Original Article

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The effect of placement and management of intrathecal catheters following accidental dural puncture on the incidence of postdural puncture headache and severity: a retrospective real-world study

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Summary

Accidental dural puncture during an attempt to establish labour epidural analgesia can result in postdural puncture headache and long-term debilitating conditions. Epidural blood patch, the gold standard treatment for this headache, is invasive and not always successful. Inserting an intrathecal catheter after accidental dural puncture may prevent postdural puncture headache. We evaluated the effect of intrathecal catheter insertion on the incidence of postdural puncture headache and the need for epidural blood patch and whether duration of intrathecal catheterisation or injection of intrathecal saline affected outcome. Our retrospective study was conducted at two tertiary, university-affiliated medical centres between 2017 and 2022 and included 92,651 epidurals and 550 cases of accidental dural puncture (0.59%); 219 parturients (39.8%) received an intrathecal catheter and 331 (60.2%) a resited epidural. Use of an intrathecal catheter versus resiting the epidural did not decrease the odds of postdural puncture headache, adjusted odds ratio (aOR) (95%CI) 0.91 (0.81–1.01), but was associated with a lower need for epidural blood patch (aOR (95%CI) 0.82 (0.73–0.91), p < 0.001). We found no benefit in leaving in the intrathecal catheter for 24 h postpartum (postdural puncture headache, aOR (95%Cl) 1.01 (1.00–1.02), p = 0.015; epidural blood patch, aOR (95%Cl) 1.00 (0.99–1.01), p = 0.40). We found an added benefit of injecting intrathecal saline as it decreased the incidence of postdural puncture headache (aOR (95%CI) 0.85 (0.73-0.99), p = 0.04) and the need for epidural blood patch (aOR (95%Cl) 0.75 (0.64–0.87), p < 0.001). Our study confirms the benefits of intrathecal catheterisation and provides guidance on how to best manage an intrathecal catheter.

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Introduction

Epidural analgesia provides excellent analgesia for labouring women but is associated with some serious complications. Accidental dural puncture is the most common complication in obstetric anaesthesia, occurring in 0.5-1% of all epidurals [1] and resulting in a postdural puncture headache (PDPH) in 60–70% of these women [2]. Postdural puncture headache is a debilitating condition and has been shown to be associated with decreased breastfeeding and increased incidence of postpartum depression [3]. Postdural puncture headache is also known to increase the chances of devastating neurological consequences such as subdural haematoma [4] and cerebral venous thrombosis [5]. In addition, it has been shown to lead to chronic headache and backache in some patients [6-8]. Prevention of accidental dural puncture has become a quality indicator to support the implementation of quality standards in obstetric anaesthesia [9].

To date, epidural blood patch is the definitive treatment for PDPH. Unfortunately, it is an invasive procedure associated with temporary back pain and can be associated with serious and devastating complications like meningitis, epidural haematoma and arachnoiditis [10]. In addition, epidural blood patch is not always successful [11], as 20% of women may require a second blood patch and 1% even a third blood patch [12]. Furthermore, epidural blood patch has not been shown to prevent most of the long-term complications of PDPH [7, 8].

Because of the high morbidity associated with PDPH, many studies have focused on prevention and mitigating its severity [13]. Unfortunately, accidental dural puncture prevention studies have found that many factors are not modifiable [14]. Therefore, research has delved into preventing PDPH once an accidental dural puncture has occurred. There has been growing interest in leaving an intrathecal catheter after the initial accidental dural puncture, but evidence for its utility is mixed [15]. A recent meta-analysis and sequential trial analysis was unable to find that intrathecal catheter decreased the rate of PDPH [16], but this meta-analysis included studies with different intrathecal catheter protocols and duration.

It has been suggested that leaving the intrathecal catheter in for 24 h may decrease PDPH by generating a thrombin plaque. Studies by Rana et al. [17] and Verstraete et al. [18] demonstrated a marked decrease in the incidence of PDPH when a catheter was left in for 24 h, but other studies disputed this [19]. Recent consensus guidelines suggested leaving the catheter in for 24 h but this recommendation has yet to be proven [15].

