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Chronic disabling postpartum headache after unintentional dural puncture during epidural anaesthesia: a prospective cohort study

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Abstract

Background: Unintentional dural puncture with an epidural needle complicates approximately 1% of epidural anaesthetics and causes an acute headache in 60–80% of these patients. Several retrospective studies suggest an increased risk of chronic headache. We assessed the relationship between unintentional dural puncture and chronic disabling headache, defined as one or more functionally limiting headaches within a 2-week interval ending 2, 6, and 12 months postpartum.

Methods: In this prospective observational study, parturients who experienced unintentional dural puncture were matched 1:4 with control patients. Patients completed questionnaires regarding characteristics of headache and back pain pre-pregnancy, during pregnancy, immediately postpartum, and at 2, 6, and 12 months postpartum. The primary outcome was prevalence of disabling headache in the past 2 weeks, assessed at 2 months postpartum. Secondary outcomes included prevalence and characteristics of headache and back pain at these time points.

Results: We enrolled 99 patients. At 2 and 6 months postpartum, the prevalence of disabling headache was greater among patients with unintentional dural puncture than matched controls (2 months, 74% *vs* 38%, relative risk 1.9, 95% confidence interval 1.2–2.9, P=0.009; 6 months, 56% *vs* 25%, relative risk 2.1, 95% confidence interval 1.1–4.0, P=0.033). There was no difference in the prevalence of back pain at any time point.

Conclusions: Our prospective trial confirms retrospective studies that chronic headache is more prevalent among women who experienced unintentional dural puncture compared with controls who received uncomplicated neuraxial anaesthesia. This finding has implications for the. patient consent process and recommendations for long-term follow-up of patients who experience unintentional dural puncture.

Keywords: chronic back pain; chronic headache; dural puncture; headache; migraine; obstetric anaesthesiology; wet tap

Editor's key points

- Unintentional dural puncture during epidural anaesthesia has been implicated as a cause of chronic disabling postpartum headache.
- In a prospective observational study, parturients who experienced unintentional dural puncture were matched with controls and followed for up to 12 months.
- Of 99 patients enrolled, the prevalence of disabling headache was greater in patients with unintentional dural puncture than in matched controls.
- These finding confirm suggestions from retrospective studies and have implications for patient consent and recommendations for long-term follow-up.

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Unintentional dural puncture, in which a continuous stream of clear fluid is observed from a large-bore epidural needle during attempted epidural anaesthesia, complicates 0.7–1.5% of all epidural anaesthetics.[1] As 2.8 million women receive epidural analgesia in the USA for childbirth each year, an estimated 20–40 000 women are affected by unintentional dural puncture annually as a complication of their peripartum care.[2,3] This complication causes a severe acute headache in approximately 60–80% of women but is generally thought to be benign and without long-term consequences.[4,5] However, an increasing body of literature links unintentional dural puncture with chronic disabling headache and back pain in addition to the well-known rare, but severe complications such as subdural haematoma and venous sinus thrombosis.[6] As early as 1993, a postal survey found a 15-fold higher relative risk (RR) of long-term postpartum headache in women who experienced unintentional dural puncture during epidural anaesthesia.[7] The increased risk of long-term headaches has since been replicated by several retrospective, one prospective uncontrolled, and one prospective controlled observational study with varying outcome periods.[4,8–12] An association with chronic back pain was also noted in three trials.[9,10,12]

If unintentional dural puncture indeed causes long-term headache, back pain, or exacerbates pre-existing disability, it has significant implications for the consent discussion and follow-up recommendations. Previous studies share with all retrospective studies weaknesses of recall and selection bias. Characteristics of headaches and back pain have not been evaluated. To address the limitations of retrospective studies, we designed a 12-month, prospective, observational study with repeated observations of women who had unintentional dural puncture each matched with four control patients who had uncomplicated epidural anaesthesia and the same mode of delivery within 3 days of the index case. Our hypothesis was guided by our previous findings that women who had unintentional dural puncture had an increased prevalence of chronic headache and back pain.[11] The primary outcome variable was the prevalence of disabling headache at 2 months postpartum. Severity, duration, and migrainous features of headaches, back pain prevalence and severity, and breast-feeding were pre-planned secondary outcome variables.

