Original Article

Persistent headache and low back pain after accidental dural puncture in the obstetric population: a prospective, observational, multicentre cohort study

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Summary

Accidental dural puncture following epidural insertion can cause a post-dural headache that is defined by the International Headache Society as self-limiting. We aimed to confirm if accidental dural puncture could be associated with persistent headache and back pain when compared with matched control parturients. We performed a prospective multicentre cohort study evaluating the incidence of persistent headache following accidental dural puncture at nine UK obstetric units. Parturients who sustained an accidental dural puncture were matched with controls who had undergone an uneventful epidural insertion. Participants were followed-up at six-monthly intervals for 18 months. Primary outcome was the incidence of persistent headache at 18 months. Ninety parturients who had an accidental dural puncture were matched with 180 controls. The complete dataset for primary analysis was available for 256 (95%) participants. Incidence of persistent headache at 18 months was 58.4% (52/89) in the accidental puncture group and 17.4% (29/167) in the control group, odds ratio (95%CI) 18.4 (6.0–56.7), $p \leq 0.001$, after adjustment for past history of headache, Hospital Anxiety and Depression Scale (depression) and Hospital Anxiety and Depression Scale (anxiety) scores. Incidence of low back pain at 18 months was 48.3% (43/89) in the accidental puncture group and 17.4% (29/167) in the control group, odds ratio (95%CI) 4.14 (2.11–8.13), with adjustment. We have demonstrated that accidental dural puncture is associated with long-term morbidity including persistent headache in parturients. This challenges the current definition of post-dural puncture headache as a self-limiting condition and raises possible clinical, financial and medicolegal consequences.

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Introduction

Accidental dural puncture is a well-recognised complication of epidural insertion for labour analgesia, with a reported incidence of 1.2–2.6% [1–3]. Dural puncture and the subsequent intracranial hypotension can activate the trigeminocervical complex, resulting in post-dural puncture headache for which the use of an epidural blood patch remains the gold standard management [4–7]. Although

post-dural puncture headache can result in significant short-term distress and morbidity, the general consensus is that it is a self-limiting condition [8–10] and the International Headache Society's definition of post-dural puncture headache reflects this consensus [11]. However, there is emerging evidence from retrospective studies that accidental dural puncture may be associated with persistent headache [12–18]. In addition, there is low-quality evidence that accidental dural puncture and subsequent epidural blood patch may actually increase the risk of new onset low back pain [17, 19, 20]. To investigate this further, we performed a multicentre prospective matched cohort study to evaluate the incidence of persistent headache at 18 months following an accidental dural puncture during epidural insertion in an obstetric population. We hypothesised that the incidence of persistent headache would be significantly greater in women who had sustained an accidental dural puncture during an epidural insertion than in women who had an uneventful epidural insertion.

Methods

The accidental dural puncture outcomes study was conducted in nine obstetric units in the UK. The study received ethical approval and all participants gave informed written consent.

A cohort of parturients who sustained an accidental dural puncture with a 16G Tuohy needle during an epidural insertion for labour analgesia or during combined spinal-epidural anaesthesia for caesarean section (accidental dural puncture group) were matched with parturients who had undergone uneventful epidural insertion (control group) in a ratio of one accidental dural puncture case to two control cases. Participants in the control group were recruited within 8 weeks of recruiting the accidental dural puncture participant. Any patient reporting a history of chronic headache (≥ 15 headache days/month for 3 months) or pre-existing persistent low back pain (≥ 7 days/month) was not included.

Following delivery of the infant, on the postnatal ward, participants completed three questionnaires: the Hospital Anxiety and Depression Scale; von Korff questionnaire; and Oswestry Disability Index. In the accidental dural puncture group, questionnaires were given to the participant after they had received treatment for post-dural puncture headache.

The von Korff questionnaire assesses headache intensity, persistence, interference with daily activity and disability over a 6-month period [21]. It provides a composite score to grade the severity of headache (0 = headache free, 1 = low disability, low intensity, 2 = low disability, high intensity, 3 = high disability, moderately limiting and 4 = high disability, severely limiting). The Oswestry Disability Index questionnaire assesses the functional disability present as a result of low back pain [22]. This provides a composite score that grades disability as a result of low back pain into minimal (0–20%), moderate (21–40%), severe (41–60%), crippled (61–80%) and bedridden (> 81%). The Hospital Anxiety and Depression Scale questionnaire scores were graded into normal (0–7), borderline (8–10) and abnormal (> 10).

