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Efficacy of a Prophylactic Epidural Blood Patch in Preventing Post Dural Puncture Headache in Parturients after Inadvertent Dural Puncture

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Background: **Postdural puncture headache (PDPH) occurs in up to 80% of parturients who experience inadvertent dural puncture during epidural catheter placement. The authors performed a randomized double blind study to assess the effect of prophylactic epidural blood patch on the incidence of PDPH and the need for therapeutic epidural blood patch.**

Methods: **Sixty-four parturients who incurred inadvertent dural puncture were randomized to receive a prophylactic epidural blood patch with 20 ml autologous blood (prophylactic epidural blood patch group) or a sham patch (sham group). Subjects were evaluated daily for development of PDPH for a minimum of 5 days after dural puncture. Those who developed a PDPH were followed daily for a minimum of 3 days after resolution of the headache. Subjects with moderate headaches who reported difficulties performing childcare activities and all those with severe headaches were advised to receive a therapeutic epidural blood patch.**

Results: **Eighteen of 32 subjects in each group (56%) developed PDPH. Therapeutic blood patch was recommended in similar numbers of patients in each group. The groups had similar onset time of PDPH, median peak pain scores, and number of days spent unable to perform childcare activities as a result of postural headache. The median duration of PDPH, however, was shorter in the prophylactic epidural blood patch group.**

Conclusions: **A decrease in the incidence of PDPH or the need for criteria-directed therapeutic epidural patch was not detected when a prophylactic epidural blood patch was administered to parturients after inadvertent dural puncture. However, prophylactic epidural blood patch did shorten the duration of PDPH symptoms.**

THE incidence of inadvertent dural puncture during the initiation of epidural analgesia/anesthesia in the obstetric population is between 0.04% and 6%.[1] Postdural puncture headache (PDPH) occurs in up to 80% of these patients, and the headache is often severe and incapacitating.[2]

Several studies have suggested that a prophylactic epidural blood patch (EBP), administered shortly after delivery before the epidural catheter is removed, may decrease the incidence of PDPH or the need for therapeutic EBP.[3–5] Interpretation of these study results is limited by a lack of proper randomization, blinding, or standard treatment protocol. Anecdotal experience and retrospective review of cases at our institution did not support these results. We hypothesized that prophylactic EBP, performed shortly after labor and delivery, would not decrease the incidence of PDPH and the need for therapeutic EBP. The purpose of this prospective, randomized, double blind trial was to examine the efficacy of a prophylactic EBP administered to obstetric patients with an inadvertent dural puncture from a 17-gauge epidural needle.

Materials and Methods

The Institutional Review Board of Northwestern University approved this study. Obstetric patients who incurred an inadvertent dural puncture with a 17-gauge epidural needle during initiation of neuraxial analgesia/anesthesia and subsequently had an epidural catheter placed successfully at the same or a different interspace were eligible to participate. Exclusion criteria included temperature greater than 37.8°C and coagulopathy. After delivery, written informed consent was obtained and subjects were randomized (*via* a computer-generated random number table) to a treatment (PEBP) group or a control/sham (SHAM) group. Group assignment was determined by opening an opaque envelope labeled with the study subject number. After resolution of analgesia/anesthesia all subjects had 20 ml blood withdrawn from an arm vein using aseptic technique. The subject was placed in the lateral position, and the syringe was attached to the epidural catheter and held out of view of the subject behind her back. An unblinded anesthesiologist investigator injected the autologous blood through the epidural catheter (PEBP group) or pretended to inject the blood but did not actually make an injection (SHAM group) over a several minute period. If the subject complained of lower back or sacral pain, the injection was stopped before 20 ml was injected. All subjects were asked to report sacral pressure during the injection or sham injection. At the end of the injection period, the epidural catheter was removed. The catheter and syringe were dropped onto an opaque towel behind the back of the subject. The towel was wrapped around the catheter and syringe and disposed of so that the subject and her family members, physicians, and nurses were blinded as to treatment group.

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Maternal age, height, weight, mode of delivery (vaginal *versus* Cesarean), duration of pushing efforts, and history of migraine or other headaches were recorded. The intervertebral level of dural puncture and the level of the successfully placed epidural catheter, use of neuraxial opioids, volume of local anesthetic solution infused and blood injected through the epidural catheter, and the time interval between dural puncture and prophylactic or sham patch were noted, as was the presence or absence of sacral pressure on injection. An anesthesiologist investigator unaware of treatment group evaluated the subjects postpartum to ascertain the presence of PDPH. Subjects were seen initially between 12 and 24 h postpartum and were subsequently seen daily while in the hospital and contacted by phone daily after discharge for a minimum of 5 days after dural puncture if they remained headache free. Subjects who developed a PDPH were followed for a minimum of 3 days after resolution of the headache. PDPH was defined as the presence of a headache or neck ache that improved significantly or completely when the subject assumed the supine position. Headache severity was assessed using a verbal rating score for pain (VRSP: 0 = no pain and 10 = worst possible pain). Each subject with a headache was asked if the headache was severe enough to prevent her from performing childcare duties regarding her newborn or other children. Presence or absence of backache was recorded daily.