Methods

Study design, setting, and subjects

This prospective, observational cohort study was designed to compare the prevalence of chronic, disabling postpartum headache between women who had unintentional dural puncture and matched control patients with repeated measures at preplanned intervals. The study was approved by the Stanford University Institutional Review Board (IRB) before enrolment (Stanford, CA, USA; Protocol: 30569; June 2014). Informed consent was obtained from all women who agreed to participate in their preferred language (English or Spanish) using an IRB-approved consent script either in person or over the telephone by investigators JA and PF with a translator when appropriate. Enrolment occurred at Lucile Packard Children's Hospital, Palo Alto, CA, USA between August 2014 and November 2017.

Consecutive patients who had unintentional dural puncture as evidenced by continuous clear fluid return through the epidural needle during the neuraxial procedure were offered enrolment each along with four matched control patients. Control patients underwent the same mode of delivery as the index patient (vaginal *vs* Caesarean) with uncomplicated neuraxial anaesthesia within 3 days of the delivery of the index patient. Patients who delivered closest in time to the index patient were offered enrolment first. As temporal relationship between delivery of unintentional dural puncture patients and controls was a priority, up to two of four control patients for each unintentional dural puncture patient who underwent Caesarean delivery were permitted to have received a single shot spinal anaesthetic with a 25 gauge Whitacre needle. Additional inclusion criteria were age 18–45 yr and ability to provide informed consent in either English or Spanish. Exclusion criteria included inability to have telephone follow-up, general anaesthesia for delivery, and significant postpartum complications including severe haemorrhage, sepsis, or ICU admission.

Initial data for pre-pregnancy, pregnancy, and immediate postpartum time periods and consent were collected in person on the postpartum ward or over the telephone using IRB-approved scripts (Supplementary material S1). With the exception of the first 10 patients (two index and eight controls), who were only contacted by telephone 1 week after delivery, all women consented for study participation and completed pre-pregnancy and pregnancy assessments on postpartum Days 1–3 on the postpartum ward. Women were then contacted by telephone at the end of postpartum week one to identify and characterise any new postpartum headaches. Two-, 6-, and 12-month follow-up surveys were administered by telephone by investigator JA. Study data were collected and managed using REDCap electronic data capture tools hosted at Stanford University.[13] All missing data are indicated in the tables and figures. English-language version of scripts may be found in Supplementary material S1.

Patient characteristics including age, weight, height, BMI, ethnicity, mode of delivery, and mode of anaesthesia were obtained from chart review (Supplementary material S1). Patients were classified as Spanish-speaking if they required or preferred communication in Spanish by the healthcare team. For Spanish-speaking patients, a hospital telephone interpreter was used for consent and all telephone follow-up. The diagnosis of postdural puncture headache was based on the international headache society ICDH-3 criteria: a headache that occurs within 5 days of a dural puncture and exhibits signs and symptoms of a low-pressure headache.[14]

Management of unintentional dural puncture was determined by the primary anaesthesiology service and not influenced by study participation. At the study institution, intrathecal catheters are not left in place in the postpartum period. Postpartum care including treatment of headaches with or without epidural blood patch was managed by non-study clinicians.

Primary outcome variable

The primary outcome variable was the difference in prevalence of disabling headache assessed by phone call at 2 months postpartum. Disabling headache at each follow-up interview was based on the subject's response to the question: 'In the past 2 weeks, have you experienced headaches that limited you from working, studying, or doing what you needed to do?' We defined a chronic headache based upon the work by Lipton in the screener for migraine in primary care.[15] We modified the timeframe used by Lipton from 3 months to 2 weeks to ensure that patients' recollection was not contaminated by an acute postpartum headache.[15] Thus, our definition of 'chronic'

