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ORIGINAL ARTICLE

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Risk factors for post-dural puncture headache following injury of the dural membrane: a root-cause analysis and nested case-control study

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ABSTRACT

Background: Post-dural puncture headache following trauma to the dural membrane during neuraxial anaesthesia occurs in 0.13–6.5% of pregnant patients. Identifying factors beyond individual performance that contribute to this adverse event is crucial to developing improvement strategies.

Methods: We used a root cause analysis framework, in a nested case-control study, to identify associated factors. Cases were all patients who had a post-dural puncture headache requiring an epidural blood patch. These patients were matched to a random group of control patients without post-dural puncture headache or known dural injury. Mixed logistic modelling was used.

Results: Within a dataset of 35 763 patients, we selected all 154 patients with post-dural puncture headache and compared them with 616 controls. Migraine (odds ratio [OR] 10.60, 95% CI 2.74 to 41.05), obstetric and perinatal pathology (OR 10.85, 95% CI 4.29 to 21.42), and multiple insertion attempts (OR 11.48, 95% CI 6.29 to 20.94), increased the risk of post-dural puncture headache. In contrast, training >3 years (OR 0.20, 95% CI 0.55 to 0.76) and a nurse anaesthetist present during the procedure (OR 0.05, 95% CI 0.01 to 0.29) decreased the risk. The anaesthetist's identity, the size of the labour room, the timing of the procedure or workload did not modify the risk.

Conclusion: Post-dural puncture headache in this setting is not the result of the individual anaesthetist's characteristics alone. Additional factors including team composition, the presence of obstetrical perinatal pathology, and associated patient's conditions, are also associated with this event. Improvement strategies should consider all these factors.

Keywords: Human factors; Medical errors; Headache; Post-dural puncture; Obstetric patient safety; Root cause analysis

Introduction

Neuraxial anaesthesia is the most prevalent method of obstetric anaesthesia and analgesia. Recent figures show that 62.9% of women in labour in the United Kingdom give birth under neuraxial anaesthesia; 61% in the United States, 58.7% in Canada and 79.3% in France.[1–4] Despite their widespread use, neuraxial techniques are not free of complications. They are associated with maternal hypotension, fetal distress, neurological or infectious complications and, more commonly, post-dural puncture headache (PDPH).[5,6] This complication occurs in 0.38–6.3% of procedures[7–9] and is the second most common reason for lawsuits in the United States.[10] It can cause severe discomfort and, exceptionally, leads to secondary brain injuries.[11,12]

In order to prevent PDPH, it is crucial to identify factors contributing to its occurrence. Several factors have been identified, for example patient-related factors (lower body mass index [BMI], past history of PDPH),

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technical factors (use of large gauge, cutting spinal needles) and procedure-related complications.[13–15] The latter includes injuries following laceration of the dural membrane by repeated dural punctures with spinal needles and accidental dural perforation with Tuohy needles.[16,17] Injuries to the dural membrane are considered as being mostly related to individual staff performance and characteristics. Current accident theory suggests however that hazards are more often caused by defects at a system level (i.e. lack of familiarity with equipment, work environment constraints, poor supervision, fatigue) rather than deficiencies at the individual level.[18,19]

Root cause analysis (RCA) offers interesting perspectives to explore key system-level factors that contribute to the occurrence of accidents.[20] It has been endorsed by many healthcare organisations to improve clinical practices.[21] We performed a nested case-control study, using a RCA framework, to identify key risk factors for PDPH as a procedure-related complication.

Materials and methods

The study was performed at the Maternity Department of the Geneva University Hospitals (Geneva, Switzerland), a tertiary centre with 3500 (in 2001) to 4130 (in 2013) deliveries per year. Following Institutional Ethics Committee approval (Geneva University Hospital Ethics Committee CER 09-206R), we performed a case-control study, nested on a retrospective cohort of patients undergoing analgesia for labour and anaesthesia for caesarean delivery, between 2001 and 2013. We included all patients who received neuraxial block (spinal, epidural, combined spinal-epidural) for labour analgesia or caesarean section. Patients who underwent general anaesthesia and those having a stillbirth delivery were excluded.

Cases were patients who had PDPH symptoms requiring an epidural blood patch following traumatic puncture of the dural membrane. Symptoms were defined as typical postural and non-postural headaches with at least one of the following associated symptoms: neck stiffness, tinnitus, hypoacusia, photophobia or nausea.[8,22] Traumatic puncture was defined as an accidental dural puncture (evidence of cerebrospinal fluid (CSF) leak through a Tuohy needle or catheter during an epidural insertion) or as an intentional but likely traumatic laceration of the dural membrane (multiple attempts at several different spinal levels or by several operators during spinal or spinal-epidural techniques).

