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Original article

Breakthrough pain during cesarean section under neuraxial anesthesia: a two-center prospective audit

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Abstract

Worldwide, most Cesarean sections (CS) are performed under neuraxial anesthesia. However, neuraxial anesthesia can fail and intraoperative breakthrough pain can occur. The aim of the present investigation was to evaluate the incidence of breakthrough pain in consecutive CS and to describe the potential risk factors for breakthrough pain. In a two center, prospective audit all CS performed under neuraxial anesthesia were included and the occurrence of breakthrough pain as well as all possible risk factors of breakthrough pain were recorded as well as the alternative anesthetic strategy. A total of 393 patients were enrolled in the study over 6 months, 206 in UZ Leuven and 187 in ZNA Middelheim, 295 elective CS and 98 secondary CS. Of all 393 participants, 65 experienced breakthrough pain during the CS (16.5%). Twoo significant risk factors for breakthrough pain during CS were observed: the duration of surgery (p <0.001) and the epidural drug used (p=0.0032). Breakthrough pain during a CS is extremely uncomfortable for the mother. In this observational study, the incidence of breakthrough pain during CS was 16.5%.
uration of surgery and epidural drug used were both significant risk factors of breakthrough pain during CS in this audit. A pro-active policy is required in order to prevent breakthrough pain or discomfort during CS. Early identification of problematic epidural catheters for labor analgesia, adequate level of anesthetic block before surgery, and administration of a prophylactic epidural top-up if duration of surgery is prolonged as opposed to the choice of local anesthetic used, could be essential in the prevention. Further high-quality studies are needed to evaluate the many potential risk factors associated with breakthrough pain during CS.

Keywords: **Breakthrough pain; Cesarean section; neuraxial anesthesia; intraoperative pain.**

Introduction

Worldwide, cesarean section (CS) is the most commonly performed surgical procedure with an estimated 30 million procedures performed globally each year[1]. Neuraxial anesthesia is generally preferred as anesthetic approach, especially in elective circumstances. This allows for an awake mother fully enjoying the birth experience and provides safe conditions both for mother and newborn. Depending on the situation and routine of the operator, different neuraxial techniques are used including single shot spinal anesthesia (SSS), combined spinal epidural anesthesia (CSE) and topping-up of a labor epidural catheter[2].

Neuraxial anesthesia is safe provided usual measures to prevent spinal induced hypotension are taken such as reducing the spinal dose, left lateral tilt, fluid co-loading and most importantly vasopressor therapy[3,4,5]. Furthermore, the risk of spinal hematoma is minimal especially if neuraxial anesthesia is avoided in parturients with coagulation abnormalities.

Currently, breakthrough pain during neuraxial anesthesia is probably the most important problem that can occur during CS. It was eloquently

described by a patient when she experienced breakthrough pain[6]. Breakthrough pain is defined as pain or a feeling of intense abdominal pressure that requires supplemental anesthesia or a change in anesthetic technique. Breakthrough pain is discomfortable for the mother but also increases the workload of anesthetists in a busy operating theater. Breakthrough pain has important physical and emotional effects on the mother and can cause serious medicolegal consequences[7,8].

The goal of the present investigation was to evaluate the incidence of breakthrough pain in consecutive CS and to describe the potential risk factors for breakthrough pain.

Methods

The study was performed at the anesthetic departments of two Belgian hospitals: UZ Leuven and ZNA Middelheim Antwerp. The study protocol was approved by the ethic committees of both hospitals; in UZ Leuven by chairman Prof. Dr. Casteels M-R on 13th December 2017 with E.C. approval number 61018 and in ZNA Middelheim Antwerp by chairman Prof. Dr. De Deyn on 10th of January 2018 with E.C. Approval number 5044.

The design of the study was an observational prospective study. During a 6-month study period, all consecutive women undergoing a planned or unplanned CS performed under any type of neuraxial anesthesia were included and this at any possible time of day including weekends and after hours (24/24, 7/7). There were no exclusion criteria.

All participants received normal standard of care, routine for the hospital and attending anesthetist. Patients were treated either by a consultant or trainee. In principle and per routine care pathway, the effect of neuraxial anesthesia was tested and an adequate block had to be established before surgery could start. An adequate block is defined as a block for cold to T4 with complete absence of cold sensation up to and including the T4 dermatome.