Participants were followed-up by telephone at 6, 12 and 18 months, between July 2017 and May 2020, by an independent assessor who was aware of the group allocation. They were asked about any new onset headache and/or low back pain, or worsening of any pre-existing headache and low back pain that developed following the birth. Participants completed the von Korff and Oswestry Disability Index questionnaires at each follow-up. Participants who reported persistent headache at the 18-month review were offered a referral to the pain medicine clinic. Magnetic resonance imaging (MRI) of the head with contrast agent was performed to look for any cause for the headache, including signs of intracranial hypotension.

The primary outcome measure was the incidence of persistent headache at the 18-month follow-up. Secondary outcome measures included the incidence of persistent low back pain at 6, 12 and 18 months and the incidence of persistent headache at 6 and 12 months. Exploratory outcomes included the impact of intrathecal catheter and epidural blood patch on the incidence of persistent headache and low back pain.

For sample size calculations, the incidence of persistent headache at 18 months was estimated to be 18% in the accidental dural puncture group and 5% in the control group from previous studies [15, 16]. Under these assumptions, 90 accidental dural puncture participants and 180 control participants were required to achieve a power of 0.8 with the significance level set at 0.05 and a 20% loss to follow-up at 18 months.

Participants were matched for: age (< 20, 20–35, > 35 y); BMI (< 21, 21–35, > 35 $kg.m^{-2}$); parity (primiparous or multiparous); and mode of delivery (vaginal or caesarean section), all reported to be potential risk-factors for short-term or long-term headache after accidental dural puncture [12, 16, 17, 23, 24].

Group matching provided data that have a two-level hierarchical structure with individual participants (level 1) nested within clusters consisting of one accidental dural puncture patient and two matched control patients (level 2). Two-level logistic regression was first used for

between-groups comparison of confounding factors (anxiety, depression, history of previous headache, history of previous low back pain). Standard multilevel logistic regression was used for binary variables while multilevel ordinal logistic regression was used for the variables measured on an ordinal scale. No formal comparisons were made between groups for the matching variables, as by design they were considered equivalent.

Variables that were found to be significantly different between groups were entered into multilevel regression analyses used for the primary outcome (headache at 18 months) as well as secondary outcomes (headache at 6 and 12 months, low back pain at 6, 12 and 18 months). For each of these outcomes, different comparisons were made between groups: unadjusted; adjusted for history of headaches (headache outcomes only); or adjusted for other factors found to vary between groups. Associations between patient characteristics and outcomes with each of the index and control groups were analysed separately. As all variables were measured on a categorical scale, assessment was made using the Chi-squared test.

Change in severity due to persistent headache, based on von Korff Questionnaire (rated on the four-step ordinal scale described above) and changes in disability due to low back, pain based on Oswestry Disability index (rated on an ordinal five-step scale based on the original five categories described above) between the three time-points (6, 12 and 18 months) were analysed within the accidental dural puncture group and control group separately using the Friedman test. The incidence of headache and low back pain at different time-points in the accidental dural puncture group was compared between those who received an epidural blood patch and those who did not, using Chi-squared test, while the categories of severity (mild, moderate, severe) were compared using the Mann–Whitney U test. Missing data were imputed by the 'last observation carried forward' method. All analyses were done using Stata version 15.1 (Statacorp LLC 2017, Stata Statistical Software Release 15, College Station, TX, USA).

Results

Ninety parturients who suffered accidental dural puncture and 180 matched control parturients were recruited at nine obstetric units in the UK between February 2017 and October 2018. One of 90 (1.1%) participants in the accidental dural puncture (study) group and 13 of 180 (7.2%) participants in the control group were lost to follow-up (14/270, 5%). For the primary outcome, 256 participants (95%) were included in the final analysis (Fig. 1).