The physician observer made treatment recommendations according to the following protocol: All mild postural headaches (VRSP <4) were treated conservatively with oral hydration, recommendations to increase oral caffeine intake, and oral analgesics as needed. Subjects who reported moderate headaches (VRSP = 4–6) also received conservative treatment if they reported no difficulty in performing childcare. If childcare difficulty was reported, the anesthesiologist investigator recommended a therapeutic EBP. All subjects with severe headaches (VRSP >6) were advised to receive a therapeutic EBP. Therapeutic EBP was not to be performed earlier than 24 h after dural puncture. These same criteria were used to determine need for a second therapeutic EBP if PDPH persisted or recurred after one therapeutic EBP. If the subject did not accept treatment recommendations (*e.g.*, the subject refused therapeutic blood patch although she met criteria for it), note was made both of the recommendation and the actual treatment performed.

Statistics

A sample size analysis indicated that 32 subjects were needed in each group to detect a 50% decrease in the incidence of PDPH from 75% to 37.5% with alpha of 0.05 and power of 0.80. Data were analyzed using the chi-square or Fisher's exact test (mode of delivery, prior history of migraine or other headaches, intervertebral level of the epidural catheter relative to dural puncture, neuraxial opioid bolus, presence of sacral pressure, presence of PDPH, ability to perform childcare, presence of backache, and need for therapeutic EBP) and the Mann-Whitney *U*-test (age, height, weight, body mass index, total volume of epidural infusion, volume of prophylactic EBP, time intervals, VRSP, area under the pain (VRSP) $\times$ time (days) curve). Data were also compared for subjects who developed a PDPH (regardless of group assignment) *versus* those who did not. A $P < 0.05$ was used to reject the null hypothesis.

Results

Thirty-two subjects were randomized to each group and received the assigned therapy. Two subjects in the

Table 1. Group Characteristics

	PEBP (n = 32)	SHAM (n = 32)	*P* value
Age (yr)	32 (27–36)	33 (29–37)	0.19
Height (cm)	164 (157–170)	165 (160–170)	0.59
Weight (kg)	82 (71–85)	88 (75–94)	0.18
Body mass index (kg/m^2)	28 (26–34)	30 (27–34)	0.13
History of headache (n)	9	7	0.56
History of migraine (n)	5	6	0.74
Vaginal delivery (n)	25	26	0.76
Duration of pushing (min)	42 (12–63)	20 (5–43)	0.13
Neuraxial opioid (n)	32	30	0.24
Volume of epidural infusion (ml)	90 (50–127)	79 (45–98)	0.22
Dural puncture to PEBP/SHAM interval (h)	6.4 (4.8–11.0)	6.3 (4.2–8.0)	0.39
Vertebral level of catheter relative to dural puncture (n)			
+1	4	6	
0	6	7	0.71
−1	22	19	
Sacral pressure (n)	8	1	0.03

Data presented as median (interquartile range) unless otherwise specified.

PEBP = prophylactic epidural blood patch; SHAM = sham blood patch; +1 = PEBP 1 vertebral level cephalad to dural puncture; 0 = PEBP at same level as dural puncture; −1 = PEBP 1 vertebral level caudad to dural puncture.

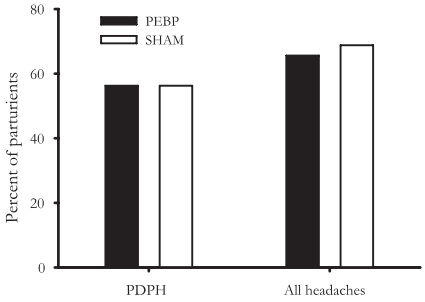

Fig. 1. The incidence of postdural puncture headaches (PDPH) as well as all reported headaches in subjects that received a prophylactic epidural blood patch (PEBP) or sham injection.