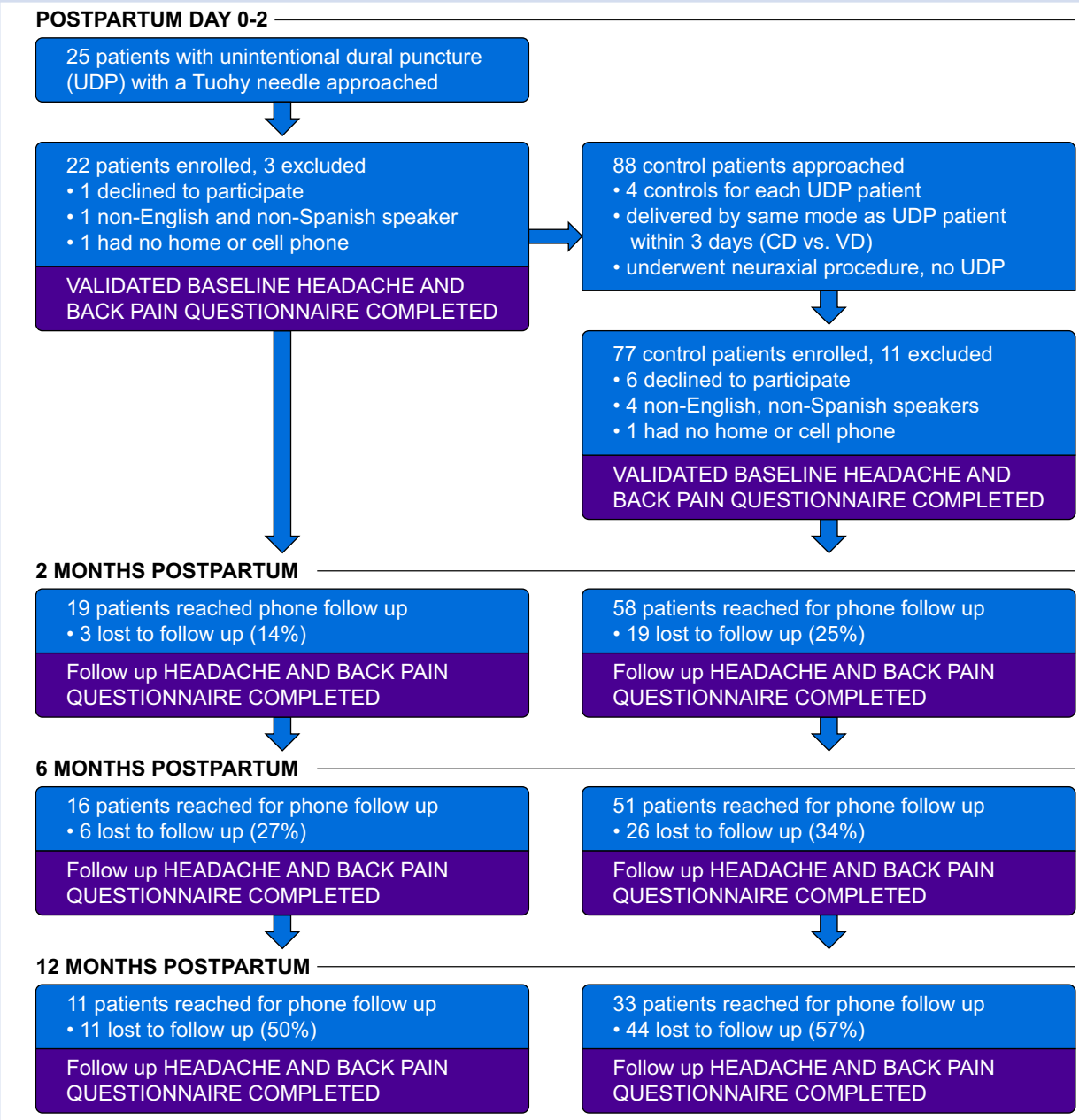

Fig 1. Enrollment flow chart. CD, Caesarean delivery; UDP, unintentional dural puncture; VD, vaginal delivery.

headache is one or more disabling headaches within a 2-week interval ending 2, 6, and 12 months postpartum.

Secondary headache variables

The prevalence of headache was also evaluated before pregnancy, during pregnancy, during the first week postpartum, and 6 and 12 months after delivery. As study enrolment occurred shortly after delivery, the details of pre-pregnancy and pregnancy-related headaches were provided from patients' retrospective recollection at the time of enrolment.

