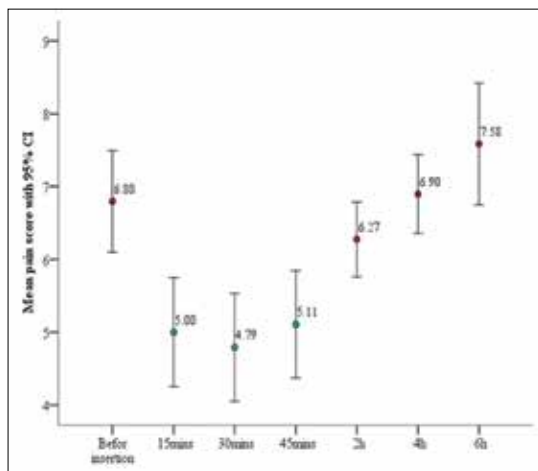


Figure 1: Mean pain score (NRS) of patients who reported unsatisfied with respect to time ($n = 55$)

Table 2: Comparison of failure rates with failure characteristics between different levels of anesthesiologistsa

Level of anesthesiologists	n	Pain Score >4 at 45 min	Need to Re-site	Abandoned	ADP	Dissatisfied at follow-up	Overall failure*	Odds Ratio [95%CI]
2 nd or 3 rd Years	190	21	4	3	2	29	37 (19.5%) [†]	2.08 [1.17-3.67]
4 th Years	99	8	2	0	2	11	17 (17.2%) [‡]	1.78 [0.89-3.53]
5 th years and above	211	10	5	0	4	15	22 (10.4%)	Ref
Total	500	39 (8%)	11 (2.2%)	3 (0.6%)	8 (1.6%)	55 (11%)	76 (15.2%)	

^aData are number (%). ADP: accidental dural puncture; Logistic regression was used to observe [†]P=0.012 and [‡]P=0.098 vs. 5th years and above. *Some women had more than one reason for failure. Ref=References group

to spine with easily seen and palpable spinous process and intervertebral space (grade 1 and 2).

Resiting is an important cause of failure and can occur due to catheter migration any time during labor and is performed when pain relief is inadequate due to catheter malfunction or misalignment. Literature has reported deterioration in pain relief during labor due to inward catheter migration in 13.7% or outward catheter migration in 22.2% of cases.^[16] One retrospective analysis of more than 19,000 deliveries reported an overall failure rate of 46%, which was dropped to 12% with simple manipulation of poorly functioning epidurals.^[8] With active management of malfunctioning epidurals, including replacement, 98.8% of patients reported achieving adequate labor analgesia.^[8] However, as with any invasive procedure, epidural catheter resiting poses distress to the patient and usually perceived as an adverse event. Therefore, this study has taken resiting as one of the criteria for epidural failure, as catheter resiting could be taken as a surrogate marker for inadequate analgesia that may contribute to lower patient satisfaction.^[15] In addition, abandoning the procedure was another criteria of failure, which was found to be more common among junior level trainee residents in this study. The previous study on the subject of labor epidural failure rate has found a high rate of abandonment of the procedure and need to resite among the junior level trainee resident, however, they have reported abandonment and resiting as a single factor.^[11]

The strength of this study is its prospective design for data collection using a standardized definition of epidural failure rate. In addition, this is the first such study from a developing country relating the incidence of failure to the different level of anesthesia trainee. As there is a difference in the training modules for obstetric anesthesia training between developing and developed countries, therefore finding from this study will add to the existing literature, as previous studies on this subject are from developed countries.^[1-5]

Nevertheless, we acknowledge the limitations of this study; first, we did not consider the effect of loss of resistance to air or saline as compared to other studies.^[16] Second, grading of the anesthesia care providers has been made based on 2nd, 3rd, 4th,

and 5th year trainees and not based on experience and number of epidurals performed which could have influenced the results. However, the residency program has fixed competency list for procedures performed for every level of residency, therefore, more or less residents each year have the same level of experience and number of epidural performed. Third, satisfaction score as one of the failure criteria was measured 12 hours, therefore, we could not mitigate the chances of recall bias. In addition, patients might not be able to rate satisfaction with the pain control of the first stage of labor and may be influenced by the pain in the second stage and post-surgical pain for the patient who ended up in cesarean section. Furthermore, satisfaction is multidimensional and could be influenced by other factors like family support, environmental changes, and mood changes.^[17] However, to remove the chance of bias, the patient satisfaction score in this study was obtained by a research assistant and not by the person instituting the labor epidural or investigators of the study.

In conclusion, this study using set criteria of failure revealed a failure rate of 15.5%, which is comparable to the literature from developed countries quoting variable failure rate ranging from 8% to 23%. This study further revealed that the incidence of FEA was negatively correlated with the experience of an anesthesiologist, as the incidence was more when labor epidural was instituted by junior trainees compared to their more experienced peers. The results from this study would help in lowering the incidence of FEA by improving the training and exposure of junior level trainee anesthesiologists. We recommend that healthcare facilities providing labor epidural services need to identify their failure rate and factors responsible for failure to improve the quality of labor epidural service.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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APPENDIX 1

Failure rate of labor epidural: An observational study among different level of trainee anesthesiologists in a university hospital of a developing country

Date:

Time:

Age (Years):

Gestational weeks:

Weight (kg):

Height (cm): BMI (kg/m²):

Cervical dilatation at the time of epidural insertion: _____ cm

ANATOMICAL FINDING OF SPINE:

- Grade 1 = spinous processes visible.
- Grade 2 = spinous processes easily palpable but not visible.
- Grade 3 = spinous processes not seen or easily palpable but interspace palpable.
- Grade 4 = none of the above.

LEVEL OF ANESTHESIOLOGIST:

Resident level/year: 1 2 3 4 5

Fellow:

Consultant:

NRS- Numeric Rating score (0-10)

Before insertion: _____

After insertion:

- At 15 minutes: _____
- At 30 minutes: _____
- At 45 minutes: _____
- At 2 hours-----
- At 4 hours-----
- At 6 hours-----

Number of attempts: _____

OUTCOME OF EPIDURAL:

Successful Failed

In case of failed epidural:

CRITERIA OF FAUILURE (Can mark more than one)

1. Inadequate pain relief 45 minutes after placement
2. Accidental dural puncture
3. Re-siting
4. Inability to site or abandonment of procedure
5. Patients' dissatisfaction with labor epidural pain relief at follow up

PATIENT SATISFACTION:

How satisfied was the patient with the epidural procedure and its effects on her labor pains?

a) Perfect. Patient did not have any pain at all

- b) Very satisfied. Helped relieve most of her pains
- c) **Satisfied.** The epidural relieved major pains, but she still experienced minor pains
- d) The epidural helped a bit only
- e) The epidural did not help at all