Table 1 provides the details of participants' baseline characteristics. The control group included 34 participants who received an uneventful epidural analgesia for labour pain and additional spinal anaesthesia for caesarean section (anaesthetist/patient choice at time of surgery); incidence of persistent headache at 18 months in this subset was 26% (9/34). A past history of headache (< 15 headache days/month) was reported by 24.4% of participants in the accidental dural puncture group when compared with 15% of control participants ($p = 0.06$). A previous history of low back pain (< 7 back pain days/month) was similar in both groups. More participants in the accidental dural puncture group than the control group reported moderate/severe depression at the time of recruitment ($p < 0.005$).

The results of the multilevel logistic regression analysis are presented in Tables 2 and 3. Incidence of persistent headache at 18 months was significantly higher in the accidental dural puncture group when compared with the control group (58.4% accidental dural puncture group vs. 17.4% control group, odds ratio (95%CI) 18.4 (6.0–56.7), $p < 0.001$, after adjustment for past history of headache, Hospital Anxiety and Depression Scale (depression) and Hospital Anxiety and Depression Scale (anxiety) scores). The difference between the two groups was present at 6 and 12 months. Incidence of persistent low back pain was greater in the dural puncture group at all time-points (Table 3). In each study group, the severity of headache (based on von Korff questionnaire) and disability due to low back pain (based on Oswestry Disability Index questionnaire) remained unchanged over time (Fig. 2).

In the accidental dural puncture group, 22 of 90 (24.4%) participants reported a past history of headache. Although 9 of these 22 (41%) reported persistent headache at 18 months, 11 (50%) reported no headache at any of the three time-points. Accidental dural puncture was managed by placement of an intrathecal catheter at the time of dural puncture in 27 of 90 (30%) participants. Placement of intrathecal catheter did not affect the incidence of headache or low back pain at any time-point (Fig. 3).

Following accidental dural puncture, 71/90 (79%) participants developed post-dural puncture headache in the following days. It was initially managed with conservative measures, but an epidural blood patch was eventually performed in 53 (59%) participants (Table 1). Ten participants received two blood patches. In those who did not receive an epidural blood patch, it was either refused by the participant (12/18), contraindicated (1/18) or not offered (5/18). Incidence of persistent headache in 52 participants (one was lost to follow-up) at 18 months was higher in those