Among patients who reported at least one disabling headache in the prior 2 weeks at any assessment, headache features were further assessed as follows. Headache duration was dichotomised to greater or less than 4 h. Headache severity was requested as a numerical rating scale (NRS) from 0 to 10 with 0 being no headache pain and 10 being the worst headache pain imaginable. The presence of a postural component as defined by worsening headache upon sitting or standing was evaluated after delivery and at 2, 6, and 12 months postpartum. Migraine was defined as a recurrent headache disorder lasting 4–72 h. Differentiation between migrainous headaches and other types of headaches was designated by author MB, a board-certified neurologist and headache specialist who was blinded to unintentional dural puncture status. MB used criteria from the MIGRAINE ID

screener, which shows high predictive value based upon a positive screen of at least two of the three following features: functionally limiting pain, photophobia, and nausea or vomiting.[15–17]

The prevalence of breastfeeding was evaluated as a binary variable reported by the patient at 2, 6, and 12 months postpartum.

Back pain variables

We evaluated the prevalence of disabling back pain defined as 'back pain that limited you from working, studying, exercising, sleeping, or doing what you needed to do', and, when present, the severity (NRS) and frequency (days per month), pre-pregnancy, and at 2, 6, and 12 months after delivery. At 2, 6, and 12 months, patients were specifically asked if they had experienced disabling back pain within the past 2 weeks.

Sample size calculation

The sample size calculation was based on the primary outcome variable, headache prevalence at 2 months postpartum. Sample size was calculated using the method described by Chow and colleagues.[18] Using headache prevalence data from our previous retrospective study,[9] we assumed that 5% of our control patients and 30% of our unintentional dural puncture patients would have headaches. Given an effect size of 0.7, a medium to large effect, and assuming 4:1 matching, the power analysis requires 20 index and 80 control subjects with alpha=0.05 and beta=0.20.

We hoped to enrol enough patients to address a secondary hypothesis that epidural blood patch is protective against chronic headache. If epidural blood patches were to reduce the proportion of patients with 2-month headaches by half as described by Webb and colleagues,[9] we would need to enrol 236 index cases. This secondary aim was discarded after 3 yr of enrolment when the sample required to address the primary outcome variable had been enrolled. It is not feasible to enrol the patients required to address this secondary hypothesis in a single-centre study.

Data analysis plan

The primary outcome variable was the prevalence of disabling headache in the last 2 weeks, assessed at 2 months postpartum. The prevalence of disabling headache pre-pregnancy, during pregnancy, immediately postpartum, and at 6 and 12 months postpartum were secondary outcomes. Statistical significance was defined *a priori* at 0.05 for the primary outcome variable. The *P* values for secondary comparisons are reported only to document the strength of association and not intended for statistical inference. Statistical analyses were completed using R programming language (R Foundation for Statistical Computing, Vienna, Austria) version 4.0.3 ('Bunny-Wunnies Freak Out', 2020-10-10.[19] Additional R packages are discussed in the descriptions of the statistical tests. The figures were created with ggplot 2.[20]

The probability of a difference in headache prevalence between unintentional dural puncture and control groups was assessed with a two-sided Fisher's exact test. The RR of having a headache with 95% confidence interval (CI) is presented as RR [95% CI]. RR was calculated using unconditional maximum likelihood estimation with small sample adjustment using riskratio.small in the epitools package in R. CI were calculated using normal approximation with small sample adjustment. Correlation between binary outcomes was performed using Kendall's rank correlation test (e.g. cor.test [method='kendall']).

We used a proportions test (the R function prop.test) to determine whether the patient characteristics were distributed similarly between groups. Because unintentional dural puncture was more common in women who preferred Spanish and in women with higher BMI, we created a logistic regression model to determine whether the most succinct model required both characteristics. The dependent variable for the logistic regression was unintentional dural puncture. The explanatory variables in the model were patient characteristics, Spanish as the preferred language, and BMI.

Among those who reported disabling headache or back pain, average severity (1–10 scale [NRS]) was considered a continuous variable and compared between groups using a two-sided Wilcoxon Rank sum test with computed mean and 95% CI.

Results

Headache

Of 99 patients enrolled, 22 had unintentional dural puncture, each matched with four controls according to the paradigm described in the Methods, of whom 77 agreed and qualified to participate (Fig. 1). Eleven unintentional dural puncture patients of the 18 with acute headaches (61%) were treated with an epidural blood patch. Only conservative treatments were provided to the others. There was no difference in prevalence of headache at 2 months related to blood patch in this small sample. Patient characteristics are shown in Table 1. There was an imbalance between groups with respect to BMI and Spanish as the preferred language. After adjustment with logistic regression, only Spanish as a preferred language remained a significant predictive factor for unintentional dural puncture ($P<0.001$). The type of neuraxial anaesthesia used (including intrathecal catheter), mode of delivery, development of postdural puncture headache, severity of postdural puncture headache, day headache occurred, and epidural blood patches were all recorded and may be accessed in Supplementary Table S2.

