Combined Spinal Epidural Technique for Labor Analgesia Does Not Delay Recognition of Epidural Catheter Failures

A Single-center Retrospective Cohort Survival Analysis

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CME This article has been selected for the ANESTHESIOLOGY CME Program. Learning objectives and disclosure and ordering information can be found in the CME section at the front of this issue.

ABSTRACT

Background: It is unclear whether recognition of epidural catheter failures is delayed with combined spinal epidural technique (CSE) compared to traditional epidural technique (EPID) when used for labor analgesia. The authors hypothesized that recognition of failed catheters is not delayed by CSE.

Methods: Anesthetic, obstetric, and quality assurance records from 2,395 labor neuraxial procedures (1,440 CSE and 955 EPID) performed at Forsyth Medical Center (Winston-Salem, North Carolina) between June 30 and December 31, 2012, were retrospectively analyzed. The primary outcome was catheter survival (failure-free) time during labor analgesia. A proportional hazards model with the counting method was used to assess relationships between the techniques and survival (failure-free) time of catheters, while controlling for subjects' body mass index and providers' level of training in the final best-fit multivariable regression model.

Results: Cumulative incidence of epidural catheter failures was 6.6% for CSE and 11.6% for EPID ($P = 0.001$). In the multivariable regression model, catheters placed with CSE *versus* epidural were less likely to fail (hazard ratio, 0.58; 95% CI, 0.43 to 0.79; $P = 0.0002$) for labor analgesia. Among the catheters that failed, there was no overall difference in failure time course between the techniques (hazard ratio, 1.17; 95% CI, 0.89 to 1.54; $P = 0.26$) even though more failed catheters with CSE (48.4%) than with EPID (30.6%) were recognized within the first 30 min of placement ($P = 0.009$).

Conclusions: In this cohort, CSE has a significantly lower risk of overall epidural catheter failures than EPID and does not delay recognition of epidural catheter failures. Choice of CSE *versus* EPID should be based on overall risk of failure, efficacy, and side effects. **(ANESTHESIOLOGY 2016; 125:516-24)**

EPIDURAL analgesia has long been the mainstay of labor analgesia because it allows effective drug delivery throughout the course of labor, including cesarean delivery if necessary. Furthermore, epidural analgesia has a long-standing history of superior maternal and fetal safety compared to other forms of analgesia and anesthesia. Initially, combined spinal epidural technique (CSE) began as a refinement of traditional epidural technique (EPID).[1] Over the last two decades, CSE for labor analgesia has become popular because of its advantages over EPID. A Cochrane systematic review[2] comparing CSE and EPID indicated that the onset of completed analgesia was significantly faster with CSE (–5.42 min [95% CI, –7.26 to –3.59]), and more women with CSE achieved effective analgesia at 10 min (relative risk, 1.94 [95% CI, 1.49 to 2.54]). In addition, motor blockade and risk of hypotension may be lower with CSE; in turn, patients may be able to ambulate

What We Already Know about This Topic

- Combined spinal epidural analgesia has become a common technique for analgesia in the laboring patient due to its more rapid onset compared with epidural analgesia alone
- However, concern exists that combined spinal epidural could delay recognition of failed epidural catheter placement.

What This Article Tells Us That Is New

- A single-center retrospective analysis of 2,395 neuraxial procedures for labor analgesia found that combined spinal epidural did not delay recognition of failed epidural catheter placements
- Moreover, the risk of epidural analgesia failure was lower for combined spinal epidural than for epidural alone

during labor or at least have a better sense of motor control.[3] Compared to EPID, CSE also has been associated with a lower cumulative incidence of epidural catheter failures during labor

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analgesia,[4,5] increased speed of cervical dilatation, and shortened duration of the first-stage labor in nulliparous parturients.[6,7] Verification of the correct placement of a spinal needle with cerebrospinal fluid (CSF) return *via* the spinal needle may increase the likelihood that the epidural needle tip and the epidural catheter are correctly placed in the midline of the epidural space.[4,5,8,9]

Despite this evidence, many authors, a number of major anesthesia texts, and institutional policies still recommend against the use of CSE labor analgesia for parturients at risk for cesarean delivery (such as those with severe preeclampsia, history of abruption, abnormal presentation, multiple gestation, and fetal macrosomia) and those with difficult airway indices or morbid obesity.[8–10] The concern is that with CSE, delayed recognition of epidural catheter failures could occur because parturients may be comfortable with the spinal dose of CSE, while the epidural catheters have not been fully tested or utilized to provide analgesia.[9,11] However, to our knowledge, there has been no published study to compare characteristics in the timing of catheter failures between CSE and EPID. We hypothesized that CSE did not delay recognition of epidural catheter failures and that the overall timing of catheter failures would not differ between CSE and EPID during the course of labor analgesia.