For every case identified, four random controls were selected within the cohort of patients. Controls were patients in labour having a neuraxial block but without evidence of PDPH and without suggestion of traumatic dural membrane puncture. This 1:4 ratio provides an optimal balance between the resources required to collect data from controls and the statistical power gained by increasing the control-to-case ratio.[23] A computerised random sampling technique was used. The only matching criterion for cases and controls was the year of procedure.

Risk factors following procedure-related complications such as PDPH were selected according to the Association of Litigation and Risk Managers (ALARM) model developed for accident RCA[24,25] (Fig. 1). This model identifies seven categories of factors that can contribute to an accident: (1) Institutional and Regulatory Context, (2) Organizational and Management-Related Factors, (3) Work Environment-Related Factors, (4) Team-Related Factors, (5) Individual (staff)-Related Factors, (6) Task-Related Factors, and (7) Patient-Related Factors. As the study aimed to analyse factors that are directly under control of anaesthetists, the first two categories of the model (Institutional and Regulatory Context and Organizational/Management-Related Factors) were not considered for the analysis. Table 1 provides detailed definitions of contributing risk factors according to the ALARM model.

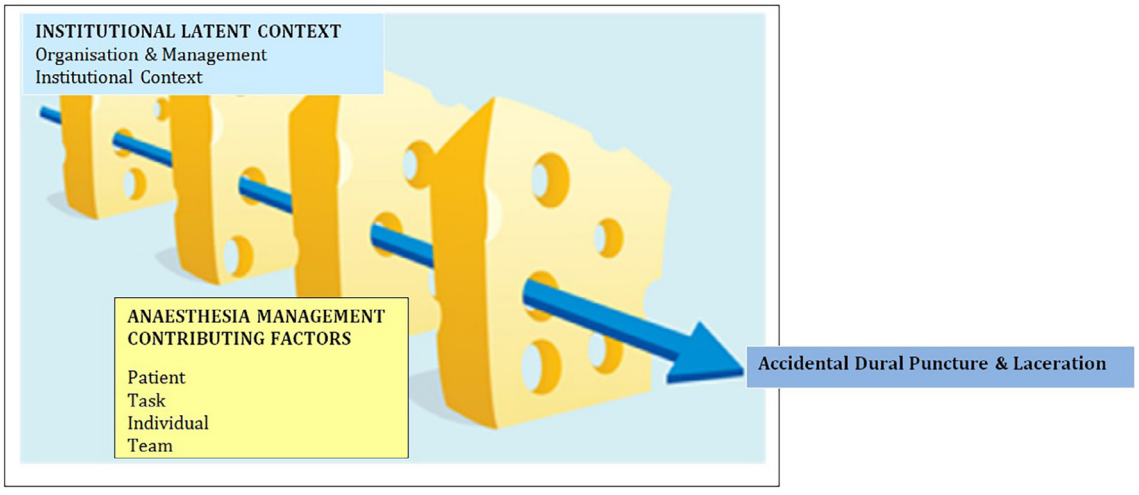

Fig. 1 The ALARM® model in the context of post-dural puncture headache following injury of the dural membrane

As part of the anaesthesia department quality assurance process, all patients are seen by a staff member (anaesthetist or nurse anaesthetist) during a follow-up visit at 24 or 48 hours after delivery. Patients who develop PDPH are systematically recorded on a notification form and reviewed by both midwives and anaesthetists during and after hospital discharge. Midwives also record information on handwritten charts about events occurring in labour rooms or wards. Overall patient information is available in the anaesthesia and hospital electronic patient record. For the purposes of the study, we retrieved all patients recorded in the notification form as having a PDPH treated with an epidural blood patch. We then identified patients having a traumatic puncture, according to our case definition, using complementary information available in the notification form or the anaesthesia incident reporting system that is integrated into the anaesthesia electronic patient record.

