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Efficacy of prophylactic epidural saline for reducing postdural puncture headache in patients undergoing caesarean section

Sezaryen uygulanan hastalarda postdural ponksiyon baş ağrısının azaltılmasında profilaktik epidural salinin etkinliği

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Abstract

Aim: Post-Dural Puncture Headache (PDPH) is a common complication of spinal anesthesia during the postoperative period. The optimal means of prevention, management, and treatment of this disorder are uncertain. The objective of this current study was to investigate the effect of a 24 hours-continuous infusion of saline on the occurrence of PDPH in patients undergoing caesarean section and to provide a reference for the clinical prevention of PDPH.

Methods: This study included 126 patients aged between 18 and 45 years with an American Society of Anesthesiology physical status (ASA) score of 1-2, who underwent elective caesarean operation. Patients were randomized into control (n=63) and study groups (n=63). Spinal anesthesia was administered to both groups via a 27-gauche spinal needle. The study group was administered normal saline infusion for 24 hours with an easy-pump device through an epidural catheter.

Results: Seven control-group patients developed PDPH within the first 72 hours postoperatively while it was not observed in any of the study-group patients. Visual analogue scale and numerical rating scales were used for pain measurement. Five patients described mild pain while two described moderate pain. Severe headache was not observed in any patients at any time.

Conclusion: This study demonstrated that the administration of epidural saline during an elective caesarean under spinal anesthesia significantly reduced the incidence of PDPH and was not associated with any side-effects.

Keywords: Postdural Puncture Headache, Epidural saline, Spinal anesthesia, Cesarean section

Öz

Amaç: Postdural ponksiyon baş ağrısı (PDPH), ameliyat sonrası dönemde spinal anestezinin sık görülen bir komplikasyonudur. Bu bozukluğun önlenmesi, yönetimi ve tedavisi için en uygun yöntem belirsizdir. Bu çalışmanın amacı, 24 saat devam eden epidural salin infüzyonunun sezaryen geçiren hastalarda PDPH oluşumu üzerindeki etkisini araştırmak ve PDPH'nın önlenmesi için referans bilgi sağlamaktı.

Yöntemler: Çalışmaya Amerikan Anesteziyoloji Derneği fiziksel durumu (ASA) 1-2 olan, 18-45 yaş arası, elektif sezaryen ameliyatı yapılan 126 hasta dâhil edildi. Kontrol grubu (n=63) ve çalışma grubu (n=63) olarak belirlendi. Her iki gruba da 27 gauche spinal iğne ile spinal anestezi uygulandı. Çalışma grubuna epidural kateter yoluyla kolay pompa cihazı ile 24 saat boyunca normal salin infüzyonu yapıldı.

Bulgular: Kontrol grubunda 7 hastada ilk 72 saatte PDPH görülürken, çalışma grubunda PDPH görülmedi. Kontrol grubunda bulunan beş hasta, görsel analog skala ve sayısal derecelendirme skalasına göre PDPH'yi hafif ağrı ve iki hasta orta ağrı olarak tanımladı. Hastalarda şiddetli baş ağrısı görülmedi.

Sonuç: Bu çalışma, spinal anestezi altında elektif sezaryen sonrasında epidural salin uygulanmasının PDPH insidansını anlamlı derecede azalttığını ve herhangi bir yan etki ile ilişkili olmadığını göstermiştir.

Anahtar kelimeler: Postdural Ponksiyon Baş Ağrısı, Epidural salin, Spinal anestezi, Sezaryen

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Introduction

Cesarean section is preferably performed via regional anesthesia [1]. Minimizing complications by the introduction of new local anesthetic drugs and spinal needles rises its widespread use [2]. Post Dural Puncture Headache (PDPH) is a complication of regional anesthesia in the postoperative period. PDPH was defined as headache occurring in within 5 days of after lumbar puncture by the International Headache Society [3]. The pathophysiology of PDPH is not certain. Perforation of the dura causes cerebrospinal fluid (CSF) to leak through the subarachnoid space, decreasing CSF volume and pressure [4]. Typically, the headache is continuous, bilateral, frontal, retro-orbital, occipital, and extending to the neck, and may be accompanied by photophobia, nausea, tinnitus and hearing disorders. In more severe cases, diplopia and cranial nerve palsy may develop. These findings may be due to the traction of these cranial nerves [5]. Incidence is related to needle diameter, needle type and patient group. Young age, female gender and pregnancy are factors that increment the risk of PDPH [6]. The optimal means of prevention, management, and treatment of this disorder are indefinite. Conservative treatment consists of resting in the supine position, oral or intravenous fluid administration, analgesics, and caffeine. Despite conservative treatment, headaches may last for days. Epidural blood patch is a treatment method for this headache: Autologous blood is injected in the epidural space of the puncture level or one level below. This method is thought to stop CSF from further seepage by mass effect or coagulation [7].