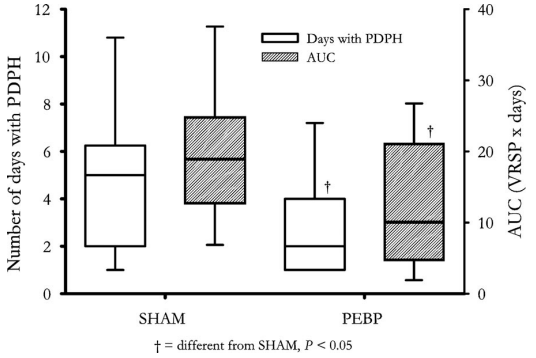

Fig. 2. Box plot of the duration of postdural puncture headaches (PDPH) and the pain intensity-duration (verbal rating score for pain (VRSP) × days) curve area (AUC) for the subjects that received a prophylactic epidural blood patch (PEBP) or sham injection. The box solid line represents the median value, the boxes are the interquartile range, and the whiskers are the 10th and 90th percentile range.

PEBP group and four subjects in the SHAM group were followed for only 1 or 2 days, rather than 3, after resolution of PDPH. Subjects in the PEBP group received a median of 20 ml of blood as a prophylactic patch. Three subjects in the PEBP group reported back pain during injection and were therefore given 18, 16, and 10 ml of blood, respectively. An additional four subjects received 18.5, 15, 11, and 10 ml of blood but no note was made explaining why less than 20 ml was injected.

Groups were similar with respect to age, height, weight, body mass index, and history of migraine or other headaches (table 1). The groups did not differ in terms of mode of delivery (vaginal *versus* Cesarean), time spent actively pushing, use of neuraxial opioids (including intrathecal or epidural morphine or fentanyl), total volume of local anesthetic solution infused through the epidural catheter during labor, or time interval between dural puncture and PEBP or sham EBP. The vertebral level of the dural puncture relative to the level of the epidural catheter was not different between groups. Subjects were more likely to feel sacral pressure during blood than during a sham injection. The percentage of subjects reporting backache during follow-up was 75% and 72% in the PEBP and SHAM groups, respectively ($P = 0.72$).

Table 2. PDPH and Treatment Outcomes

	PEBP (n = 32)	SHAM (n = 32)	*P* value
Onset of PDPH (d)*	2.0 (1–3)	1.5 (1–3)	0.57
Maximum VRSP (0–10)*	7 (4–8)	6 (5–9)	0.21
Inability to perform childcare (n)	10	13	0.69
Number of days unable to perform childcare (d)	1 (0–2)	1 (0–1)	0.69
Recommend therapeutic EBP (n)	11	15	0.14
Therapeutic EBP performed (n)	9	14	0.08
PDPH completely alleviated with therapeutic EBP (n)	3	9	0.15
>1 Therapeutic EBP (n)	2	1	0.30

Data presented as median (interquartile range) unless otherwise specified.

PEBP = prophylactic epidural blood patch; SHAM = sham blood patch; PDPH = postdural puncture headache; VRSP = verbal rating score for pain; EBP = epidural blood patch.

* Subset of subjects who had PDPH (n = 18 in each group).

The incidence of PDPH was the same in the PEBP and the SHAM groups (18 of 32, 56% of subjects in each group), as was the incidence of any headache (fig. 1). The groups had similar onset time of PDPH, maximum VRSP, and number of subjects, as well as the number of days spent unable to perform childcare as a result of postural headache (Table 2). The median duration of PDPH, however, was shorter in the PEBP group. Because of this, severity, as measured by area under the pain intensity-duration curve, was less for PEBP subjects (fig. 2).

PDPH severe enough to meet criteria for therapeutic EBP occurred at a similar frequency in the two groups (table 2). Therapeutic blood patches were recommended in 11 and 15 subjects and performed in nine and 14 subjects in the PEBP and SHAM groups, respectively. Two subjects in the PEBP group and one in the SHAM group met criteria for and received two therapeutic EBP.

When comparing subjects who developed PDPH with those who did not, the rate of Cesarean delivery was greater in subjects who did not develop PDPH (fig. 3). Likewise, those subjects who did not develop PDPH had a longer dural puncture to prophylactic EBP/SHAM interval and received a greater epidural infusate volume than those who developed PDPH (fig. 4).

There were no differences between subjects with PDPH and those without with regards to age, height,

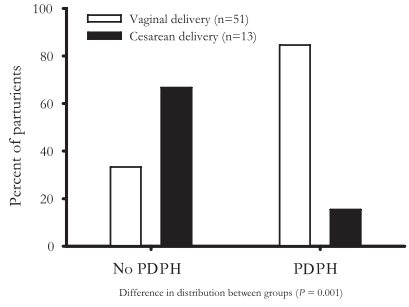

Fig. 3. Distribution of vaginal and cesarean delivery in subjects with or without a postdural puncture headache (PDPH).