Materials and Methods

After approval and waiver of informed consent from the Institutional Review Boards at Forsyth Medical Center (Winston-Salem, North Carolina) and Wake Forest School of Medicine (Winston-Salem, North Carolina), we conducted a retrospective analysis of the timing and characteristics of epidural catheter failures during labor neuraxial analgesia. We used data extracted from paper-based anesthetic and obstetric records and quality assurance (QA) records collected from June 30, 2012, to December 31, 2012. As a part of our normal QA practice, a dedicated anesthesiologist reviewed all anesthetic records daily and contacted the anesthesia provider regarding possible issues and complications or if the record was unclear or incomplete.[5] The paper-based anesthetic record contained preoperative, intraoperative, and postoperative information, as well as a QA form (incorporated as part of our multipage anesthetic record) with check boxes for a predefined list of complications.[5] These complications included, but were not limited to, catheter failures requiring replacement and associated reasons such as inadequate anesthesia, no block, intravenous or intrathecal catheter, and inadvertent dural puncture by the epidural needle (wet tap). In addition, there was a free text box for the provider to add further details. This study included all patients who received EPID or CSE for labor analgesia in the labor and delivery suite during the study period. This study did not include patients with an intentional continuous spinal catheter, patients with dural puncture by epidural needle (wet tap),

or patients scheduled for cesarean delivery before initiation of CSE or EPID because our routine management of these catheters differs significantly from that of the catheters used for patients with the usual EPID and CSE.

Patients' anesthetic and obstetric records were reviewed with any additional documentation from the QA review to extract data on the time of epidural catheter insertion, failure, and replacement; reasons for replacement; technique used; need for supplemental epidural top-ups; providers' level of training in performing the procedure; need for and success of conversion to cesarean epidural anesthesia; patient demographics; and timing and mode of delivery. Data extracted were tabulated in an Excel spreadsheet (Microsoft Office; Microsoft Inc., USA) and analyzed by the statistician after patient identifiers were removed.

Our clinical practice setting consists of 24-h dedicated obstetric anesthesia faculty attendings and obstetric anesthesia fellows (CA4) who directly supervise clinical anesthesia (CA) residents (CA1 = first year, CA2 = second year, CA3 = third year, and CA4 = fourth year [fellowship year] of CA training in U.S. anesthesiology residency programs) during their obstetric anesthesia rotations. For the purpose of this study, the providers' level of training was classified into groups 1, 2, 3, and 4 for CA1, CA2, CA3, and combined CA4 with attendings, respectively. Residents rotating for their first time to obstetric anesthesia are closely observed one-to-one or assisted by an attending anesthesiologist and/ or an obstetric anesthesia fellow during the neuraxial procedures. For the study and in our usual practice, the choice of CSE or EPID for patients is mostly based on preferences of the individual anesthesia providers of the day, and if needed, in consultation with the attending anesthesiologist of the day.

To administer EPID, a 17-gauge, 9-cm Tuohy needle and a 19-gauge closed-tip multiport Springwound epidural catheter (B Braun Medical Inc., USA) were used. For CSE, a needle-through-needle technique with a 27-gauge 127-mm Whitacre spinal needle (BD Medical, USA) was used for spinal drug administration. The epidural portion of CSE utilized the same epidural needle and catheter as with EPID. For CSE, 0.7-ml bupivacaine, 0.25%, with 15 μg (0.3 ml) fentanyl was administered intrathecally *via* the spinal needle after demonstration of clear CSF flow return from the spinal needle. After removal of the spinal needle, an epidural catheter was inserted in the usual manner and tested only for inadvertent subarachnoid placement with 2 ml of 2% lidocaine. For EPID, the catheters were tested with the administration of 2- and 5-ml lidocaine, 2%, separated by 5 min, for discriminating inadvertent subarachnoid or intravenous placement from correct epidural placement, respectively.

As in our usual practice, if the spinal dose with CSE was not administered as intended or did not provide adequate labor analgesia, the provider used the epidural catheter to administer additional local anesthetic, as in the case of EPID. The technique was still classified as CSE because the procedure type was assigned based on the intended procedure.

Both CSE and EPID procedures were performed with the patient in the sitting position, and the epidural catheter was inserted 5 cm inside the epidural space (6 to 7 cm for morbidly obese patients). The epidural catheter was then secured and taped with the patient lying laterally. If there was no positive response to the test dose(s), patient-controlled epidural analgesia was initiated using 0.1% bupivacaine with 2 µg/ml fentanyl, with the following settings: basal rate of 10 ml/h, demand dose of 5 ml, lock-out time of 10 min, and hourly maximum of 35 ml. Patients with neuraxial labor analgesia were assessed every 1 to 2 h by the anesthesia provider for the level of analgesia, side effects, and appropriate utilization of patient-controlled epidural analgesia. Parturients were evaluated more frequently, if needed, for inadequate analgesia requiring supplemental epidural top-ups administered. Our usual supplements consisted of 5-ml increments of 0.25% bupivacaine up to 10 ml and, if needed, additional 2% lidocaine in 3- to 5-ml increments up to 10 ml. If inadequate analgesia was due to an asymmetrical sensory block, the catheter was pulled back 1 to 2 cm as appropriate before the administration of a supplemental top-up.

The definition of catheter failure due to inadequate analgesia was when a patient reported some sensory and/or motor blockade but still complained of inadequate labor pain relief, after the provider had already administered our usual adequate amount of supplemental anesthetic as described in the last part of the immediately preceding paragraph. The provider then documented on the anesthetic record the time and reason for the failure. If there was no sensory or motor block and the patient complained of inadequate labor pain relief (despite administration of an adequate amount of supplemental local anesthetic as described in the last part of the immediately preceding paragraph), this was defined as failure due to no block. The time of catheter insertion, failure, replacement, drugs administered, and their associated reasons and effects were documented on the anesthetic records by the care providers and reviewed by our QA personnel.