Historical case reports and series [20, 21] and two retrospective studies from the same institution [19, 22] showed a decreased incidence of headache when intrathecal saline was injected. The theory behind this was increased cerebrospinal fluid volume.

In our two Clalit health management organisation hospitals in Israel we have a combined delivery rate of 23,000 with an epidural rate of 70%. Both hospitals have very similar epidural, intrathecal catheter and postdural puncture headache management protocols. We decided to perform this retrospective study to investigate ways to decrease the incidence of postdural puncture headache and the need for epidural blood patch.

Therefore, we performed a study that aimed to answer the following questions. First, we wanted to evaluate whether intrathecal catheter insertion compared with resiting an epidural catheter affected the incidence of PDPH and the need for epidural blood patch; second, we asked whether the duration of intrathecal catheter catheterisation made a difference; and third, whether injecting intrathecal catheter saline affected the incidence of PDPH and the need for epidural blood patch. Finally, we did an exploratory analysis comparing the optimal protocol with the rest of the treatments.

Methods

We conducted a retrospective study of all accidental dural punctures and all PDPHs after epidural insertion during delivery between 2017 and 2022 at two tertiary, universityaffiliated medical centres. The local institutional review boards of the hospitals approved the study.

In both hospitals, accidental dural punctures and PDPHs were recorded in a handwritten log and confirmed via electronic medical data. In cases of accidental dural puncture, the anaesthetist either inserted an intrathecal catheter and continued with this throughout labour or reinserted the epidural catheter in a different site. Whereas both hospitals have an identical written intrathecal catheter protocol and this was the recommended protocol, the choice of treatment was left to the anaesthetist's discretion. In addition, the anaesthetist chose the duration of intrathecal catheter catheterisation (removed immediately after labour or kept in situ for 24 h). The anaesthetist also chose whether to inject 10 ml of normal saline intrathecally. In cases when an intrathecal catheter was threaded, both departmental protocols instituted continuous spinal analgesia with 2–4 ml. h^{-1} of bupivacaine 0.08% and fentanyl $2 \mu g.ml^{-1}$ solution. If the visual numeric scale was > 70/100 at 30 min or any time afterwards, a top-up dose of 2 ml of the same solution was given by an anaesthetist. In cases of resited epidurals, the protocol was an initial bolus of 15 ml of bupivacaine 0.1% and fentanyl 100 μ g given as two separate doses followed by patient-controlled epidural analgesia (bupivacaine 0.08% and fentanyl 2 μ g.ml⁻¹, basal rate 8–12 ml.h⁻¹, patient-administered bolus 5 ml, lockout interval 15 min). At the time of the study, combined spinal epidurals were not routinely performed in either hospital.

In cases of PDPH, women were assessed daily by an anaesthetist. To confirm that the headache was a PDPH, it had to fit the classification of the International Headache Classification System; in cases where the headache was not typical, it was deemed a PDPH only after a consultation by a neurologist. In cases of PDPH, all women were given oral acetaminophen 4 g.d⁻¹, caffeine 300 mg.d⁻¹ and dipyrone 3 g.d⁻¹. The anaesthetist could also decide whether to initiate treatment with either hydrocortisone or cosyntropin, a medication affecting the adrenocortical pituitary axis.

If the visual numeric scale was > 40/100 after 24 h, or if there was no improvement in symptoms after initiation of conservative treatment, an epidural blood patch was offered. The epidural blood patch procedure was performed by a senior anaesthetist. In one hospital, the epidural blood patch was performed in the operating theatre, while in the other hospital, the epidural blood patch was either performed in the operating theatre or in the pain clinic. If the patient complained of headache recurrence after the blood patch, a neurologist was consulted and either a computed tomography brain scan or magnetic resonance imaging was performed. A repeat blood patch was performed if imaging was normal and pain persisted.