Table 1 Risk categories and definitions of procedure-related complications associated with PDPH (ALARM® model)

Risk categories	Risk factors	Definitions/categorizations of the risk factors
Work environment-related factors	Type of room	Size of operating theatre or labour room (small < or large > 17 square metres)
	Day of the procedure	Day of the week
	Timing of the procedure	Night (0:00–6:00); Morning (6:01–12:00); Afternoon (12:01–18:00), Evening (18:01–23:59)
	Workload	Number of neuraxial blocks performed on a daily basis over the study period and categorised into tertiles: low (1–7 procedures/day), intermediate (8–15 procedures/day), high workload (16–32 procedures per/day)
Team-related factors	Team structure	Anaesthesia nurse present or not during the procedure
	Team shifts	A change in the anaesthesia nurse and/or anaesthetist in charge during the procedure
Individual (staff)-related factors	Individual anaesthetist attributes	Anaesthetist's identification number if recorded as primary operator
	Level of training	≤3 years or >3 years of practice in anaesthesia since graduation from medical school
	Number of attempts	"Multiple attempts" defined as more than two attempts by one or several different anaesthetists
Task-related factors	Type of procedure	Epidural; Combined Spinal-Epidural, Spinal
	Patient position	Sitting; left or right decubitus
	Cervical dilation	Cervical dilation at the time of procedure: 0 cm; 1–5 cm; 6–10 cm
	Distance to epidural space	Distance to epidural space in cm
	Use of special long needle	27/25G pencil-point ≤ 12 cm and Tuohy ≤10 cm (yes or no)
	Intervertebral space	L4–L5; L3–L4; L2–L3; L1–L2 or above
	Type of labour	Not in labour; Spontaneous labour; Induced or stimulated labour
	Mode of delivery	Vaginal delivery; Caesarean section classified as: Elective, Delayed emergency (within 2 h), Emergency (within 30 min) or Absolute emergency (within 5 min)
Patient-related factors	Age	Maternal age categorised as: ≤28; 29–33; >33 year-old
	Marital status	Single; married; separated or divorced
	Profession	Categorised as student/housewife; employee; manager; shop manager
	Continent of origin	Europe; Africa; Asia; South America; North America
	Type of insurance	Basic or premium insurance scheme
	Financial dependence	Financial dependence on a social welfare institution
	Gravidity	Categorised as G1; G2; G3 or more
	Parity	Categorised as P1; P2; P3 or more
	BMI	Categorised as: normal/moderate overweight (BMI <30) or obesity BMI (≥30)
	Other significant morbidity	Absence or presence of the following factors: past lumbar surgery or malformation or neurological disorders; current lumbosciatica; migraine; obstetric and perinatal pathologies; smoking status active

BMI: body mass index. PDPH: post-dural puncture headache.

When PDPH symptoms or adverse event circumstances were ambiguous, handwritten charts were also used to rectify these and cases systematically discussed by two senior staff anaesthetists (CK, GH).

For descriptive analyses, we used frequencies, proportions, and means with standard deviations (SD). Continuous variables such as age, body mass index (BMI) at the end of pregnancy, number of gestations, parity, birthweight, timing of anaesthetic procedures, cervical dilation, distance to epidural space and level of training were recoded into separate and mutually exclusive categories. Tertiles or quartiles were generated according to statistical distribution for all continuous variables except BMI, cervical dilation and distance to epidural space, for which commonly accepted and available norms were used (Table 1). For the level of training, we used $\leq$ or >3 years to discriminate junior from senior trainees, according to local definitions and practices at our hospital. Differences in contributing factors between the cases and controls were compared using chi-square test, Fisher's exact test, or binary logistic regression. Derived odds ratio (OR) with 95% confidence intervals (CI) were calculated. An OR >1.0 indicated an increased risk of PDPH.

To identify the specific contribution of each factor category to the occurrence of PDPH and account for unexplained variability among anaesthetists (i.e. past experience, personal skills), we built a mixed effect logistic regression model with a random intercept for the individual anaesthetist's identification number. We built models using a forward selection technique, considering only univariate risk factors with a *P*-value <0.05 or factors considered as clinically relevant. Possible collinearity between factors selected for the model was tested.

We assessed variance inflation during model construction and also used principal component analysis. We found a relative uniformity of variance explained by each component tested, suggesting limited or no collinearity between the factors used in the model. We also tested variables that had a number of missing values (past migraine, repeated procedure) to assess a possible association between the missing status and the occurrence of PDPH. Such associations could severely bias the study results. No such significance was found (chi^2=0.253, df=1, *P* value=0.615). To model the interaction effect between training level and team composition, we created and tested an interaction factor between level of training and the presence of a nurse anaesthetist during the procedure. The final results are expressed as adjusted 95% CI and *P*-values. A *P*-value of <0.05 was considered statistically significant. Because we performed an observational, hypothesis-generating study, we used all identifiable cases during the study period and did not perform an a priori sample-size calculation. We used the Statistical Package for Social Sciences-SPSS® (Version 22, SPSS, Inc., Chicago-Illinois/US) and R® (release 2.13.1; R Foundation for Statistical Computing, Vienna, Austria) for all analyses.