For data collection, a paper version of a case report form is used for each individual patient. This form was completed by the attending anesthetist during surgery. Only pain during surgery was studied. Duration of surgery was defined as the time of completion of the spinal injection to wound closure or as the time of start of the epidural bolus to wound closure. Within 24 hours after each CS, a study collaborator collected the forms and checked them for accuracy and completion against the clinical records. Missing information was added by interviewing the attending anesthetist. At each participating centre, all relevant patient data were anonymously entered in an Excell database file. Only through the individual study identification number, it was possible to track back patients.

The primary endpoint of this study is the incidence of breakthrough pain. Breakthrough pain is defined as pain for which the patient requires a change in anesthesia strategy or the administration of an additional anesthetic in order to treat pain. Prophylactic additional local anesthetic administration through the epidural catheter in order to prevent possible breakthrough pain was not seen as breakthrough pain or management of breakthrough pain.

The secondary recorded data were: the level of experience of the anesthestist (trainee or staff member), expected difficult airway, labor epidural catheter, number of top-ups during labor + which drugs used during labor, epidural volume expansion (EVE) including time and volume, duration of analgesia during labor, number of PCEA boluses during labor, VNRS score before CS, VNRS score during CS, history of previous failed epidurals, chronic pain medication, deviation of the standard operating protocol, adequacy of the block before CS starts, ease of insertion of the catheter, the spinal drug, BMI of mother, maternal weight, maternal height, maternal age, maternal race, gestational age, repeat section, conversion from labor to CS, nulliparity, Lucas classification of urgency, breech, duration of surgery, Apgar score baby, weight of the baby at birth, umbilical blood gasses of the baby.

Statistical analysis is performed by using appropriate statistical techniques for parametric and non-parametric data. All analyses were performed using SAS software version 9.4.

Univariate analysis of factors that might influence the origin of breakthrough pain was performed using a 2-sample t-test, or a Wilcoxon rank-sum test. All categorical variables were assessed using a chi-squared test. The univariate analysis was used to determine the factors that correlated with the origin of breakthrough pain. Factors that actually were associated with the origin of breakthrough pain in the univariate analysis, were put into a multiple logistic regression analysis to determine which factors are significant predictors for the outcome. Sub-analyses were made for primary and secondary CS.

A post-hoc testing was used to compare all the drugs to each other, with a correction to the p-value for multiple testing. A p-value <0.05 defines statistical significance. All reported p-values are two-sided.

Results (Tables 1 – 8)

A total of 393 patients were enrolled in the study over 6 months, 206 in UZ Leuven and 187 in ZNA Middelheim, 295 elective CS and 98 secondary

Table I. — Treatment of breakthrough pain.

Treatment of breakthrough pain	Antwerp	Leuven	Total N=65
General anaesthesia	4/26(15.4%)	1/37 (2.7%)	5/63 (7.9%)
Change in Anaesthetic strategy	7/26(26.9%)	5/37(13.5%)	12/63(19.1%)
Extra Epidural Anaesthesia	7/26(26.9%)	30/37(81.1%)	37/63(58.7%)
Reassurance	7/26(26.9%)	1/37(2.7%)	8/63(12.7%)
Strategy change & extra epidural bolus	1/26(3.9%)	0/37(0%)	1/63(1.6%)
Missing data			2/65
Values are number n/N (%)			

CS. Of all 393 participants, 65 experienced breakthrough pain during the CS (16.5%), with a median (Q1; Q3) VNS (visual numeric scale out of 10) pain score of 6 (5; 7). In 39 of the 65 parturients (60%) who experienced breakthrough pain, the pain was described as a sharp, acute pain, while in 26 of the 65 participants (40%) the pain was described as an uncomfortable feeling.

Both elective (n=295) and unplanned operative deliveries (n=98) were included in this audit. In elective CS 45 patients experienced breakthrough pain (15.3%), while in unplanned, secondary CS 20 patients experienced breakthrough pain (20.4%). This difference was not statistically significant (p=0.234).