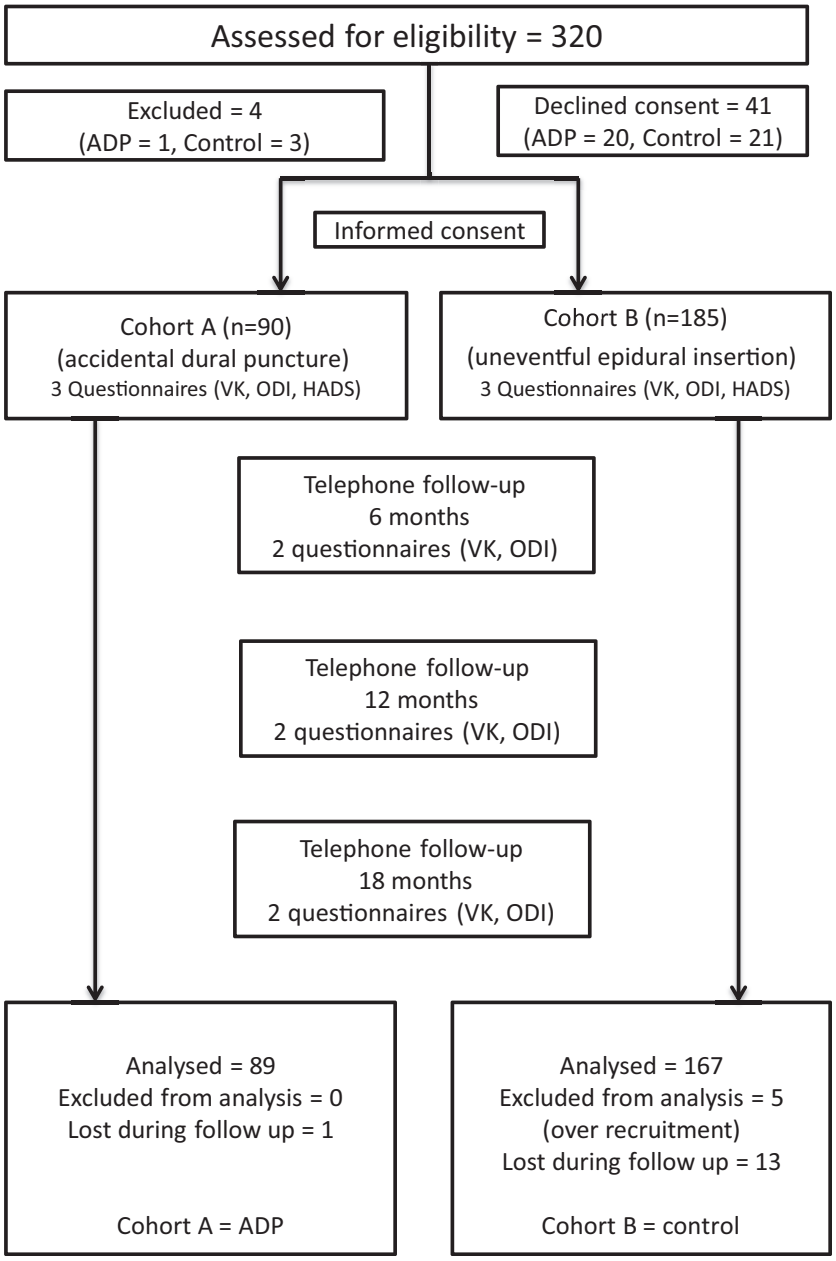

Figure 1 Accidental dural puncture outcomes study flow chart. ADP, accidental dural puncture; VK, von Korff; HADS, hospital anxiety depression scale; ODI, Oswestry Disability Index.

who did not receive an epidural blood patch (83%) when compared with those who received an epidural blood patch (56%) (Table 4; Fig. 4). Severity of headache was also significantly less among epidural blood patch recipients at 18 months.

In the accidental dural puncture group, 43 out of 52 (87%) participants with persistent headache at 18 months were offered a specialist review. The onset of the SARS-CoV-2 pandemic resulted in a delay in the review in the remaining nine (13%) participants. Thirty-nine participants were assessed while four declined to attend. Thirty of 39 (77%) participants reported headache at hospital discharge or recurrence of headache within 6 weeks of accidental dural puncture. Magnetic resonance imaging of the head with contrast was performed in 25 participants; no features compatible with intracranial hypotension were found.

Table 1 Participants' baseline characteristics groups matched for age, BMI, parity and mode of delivery. Values are number (proportion).

	Category	ADP group n = 90	Control group n = 180	p value
Age; years	< 20	1 (1.1%)	2 (1.1%)	
	20–35	72 (80%)	152 (84.4%)	
	> 35	17 (18.9%)	26 (14·4%)	
BMI; $kg.m^{-2}$	< 21	19 (21.1%)	16 (8.9%)	
	21–35	61 (67.8%)	150 (83.3%)	
	> 35	10 (11.1%)	14 (7.8%)	
Parity	Primiparous	59 (65.6%)	100 (55.6%)	
	Multiparous	31 (34.4%)	80 (44.4%)	
Mode of delivery	Vaginal	53 (58.9%)	106 (58.9%)	
	CS	37 (41.1%)	74 (41.1%)	
EBP performed	No	37 (41.1%)		
	Yes	53 (58.9%)		
HADS (anxiety)	Normal	53 (60.2%)	119 (69.6%)	0.092
	Borderline	18 (20.5%)	33 (19.3%)	
	Severe	17 (19.3%)	19 (11.1%)	
	Missing	2 (2.2%)	9 (5.0%)	
HADS (depression)	Normal	68 (77.3%)	155 (90.6%)	0.005
	Borderline	14 (15.9%)	10 (5.9%)	
	Severe	6 (6.8%)	6 (3.5%)	
	Missing	2 (2.2%)	9 (5.0%)	
Past history of headaches	No	68 (75.6%)	153 (85%)	0.052
	Yes	22 (24.4%)	27 (15%)	
Past history of low back pain	No	75 (83.3%)	154 (85.6%)	0.621
	Yes	15 (16.7%)	26 (14.4%)	

ADP, accidental dural puncture; CS, caesarean section; EBP, epidural blood patch; HADS, Hospital Anxiety and Depression Scale.