Results

During the study period, 35 763 patients underwent a neuraxial procedure during labour and vaginal delivery or for caesarean section. Among them, 154 (0.43%, 95% CI 0.37 to 0.48) experienced PDPH requiring an epidural blood patch. Patient characteristics of those with PDPH are described in Table 2. In 25 patients, the diagnosis was confirmed by a formal evaluation by a neurologist, a CT scan or an MRI. All the patients

Table 2 Signs, symptoms, investigations and treatments of patients with PDPH following injury of the dural membrane

Characteristics	N (%) Total: 154
Type of headache	
Postural	145 (94.2)
Non-postural	9 (5.8)
Location of headache	
Frontal	74 (46.2)
Temporo-parietal	39 (24.4)
Occipital	47 (29.4)
Associated symptoms	
Diplopia, photophobia, tinnitus	34 (22.1)
Vertigo	14 (9.1)
Nausea/vomiting	20 (13.0)
Complementary exams	
Neurological consultation	7 (4.5)
CT scan	10 (6.5)
MRI	8 (5.2)
Delay between onset of symptoms and first therapeutic blood patch	
≤24 h	65 (42.2)
24–72 h	61 (39.6)
>72 h	28 (18.1)
Number of blood patches	
1	120 (77.9)
2	26 (16.9)
3	3 (1.9)
No information	5 (3.2)
Volume of blood administered [mean (SD)]	
First blood patch	26.0 (8.0)
Second blood patch	20.2 (8.5)
Outcome at seven days	
Full recovery	151 (98.1)
Persistent headache symptoms	3 (1.9)

PDPH: post-dural puncture headache. CT: computed tomography. MRI: magnetic resonance imaging.

received an epidural blood patch, mostly within 72 hours of dural injury. The average amount of blood injected was 26 (SD 8) mL. In 77.9% of the cases, one epidural blood patch was necessary to relieve symptoms. Only three patients (1.9%) had persistent symptoms after seven days.

Crude associations between the occurrence of PDPH requiring an epidural blood patch and patient, task, team and individual staff characteristics and performance-related factors are presented in Table 3. Patients from a foreign country, particularly those from South America, were at a higher risk (OR 2.37, 95% CI

Table 3 Characteristics of cases and control patients and crude associations with PDPH following injury of the dural membrane

Risk factors	Case patients (N=154)	Control patients (N=616)	OR (95% CI)	*P*-value
Patient-related factors				
Age				
≤28 years	51 (33.1)	215 (34.9)	1.0 (reference)	0.892
29–33 years	57 (37.0)	227 (36.9)	1.05 (0.69–1.61)	
>33 years	46 (29.9)	174 (28.2)	1.11 (0.71–1.74)	
Marital status				
Single	29 (18.8)	147 (23.9)	1.0 (reference)	0.332
Married	118 (76.6)	435 (70.6)	1.38 (0.89–2.18)	
Divorced/separated	7 (4.5)	34 (5.5)	1.04 (0.39–2.47)	
Profession				
Student/housewife	57 (37.0)	188 (30.5)	1.0 (reference)	0.320
Employee	79 (51.3)	332 (53.9)	0.78 (0.53–1.16)	
Manager	9 (5.8)	57 (9.3)	0.52 (0.23–1.07)	
High-level manager	9 (5.8)	39 (6.3)	0.76 (0.33–1.6)	
Continent of origin				
Europe	104 (67.5)	493 (80.0)	1.0 (reference)	0.006
Africa	19 (12.3)	60 (9.7)	1.5 (0.84–2.58)	
Asia	11 (7.1)	20 (3.2)	2.61 (1.17–5.51)	
South America	19 (12.3)	38 (6.2)	2.37 (1.29–4.23)	
North America	1.0 (0.6)	5 (0.8)	0.95 (0.05–5.96)	
Type of insurance				
Basic scheme	146 (94.8)	591 (97.2)	1.0 (reference)	0.142
Premium scheme	8 (5.2)	17 (2.8)	1.9 (0.76–4.37)	
Financial dependence	61 (39.6)	181 (29.4)	1.58 (1.09–2.27)	0.015
Gravidity (G)				
G1	53 (34.4)	226 (36.7)	1.0 (reference)	0.733
G2	48 (31.2)	198 (32.1)	1.03 (0.67–1.6)	
≥G3	53 (34.4)	192 (31.2)	1.18 (0.77–1.8)	
Parity (P)				
P1	80 (51.9)	329 (53.4)	1.0 (reference)	0.310
P2	46 (29.9)	204 (33.1)	0.92 (0.62–1.38)	
P3 and more	28 (18.2)	83 (13.5)	1.33 (0.81–2.20)	
Individual conditions				
Normal/overweight (<30) (BMI)	109 (71.2)	433 (71.1)	1.0 (reference)	0.972
Obesity (≥30) (BMI)	44 (28.8)	176 (28.9)	0.99 (0.67–1.46)	
Past lumbar surgery or malformation or neurological disorder	10 (6.5%)	30 (4.9)	1.35 (0.64–2.83)	0.417
Current lumbosciatica	5 (3.3)	30 (4.9)	0.66 (0.22–1.59)	0.398
Migraine	16 (10.4)	9 (1.5)	7.82 (3.45–18.83)	<0.001
Obstetric and perinatal pathologies	42 (27.3)	12 (1.9)	18.87 (9.93–38.53)	<0.001
Smoking status active	31 (20.1)	134 (21.8)	0.91 (0.58–1.39)	0.661