When the literature is investigated, besides epidural blood patch, treatment options such as intrathecal catheter, epidural saline infusion and epidural morphine have been suggested. However, there is still a need for clinical evidence for their efficacy. Therefore, in our study, we aimed to determine the effect of a 24-hour continuous epidural prophylactic saline administration on PDPH in patients undergoing elective cesarean section.

Materials and methods

This case-control study was approved by the Institutional Review Board (Adiyaman University Ethics Committee, Approval no: 2014/10-7) and performed between January and December 2017 at Adiyaman University Educational and Research Hospital, Adiyaman, Turkey. A power analysis was done with G Power software to determine the appropriate sample size. The sample size calculation was based on an alpha error of 0.05 and a power of 80%. This gave a required total sample size of 63 for each group. Accordingly, a total of 126 ASA I-II patients who underwent elective caesarean operations between 18 and 45 years of age (pregnancy range, 38–42 weeks) were included in the study. Patients were divided into equal control and study groups using randomized numbers provided by an anesthesiologist. All included patients provided written informed consents prior to the study. Patients with coagulation disorders, migraine, vertigo or similar complaints, infection at the site of treatment, anticoagulant drug use, sepsis, spinal deformity, severe central nervous system disease, failure of the spinal canal puncture (epidural or spinal needle puncture failure) and those who did not accept the procedure were excluded from the study.

In both groups, vascular access was achieved with a 20 G cannula in the premedication room. 10 ml/kg 0.9% isotonic NaCl infusion was administered before the procedure for 30 minutes. After the patients were taken to the operating room, electrocardiography (ECG), heart rate (HR), noninvasive systolic blood pressure (SBP), diastolic blood pressure (DBP) and peripheral oxygen saturation (SpO2) were monitored in standard DII lead. Two experienced anesthesiologists performed all anesthesia procedures in a single operation. Aseptic and antiseptic conditions were achieved in all patients. Lumbar puncture was performed through the L3-4 intervertebral interspace with the patient in the sitting position. Patients in the control group received spinal anesthesia via 27 Gauge spinal needles (Pencan, B.Braun®, Melsunger, Germany). The flow of free CSF was observed and 12.5 mg hyperbaric bupivacaine was injected into the subarachnoid space. Patients in the study group received combined spinal and epidural anesthesia. Infiltration anesthesia was performed with lidocaine 3 ml (60 mg) by entering the L3-L4 interval space. Epidural interval was determined by resistance loss method with 18 G Tuohy needle. After detecting the epidural interval, dural puncture was performed through a 27 G spinal needle (Espocan; Set for combined spinal and epidural anesthesia, B.Braun®, Melsunger, Germany). The 12.5 mg hyperbaric bupivacaine was injected into the subarachnoid space after free CSF flow. After completion of the subarachnoid injection, the epidural catheter was fixed in the epidural space by moving 2-3 cm in the cranial direction, through the Tuohy needle. The tip of the catheter was connected to the easy pump and the preservative-free normal saline infusion at 2 ml/h was adjusted to last for 24 hours. The operation was allowed to start when spinal anesthesia was sufficient. Before regional block, measured heart rate, SBP, DBP, SPO2 values at 1, 5, 10, 15, 30, 45 minutes were recorded. Immediate complications such as hypotension were treated with appropriate doses of ephedrine (5-10 mg) in increments. The patients were at bed rest for first 6 postoperative hours, as part of the standard protocol of postoperative patient follow up. All patients received IV analgesics postoperatively. All participants were visited on the second day of the surgery. PDPH was defined as a frontal or occipital headache in the erect or sitting posture that was relieved with the supine position. PDPH was diagnosed based on visual analogue scale (VAS) and numerical rating scale (NRS). In the case of a headache, the pain of each patient was categorized into one of the three groups, according to VAS and NRS, as mild (VAS/NRS 1-3), moderate (VAS/NRS 4-7) and severe (VAS/NRS 8-10). All patients received a telephone call one week later by the anesthesiologist and were questioned about the possible delayed-onset symptoms.