Table 2 Incidence of persistent headache between the two study groups at 6, 12 and 18 months. Values are number (proportion) or odds ratio (95%CI).

	Adjustments	ADP group n = 89	Control group n = 172	Odds ratio* (95%CI)	p value
Headache 6 months	None	53 (59.6%)	34 (19.8%)	10.6 (4.6–23.8)	< 0.001
	Headache history, HADS			10.4 (4.4–24.2)	< 0.001
Headache 12 months	None	52(58.4%)	35† (20.8%)	6.01 (3.1–11.5)	< 0.001
	Headache history, HADS			6.38 (3.1–12.8)	< 0.001
Headache 18 months	None	52 (58.4%)	29‡ (17.4%)	13·5 (5.5–33.0)	< 0.001
	Headache history, HADS			18.4 (6.0–56.7)	< 0.001

ADP, accidental dural puncture; HADS, Hospital Anxiety and Depression Scale.
*Odds ratio calculated as odds of outcome in accidental dural puncture group relative to odds in control group.
†Four participants lost to follow-up.
‡Five participants lost to follow-up.

Discussion

In this multicentre prospective matched cohort study, we have shown that accidental dural puncture during epidural insertion was associated with a significantly higher incidence of persistent headache at 18 months when compared with parturients who had uneventful epidural

Table 3 Incidence of low back pain between the two study groups at 6, 12 and 18 months. Values are number (proportion) or odds ratio (95%CI).

	Adjustments	Total n	ADP group n = 89	Control group n = 172	Odds ratio* (95%CI)	p value
Low back pain 6 months	None	260	40 (44.9%)	37† (21.6%)	3.20 (1.7–5.8)	< 0.001
	HADS	250			3.14 (1.6–5.9)	< 0.001
Low back pain 12 months	None	257	44 (49.4%)	26‡ (15.5%)	4.89 (2.7–8.7)	< 0.001
	HADS	247			4.40 (2.4–8.0)	< 0.001
Low back pain 18 months	None	256	43 (48.3%)	29§ (17.4%)	4.51 (2.3–8.60)	< 0.001
	HADS	246			4.14 (2.1–8.13)	< 0.001

ADP, accidental dural puncture; HADS, Hospital Anxiety and Depression Scale.
*Odds ratio calculated as odds of outcome in ADP group relative to odds in control group.
†One participant lost to follow-up.
‡Four participants lost to follow.
§Five participants lost to follow-up.

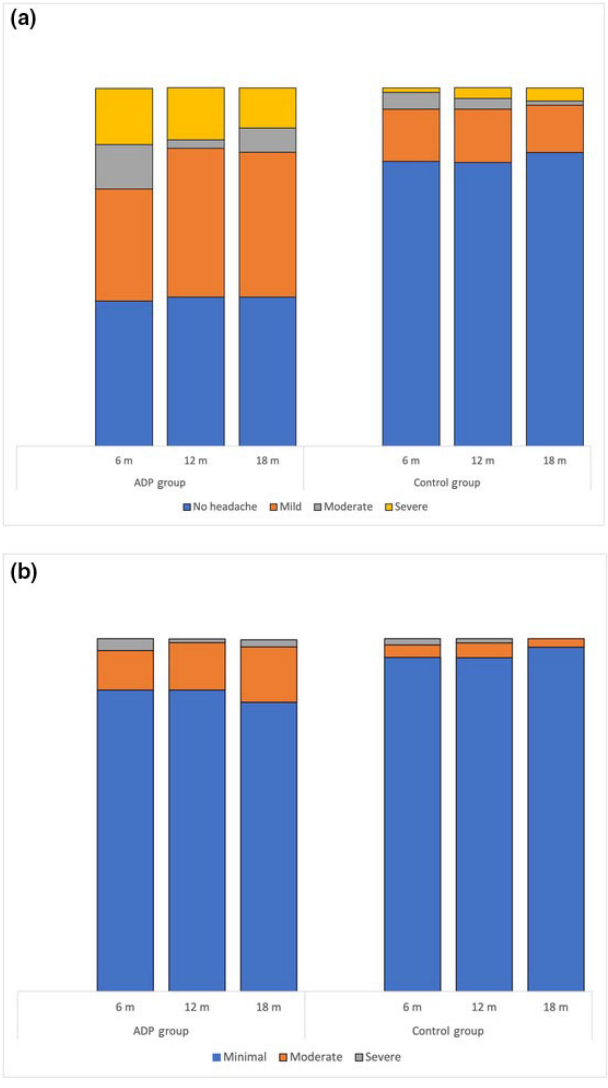

Figure 2 Severity of (a) persistent headache and (b) low back pain in the two study groups at 6, 12 and 18 months. ADP, accidental dural puncture.