(*continued on next page*)

Table 3 (*continued*)

Risk factors	Case patients (N=154)	Control patients (N=616)	OR (95% CI)	*P*-value
Task-related factors				
Type of neuraxial anaesthesia				
Epidural	25 (16.2)	82 (13.4)	1.0 (reference)	0.621
CSE/epidural	101 (65.6)	407 (66.5)	0.81 (0.49–1.33)	
Spinal	28 (18.2)	123 (20.1)	0.74 (0.40–1.37)	
Level of regional procedure				
L1–L2 or above	1 (0.7)	10 (1.7)	1.0 (reference)	0.747
L2–L3	7 (5.0)	34 (5.8)	2.05 (0.22–18.78)	
L3–L4	99 (70.2)	420 (71.1)	2.35 (0.29–18.62)	
L4–L5	34 (24.1)	127 (21.5)	2.67 (0.33–21.64)	
Type of labour				
Not in labour	20 (13.5)	104 (16.9)	1.0 (reference)	0.347
Spontaneous labour	81 (54.7)	298 (48.4)	1.41 (0.84–2.47)	
Induced or stimulated labour	47 (31.8)	214 (34.7)	1.14 (0.65–2.06)	
Patient position				
Left lateral decubitus	13 (8.8)	56 (9.3)	1.0 (reference)	0.190
Right lateral decubitus	4 (2.7)	4 (0.7)	4.31 (0.91–20.53)	
Sitting position	100 (67.6)	420 (69.4)	1.03 (0.56–2.02)	
Not specified	31 (20.9)	125 (20.7)	1.07 (0.53–2.26)	
Dilation at needle insertion				0.795
0	76 (54.7)	253 (54.2)	1.0 (reference)	
1–5	53 (38.1)	172 (36.8)	1.02 (0.68–1.53)	0.795
6–10	10 (7.2)	42 (9.0)	0.79 (0.38–1.65)	
Use of special long needles	1 (0.2)	1 (0.6)	4.02 (0.25–64.62)	0.288
Distance to epidural space				
2–4 cm	28 (23.5)	177 (38.0)	1.0 (reference)	<0.001
5–7 cm	81 (68.1)	281 (60.3)	1.82 (1.14–2.91)	
8–10 cm	10 (8.4)	8 (1.7)	7.90 (2.87–21.72)	
Caesarean section				
No (vaginal delivery)	116 (75.3)	368 (59.7)	1.0 (reference)	<0.001
Elective	10 (6.5)	175 (28.4)	0.18 (0.09–0.35)	
Delayed emergency	10 (6.5)	31 (5.0)	1.02 (0.48–2.15)	
Emergency	14 (9.1)	35 (5.7)	1.26 (0.66–2.44)	
Absolute emergency	4 (2.6)	7 (1.1)	1.81 (0.52–6.30)	
Emergency status	34 (22.1)	125 (20.3)	1.11 (0.72–1.69)	0.624
Individual staff-related factors				
Level of training				
≤3 years	18 (11.7)	54 (8.8)	1.0 (reference)	0.265
>3 years	136 (88.3)	562 (91.2)	0.72 (0.41–1.27)	
Multiple attempts	80 (51.9)	54 (8.8)	11.25 (7.41–17.25)	<0.001
Team-related factors				
Team shift	17 (11.0)	85 (13.8)	0.78 (0.43–1.32)	0.367
Nurse anaesthetist present during the procedure	122 (79.2)	528 (85.7)	0.63 (0.40–0.99)	0.047
Work environment-related factors				
Type of labour room				
Operating theatre	23 (14.9)	114 (18.5)	1.0 (reference)	0.761
Small labour room	74 (48.1)	283 (45.9)	1.3 (0.78–2.21)	
Large labour room	53 (34.4)	206 (33.4)	1.28 (0.75–2.22)	