Determination of a catheter failure was made by the anesthesia provider caring for the patient and, occasionally if needed, in consultation with the attending anesthesiologist. For the purpose of this study, we grouped the reasons for epidural catheter failures into two main categories: (1) nontechnical failures from inadequate analgesia/anesthesia or no sensory block despite adequate epidural local anesthetic administered and (2) technical failures such as kinked, obstructed, and dislodged catheters, and inadvertently placed intravenous or subarachnoid catheters. An inadvertent intravenous catheter was defined as any epidural catheter with frank blood return (spontaneously, by gravity or aspiration) and/or clinical evidence of cardiovascular or central nervous system symptoms after an intravenous test dose. Similarly, an inadvertent subarachnoid catheter was defined as any epidural catheter with clear CSF return (spontaneously, by gravity or aspiration)

or clinical evidence consistent with a dense subarachnoid block. Multiple replacement was defined as an epidural catheter replaced two or more times in the same patient during the same labor and delivery course.

Epidural catheter survival (failure-free) time was the primary outcome measure in comparing catheter failure between CSE and EPID during the course of labor analgesia. For catheters that failed, epidural catheter survival time was defined as the difference between the time of completed catheter insertion and the time of recognition of catheter failure, as documented by the anesthesia providers on the anesthesia records. For catheters that did not fail, epidural catheter survival (failure-free) time was defined as the difference between the time of completed catheter insertion and the time of fetus delivery (birth time) for vaginal or cesarean delivery. A catheter utilized for cesarean anesthesia was deemed to be a failure when an alternative technique (repeated neuraxial or general anesthetic) was required despite epidural administration of at least a typical surgical amount of local anesthetic, which is 25-ml bicarbonated 3% 2-chloroprocaine with or without 100 µg of epidural fentanyl. A small amount of fentanyl and midazolam was also sometimes administered intravenously in a small number of very anxious patients during cesarean delivery. For catheters not previously declared as a failure, which were not dosed for cesarean anesthesia due to lack of time in an emergent situation and/or maternal or fetal instability, the end of survival time was the time of decision for cesarean delivery; these catheters were not declared as failures.

Statistics

For statistical analyses, SAS, version 9.4 (SAS Institute, USA), and Sigma Stat 3.1 (SPSS, Inc., USA) were used. Descriptive statistics were calculated for variables presented in tables 1 and 2 and compared between groups, such that mean ± SD was expressed for normally distributed continuous data; median (interquartile range) for data that were not normally distributed or for data with outliers or ordinal data; and number (percentage) for categorical data. The Kolmogorov–Smirnov (with Lilliefors correction) test was applied to test for normality of data distribution. An unpaired two-tailed t test was used for comparing parametric data between groups, and Mann–Whitney U and Wilcoxon rank sum tests were used for nonparametric data. The chi-square test or Fisher exact test was applied as appropriate for comparing proportions between groups. $P < 0.05$ was considered as statistically significant.

The confounding variables that have been consistently identified in the previous studies to be associated with epidural catheter failures are procedure type (CSE *vs.* EPID), body mass index (BMI), providers' level of training, and private *versus* academic practice.[5,9,11–13] From our QA experiences, we felt anecdotally that gestational age and parity may impact the patients' demand on the level of pain relief based on their obstetric experiences, and these were

Table 1. Descriptive Statistics for Patient Demographics and Baseline Characteristics

Baseline Characteristics	CSE	EPID	P Value
No. of all epidural catheters placed	1,440	955	–
BMI (kg/m^2), median (IQR)	30 (26–34)	32 (27–37)	0.001
BMI (kg/m^2) of patients required CD, median (IQR)	33 (29–37)	35 (29–41)	0.08
Gestational age (wk), median (IQR)	39 (38–40)	39 (37–40)	0.001
Gravidity, median (IQR)	2 (1–3)	2 (1–3)	0.96
Parity, median (IQR)	1 (0–1)	1 (0–1)	0.22
ASA physical status class, median (IQR)	2 (2–2)	2 (2–2)	0.001
Mallampati class, median (IQR)	2 (1–3)	2 (1–3)	0.07
Providers' level of training, median (IQR)	3 (3–4)	3 (2–4)	0.001

Providers' level of training: 1 = clinical anesthesia training year (CA) 1, 2 = CA2, 3 = CA3, 4 = CA4 and attendings.
ASA = American Society of Anesthesiologists; BMI = body mass index; CD = cesarean delivery; CSE = combined spinal epidural technique; EPID = traditional epidural technique; IQR = interquartile range.