Statistical analysis

The Statistical Package for the Social Sciences 15.0 program (SPSS Inc., Chicago, IL, USA) was used for the statistical study. One-sample Kolmogorov-Smirnov test was used to determine whether the data was distributed normally. Independent Two Samples t-test was used to compare the differences between spinal and epidural in terms of all the

variables. The results were reported as mean (standard deviation (SD)). Categorical variables were compared using the Chi-square test or Fisher's exact chi-square test, whichever was appropriate, and were expressed as counts and percentages. *P*-value <0.05 was considered statistically significant.

Results

One hundred and twenty-six patients were recruited in the study. Age, weight and height distribution were similar in both groups (Table 1). The total amount of IV fluids administered during the operation was 1728.57 (506.22) ml in control group and 1517.46 (429.75) ml in study group (*P*=0.001). There was no statistically significant difference between the two groups in terms of SBP, DBP and heart rate before operation (Table 2).

Table 1: Comparison between groups

	Control group	Study group	Total	*P*-value
Age (years)	31.30 (5.01)	30.83 (5.72)	31.06 (5.36)	0.62
Weight (kg)	80.13 (11.38)	77.97 (11.78)	79.05 (11.58)	0.29
Height (cm)	163.24 (5.68)	163.75 (6.51)	163.49 (6.09)	0.64
Total amount of administered intravenous fluid	1728.57 (506.22)	1517.46 (429.75)	1623.02 (479.52)	0.01

Values are presented as mean (Standard deviation).

Table 2: Preoperative parameters

Preoperative parameters	Control group	Study group	*P*-value
PRE-SBP	129 (16.20)	133.06 (18.89)	0.74
PRE-DBP	78.00 (16.50)	80.98 (21.94)	0.39
PRE-HR	97.79 (13.72)	98.16 (13.29)	0.88

SBP: Systolic blood pressure, DBP: Diastolic blood pressure, HR: Heart rate. Values are present as mean (Standard deviation) .

Intraoperative vital parameters were measured at 1, 5, 10, 15, 20, 30 and 45 minutes. The results were similar in both groups (Table 3). Postoperative parameters were measured at 1, 5, 10, 15, 20, 30 minutes. The mean SBP value was measured at the 1st postoperative minute, which was higher in control group (*P*=0.005). The SBP values at the 30th postoperative minute (*P*=0.007) were lower in the control group (*P*=0.007). Other values were similar between the two groups (Table 4). The mean durations of operation (DO) were 45 minutes in both groups (Range of DO in the control group: 30-60 min, in the study group: 40-60 min). There was no significant difference in terms of operation time (*P*=0.158). The mean amount of ephedrine used in both groups was 10 mg (range, 0-40) (*P*=0.045) (Table 5). Nausea occurred in one patient from each group (*P*=0.75). Vomiting occurred in two patients in both groups (*P*=0.69). PDPH was observed in 7 patients in the control group within 72 hours and in no patients in the study group (*P*=0.007) (Table 6). Five patients described mild pain (VAS/NRS 1-3) and two patients described moderate (VAS/NRS 4-7) pain in control group. Severe headache (VAS/NRS 8-10) was not observed in any patients at any time. Mild PDPH was treated with bed rest and oral hydration at home. Moderate PDPH was treated with a combination of 250 mg oral paracetamol, 150 mg propyphenazone and 50 mg caffeine (Minoset Plus ®, Bayer), bed rest and oral hydration.

Table 3: Intraoperative parameters

Intraoperative parameters	Control group	Study group	*P*-value
SBP 1 min	116.11 (20.16)	117.37 (18.97)	0.72
SBP 5 min	102.94 (20.44)	104.76 (22.86)	0.63
SBP 10 min	109.03 (15.29)	109.21 (15.27)	0.94
SBP 15 min	108.30 (14.30)	111.43 (15.27)	0.23
SBP 20 min	112.33 (17.58)	108.79 (18.19)	0.26
SBP 30 min	125.86 (18.78)	112.17 (17.50)	0.98
SBP 45 min	113.24 (10.37)	147 (18.25)	0.15
DBP 1 min	65.78 (15.18)	68.48 (17.02)	0.35
DBP 5 min	54.60 (13.95)	59.02 (14.69)	0.08
DBP 10 min	57.33 (13.05)	58.75 (13.18)	0.54
DBP 15 min	57.79 (13.39)	58.08 (12.27)	0.90
DBP 20 min	60.46 (13.01)	58.14 (12.51)	0.31
DBP 30 min	60.41 (11.99)	60.79 (10.90)	0.85
DBP 45 min	61.60 (9.95)	62.92 (10.93)	0.48
HR 1 min	95.57 (16.68)	92.62 (18.87)	0.35
HR 5 min	94.57 (16.41)	94.06 (17.90)	0.86
HR 10 min	96.14 (14.69)	97.89 (14.58)	0.50
HR 15 min	96.73 (14.26)	96.97 (13.11)	0.92
HR 20 min	92.37 (16.41)	94.59 (12.11)	0.38
HR 30 min	95.92 (13.56)	94.52 (11.18)	0.52
HR 45 min	94.75 (12.01)	94.35 (11.53)	0.77