The timing of occurrence of breakthrough pain was in 3% during skin incision, in 9% during peritoneal incision, in 20% between peritoneal incision and birth of the baby and in 68% after birth (near the end of the intervention). Breakthrough pain occurred with a median (Q1. Q3) time of 35 (22; 51) minutes after start of surgery. In most of the participants (58.7%), breakthrough pain was treated with an extra epidural bolus of an anesthetic solution. Other treatments of breakthrough pain were conversion to general anesthesia (7.9%), a change in anesthetic strategy (e.g. the addition of IV remifentanil, IV midazolam) (19.1%) and reassurance only of the patient (12.7%). In 1.6% a combination of the above was used.

In elective CS, 16% of patients (n=49) were performed under SSS anesthesia, 82% (n=241) with a CSE technique, 2% (n=5) were de novo epidurals because of failed spinal puncture or because the anesthetist felt the need for perfect hemodynamic stability. Hyperbaric bupivacaine 0.5% (6.6-8mg) was the most commonly used local anesthetic, in 231 CS (78.6 %). Prilocaine (50mg) was used in 11 patients (4%) and levobupivacaine (12.5-13.5mg) in 51 patients (17.4%). Breakthrough pain occurred in 45 patients. The incidence of breakthrough pain (n/N (%)) was respectively 36/231 (15.6%) for hyperbaric bupivacaine 0.5%, 4/11 (36.4%) for prilocaine and 4/51 (7.84%) for levobupivacaine (p=0.0487). After pairwise comparisons for multiple testing a statistical difference could not be shown between the 3 spinal local anesthetics. A larger sample size is needed to possibly show a significant difference.

In patients who received a CSE as primary anesthetic technique for elective CS (n=241), 41 patients experienced breakthrough pain (17%). Hyperbaric bupivacaine 0.5% was the most common used local anesthetic. 215 patients received hyperbaric bupivacaine as spinal drug (89.2%), eleven patients received prilocaine as spinal drug (4.6%) and levobupivaine 0.5% was used in 13 patients (5.4%). In 2 patients the spinal space couldn't be identified and no spinal anesthetic solution was administered. The incidence of breakthrough pain (n/N (%) was respectively 34/215 (15.8%) for hyperbaric bupivacaine 0.5%, 4/11 (36.4%) for prilocaine and 2/13 (15.4%) for levobupivacaine.

In patients who received a single shot spinal technique (49 patients), 3 patients experienced breakthrough pain. Twelve patients received hyperbaric bupivacaine 0.5% (24.5%), of which

Table II. — Difference in breakthrough pain in elective vs unplanned CS.

Caesarean Section	No pain	Pain	Total	P-value
				0.234
Elective	250/295(87.7%)	45/295(15.3%)	295	
Unplanned	78/98 (79.6%)	20/98 (20.4%)	98	
Total	328 (83.5%)	65 (16.5%)	393	
Values are number n/N (%)				

Table III. — Spinal drug used and incidence of breakthrough pain.

Spinal drug	Estimate	95% confidence interval	P-value
			0.0487
Hyperbaric Marcaine	36/231 (15.6%)	11.2%; 20.9%	
Prilocaine	4/11 (36.4%)	10.9%; 69.2%	
Levobupivacaine	4/51 (7.8%)	2.2%; 18.9%	
Total	44/293		
Values are number n/N (%)			

Table IV. — Pairwise comparison of spinal products used and the incidence of breakthrough pain.

Spinal Drug	Adjusted P-Value (*)
Levobupivacaine vs Marcaine	0.4810
Levobupivacaine vs Prilocaine	0.0584
Marcaine vs Prilocaine	0.2500
(*) Adjusted using Bonferroni correction	

one patient experienced breakthrough pain. Of the 37 patients (75.5%) who received levobupivacaine, 2 patients experienced breakthrough pain. There was no statistically significant difference between the type of spinal drug used and the incidence of breakthrough pain.

In elective CS, the primary anesthetic technique was not a risk factor for breakthrough pain with a 6% incidence in the SSS group versus 17% in the CSE group. (p= 0.0527).