Table 2. Descriptive Statistics of Overall Outcomes

Outcome Statistics	CSE	EPID	P Value
No. of all catheters placed	1,440	955	
Survival duration (min) of all catheters, median (IQR)	290 (151–496)	302 (151–559)	0.18
Failed catheters among all catheters	95/1,440 (6.6)	111/955 (11.6)	0.001
Duration (min) to failure, median (IQR)	41 (7–267)	75 (15–324)	0.048
Nontechnical failures among all those failed	47/95 (49.5)	77/111 (69.4)	0.006
Technical failures among all those failed	48/95 (50.5)	34/111 (30.6)	
Failures *during* first 30 min after placement	46/95 (48.4)	34/111 (30.6)	0.009
Failures *after* first 30 min from placement	49/95 (51.6)	77/111 (69.4)	
Nontechnical failures *during* first 30 min after placement	4/46 (8.7)	3/34 (8.8)	0.31
Technical failures *during* first 30 min after placement	42/46 (91.3)	31/34 (91.2)	
Nontechnical failures *after* first 30 min from placement	43/49 (87.8)	74/77 (96.1)	0.06
Technical failures *after* first 30 min from placement	6/49 (12.9)	3/77 (3.9)	
Catheters needed for CD	113/1,440 (7.9)	165/955 (17.3)	0.00001
Survival duration (min) of catheters needed for CD, median (IQR)	606 (407–862)	437 (234–760)	0.001
Failures among catheters needed for CD	3/113 (2.7)	17/165 (10.3)	0.03

Data are expressed as number, n/N (%) or median (interquartile range [IQR]). n is the number of events of concern, and N is the number of total events (denominator) in the corresponding category. Nontechnical failure = no block or inadequate analgesia; technical failure = inadvertent intravenous or intrathecal catheter or other technical failures such as obstructed or dislodged catheter.
CD = cesarean delivery; CSE = combined spinal epidural technique; EPID = traditional epidural technique.

included for consideration as covariates. Since the need for supplemental epidural top-ups and cesarean deliveries, if required, occurred only after catheter placement, they could not be determinants of the treatment (technique) or included as covariates. American Society of Anesthesiologists (ASA) physical status (PS) was also not included as a covariate because ASA PS (which is inherently subjective and has low interrater reliability, especially for obstetric patients) was less accurate or consistent than the other covariates included.[14–16] Furthermore, ASA PS is significantly correlated with BMI, already included as a covariate.

Single-variable proportional hazards regression models were created for gestational age, parity, providers' level of training, BMI, and procedure type. The catheter failure estimates ±SE for both types (CSE and EPID) of catheters at 1, 3, 5, and 10 h after catheter placement were calculated from the single-variable model. Using $P < 0.10$ from the univariate models as a threshold for inclusion in the multivariable

model, the best-fit multivariable model was then generated by removing variables with $P > 0.05$ from the multivariable model in a backward stepwise fashion. Initially, the multivariable model included all variables that met the univariate inclusion criteria and then the stepwise algorithm began, removing nonsignificant variables one at a time until only variables with $P < 0.05$ remained in the multivariable model. Provider's level of training was included in the multivariable model, even if not significant, to control for its effect in our final best-fit multivariable model. In addition, we generated an all-inclusive multivariable model analysis including all covariates (procedure type, BMI, providers' level of training, gestational age, and parity) considered from the univariate analyses regardless of inclusion threshold, to confirm if results were consistent with those of the final best-fit multivariable model.

To assess the primary outcome on the relationship between technique types (CSE *vs.* EPID) and survival (failure-free)

time, a proportional hazards model (PROC PHREG) with the counting method was used to assess the effect of the technique type, with effects of patients' BMI and providers' level of training controlled in the best-fit multivariable model. Using model-based estimates for the covariance matrix and a robust SE for the parameter estimates, this model correctly adjusted for within-subjects correlations in cases of multiple procedures within the same patient because of repeated catheter failures and replacements. A sensitivity test was performed to show if the results from our best-fit multivariable model were consistent when repeated procedures from the same patient were excluded from the analyses. Additional secondary sensitivity analyses—in which ASA PS and CD were added as covariates to the all-inclusive multivariable model described in the last part of the immediately preceding paragraph or when all catheters needed for CD were excluded from the best-fit multivariable model—were performed to further confirm the consistency in primary outcome from our final best-fit multivariable model.

To further examine differences in the timing of failure during the first 120 min after catheter placement within only those patients with catheter failure (failure-only analysis), Fisher exact test was applied to test for differences in proportion of total failures in 15-min interval time points. We also tested failure patterns in 15-min intervals, with the P value reported from the approximate chi-square statistic from the log-rank test. The former considers failures (odds ratio [OR]) in absolute terms (yes/no) within different time intervals, while the latter analyzes and compares the corresponding length of survival (hazard ratio [HR]). Each 15-min interval was viewed as an independent trial; each trial was tested at the $\alpha = 0.05$ level, with no adjustments for multiple comparisons.

For the survival analysis (the HR part of the study), we used QA records from previous years to estimate a risk ratio of failures of about 0.5 favoring CSE and an estimated cumulative failure incidence of 10% (data not shown). A sample size of 1,800 subjects with 10% failed epidural catheters was estimated *a priori* as adequate to show an HR of 0.50, with a power of 80%, and the two-sided $\alpha = 0.05$. For HRs and ORs, the expressed values compared CSE to EPID; a value below 1 indicated that CSE had a lower risk of epidural catheter failures, while a value above 1 indicated an increased risk for CSE. In cases of missing data, statistical procedures were fit in a model that included only patients with complete data for the variables being modeled.