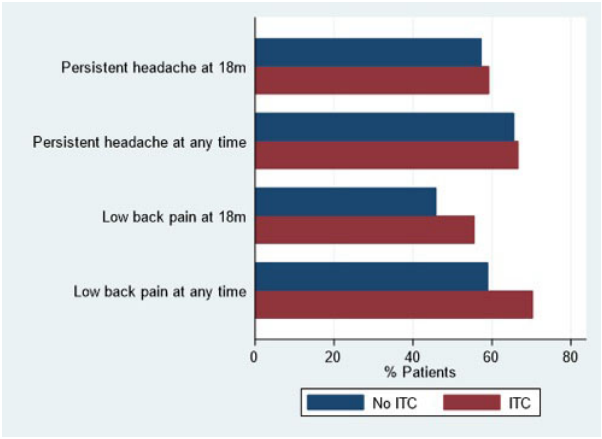

Figure 3 Incidence of persistent headache and low back pain in the accidental dural puncture sub-groups receiving/not receiving an intrathecal catheter (ITC). m, months.

insertion. This association was independent of a past history of headache or low back pain and degree of depression or anxiety at the time of birth.

To our knowledge, the present study is the first prospective, adequately powered study evaluating long-term outcomes following accidental dural puncture. A previous study has demonstrated chronic persistent headache in up to 28% of parturients who had sustained accidental dural puncture 18 months earlier; however, in that study, all parturients with a past history of headache were not included [16]. We felt that to not include these women, given the high prevalence of headache among women of reproductive age, would limit the applicability of our results. MacArthur et al., who were the first to study long-term effects of accidental dural puncture systematically, reported headache in 23% of accidental dural puncture

Table 4 Incidence and severity of persistent headache and low back pain in the accidental dural puncture sub-groups receiving/not receiving an epidural blood patch (EBP). Values are number (proportion).

	Category	No EBP	EBP	p value
Headache at 18 m	No	3 (16.7%)	23 (44.2%)	0.04
	Yes	15 (83.3%)	29 (55.8%)	
Headache grade 18 m				
Grade 0	No headache	3 (16.7%)	23 (44.2%)	0.02
Grade 1	Mild	9 (50.0%)	21 (40.4%)	
Grade 2	Moderate	1 (5.6%)	4 (7.7%)	
Grade 3, 4	Severe	5 (27.8%)	4 (7.7%)	
Low back pain at 18 m	No	7 (38.9%)	26 (50%)	0.42
	Yes	11 (61.1%)	26 (50%)	
Low back pain grade 18 m				
Grade (0–20%)	Minimal*	13 (70·3%)	47 (90.4%)	0.06
Grade (21–40%)	Moderate	4 (22.2%)	4 (7.7%)	
Grade (41–60%)	Severe	1 (5.6%)	1 (1.9%)	

m, months.
*Participants reporting no or mild low back pain on Oswestry Disability Index questionnaire.

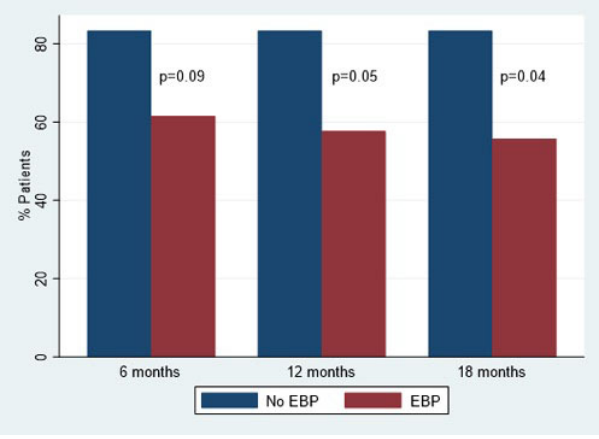

Figure 4 Incidence of persistent headache in the accidental dural puncture sub-groups receiving/not receiving an epidural blood patch (EBP).

cases compared with 7.1% in the control group [15]. We report higher levels of reported persistent headache in both accidental dural puncture patients and controls; it is possible that this results from inclusion of participants with a positive headache history.