Difference in the prevalence and characteristics of headaches at the individual time points are described below. Details are provided in Fig. 2 and Table 2. There was no difference in the loss to follow up between groups at any time point (Fig. 1).

Table 1 Patient characteristics. Brackets designate the interquartile range. *Wilcoxon rank sum test. †Proportions test

Variables	Unintentional dural puncture (*n*=22)	Control (*n*=77)	P-value
Age, yr (range)	32 (28–37)	33 (29–35)	0.993*
Weight, kg (range)	82 (68–93)	76 (68–84)	0.256*
BMI, kg m^{-2} (range)	31 (27–35)	28 (26–32)	0.047*
Hispanic ethnicity, n (%)	11/22 (50)	20/77 (26)	0.060†
Primary language Spanish, n (%)	10/22 (45)	8/77 (10)	<0.001†

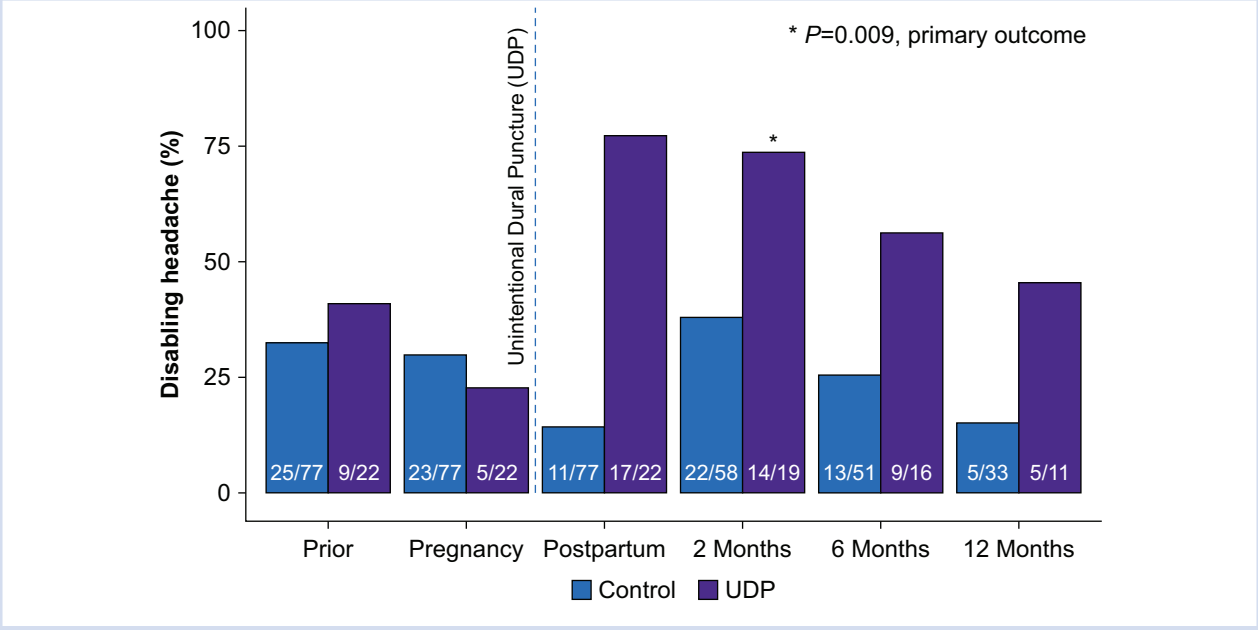

Fig 2. Participants with 'headaches that limit work, study, or doing the things you need to do' before pregnancy, during pregnancy, immediately after birth, and at 2, 4, and 6 months after delivery. Results from patients who had a dural puncture are depicted in purple and those who did not are depicted in blue. The fraction of patients who reported a headache/all responders is indicated at the base of each bar. There was no difference in the prevalence of headache before or during pregnancy. The relative risk [95% confidence intervals on the relative risk] of headache within the first week after delivery was 5.0 [2.8–9.1], $P<0.001$, in women who had a dural puncture. The relative risk at 2 months was 1.9 [1.2–2.9], $P=0.009$. The relative risk at 6 months was 2.1 [1.1–4.0], $P=0.033$. The relative risk at 12 months was 2.6 [0.92–7.3], $P=0.090$. *The primary outcome, prevalence of disabling headache as assessed at 2 months postpartum. UDP, unintentional dural puncture.