Results

Overall Differences between CSE and EPID

Data from 2,210 unique patients with 2,395 neuraxial procedures (1,440 CSE and 955 EPID) for labor analgesia were obtained. No clinically relevant changes in guidelines, policies, or equipment occurred during the study period. One hundred seventy-nine patients required epidural catheter replacement once, 22 patients twice, and 5 patients thrice. Overall, 206 catheters failed and required replacement; only 185 were replaced and 21 were not replaced, either because of patient refusal or immediate delivery. Providers from training levels 1, 2, 3, and 4 placed 216, 563, 922, and 687 of the catheters, respectively; their corresponding cumulative catheter failure incidences were 7.9, 8.5, 8.4, and 8.9%, respectively. Data were complete for all patients for catheter failures (yes/no) and duration of catheter usage. Provider type was missing for seven patients (0.3%), BMI for 33 patients (1.4%), gestational age for 7 patients (0.3%), and parity for 2 patients (less than 0.1%). Even in the all-inclusive multivariable regression model of catheter failures that included all considered covariates regardless of inclusion threshold, 98% of data were included in the model, since 2,348 of the 2,395 records were complete for the variables that were fit.

Descriptive statistics for patient demographics, providers' level of training, and overall outcome characteristics of catheter failures are shown in tables 1 and 2. Cumulative incidence of epidural catheter failures was significantly different between CSE and EPID ($P = 0.001$), but the overall types of failures did not differ between groups (table 2). The median time to failure was significantly shorter for CSE than for EPID ($P = 0.048$). In addition, 11.6% of all catheters placed for labor analgesia were later needed for cesarean anesthesia; among these, significantly more failed with EPID, despite the shorter duration of catheter usage (table 2).

Overall Catheter Survival (Failure-free) Time
Univariate Analysis. In the univariate analysis model (table 3), BMI, gestational age, and procedure type were significantly associated with epidural catheter failures, but providers' level of training and parity were not. Figure 1 shows the Kaplan–Meier survival curve for the time until recognition of all failures (nontechnical and technical) *versus* proportion surviving (or event-free proportion) for all catheters through the course of labor and delivery in a single variable model. The failure estimates ±SE for both types (CSE and EPID) of catheters at 1, 3, 5, and 10 h after catheter placement were 3.5 ± 0.5, 4.3 ± 0.5, 6.0 ± 0.7, and $7.9 \pm 0.9\%$ with CSE, respectively; for EPID, they were 5.3 ± 0.7, 7.7 ± 0.9, 9.5 ± 1.0, and $13.6 \pm 1.4\%$, respectively. Figure 2A shows the survival curve of all catheters when only nontechnical failures were considered in a single variable model; in these cases, catheters placed with CSE were less likely (HR, 0.46; 95% CI, 0.32 to 0.66; $P < 0.0001$) to fail over the course of labor and delivery. However, when only technical failures are considered among all catheters, the overall likelihood of failure did not differ between CSE and EPID (HR, 0.94; 95% CI, 0.60 to 1.46; $P = 0.78$; fig. 2B).
Multivariable Analysis. The final best-fit multivariable model includes BMI and the type of procedure; both were significantly associated with EPID catheter failures ($P = 0.0002$ and $P < 0.0001$, respectively; table 4). Although not significant ($P = 0.75$), the effect of provider was

Table 3. Univariate Models of Covariates

Parameter	df	Parameter Estimate	SE	Chi-square	P Value	Hazard Ratio	95% CI
Procedure	1	−0.543	0.142	14.630	0.0001	0.58	0.44–0.77
BMI (kg/m²)	1	0.035	0.009	15.883	< 0.0001	1.04	1.02–1.05
Provider	3				0.97		
Provider 1	1	−0.070	0.275	0.066	0.78	0.93	0.54–1.60
Provider 2	1	−0.088	0.193	0.208	0.65	0.92	0.62–1.34
Provider 3	1	−0.067	0.172	0.152	0.70	0.94	0.67–1.31
Gestational age (wk)	1	−0.040	0.022	3.337	0.07	0.96	0.92–1.003
Parity	1	0.038	0.059	0.406	0.52	1.04	0.92–1.17

Total numbers of catheters analyzed for each covariate's univariate model: procedure = 2,395; body mass index (BMI) = 2,362; provider = 2,388; gestational age = 2,388; parity = 2,393. Provider = providers' level of training: 1 = clinical anesthesia training year (CA) 1, 2 = CA2, 3 = CA3, 4 = CA4 and attending combined, where 4 is the referent group. Referent group for procedure is traditional epidural technique, while exposure group is combined spinal epidural technique. For hazard ratios, a value below 1 indicates a lower risk of catheter failures, while a value above 1 indicates an increased risk of catheter failures. df = degrees of freedom.
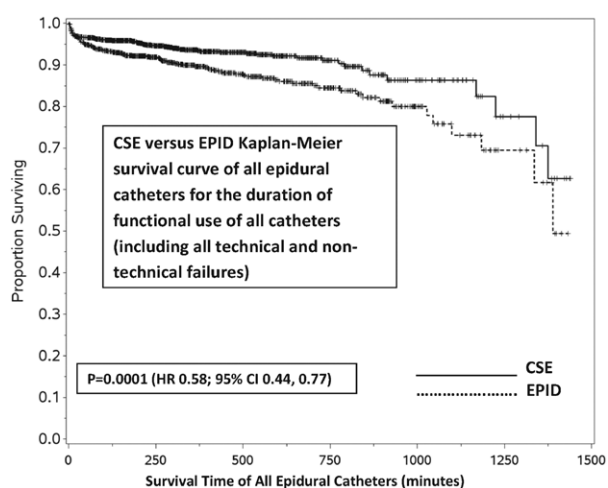