SAP: Systolic blood pressure, DAP: Diastolic blood pressure, HR: Heart rate, min: Minute. Values are presented as mean (Standard deviation) .

Table-4: Postoperative parameters

Postoperative parameters	Control group	Study group	*P*-value
SBP 1 min	132.89 (13.05)	121.65 (9.93)	0.005
SBP 5 min	117.21 (6.95)	119.70 (9.99)	0.04
SBP 10 min	120.79 (5.19)	122.16 (10.33)	0.35
SBP 15 min	122.79 (6.03)	122.90 (8.59)	0.62
SBP 20 min	120.60 (5.30)	121.60 (6.59)	0.53
SBP 30 min	116.62 (9.10)	121.16 (7.62)	0.007
DBP 1 min	65.57 (8.67)	66.81 (7.31)	0.38
DBP 5 min	67.41 (7.45)	67.37 (7.82)	0.97
DBP 10 min	68.75 (7.02)	69.38 (9.07)	0.35
DBP 15 min	71.05 (4.92)	70.19 (8.72)	0.66
DBP 20 min	71.05 (4.92)	70.19 (8.72)	0.91
DBP 30 min	64.63 (9.86)	67.54 (7.62)	0.06

SBP: Systolic blood Pressure, DAP: Diastolic blood pressure, min: Minute. Values are presented as mean (Standard deviation).

Table 5: Data

	Control group	Study group	*P*-value
Ephedrine (ml)	10 (0.40)	10 (0.40)	0.045
Duration of operation (minute)	45 (30.60)	45 (40.60)	0.158

Values are presented as median (min, max).

Table 6: Postoperative complications

Complications	Control group	Study group	*P*-value
Nausea	n : 1 (1.6 %) n : 62 (98.4 %)	n : 1 (1.6 %) n : 62 (98.4 %)	0.75
Vomiting	n : 2 (3.2 %) n : 61 (96.8 %)	n : 2 (3.2 %) n : 61 (96.8 %)	0.69
Post spinal headache (PDPH)	n : 7 (11.1 %) n : 56 (88.9 %)	n : 0 (0.0 %) n : 63 (100.0 %)	0.007

n: Number of patients. Values are presented as n (%).

Discussion

PDPH is more common in obstetric cases due to dehydration, rapid changes in blood volume and intraabdominal pressure changes during delivery [8]. We planned to study caesarean section patients due to the high risk of PDPH occurrence in obstetric spinal anesthesia. The consensus is that the incidence of PDPH is lower in the procedures performed with pencil point needles. The longitudinal extension of the fibers forming the dura membrane and the sharp-edged needles are referred to as the reason for the transverse cutting of these fibers. It is stated that pencil-point needles do not cut off the fibers forming the dura membrane and cause less CSF seepage [9]. There is moderate-quality proof that atraumatic needles derogate the risk of PDPH without increasing adverse events such as paresthesia or backache [10]. Needle tip design was important to avoid PDPH. For these reasons, we preferred to use atraumatic pencil point needles in our study. Overall epidural anesthesia procedure uses larger gauge needles compared with spinal anesthesia. However, it has been shown that pencil-point needles

used in epidural anesthesia, despite their larger gauge with spinal anesthesia, leads to lower PDPH incidence after an accidental dural puncture [9,10]. The 18-gauge tuohy epidural needle has an opening at the end of the needle and a curved tip intended to prevent dural puncture. It has been documented that 90% of PDPH occurs within approximately 72 hours of dural puncture [11]. Therefore, we evaluated patients who underwent cesarean section in terms of PDPH after 72 hours.

PDPH is an important complication occurring due to a decrease in CSF pressure after loss of CSF from the bore opened in the dura with the guide of the needle used in spinal anesthesia. To prevent PDPH, needle tips were designed conveniently, and needle diameters were reduced [10]. Therefore, we used a 27 G spinal needle in our study.