We collected patient data (age, height, weight), and obstetric data (gravidity, parity, cervical opening during epidural insertion and delivery mode) for each patient. Data were also collected on how the epidural was performed (loss of resistance technique, number of attempts, intrathecal catheter left, intrathecal catheter catheterisation duration, intrathecal catheter saline injection); PDPH onset; conservative treatment; steroids; cosyntropin; epidural blood patch performance; and the need for repeat epidural blood patch.

The primary study outcome measures were the development of PDPH and the need for epidural blood patch. Our primary research question was whether intrathecal catheter insertion was associated with a decreased risk of PDPH and reduced the need for epidural blood patch. Our secondary research questions were whether there was an association between duration of intrathecal catheter catheterisation or injection of intrathecal catheter saline with the development of PDPH or the need for epidural blood patch.

To assess the associations between intrathecal catheter and PDPH, as well as epidural blood patch, we conducted multivariable logistic regression. Independent variables were: BMI; parity; mode of delivery (vaginal, vacuum or caesarean section); multiple attempts; hospital; and use of an intrathecal catheter (vs. resiting), while PDPH and epidural blood patch were dependent variables. To assess the association between the use of saline through the intrathecal catheter/duration of intrathecal catheter catheterisation (in hours) and PDPH and epidural blood patch, multivariable logistic regression models were created using the same variables as above. For continuous variables and in case of normal distribution, a t-test was used. In case of non-normal distribution, a Mann–Whitney test was used. Fisher's exact test was used to test for differences between categorical variables. A p value < 0.05 was considered statistically significant. All statistical analyses were conducted using R statistical software (version 4.2.2, R Foundation, Vienna, Austria).

Results

During the study period, there were 92,651 epidurals and 550 cases of accidental dural puncture (0.59%). Of these, 322 parturients developed PDPH (58.5%) and 215 (39.1%) required an epidural blood patch; 15 (2.7%) required a second epidural blood patch. A total of 219 parturients (39.8%) received an intrathecal catheter and 331 (60.2%) a resited epidural. Patient characteristics are presented in Table 1.

Out of 219 parturients that received an intrathecal catheter after accidental dural puncture, 124 (56.6% (95%CI 50.0–63.2%)) developed a PDPH, while 198 of 331 (59.8% (95%CI 54.3–65.1%)) who had a resited epidural developed a PDPH (p = 0.54). Sixty-eight of 219 (31.0% (95%CI 25.1–37.7%)) parturients from the intrathecal catheter group needed an epidural blood patch and 147 of 331 (44.4% (95%CI 39.0–49.9%)) of the resited epidural group required an epidural blood patch (p = 0.003).

Use of an intrathecal catheter vs. resiting the epidural did not decrease the odds of postdural puncture headache, adjusted odds ratio (aOR) (95%CI) 0.91 (0.81–1.01), p = 0.08, but decreased the odds of requiring an epidural blood patch by 18%, aOR (95%CI) 0.82 (0.73–0.91), p < 0.001.

We found that duration of intrathecal catheter catheterisation (in hours) was associated with increased odds of PDPH, aOR(95%CI) 1.01 (1.00–1.02), p = 0.015, but

	Overall n = 550	Intrathecal catheter n = 219	Resited n = 331	p value
Age, y	30.0 (26.0–34.0 [18.0–44.0])	31.0 (27.0–34.5 [18.0–43.0])	29.0 (25.0–34.0 [18.0–44.0])	0.07
BMI, kg.m ⁻²	28.1 (25.2–31.6 [11.1–58.4])	28.1 (25.3–31.4 [11.1–41.0])	28.2 (25.3–31.6 [18.7–58.4])	0.40
Gravidity	2.0 (1.0-4.0 [0.0-15.0])	2.0 (1.0-4.0 [0.0-13.0])	2.0(1.0-4.0[0.0-15.0])	0.07
Parity	1.0 (0.0–2.0 [0.0–12.0])	1.0 (0.0–2.0 [0.0–10.0])	1.0 (0.0–2.0 [0.0–12.0])	0.33
Gestational week	39.0 (38.0-40.0 [27.0-42.0])	39.0 (38.0-40.0 [27.0-42.0])	39.0 (38.0–40.0 [32.0–41.0])	0.57
Delivery mode				
Caesarean section	480 (87.3%)	187 (85.4%)	293 (88.5%)	0.51
Vaginal	33 (6.0%)	16(7.3%)	17 (5.1%)	
Ventouse	37 (6.7%)	16(7.3%)	21 (6.4%)	
Need for multiple epidural attempts	327 (61.6%)	64 (31.4%)	263 (80.4%)	< 0.001
Use of intravenous steroids	33 (6.0%)	19 (8.7%)	14(4.2%)	0.05
Use of intravenous cosyntropin	81 (14.8%)	25(11.4%)	56 (17.0%)	0.09