Fig. 1. Kaplan–Meier survival analysis of all epidural catheters placed with combined spinal epidural technique (CSE, n = 1,440) *versus* traditional epidural technique (EPID, n = 955) in a univariate model. HR = hazard ratio; survival time = duration of catheter remained failure free or until end of functional usage.

controlled for in the final model. Gestational age met the inclusion threshold in the univariate analysis but became insignificant and was removed in the stepwise algorithm of the final best-fit multivariable model. The cumulative incidence of epidural catheter failures was 8.5% overall, 6.3% for CSE, and 11.7% for EPID (P < 0.000001). When only nontechnical failures were considered in the multivariable model, catheters placed with CSE remained less likely (HR, 0.49; 95% CI, 0.33 to 0.73; P = 0.0004) to fail over the course of labor and delivery. However, when only technical failures are considered, the overall likelihood of failures did not differ between techniques (HR, 0.94; 95% CI, 0.60 to 1.46; P = 0.78). In addition, when all considered covariates were modeled in an all-inclusive multivariable model regardless of their inclusion threshold or P value, the results for the primary outcome (HR, 0.60; 95% CI, 0.44 to 0.82; P = 0.001) were consistent with those in our final multivariable model and did not add any statistically significant variables to it.

Consistency of the Model

The proportional hazards model (PROC PHREG) used correctly accounted for repeated procedures within the same patients. Results did not change in a sensitivity analysis when only the first procedure of each patient was included. When the primary analysis (catheter failures between techniques) was performed including only the first procedure for each patient, results for the primary outcome from the single-variable model (HR, 0.63; 95% CI, 0.47 to 0.84; P = 0.002) and the all-inclusive multivariable model (HR, 0.65; 95% CI, 0.47 to 0.91; P = 0.01) were consistent with results from models that included repeated procedures within the same patients (tables 3 and 4). Similarly, when catheters needed for CD were excluded from the final best-fit multivariable model, the primary outcome (HR, 0.58; 95% CI, 0.42 to 0.80; P = 0.0009) remained essentially unchanged. Finally, even when ASA PS and CD were included to the covariates (procedure type, BMI, providers' level of training, gestational age, and parity) of the all-inclusive multivariable model, the primary outcome findings (HR, 0.61; 95% CI, 0.44 to 0.83; P = 0.002) were consistent and the conclusion was the same.

Failure Pattern and Analyses of Only Failed Catheters (Failure-only Model)

Figure 3A shows the survival curve in a univariate model of only all failed catheters. There were no overall differences in the catheter failure time between CSE and EPID (HR, 1.17; 95% CI, 0.89 to 1.54; P = 0.26; fig. 3A). When the survival time for the first 120 min of catheter placement was analyzed, only the survival time during the first 30 min differed between CSE and EPID (HR, 1.86; 95% CI, 1.19 to 2.90; P = 0.005). Beyond 30 min, there was no overall difference in survival time between procedure types (fig. 3B). Similar results were seen with ORs (CSE *vs.* EPID as referent) when looking at failure proportions, rather than length of survival, in 15-min intervals. Among catheters that eventually failed, the ORs of catheter failures (CSE *vs.* EPID as referent) at the first three 15-min interval time points after catheter
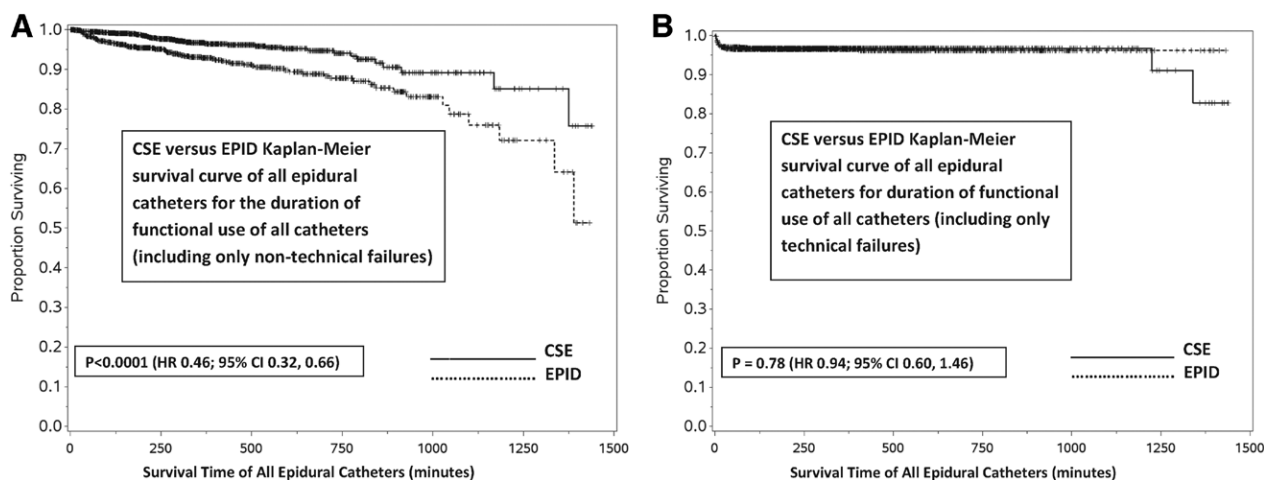
Fig. 2. (*A*) Kaplan–Meier survival analysis of all epidural catheters placed with combined spinal epidural technique (CSE) *versus* traditional epidural technique (EPID), including only nontechnical failures in a univariate model (47 and 77 nontechnical failures occurred with CSE and EPID, respectively). (*B*) Kaplan–Meier survival analysis of all epidural catheters placed with CSE *versus* EPID, including only technical failures in a univariate model (48 and 34 technical failures occurred with CSE and EPID, respectively). HR = hazard ratio; nontechnical failures = no block or inadequate analgesia; survival time = duration of catheter remained failure free or until end of functional usage; technical failures = inadvertent intravenous or intrathecal catheter, or other technical failures such as obstructed or dislodged catheter.