One hundred and three patients received an epidural drug top up. Most patients received the epidural top-up because of conversion from labor analgesia to secondary CS (n=93). Ten patients received the epidural top-up as part of a planned CS in which epidural local anesthetic was given prior to start of surgery, because of a de novo epidural technique or because of a failed spinal component during a CSE technique. There was a statistically significant difference between the type of epidural local anesthetic drug used for CS and the occurrence of breakthrough pain (p= 0.0032). Breakthrough pain occurred in 23 patients (22.3%), of which 4 (14.8%) received ropivacaine 0.75%, 11 (22%) received 2-chloroprocaine 3%, 1 (6.7%) received lidocaine 2% and 7 (63.6%) received a combination of ropivacaine + lidocaine. There was a higher chance of breakthrough pain when the combination of ropivacaine + lidocaine was used compared to the other local anesthetics. These results were also confirmed in pairwise comparison of the different epidural drugs. A pairwise comparison between the four epidural products used, demonstrated a statistically significant difference in incidence of breakthrough pain between lidocaine vs ropivacaine + lidocaine (p=0.049) and ropivacaine vs ropivacaine + lidocaine (p=0.032).

In patients with a CS performed under CSE (241 elective CS and 6 secondary sections of which 3 did not report on top-ups, n=244), preventive top-ups were given in 50 patients and no preventive top-up was given in 194 patients. Breakthrough pain occurred in 42 patients (17%). In patients with a preventive epidural top-up, 6 had breakthrough

Table V. — Epidural drug and occurrence of breakthrough pain.

Epidural drug	Estimate probability of pain	95% CI	P-value
			0.0032
Ropivacaine	4/27 (14.8%)	(4.2% ; 33.7%)	
Chloroprocaine 3%	11/50 (22.0%)	(11.5% ; 36.0%)	
Lidocaine	1/15 (6.7%)	(0.17%; 31.9%)	
Ropivacaine+Lidocaine	7/11 (63.6%)	(30.8% ; 89.1%)	
Values are number n/N (%)			

Table VI. — Pairwise comparison of epidural local anaesthetics used and the incidence of breakthrough pain.

Epidural Drug	Adjusted P-Value (*)
Chloroprocaine 3% vs Lidocaine	1.0
Chloroprocaine 3% vs Ropivacaine	1.0
Chloroprocaine 3% vs Ropivacaine+Lidocaine	0.063
Lidocaine vs Ropivacaine	1.0
Lidocaine vs Ropivacaine+Lidocaine	0.049
Ropivacaine vs Ropivacaine+Lidocaine	0.031
(*) Adjusted using Bonferroni correction	

Table VII. — Patient and baby characteristics by occurrence of breakthrough.