Table 1 Patient characteristics stratified by use of intrathecal catheter and resiting of the epidural catheter. Values are median(IQR [range]) and number (proportion).

not with odds of requiring an epidural blood patch, aOR (95%CI) 1.00(0.99-1.01), p = 0.40.

Of the 82 parturients that received saline through the intrathecal catheter, <u>38</u> (46.3% (95%CI 35.4–57.6%)) developed a PDPH, while 87 of 137 (63.5% (95%CI 54.8–71.4%)) that received no saline developed a PDPH (p = 0.02). <u>Twelve</u> of 82 parturients in the intrathecal catheter saline group (14.6% (95%CI 8.1–24.6%)) required an epidural blood patch, while 57 of 137 (41.6% (95%CI 33.3–50.3%)) that received no saline through the intrathecal catheter required an epidural blood patch (p < 0.001).

In women that received an intrathecal catheter, saline through the intrathecal catheter decreased the odds of PDPH by 15%, aOR (95%CI) 0.85 (0.73–0.99), p = 0.04. Likewise, administration of intrathecal saline led to lower odds of requiring an epidural blood patch, aOR (95%CI) 0.75 (0.64–0.87), p < 0.001.

We performed an additional analysis that compared intrathecal catheters with saline to a combined group of intrathecal catheters without saline plus epidural resite. The aOR (95%CI) for PDPH and the need for an epidural blood patch were 0.84 (0.72–0.99) and 0.76 (0.66–0.88), respectively.

Discussion

In this study, we found several interesting findings. First, inserting an intrathecal catheter alone does not decrease the incidence of PDPH but does decrease the need for epidural blood patch. Second, there is no benefit in leaving the catheter in for 24 h postpartum. Finally, in women with an intrathecal catheter, injection of intrathecal saline decreases the incidence of PDPH and the need for epidural blood patch.

There has been much controversy in the literature regarding optimal analgesic management once an accidental dural puncture has happened. One of the most significant advantages of inserting an intrathecal catheter is the ability to provide fast adequate analgesia without the need to do another injection. In one randomised study, although prematurely stopped, leaving in an intrathecal catheter was associated with fewer complications than resiting the epidural [23]. However, opponents of intrathecal catheters suggest that leaving one in situ may lead to catastrophic complications including inadvertent drug errors, neurological injury and meningitis, even though these complications have been reported very rarely [4, 5].

There is also much controversy on whether intrathecal catheter insertion prevents the development of PDPH. The concept of inserting an intrathecal catheter to prevent PDPH was first suggested by Cohen et al. in 1989 [24]. Since then, some articles showed that intrathecal catheters lead to a decreased incidence of PDPH [18, 22, 25, 26] and a decreased need for an epidural blood patch [27], while other studies disputed this [23, 28, 29]. In a recent meta-analysis and sequential trial analysis of 13 studies representing a total of 1653 patients, the relative risk (95% CI) of developing a PDPH after intrathecal catheter insertion (compared with epidural catheter resiting) was 0.82 (0.71–0.95) and the relative risk (95%CI) of requiring an epidural

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blood patch was 0.62 (0.49–0.79) [16]. However, the trial sequential analysis provided insufficient evidence to draw a firm conclusion. Since then, a retrospective study has been published showing that insertion of an intrathecal catheter led to a significant reduction both in the incidence of PDPH (21.7% vs. 67.3%, $p \le 0.001$) and the need for epidural blood patch (12.4% vs. 50.0%, $p \le 0.001$) [22]. Our large study showed that intrathecal catheters could not prevent PDPH but may have been able to mitigate their severity, as fewer women required an epidural blood patch.