Table 3 (*continued*)

Risk factors	Case patients (N=154)	Control patients (N=616)	OR (95% CI)	*P*-value
Day of procedure				
Sunday	24 (15.6)	69 (11.2)	1.0 (reference)	0.109
Monday	30 (19.5)	87 (14.1)	0.99 (0.53–1.86)	
Tuesday	20 (13.0)	77 (12.5)	0.75 (0.38–1.47)	
Wednesday	14 (9.1)	96 (15.6)	0.42 (0.2–0.86)	
Thursday	16 (10.4)	95 (15.4)	0.48 (0.24–0.97)	
Friday	26 (16.9)	107 (17.4)	0.7 (0.37–1.32)	
Saturday	24 (15.6)	85 (13.8)	0.81 (0.42–1.56)	
Time of procedure				
Night (0:00–6:00)	40 (26.3)	165 (26.8)	1.0 (reference)	0.830
Morning (6:01–11:59)	45 (29.6)	164 (26.6)	1.13 (0.70–1.82)	
Afternoon (12:01–18:00)	35 (23.0)	139 (22.6)	1.03 (0.62–1.72)	
Evening (18:01–23:59)	32 (21.1)	148 (24.0)	0.89 (0.53–1.49)	
Workload				
Low	63 (40.9)	229 (37.2)	1.0 (reference)	0.382
Intermediate	63 (40.9)	290 (47.1)	0.79 (0.53–1.17)	
High	28 (18.2)	97 (15.7)	1.05 (0.63–1.72)	

PDPH: post-dural puncture headache. BMI: body mass index. CSE: combined spinal-epidural.

1.29 to 4.23). Financial dependence (OR 1.58, 95% CI 1.09 to 2.27), and the presence of migraine (OR 7.82, 95% CI 3.45 to 8.83) and obstetric and perinatal pathologies (OR 18.87, 95% CI 9.93 to 38.53) were also associated with PDPH. Individual staff and task characteristics and performance-related factors, such as a distance to the epidural space of 8–10 cm (Fig. 2: OR 7.90, 95% CI 2.87 to 21.72), and multiple attempts (OR 11.25, 95% CI 7.41 to 17.25), were significantly associated with this complication. When a nurse anaesthetist was present, the risk decreased (OR 0.63, 95% CI 0.40 to 0.99). None of the variables related to work environment reached statistical significance for the univariate association with PDPH (Table 3).

The specific contribution of the ALARM category of factors is described in Table 4. The strongest associations were observed for patient-related factors (migraine OR 10.60, 95% CI 2.74 to 41.05; obstetric

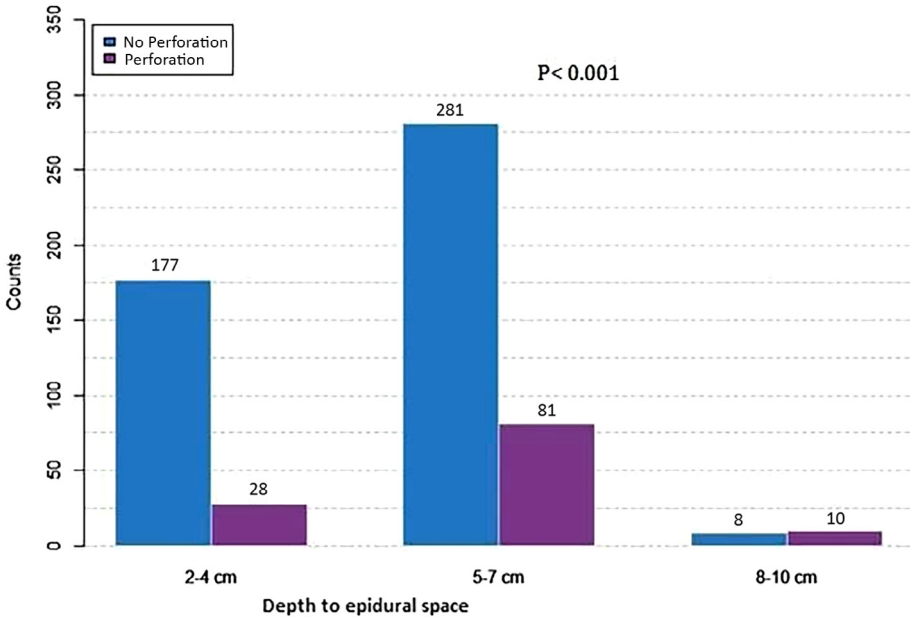

Fig. 2 Cases of perforation of the dural membrane followed by post-dural puncture headache according to epidural space distance