Headache before and during pregnancy

There was no difference in the prevalence, severity, or migrainous features of headaches reported before pregnancy between unintentional dural puncture patients and controls (Table 2, Fig 2). Because there was no difference in headache prevalence between unintentional dural puncture and control groups before the event, data were combined to evaluate the effect of pregnancy. The prevalence of headaches before pregnancy was not different from that during pregnancy (34% *vs* 29%; $P=0.472$).

Headache immediately postpartum

During the first postpartum week, women who had unintentional dural puncture were more likely than controls to report disabling headache (77% *vs* 14%, $P<0.001$, RR 5.0 [2.8–9.1]; Fig. 2). All patients who had unintentional dural puncture who had headaches reported positional symptoms. Their headaches were more severe and more likely to be migraine headaches (Table 2).

Headache 2 months postpartum

The primary outcome variable, the prevalence of disabling headache at 2 months postpartum, was higher among women who had unintentional dural puncture (74% UDP *vs* 38%, RR 1.9 [1.2–2.9], $P=0.009$, Fig. 2). Immediate postpartum headache was correlated with headache after 2 months ($P=0.005$, tau=0.322), but neither pre- nor intra-pregnancy headache predicted headache at 2 months. Headaches among women who had unintentional dural puncture were not more severe, but were more likely to last >4 h (86% UDP *vs* 33%, RR 2.4 [1.2–4.5], $P=0.005$) than control patients' headaches (Table 2). At 2 months the prevalence of migrainous headaches was not different between groups (22% UDP *vs* 19%, RR 1.1 [0.40–3.0], $P=0.774$) (Table 2). Unintentional dural puncture was associated with a lower prevalence of breastfeeding (56% UDP *vs* 84%, RR 0.66 [0.43–1.0], $P=0.024$). The negative association between unintentional dural puncture and breastfeeding at 2 months was independent of whether Spanish was the preferred language.

Headache 6 months postpartum

The increased prevalence of disabling headaches persisted 6 months after delivery (56% UDP *vs* 25%, RR 2.1 [1.1–4.0], $P=0.033$, Fig. 2). Headaches at 6 months were more likely to have a postural component, but they were not more severe and were not more likely to be migraines (Table 2). There was no difference in the prevalence of breastfeeding at this time point.

Headache 12 months postpartum

The previous difference in the prevalence of disabling headache between unintentional dural puncture and control groups was no longer statistically significant at the 12-month observation (Fig. 2). The severity of headaches at 12 months

Table 2 Headache characteristics among women who endorsed disabling headache. Average headache severity is displayed as mean numeric rating system (NRS) score from 0 to 10 [inter-quartile range]. Headache duration >4 h is displayed as number of women with average headache duration longer than 4 h/all women who endorsed headache and answered the question about duration, followed by the percent this represents. Postural nature of headache is displayed as number of women who endorsed a postural headache/all women who endorsed headache and answered the question about positional nature, followed by the percent this represents. Bold indicates p-values that are <0.05. *Unevaluable includes patients who did not have headache, did not answer the relevant question about headache characteristics, or were lost to follow-up. CI, confidence interval; RR, relative risk; UDP, unintentional dural puncture