Table 4. Final Multivariable Model for Survival Analyses of All Catheters with Procedural Type, BMI, and Provider Experience Level Controlled in the Model

Parameter	df	Parameter Estimate	SE	Chi-square	P Value	Hazard Ratio	95% CI
Procedure	1	0.544	0.154	12.430	0.0002	0.58	0.43–0.79
BMI (kg/m^2)	1	0.026	0.009	8.573	0.003	1.03	1.02–1.04
Provider	3				0.75		
Provider 1	1	−0.298	0.284	1.102	0.29	0.74	0.43–1.30
Provider 2	1	−0.117	0.196	0.360	0.55	0.89	0.61–1.31
Provider 3	1	−0.058	0.175	0.109	0.74	0.94	0.67–1.33

Number of catheters in the model = total 2,355: combined spinal epidural technique (CSE) is 1,416 and traditional epidural technique (EPID) is 939. Number of unique subjects in the model = total 2,174: CSE 1,384 and EPID 790. Provider = providers' level of training: 1 = clinical anesthesia training year (CA) 1, 2 = CA2, 3 = CA3, 4 = CA4 and attending combined, where 4 is the referent group. Referent group for procedure is EPID, while exposure group is CSE. For hazard ratios, a value below 1 indicates lower risk of catheter failures; a value above 1 indicates increased risk of catheter failures.
BMI = body mass index; *df* = degrees of freedom.

placement were 2.25 at 15 min (95% CI, 1.25 to 4.06; *P* = 0.008) and 2.13 at 30 min (95% CI, 1.20 to 3.76; *P* = 0.010), with nonsignificant differences between CSE and EPID (referent) starting at 45 min (OR, 1.39; 95% CI, 0.80 to 2.41; *P* = 0.26). Furthermore, during the first 30 min after catheter placement, 91.3 and 91.2% of the epidural catheter failures from CSE and EPID, respectively, were technical failures, and frequency did not differ between groups (*P* = 0.31; table 2).

Discussion

Compared to EPID, catheters placed *via* CSE were associated with a 0.58-times overall likelihood of failures throughout the course of labor neuraxial analgesia. When only failed catheters were compared, there was no overall difference between the two techniques in their proportion of survival (or failure) over the full-time course of usage. These results

suggest that the time to recognizing catheter failures was not delayed by CSE. When only failures occurring during the first 120 min after placement were analyzed in 15-min intervals, more failed catheters from CSE than from EPID were recognized in the first 30 min from placement; however, no differences were seen beyond the first 30 min.