Characteristics	No breakthrough pain	Breakthrough pain	Total	P-value
Maternal age [y]	[328]31(5)	[65]32(6)	[393] 32(5)	0.151
Maternal height [cm]	[326] 164 (7)	[65] 163 (7)	[391] 164 (7)	0.552
>167 cm	109/326 (33.4%)	17/65 (26.1%)	126/391 (32.2%)	0.251
BMI [kg/m²]	[326] 31 (5)	[65] 31 (5)	[391] 31 (5)	0.829
Race				0.580
Asian	20/328 (6.1%)	2/65 (3.1%)	22/393 (5.6%)	
Black	53/328 (16.2%)	9/65 (13.9%)	62/393 (15.8%)	
Hispanic	17/328 (5.2%)	6/65 (9.2%)	23/393 (5.9%)	
Caucasian	196/328 (59.8%)	41/65 (63.1%)	237/393(60.3%)	
Other	42/328 (12.8%)	7/65 (10.8%)	49/393 (12.5%)	
Gestational age [weeks]	[328] 38 (3)	[65] 38 (2)	[393] 38 (3)	0.731
Conversion	78/328 (23.8%)	20/65 (30.8%)	98/393 (24.9%)	0.234
Repeat CS	143/327 (43.7%)	30/65 (46.2%)	173/392(44.1%)	0.719
Lucas classification				0.936
Emergency	8/327 (2.5%)	2/65 (3.1%)	10/392 (2.5%)	
Urgent	70/327 (21.4%)	14/65 (21.5%)	84/392 (21.4%)	
Scheduled	76/327 (23.2%)	17/65 (26.2%)	93/392 (23.7%)	
Elective	173/327 (52.9%)	32/65 (49.2%)	205/392(52.3%)	
Primary anaestetic method				0.163
Spinal	46/328 (14.0%)	3/65 (4.6%)	49/393 (12.5%)	
CSE	205/328 (62.5%)	42/65 (64.6%)	247/393(62.9%)	
Upload	74/328 (22.6%)	19/65 (29.2%)	93/393 (23.7%)	
New epidural	3/328 (0.9%)	1/65 (1.5%)	4/393 (1.0%)	
Experience provider(trainee)	224/328 (68.3%)	52/65 (80%)	276/393(70.2%)	0.059
Difficult catheter insertion	17/283 (6.0%)	6/62 (9.7%)	23/345 (6.7%)	0.294
N° PCEA boluses during labour	[39] 1 (0;4)	[13] 5 (1;7)	[52] 1 (0;6)	0.222
Duration of labour [min] before conversion	[70] 300 (180;540)	[18] 405 (300;720)	[88] 358 (205;555)	0.255
Highest dermatome block				0.212
C2	1/307 (0.33%)	0/61 (0%)	1/368 (0.27%)	
C4	2/307 (0.7%)	0/61 (0%)	2/368 (0.5%)	
C5	2/307 (0.7%)	1/61 (1.6%)	3/368 (0.8%)	
T1	8/307 (2.6%)	0/61 (0%)	8/368 (2.2%)	
T2	53/307 (17.3%)	10/61 (16.4%)	63/368 (17.1%)	
T3	91/307 (29.64%)	16/61 (26.3%)	107/368(29.1%)	
T4	111/307 (36.2%)	22/61 (36.1%)	133/368(36.1%)	
T5	25/307 (8.1%)	6/61 (9.9%)	31/368 (8.4%)	
T6	8/307 (2.6%)	3/61 (4.9%)	11/368 (3%)	
T7	1/307 (0.3%)	2/61 (3.3%)	3/368 (0.8%)	
T8	3/307 (1%)	0/61 (0%)	3/368 (0.8%)	
T9	2/307 (0.7%)	0/61 (0%)	2/368 (0.5%)	
T11	0/307 (0%)	1/61 (1.6%)	1/368 (0.3%)	
Pain score at start conversion	[66] 0 (0;1)	[18] 0 (0;7)	[84] 0 (0;2)	0.064
Preventive top-up	53/279 (19.0%)	8/61 (13.1%)	61/340 (17.9%)	0.278
Chronic opioid use in mother	1/326 (0.3%)	0/65 (0%)	1/391 (0.26%)	0.655
Values are number n/N (%), [n]mean (SD) or [n]median (Q1; Q3)				

Table VIII. — Neonatal Outcome parameters and occurrence of breakthrough pain.

Neonatal Outcome Parameters	No Pain	Pain	Total	P-value
Weight (g)	[353] 3049 (795)	[69]2950 (809)	[422] 3032 (797)	0.346
Apgar after 1 minute				0.793
1	4/354 (1.1%)	1/69 (1.5%)	5/423 (1.2%)	
2	4/354 (1.1%)	0/69 (0%)	4/423 (1.0%)	
3	7/354 (2%)	1/69 (1.5%)	8/423 (1.9%)	
4	5/354 (1.4%)	0/69 (0%)	5/423 (1.2%)	
5	11/354 (3.1%)	3/69 (4.4%)	14/423(3.3%)	
6	9/354 (2.5%)	1/69 (1.5%)	10/423(2.4%)	
7	24/354 (6.8%)	7/69 (10.1%)	31/423(7.3%)	
8	44/354 (12.4%)	12/69 (17.4%)	56/423(13.2%)	
9	225/354 (63.6%)	42/69 (60.9%)	267/423(63.1%	
10	21/354 (5.9%)	2/69 (2.9%)	23/423 (5.4%)	
pH				0.525
6	2/333 (0.6%)	0/67 (0%)	2/400 (0.5%)	
7	331/333 (99.4%)	67/67 (100%)	398/400(99.5%)	
Values are number n/N (%) or [n]mean (SD)				

pain (12%). In patients without a preventive epidural top-up, 36 patients had breakthrough pain (19%). This difference was not statistically significant (p=0.2735). In the secondary sections with an epidural top-up (93/98), preventive top-ups were given in 11 patients, no preventive top-up in 81 patients, one patient with missing data. Breakthrough pain occurred in 18 patients, 2 patients with breakthrough pain did receive a preventive top-up, 16 did not receive a preventive top-up. This was also not statistically significant (p=0.9019).