Average headache severity (among respondents who endorsed at least one disabling headache)					
	UDP	**Control**	**Patients evaluated**	**P-value**	***Unevaluable**
Pre-pregnancy	4.5 [4.0–6.0]	6.0 [4.0–6.0]	UDP *n*=13, control *n*=29	0.281	57
Postpartum	5.5 [5.0–7.0]	3.5 [3.0–7.0]	UDP *n*=8, control *n*=19	**0.022**	72
Two months	4.5 [4.0–6.0]	4.0 [3.0–6.0]	UDP *n*=7, control *n*=29	0.085	63
Six months	5.0 [3.0–5.0]	3.0 [2.75–5.0]	UDP *n*=3, control *n*=18	0.175	78
One yr	5.0 [5.0–6.0]	3.0 [2.0–4.0]	UDP *n*=3, control *n*=7	0.011	89
Headache duration > 4 h					
	UDP	Control	RR (95% CI)	P-value	*Unevaluable
Two months	12/14 (86)	7/21 (33)	2.4 [1.2–4.5]	**0.005**	23
Six months	4/9 (44)	4/11 (36)	1.1 [0.37–3.1]	>0.999	34
One yr	4/5 (80)	1/5 (20)	2.4 [0.39–15]	0.206	55
Postural headache					
	UDP	Control	RR (95% CI)	P-value	*Unevaluable
Postpartum	17/17 (100)	2/10 (20)	3.7 [1.1–13]	**<0.001**	1
Two months	7/14 (50)	6/22 (27)	1.6 [0.70–3.9]	0.286	22
Six months	4/9 (44)	0/12 (0)	5.8 [0–Inf]	**0.021**	33
One yr	2/5 (40)	1/5 (20)	1.2 [0.15–9.4]	1.00	55
Migrainous headache/all reporters					
	UDP	Control	RR (95% CI)	P value	*Missing migraine data
Pre-pregnancy (%)	6/21 (29)	15/75 (20)	1.4 [0.60–3.1]	0.388	3
Postpartum (%)	12/22 (55)	6/77 (8)	6.1 [2.6–14]	**<0.001**	0
Two months (%)	4/18 (22)	11/58 (19)	1.1 [0.40–3.0]	0.744	1
Six months (%)	3/16 (19)	5/49 (10)	1.6 [0.42–5.8]	0.395	2
One yr (%)	3/11 (27)	4/33 (12)	1.9 [0.49–7.0]	0.341	0

was higher in the unintentional dural puncture group (Table 2). There was no difference in duration of headaches, migrainous features, or the prevalence of breastfeeding between groups (Table 2).

Back pain

There was no difference in the prevalence or severity of back pain at any time period related to unintentional dural puncture. Prepartum back pain was significantly correlated with back pain at 2 months (P=0.023, tau=0.260).

Discussion

We observed an increased prevalence of chronic disabling headache, defined as one or more disabling headaches within a 2-week interval, after unintentional dural puncture when assessed at 2 months and 6 months postpartum (Fig. 2). Headaches were not only more prevalent but longer-lasting after unintentional dural puncture compared with headaches experienced by control patients (Table 2). The finding of increased prevalence of chronic headache after unintentional dural puncture confirms prior retrospective studies[7–10] as well as a recent prospective trial,[12] and adds substantially to the weight of the evidence that unintentional dural puncture has chronic sequelae for many patients. This body of evidence supports translation to clinical care. Our prospective study allowed for more robust methods compared with those used in previous studies in a few notable ways. First, we specifically assessed the presence of headache that interfered with daily life, which is a more clinically significant patient-centred outcome than simple headache. Second, we characterised the nature of headaches, including outcomes important to headache specialists who are likely to encounter these patients in the months after their delivery.

Compared with the retrospective studies investigating chronic headache after unintentional dural puncture, we found a similar increase in the RR of long-term headache, but with higher overall prevalence of headaches in both unintentional dural puncture and control groups. MacArthur and colleagues[7] received postal survey responses from 74 unintentional dural puncture and 4700 control patients and reported an increased incidence of headache or neck pain at 6 weeks (23% *vs* 7%). Ranganathan and colleagues[10] surveyed 308 unintentional dural puncture patients and 50 controls regarding headache symptoms lasting at least 6 weeks postpartum (34.9% *vs* 2.2%). In contrast, at the 2-month time point, 74% of our unintentional dural puncture patients and 38% of controls reported headache that interfered with daily life since discharge from the hospital. The higher incidence in both

groups in our study may reflect the prospective design. The headache incidence among our controls is consistent with other prospective studies investigating postpartum headache without consideration of unintentional dural puncture. Anzola and colleagues[21] prospectively followed 900 women for 1 month after delivery, and 27% reported at least one 'headache attack'. Goldszmidt and colleagues[22] prospectively followed 985 women for 3 months and reported a 39% incidence of headaches over the study period, which closely mirrors our control population.