Table 4 Mixed model for factors associated with PDPH following injury of the dural membrane

Risk factor	OR (95% CI)	*P*-value
Patient-related		
Continent of origin		
Europe	1.0 (reference)	
Africa	1.0 (0.42–2.36)	
Asia	2.71 (0.87–8.45)	0.37
South America	1.82 (0.69–4.83)	
North America	1.21 (0.07–19.62)	
Type of insurance scheme		
Basic	1.0 (reference)	
Premium	1.16 (0.25–5.34)	0.84
Financial dependence	1.40 (0.76–2.55)	0.277
Migraine	10.60 (2.74–41.05)	<0.001
Obstetric and perinatal pathology	10.85 (4.29–21.42)	<0.001
Task-related		
Distance to epidural space		
2–4 cm	1.0 (reference)	
5–7 cm	1.20 (0.65–2.20)	0.26
8–10 cm	4.38 (1.06–18.13)	
Caesarean section		
No (labour analgesia)	1.0 (reference)	
Yes	0.43 (0.39–1.25)	0.306
Individual staff-related		
Individual anaesthetist attributes[†]		0.26
Multiple attempts	11.48 (6.29–20.94)	<0.001
Level of training		
≤3 years	1.0 (reference)	
>3 years	0.20 (0.55–0.76)	0.008
Team-related		
Nurse anaesthetist present vs. absent during the procedure	0.05 (0.01–0.29)	0.001
Nurse anaesthetist present vs. absent during procedure by training level (≤3 years vs >3 years)[*]	0.06 (0.01–0.41)	0.004

[*]Interaction factor.
[†]Random intercept.

and perinatal pathology OR 10.85, 95% CI 4.29 to 21.42); for individual staff characteristics and performance-related factors (multiple attempts OR 11.48, 95% CI 6.29 to 20.94; level of training >3 years OR 0.20, 95% CI 0.55 to 0.76), and for team-related factors (nurse anaesthetist present during the procedure OR 0.05, 95% CI 0.01 to 0.29). The latter was stratified to model the interaction between training level and team composition. The association remained statistically significant only for training level ≤3 years (P=0.004). The random factor modelling anaesthetist's identity was not significant (model random factor P=0.26).

The significance of the Hosmer–Lemeshow goodness-of-fit test for the mixed model was 0.83 (95% CI 0.78 to 0.88) and the C-index of the full model was 0.832.

Discussion

The use of a RCA framework allowed the identification of several human, environmental and organisational factors associated with PDPH following accidental dural injury. This included: (1) patient-related factors such as migraine, obstetric and perinatal pathology; (2) individual staff characteristics and performance-related factors such as multiple attempts and level of training <3 years; and (3) team-related factors such as a nurse anaesthetist not present during the procedure. This suggests that this adverse event is the consequence of a variety of contributing factors and not exclusively related to an anaesthetist's individual competence.

Some of our findings are in line with previous publications. Studies have identified an inverse relationship between operator experience and the rate of accidental

dural puncture and PDPH.[26–28] In our study, the cut-off was ≤3 years, which in our hospital corresponds to mid-level training as half of our trainees have not yet performed their formal three-month rotation in obstetrics. The trainees have limited experience with obstetric neuraxial techniques. One study suggested an average minimum of 46 (interquartile range 19–114) obstetric epidural procedures were required to reach competence.[29] In accordance with previous work,[16,30] we found that multiple attempts to locate the epidural or subarachnoid space were significantly associated with an increased risk of PDPH. This is likely because "multiple attempts" was part of our definition of a procedure-related issue, but it also confirms that it is a valid indicator of technical difficulties associated with epidural or spinal needle insertion.

In contrast with a previous publication[14] we did not identify an association between lower BMI and PDPH. Nor did we find that obesity increased the risk of procedure-related complications.[31,32] However, like a previous study,[33] we found that depth of the epidural space at 8–10 cm was significantly associated with PDPH following a procedure-related issue. These results appear somewhat contradictory. One possible interpretation is that obesity increases the risk of accidental puncture because it is associated with a deeper location of the epidural space. However, obesity may itself protect against headache following dural puncture, possibly due to a higher pre-existing pressure in the epidural space that limits CSF leakage and intracranial hypotension.