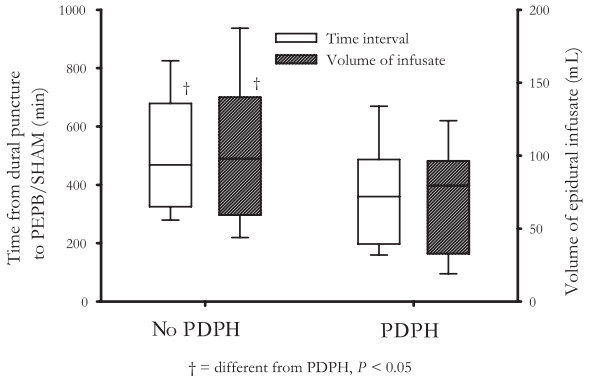

Fig. 4. Box plot of the time from dural puncture to prophylactic epidural blood patch (PEBP) or sham injection and the total volume of epidural infusate, in subjects with or without a postdural puncture headache (PDPH). The box solid line represents the median value, the boxes are the interquartile range, and the whiskers are the 10th and 90th percentile range.

weight, body mass index, history of headaches or migraines, time spent actively pushing, or use of neuraxial opioids (table 3). In subjects who received a PEBP, the vertebral level of the PEBP relative to dural puncture level was similar between subjects who developed a PDPH and those who did not. PDPH occurred at a rate of 15 of 25 patients (60%) who received 20 ml of blood and at a rate of three of seven (43%) among those who received less than 20 ml ($P = 0.42$).

Discussion

The principle finding of our study is that prophylactic EBP after inadvertent dural puncture during epidural catheter placement in parturients did not decrease the incidence of PDPH to the magnitude predicted. Neither did it decrease the need for criteria directed therapeutic EBP. The length and severity of PDPH symptoms, however, were decreased.

The efficacy of a therapeutic EBP compared to a sham procedure has been demonstrated in a randomized, controlled, double blinded trial.[6] However, therapeutic EBP is not as effective when performed within the first 24–48 h after dural puncture.[7,8] Whether this is because patients with particularly severe headaches tend to receive an EBP earlier and these severe headaches are less readily treatable or because delaying the EBP *per se* leads to a higher success rate, is unknown.

The practice of administering a prophylactic EBP to obstetric patients after inadvertent dural puncture with an epidural needle has been controversial, with approximately half of academic centers in North America employing it.[1] Uncontrolled and primarily retrospective studies, some with relatively small volumes of blood, have demonstrated either a positive effect or no effect of prophylactic EBP on the incidence and severity of PDPH.[9–12] When patients were allowed to select prophylactic EBP the rate of PDPH was 5%, compared with 87% in those that chose conservative management.[5]

Two randomized, controlled trials found a reduction in the incidence of PDPH; however, methodological considerations have led some authors to question the broad clinical application of these results.[13] Using a sequential group assignment strategy, investigators reported a decrease (21% *versus* 80%) in the incidence of PDPH in patients who received 15-ml prophylactic EBP compared with patients treated conservatively.[3] Although not statistically different, the rate of therapeutic EBP was 16% in the prophylactic EBP group *versus* 35% in the subjects treated conservatively. The investigators and subjects were aware of the group assignment. Another group of investigators, in a randomized, single-blinded study (the observer was blinded), reported PDPH in one of 10 (10%) patients who received 18–20 ml prophylactic EBP, compared with 7 of 11 (64%) patients who received only intravenous fluid hydration.[4] A limitation of this study was that subjects were assessed for PDPH by the blinded observer at 12 h and 24 h and 5 days after dural puncture but by an unblinded observer between these times. An additional limitation of both trials was the lack of standardized criteria for administering a therapeutic EBP. The trials were not blinded; this may have resulted in significant bias.

Possible explanations for the differences in results between our study and previous trials include appropriate randomization, double blinding and use of standardized criteria directing the use of therapeutic epidural blood patches. In addition, our sample size was larger than those of other trials.

Although the exact etiology of PDPH is unknown, it is presumed to be initiated by leakage of cerebrospinal

Table 3. PDPH *versus* no PDPH

	PDPH (n = 36)	No PDPH (n = 28)	*P* value
Age (yr)	33 (29–36)	33 (27–36)	0.95
Height (cm)	165 (160–170)	164 (158–170)	0.37
Weight (kg)	78 (73–87)	78 (75–90)	0.74
Body mass index (kg/m^2)	28 (26–33)	29 (27–34)	0.18
History of headache (n)	9	7	1.00
History of migraine (n)	6	5	0.90
Duration of pushing (min)	25 (15–60)	15 (0–58)	0.08
Neuraxial opioid (n)	34	28	0.19
Level of PEBP relative to dural puncture (n)*			
+1	2	2	
0	4	2	0.84
−1	12	10	

Data presented as median (interquartile range) unless specified.