Duration of surgery was a significant risk factor for breakthrough pain during CS (p-value <0.001). The median (Q1;Q3) duration of surgery in patients who experienced pain was 49 (35; 60) minutes. The median (Q1;Q3) duration of surgery in patients who did not experience pain was 38 (28; 49) minutes.

In the present prospective study, maternal age, maternal BMI, maternal height, race, gestational age, conversion, repeat CS, experience of the anesthetist (trainee vs staff member), Lucas classification of urgency, primary anesthetic method, number of PCEA boluses during labor, duration of labor before conversion, highest dermatome blocked, pain score at start of conversion, preventive topping-up the epidural catheter, difficult catheter insertion, chronic opioid use by the mother and the weight of the baby were all no statistically significant risk factors in the incidence of breakthrough pain. There were also no differences in neonatal outcome in patients with or without breakthrough pain

Discussion and conclusion

The goal of the present prospective audit of practice was to evaluate the incidence of breakthrough pain in CS and to describe the potential risk factors for breakthrough pain observed in this study and compare them to the literature. Of all 393 participants, 65 experienced breakthrough pain during CS, an incidence of 16.5%. So, our results are in line with reported incidences of breakthrough pain in literature (1 – 20%), despite using a low dose CSE technique in many cases and using a short acting local anesthetic 2-Chloroprocaine for epidural top-up[9-14]. Additionally, we need to add that our definition of breakthrough pain was broad. In literature sometimes (especially in the studies with lower incidences of breakthrough pain) the definition is rather strict and focused (e.g. conversion to GA required). Of note the majority of procedures was performed by trainees, a factor that might also contribute to breakthrough pain.

In this observation, two significant risk factors for breakthrough pain during CS were observed: the duration of surgery (p <0.001) and the epidural drug used (p=0.0032).

If surgery is prolonged, the reduced spinal local anesthetic dose commonly used in both centers as well as the short acting local anesthetic 2-chloroprocaine 3% can explain why despite good initial anesthetic conditions, breakthrough pain occurs mostly at the end of surgery and this in two thirds of patients. Therefore, it would seem logical that a preventive top-up (an epidural top-up given prior to the occurrence of pain) would prevent breakthrough pain from occurring. We noted a reduced incidence of breakthrough pain with a top-up but breakthrough pain was not eliminated.

In our audit we demonstrated that several epidural drugs are adequate to use for epidural top-up (ropivacaine 0.75%, lidocaine 2% and 2-chloroprocaine 3%). However mixed local

anesthetics, usually a fast onset drug combined with a longer acting drug, increase the risk of breakthrough pain because they lose their potential when mixed together (the dose of the long acting local anesthetic is too low). These results are in line with previous reports[15,16].

All other potential factors that have been reported to be risk factors for breakthrough pain, were not confirmed in our cohort. This might be due to a different anesthetic approach or to a type-2 error. For instance, in both centers the dermatomal level that was required per protocol was T3 full absence to cold sensation. Since most patients had such a high level, this factor could not be identified as a risk factor in our cohort. And for some risk factors, we just did not include enough patients to identify the actual risk (e.g. prilocaine spinally or e.g. number of PCEA boluses in labor).

Breakthrough pain during a CS is extremely uncomfortable for the mother. In this observational study, the incidence of breakthrough pain during CS was 16.5%.

Duration of surgery and epidural drug used were both significant risk factors of breakthrough pain during CS in this audit. A pro-active policy is required in order to prevent breakthrough pain or discomfort during CS. Early identification of problematic epidural catheters for labor analgesia, adequate level of anesthetic block before surgery, and administration of a prophylactic epidural top-up if duration of surgery is prolonged as opposed to the choice of local anesthetic used, could be essential in the prevention.

Further high-quality studies are needed to evaluate the many potential risk factors associated with breakthrough pain during CS.

Conflict of interest: None.

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