In contrast to previous studies[26,34,35] we did not find that work environment-related factors (workload, night shifts, weekends) increased the risk of PDPH following procedure-related issues. This might be explained by our workload organisation that limits shifts to sequences of four or five consecutive 12-hour periods, mixed with four to six days off work. Parallel studies in the railway industry have shown that this sequence of shifts can limit extreme fatigue caused by night shifts and high workloads.[36–38]

We found that team-related factors, such as the presence of a nurse anaesthetist during the procedure, significantly decreased the risk of PDPH when trainees had three or less years of clinical experience. There are several possible explanations for this finding. One lies in the nurse's contribution to preparing, comforting and supporting the patient. A recent systematic review suggests that patient-centred care and patient empowerment have beneficial effects on health behaviour, health status and outcomes.[39] Another possible reason is that nurses at our hospital are in charge of helping the patient maintain an appropriate position.[40] While this is also done by midwives, nurse anaesthetists are particularly helpful in all cases where midwives are busy closely monitoring babies, comforting patients, teaching trainees, recording information or unexpectedly leaving the room to look for extra material. The presence of the nurse anaesthetist may also reduce overall feelings of stress, particularly in junior trainees, and improve teamwork, resulting in an overall reduction in complication rates.[41–43]

As has been demonstrated in other studies in the field of medicine or surgery,[44,45] another interesting finding was that numerous factors related to patient socioeconomic status were significantly associated with an increased risk of PDPH in the univariate analysis. Some of these patients were of foreign origin with a limited understanding of the procedure performed, which may lead to poorer patient cooperation, and technical difficulties for the operator. However, this association did not remain significant in the multivariate analysis, suggesting a low level of risk compared with other factors.

Finally, we found that patient-related factors, such as migraine and obstetric and perinatal pathologies, were significantly associated with an increased risk of PDPH. This is likely because perinatal pathologies are surrogates for the urgent status of the requirement to alleviate pain or conduct an emergency caesarean section. The latter are known to increase the risk of failures and complications.[46,47] This is probably due to several co-existing factors such as poor preoperative assessment, poor patient cooperation during the procedure and increased operator workplace stress.

Several limitations of this study should be considered. First, this was a single-centre study and our findings may lack generalisability. This is particularly the case for work environment and team-related factors that typically reflect local work practices at the hospital and department. However, our results confirm previous findings on teamwork, stress and fatigue in other domains such as the railway industry.[36–38] Secondly, as the study was retrospective, we had to use existing data and could not analyse factors of the ALARM model[24] that may have been important. These include administrative and managerial support, verbal communication, leadership, and noise in labour rooms. Despite this limitation, we analysed a large range of factors. Thirdly, although we included all cases over a 12-year period, the sample was limited to 154 events. While the use of a case-control study design with four controls for each case increased statistical power,[48] we did not perform an a priori sample-size calculation and therefore, a type-2 error cannot be excluded. Furthermore, because we performed multiple statistical comparisons in the univariate analysis in order to identify risk factors of PDPH, we also increased the risk of identifying an association by chance (a false positive). However, as an additional multivariate analysis was performed that included nearly exclusively risk factors with a statistical significance set at $P<0.05$ (5% risk of type-1 error), the likelihood of a false discovery is low.

Finally, in contrast to previous publications,[9,28,49–51] we included both PDPH following accidental dural puncture by Tuohy needles ("dural taps") and intentional perforation of the dura by spinal needles (spinal-epidural or spinal anaesthesia). However, the latter had to be described as being repeated, difficult and therefore likely traumatic. In contrast, we did not consider cases of PDPH following non-obstetric neuraxial procedures, as symptoms are more likely to be due to patient-related factors than to procedure-related factors. This decision was made because we were interested in identifying human, environmental or organisational factors related to the occurrence of an unintentional anaesthesia-related injury which were likely to assist in the development of improvement strategies.

Despite these limitations, the use of a RCA framework allowed us to identify a broad range of system-related factors associated with PDPH following a procedure-related issue during neuraxial anaesthesia. These results remind us that undesirable adverse events cannot be solved by single interventions. A multidimensional approach that addresses the broad range of system-related factors, for example team composition, staff characteristics and task-related factors, is required. To minimise the risk of PDPH and improve patient safety in obstetrics, several adjustments to anaesthesia work practices must be made. These include more effective team work, appropriate supervision of trainees with limited experience, and special care of patients in labour who have perinatal obstetric pathologies. For these patients, new approaches such as the use of ultrasound to locate the epidural space should be considered, to minimise the risk of complications following neuraxial anaesthesia.[52,53] Future research should include the design of large prospective studies with greater power, to capture a broader range of human and organisational factors such as leadership, supervision and protocol use, that may be associated with anaesthesia-related complications such as PDPH.

In conclusion, PDPH following a procedure-related issue during neuraxial techniques in the obstetric population is not the result of an individual anaesthetist's performance alone. Additional factors such as team composition and the presence of an obstetric pathology are at play, and strategies to improve outcomes should consider these factors.

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