We have demonstrated that the occurrence and severity of headache after accidental dural puncture remained approximately the same over time, suggesting that once it becomes established, persistent headache following accidental dural puncture rarely remits. If future studies corroborate this observation, it could result in a change in current treatment and would certainly impact on patient education after accidental dural puncture.

It should be noted that we did not find any benefit from intrathecal catheter placement in the prevention of persistent headache, a result that is in line with the negative outcome from a recent meta-analysis [25]. However, epidural blood patch had a protective impact on the incidence and severity of persistent headache at 18 months, consistent with other studies [14,16]. This still left substantially more participants reporting headache at 18 months compared with those who did not sustain an accidental dural puncture. We conclude that epidural blood patch alone is insufficient in the prevention of persistent headache following accidental dural puncture.

The incidence of persistent headaches at 18 months in the control group was higher than previously reported figures from retrospective studies [12, 16]. This may in part be due to the systematic data collection in the present study. Another explanation could be the inclusion of a subset of participants who received additional spinal anaesthesia for caesarean section [3].

Proposed mechanisms for the development of persistent headache include persistent low-grade dural leak, leading to chronically reduced cerebrospinal fluid level and sustained downward pull on the intracranial pain sensitive structures or, alternatively, compensatory vasodilatation of intracranial vessels. Twenty-five participants had a contrast-enhanced MRI of the head; none showed any features consistent with intracranial

hypotension. We suggest that short-term cerebrospinal fluid loss and concomitant intracranial nociceptor activation leads to sensitisation of neurones in the trigeminocervical complex, unless the process is blocked or sufficiently limited early-on with epidural blood patch [4–6, 16, 18, 26, 27].

An intriguing finding in the present study was that accidental dural puncture independently increased the risk of the participants reporting low back pain at all time-points, up to 18 months. This is in line with the observations of Ranganathan et al. [17] and Webb et al. [16]. The connection between low back pain and headache is well recognised, reported in several studies and recently subjected to a systematic review [28]. The mechanism is not clear, one reason being that studies so far have consisted of heterogeneous populations that make identifying common denominators difficult. A fairly homogeneous obstetric population that is subjected to a single procedure, which has the potential to induce both headache and low back pain would seem an ideal opportunity to study the topic in greater depth.

Limitations of the study include its non-randomised design and our inability to strictly match all patients across four criteria, although three or more criteria were precisely matched in 82%. To address the latter issue, we compared the two groups (accidental dural puncture group and control group) using logistic regression adjusted for all confounders including those chosen for matching. The results did not change.

A further limitation is inclusion of participants who had spinal anaesthesia for caesarean section in the control group. We anticipated it to have a minor impact on the overall results yet extend the scope of the study protocol to better reflect real world practice. Importantly, any control subject's post-dural puncture headache (and subsequent persistent headache) following spinal anaesthesia would reduce the difference in the primary outcome between the two groups.

The results of this trial combined with the evidence from a number of retrospective studies challenges the current definition of post-dural puncture headache by the International Headache Society as a self-limiting headache. Headache that starts as post-dural puncture headache persists for at least 18 months in a significant proportion of parturients, although mechanisms that maintain it are likely to be different. This could have implications on clinical pathways, the informed consent process and future training of anaesthetists. It is vital that the long-term effects of accidental dural puncture are discussed with parturients during the informed consent and decision-making process for epidural analgesia in labour. There is a need for good-quality research to establish the mechanisms of persistent headache and develop novel treatments. There is also an immediate need for a well-defined multidisciplinary referral pathway that includes obstetric anaesthetists, neurologists, radiologists, general practitioners and pain medicine specialists for women who develop long-term morbidity after accidental dural puncture.

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Appendix 1 Accidental dural puncture outcomes study collaborative group

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