Although technical failures predominated during the first 30 min after placement for both CSE and EPID, a few nontechnical (inadequate analgesia or no block) failures also occurred; their incidence did not differ between groups. With group assignment based on intended procedure in this study, nontechnical failures were recognized with CSE when EPID catheters were used within the first 30 min if the spinal dose did not provide adequate analgesia, as reported elsewhere.[9,12,17] The proportions of nontechnical (inadequate analgesia or no block) failures were similarly small for both CSE and EPID during the first 30 min of placement. This result also suggests that CSE did not increase or delay unrecognized poorly
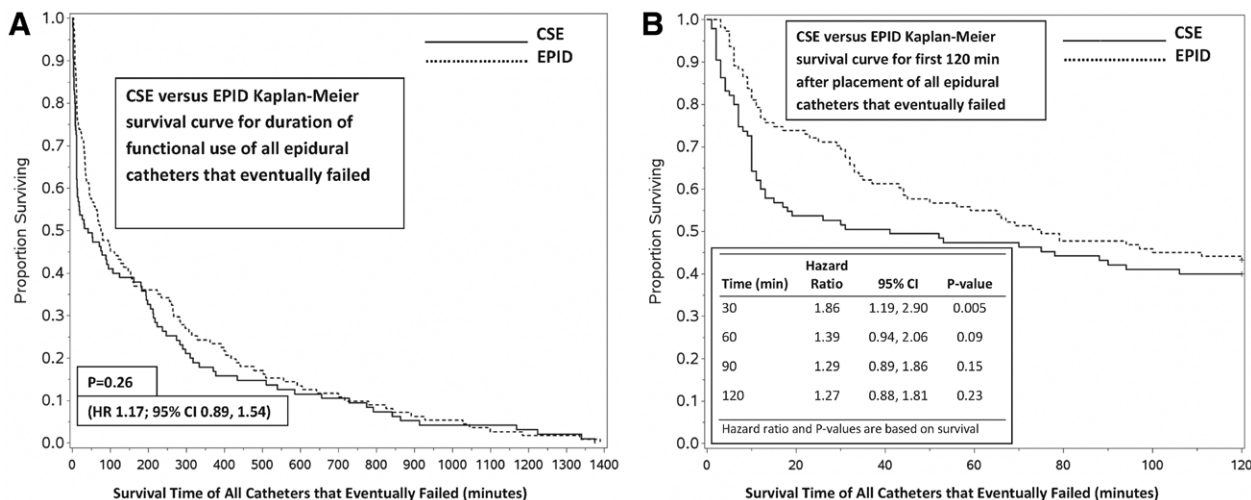
Fig. 3. (*A*) Kaplan–Meier survival analysis of all failed epidural catheters placed with combined spinal epidural technique (CSE) *versus* traditional epidural technique (EPID) in a univariate model (95 and 111 epidural catheter failures occurred with CSE and EPID, respectively). (*B*) Kaplan–Meier survival analysis of all failed epidural catheters placed with CSE *versus* EPID during the first 120 min after catheter placement in a univariate model (57 and 63 epidural catheter failures occurred during the first 120 min after placement with CSE and EPID, respectively). HR = hazard ratio; survival time = duration of catheter remaining failure free or until end of functional usage.

functioning catheters compared to EPID. Furthermore, catheters placed with CSE for labor analgesia were less likely to fail than those placed with EPID when needed for cesarean anesthesia, despite the fact that the duration of catheter usage for labor analgesia was generally already longer with CSE.

The primary purpose of this study was to determine the survival characteristics and differences, if any, in the timing of epidural catheter failures between CSE and EPID. Data supporting or refuting the concern of CSE delaying recognition of catheter failures are lacking and have not been published to our knowledge. This study is the first systematic survival analysis to show and compare the timing of catheter failures between techniques, and the first to provide clinically applicable evidence on this topic. Thus, choosing EPID or CSE should be based on evidence-based risks of catheter survival, efficacy, and technique-associated maternal and fetal side effects, such as fetal bradycardia or pathology not favorable for dural puncture.[7,18–26]

Some potential limitations of this study include its retrospective nature at a single institution, possible providers' selection bias for techniques, unblinded biases in determining catheter failures, potential overlapped etiologies between failure types, and the small sample size in the failure-only analyses. Although the overall distribution of failure types we observed is consistent with our historic QA findings, potential overlap of etiologies between failure types could exist and, together with the small sample size in the failure-only model, might have prevented detection of differences of failure between technique groups.

Our final best-fit multivariable model appropriately accounted for key clinically relevant confounders such as providers' level of training and patients' BMI, as well as repeated catheter replacement in the same patient. Furthermore,

secondary sensitivity analyses—in which ASA PS and cesarean delivery were added as covariates to the all-inclusive multivariable model or when all catheters needed for CD were excluded from the best-fit multivariable model—all indicated that the results and conclusions for the primary outcome remained essentially the same as in the best-fit multivariable model.

Potential bias from unblinded determination of catheter failures could have affected the results or conclusion. Providers could be more likely to replace an untested catheter from a CSE procedure. Although this practice does not occur at our institution, if it did, our study would have overestimated the true failures (or underestimated the survival) of catheters with CSE. It would not have altered, but strengthened, our current conclusion that CSE remains less likely to fail.

The lack of effect that providers' level of training conferred on catheter failures may be, in part, due to confounders (such as providers' past experiences or timing of most recent regional or obstetric anesthesia rotation) that could have affected the provider's skill in placement of neuraxial blocks. However, given that catheter failure incidences were within 1% among all providers' level of training, a sample size of more than 12,277 per group would be needed to find significant differences with 80% power and two-sided α of 0.05. Our best-fit multivariable model did control for effects of providers' level of training. Our usual practice guidelines might have mitigated some limitations of this retrospective study, since the determination of catheter failures was consistent among all providers. The retrospective nature of this study allowed for observation of a large sample size of patients and providers. Thus, it realistically captures a typical academic practice without the artificial situation imposed by a controlled randomized study.

In conclusion, CSE has a significantly lower risk of overall epidural catheter failures than EPID and does not delay

recognition of catheter failures. The choice of CSE or EPID labor analgesia should be based upon evidence-based risks of catheter survival, efficacy, and technique-associated maternal and fetal side effects.

Competing Interests

The authors declare no competing interests.

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