PDPH = postdural puncture headache; PEBP = prophylactic epidural blood patch; +1 = PEBP 1 vertebral level cephalad to dural puncture; 0 = PEBP at same level as dural puncture; −1 = PEBP 1 vertebral level caudad to dural puncture.

* Subset of subjects randomized to receive PEBP (PDPH n = 18, no PDPH n = 14).

fluid (CSF). The loss of CSF may lead to a decrease in hydrostatic pressure resulting in downward displacement of the brainstem and traction on pain-sensitive meningeal structures. Although removal of CSF produces headache, any possible correlation between CSF leakage and headache is incomplete.[14–16] Furthermore, neither intracranial nor spinal CSF pressures reliably correlate with presence or severity of headache.[17,18] It has been postulated that PDPH is related to sudden volume and pressure changes across the intracranial vasculature when the patient assumes the upright position, leading to adenosine mediated intracranial venous dilation.[19] This is supported by the observation that jugular compression worsens PDPH, although it increases intracranial pressure.[17]

Injection into the epidural space quickly increases not only epidural pressure but also lumbar and intracranial subarachnoid pressures.[20,21] It is postulated that the increased pressure reverses adenosine-mediated cerebral venous dilation; this may explain why most PDPH patients experience some degree of immediate relief from an EBP.[22] Epidural blood also adheres to the dura, possibly forming a patch over the dural tear and preventing further leakage of CSF.[23]

There are several limitations to our study. For example, the sample size analysis was estimated based on an intrinsic PDPH rate of 75%, whereas the observed rate was 56%. The lower observed rate in this study may be related to the use of neuraxial opioids in nearly all of our patients. Several groups of investigators have suggested that neuraxial opioids may decrease PDPH rate.[24–26] Additional explanations may be related to the employment of standard recommendations to increase oral fluid and caffeine intake or to the relatively high body mass index in our study population. Despite this, salutary effects of the PEBP would unlikely be uncovered even with a substantially larger sample because the rate of PDPH was identical in the groups. However, the observed difference in severity and duration suggests that there may be a reduction in the need for therapeutic blood patch that this study was underpowered to detect. At the rate at which therapeutic EBP was recommended in this study (PEBP, 34%; SHAM, 47%), a *post hoc* power analysis determined that 476 subjects (238 per group) would be needed to detect a significant difference at alpha of 0.05 and power of 0.80. A number needed to treat analysis revealed that 8.0 ± 0.3 (95% confidence interval) patients would need a prophylactic EBP to avoid a single therapeutic EBP.

Another possible limitation was that we did not control epidural technique, although practitioners at our institution routinely use the loss of resistance to air technique with the epidural needle bevel oriented cephalad. These factors may influence the rate of PDPH.[27,28] In addition, there was no strict protocol regarding conservative management of PDPH.

Although several of our patients received less than 20 ml blood, only three subjects received less than 15 ml; this was unlikely to have influenced our results, as PDPH occurred at a similar rate among patients who received the full 20-ml volume and those who did not. Subjects in the PEBP group were more likely than those in the SHAM group to feel sacral pressure during injection, and this may have limited patient blinding.

Subjects with vaginal delivery were more likely to have PDPH than those with Cesarean delivery, although there was no relationship between time spent pushing and PDPH. Two retrospective reviews yielded conflicting results as to whether second stage pushing increased the incidence and severity of PDPH.[29,30] The influence of pushing efforts on incidence of PDPH requires further investigation.

Subjects with longer dural puncture to PEBP/SHAM time intervals and larger epidural infusate volumes during labor also had less PDPH. Because subjects who had long labors would be more likely to have longer dural puncture to PEBP/SHAM time intervals as well as higher epidural infusate volumes, it is unclear if incidence of PDPH is influenced by time from dural puncture to prophylactic patch, by epidural infusate volume, or by some other factor associated with both variables. Epidural infusion of crystalloid after dural puncture has been reported to be beneficial.[31] Whether routinely increasing the time interval until prophylactic EBP or increasing the infusate volume would result in a decreased incidence of PDPH or a reduction in symptoms requires further investigation.

Prophylactic EBP did not decrease the incidence of PDPH or the need for criteria-directed therapeutic EBP in parturients with inadvertent dural puncture during epidural catheter placement to the magnitude predicted. However, because prophylactic EBP did shorten the length and severity of PDPH symptoms without increasing the incidence of backache or other adverse effects, prophylactic EBP may be beneficial.

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