Our study showed that leaving in an intrathecal catheter conferred absolutely no benefit in preventing PDPH. Cohen et al. suggested that leaving in an intrathecal catheter for 24 h may generate thrombin, thus closing the dural puncture [24]. This question has been widely disputed. In two small retrospective studies that compared an intrathecal catheter removed immediately postpartum with an intrathecal catheter left in for 24 h [19, 25], only one found a significant decrease in PDPH and the need for an epidural blood patch in the group in which the intrathecal catheter was left in for 24 h [25]. We believe this study will discourage leaving the intrathecal catheter for prolonged postpartum periods.

We have shown that women who received saline through the intrathecal catheter had decreased odds of developing PDPH and of requiring an epidural blood patch. Injecting normal saline intrathecally may restore cerebrospinal fluid volume and thus mitigate cerebral hypotension and PDPH [19, 22]. Two case series where saline was injected intrathecally after an accidental dural puncture suggest the risks of PDPH were mitigated [20, 21]. Two studies from the same institution found that a 10 ml intrathecal bolus of saline decreased the need for epidural blood patch but had a variable effect on PDPH [19, 22].

We feel our results could stimulate a randomised controlled trial to test the efficacy of the use of saline through an intrathecal catheter, providing further evidence for the most effective management of intrathecal catheter. Before more compelling evidence is available, we suggest injecting saline into an intrathecal catheter, given the promising data from our analysis and the low risks that may be associated with it.

The advantages of our study are the large numbers and the real-world data presented due to the inclusion of two very large study centres performing many neuraxial procedures for labour. The demand for real-world data has increased since these data are generalisable beyond the limited scope available in randomised controlled trials. In 2016, the USA enacted the 21st Century Cures Act [30], which highlighted the need for robust real-world data to demonstrate effectiveness and safety of healthcare innovations.

The disadvantage of this study is its retrospective nature, which carries a higher risk of bias than a randomised controlled trial. However, there are some serious hurdles to randomised controlled trials on this research question. The incidence of 0.5–1% of accidental dural punctures is quite low; women would have to be informed and asked for consent when epidural analgesia is discussed and there will be a large discrepancy between the effort of recruiting women for the study and the number of women who could finally be included. Moreover, randomisation and blinding will also be hard to do in this setting.

In addition, though all women received dipyrone and paracetamol to treat PDPH, some received hydrocortisone or cosyntropin, which may have impacted the need for epidural blood patch. As these medications have minimal evidence, we believe their effect on our study results is negligible. Another limitation is that the study was done in two different hospitals. Despite the similar protocols, there might have been slight variations at local level or in patient population that may have impacted results. Also, whereas there were guidelines for intrathecal catheter management in cases when an intrathecal catheter was inserted, many decisions were left to the discretion of the anaesthetist, including duration of intrathecal catheterisation and administration of intrathecal saline. We were unfortunately unable to characterise factors, e.g. seniority, time of day, workload, which would influence choices.

In conclusion, in our retrospective real-world study, we have shown that, compared with resiting the epidural, intrathecal catheter insertion did not decrease the incidence of PDPH but did decrease the need for epidural blood patch. In women with an intrathecal catheter, there seemed to be no advantage in leaving the catheter in for 24 h postpartum, but there was an advantage in injecting normal saline intrathecally. Injection of saline into the catheter is a simple procedure and our data show that this may improve the outcome of women affected by an accidental dural puncture. Whereas there are risks for intrathecal saline injection, the procedure seems safe and may become a good option to mitigate severity of postdural puncture headache. Further randomised controlled studies must be performed to confirm this finding.

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