We did not find a different prevalence or severity of back pain related to unintentional dural puncture unlike the recent prospective study[12] and several of the retrospective studies, including our own.[6,9,10] This may reflect our small sample size or may represent the limited conclusions that can be made based on secondary outcome variables. As such, potential associations between unintentional dural puncture, epidural blood patch, and chronic back pain warrant future study.

The findings of this prospective study, in combination with those from a recent prospective study[12] and four retrospective studies,[7–10] may warrant a change in consent discussion used in clinical practice. Increasingly in informed consent, the 'reasonable patient' standard is advocated both in the UK and USA: physicians should inform patients about the risks of treatment that would be considered important by a reasonable patient.[23] While most anaesthesia providers mention acute headache as a potential complication of neuraxial anaesthesia,[4,24] a reasonable patient standard may necessitate discussing the potential for chronic headache that persists for at least 2 months after unintentional dural puncture.

Furthermore, clinicians should arrange long-term follow-up for patients after unintentional dural puncture with planned referral for long-term headache follow-up should the headache persist. In turn, headache specialists should consider unintentional dural puncture-related headaches in a new mother with new or worsened headaches. This is critical, as workup and management of headaches secondary to CSF leak may entail a magnetic resonance myelogram, epidural blood patch, or other invasive procedures. The diagnosis is subtle, complex, and requires forethought, as signs and symptoms at 2 months and later are not classically migrainous and may lose the positional nature that is classically associated with acute unintentional dural puncture. The physiologic basis of chronic headaches after unintentional dural puncture is currently unknown. However, we hypothesise that headaches may either occur secondary to unresolved dural defects resulting in chronic CSF leak, or secondary to a central sensitisation phenomenon leading to chronic headache even after healing of the dural defect.

Our study has a number of limitations. First, our sample size was too small to assess the long-term impact of epidural blood patch on headache or back pain, which remains an important clinical question. This was initially a planned secondary aim of our study. However, the incidence of unintentional dural puncture at our institution proved far lower than the 1% anticipated over the study period, and as such this aim was discarded because of the lack of feasibility at a single centre. Another major limitation was our 50% loss to follow up at 12 months. The reduced sample size limited our ability to confirm longer-term outcome. During the study period, we found that many patients stopped utilising home phones altogether in favour of mobile phones. Unsolicited calls became a more common nuisance over the study period, making patients less likely to answer calls not originating from one of their known contacts. Both the initial small sample size and loss to follow-up also limited the assessment of secondary outcomes such as headache features and severity, which only applied to the subset of patients endorsing headache at any assessment time point.

All observational studies are subject to recall bias, which is likely more pronounced in retrospective than prospective assessments. Patients who suffer a complication associated with severe pain may be more likely to remember previous pain. By contrast, it may put the severity of pain before or during pregnancy into new context. In our study, there was no difference in study enrolment by group or in dropout rate at any time point.

Other potential sources of bias include heterogeneity, difference in treatment, and differential diagnosis. We identified heterogeneity in the likelihood of unintentional dural puncture related to Spanish as a primary language. Women who spoke Spanish were overrepresented among unintentional dural puncture patients than controls, which was an unexpected finding. Given the methodology of enrolling controls based on mode of delivery and temporal relationship to the unintentional dural puncture patient, this unlikely represents selection bias. We hypothesise that communication barriers during the neuraxial anaesthesia procedure may play a role in an increased likelihood of unintentional dural puncture for Spanish-speaking women. This important finding supports the importance of professional translation in healthcare and warrants independent study.

In conclusion, we show that parturients who experienced unintentional dural puncture were more likely to experience chronic disabling headaches at 2 and 6 months postpartum than parturients who did not experience this complication. Our findings confirm those of retrospective studies,[7–10] one large database study,[6] one uncontrolled prospective trial,[11] and a recent controlled prospective study,[12] all finding that unintentional dural puncture may be associated with chronic headache. Chronic disabling headache should likely be added to the list of possible complications of epidural procedures discussed in the patient consent process. Additionally, any patient who suffers unintentional dural puncture warrants long-term follow up and possibly referrals to specialists to care for possible sequelae when indicated.

Authors' contributions

Study design: JRA, PF, MB
Enrolment: JRA, PF
Data analysis: JRA, PF, MB, SS
Manuscript preparation: JRA, PF, MB
Manuscript revision: SS

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Declarations of interest

The authors declare that they have no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bja.2021.05.020.

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