There were many studies in the literature showing that pencil point and small-diameter needles diminish the incidence of PDPH. Santanen et al. [12] studied the incidence of PDPH with a 27-gauge Quincke and Whitacre (a type of pencilpoint) needle in 676 patients. The incidence of PDPH was 2.7 % in the Quincke group and 0.37% in the Whitacre group. It appeared that PDPH decreased with a 27-gauge needle, but a pencil-point needle reduced the incidence even more. Jeanjean et al. [13] reported that the incidence of PDPH was 0.08 % in 1122 patients under 50 years of age with a 24-gauge needle. In their study conducted on 776 patients aged 20-45 years, Pjevic et al. [14] reported that the incidence of PDPH was 3.5% and higher in young patients, using a 25-gauge needle. In our study, PDPH was seen in 7/126 patients using the 27 G spinal needle. Based on the results of our study, we detected an obvious advantage of our current practice of using 27 G pencil point spinal needle in patients. Severe headache was not observed in any patients at any time.

Dural puncture involves passing a needle into the fluid-filled space around the spinal cord and nerve roots. However, leakage of fluid through the puncture created by the needle may cause a headache. Researchers have suggested various interventions to help prevent PDPH. One suggestion for preventing or treating this headache is to inject the patient's own blood around the puncture to stop the seepage. Recent studies show that the role of epidural blood patching in the prevention or treatment of the headache that may occur after dural puncture is inadequate [15]. Conservative treatment is convenient for most patients with PDPH because of its benign prognosis. Bed rest in the horizontal position and adequate hydration are often recommended [16]. In a recent study, there was no evidence suggesting that routine bed rest after dural puncture is beneficial for the prevention of PDPH. The role of fluid addition in the prevention of PDPH is still vague [17]. Numerous pharmaceutical agents have been offered to treat PDPH but there is no certainty about their clinical effectiveness. Caffeine was proven valid for treating PDPH, when compared with placebo. Gabapentin, hydrocortisone, and theophylline have been shown to diminish pain validity scores [18].

Bradbury et al. [19] reported that five techniques were associated with a reduction in the incidence of PDPH: performance of a prophylactic EBP, lateral positioning of the bevel of the epidural needle at the time of insertion, using a Special Sprotte needle, administration of epidural morphine, and administration of cosyntropin. The principal disadvantage of a prophylactic blood patch is the deposition of a matter that is a potential medium for bacterial growth. Infection is very scarce but carries grave possible consequences. Because of the unclearness of the benefit of prophylactic blood patches, without further proof, routinely offering this intervention cannot be verified [20]. Concerns have been expressed about the potential danger of an autologous epidural blood patch for the treatment of post-dural puncture headache. The immediate resolution of the headache with a blood patch is attributable to thecal compression raising CSF pressure. It is generally believed that the preliminary effect of the EBP is predicated on an increase in CSF pressure caused by the mass effect of the injected blood. This mass effect on the lumbar thecal sac has been demonstrated by magnetic resonance imaging [21]. An epidural injection of saline would, in theory, produce the same mass effect, and restore normal CSF dynamics. As saline is a sterile and relatively inert solution, epidural saline bolus or infusion appears to be an attractive alternative. Usubiaga et al. [22] demonstrated that rapid injection of 20 mL saline into the epidural space increased both lumbar subarachnoid and epidural pressures to as high as 85 mmH2O. Higuchi et al. [23] founded that injection of 5, 10, or 15 mL saline into the epidural space produced variable degrees and patterns of compression of the thecal sac between individuals, and large differences in the amount that flowed out of the intervertebral foramina. CSF density is also a variable, which could be associated with the incidence of headaches. Richardson and Wissler [24] have shown that pregnancy and the immediate postpartum period were associated with the lowest CSF densities. Progesterone may be a physiologic mediator of altered CSF densities during human pregnancy, because progesterone treatment of estrogen-primed nonpregnant rabbits significantly alters Sodium-Potassium-ATPase activity in isolated choroid plexi. This enzymatic activity is the primary driving force for CSF production [25]. Gill et al. [26] reported 12 cases of blindness after epidural fluid injection during epiduroscopy. The authors postulated that the rise in ICP associated with epidural injection likely led to retinal venous obstruction and subsequent venous hemorrhage. They recommended an epidural injection rate of no more than 1 mL per 1–2 seconds. We believe that 24-hour continuous infusion with an easy pumping device might have a clinical advantage by helping avoid the generation of excessively high pressures, and thus may prevent the consequent complications associated with rapid increases in CSF pressure. A survey of anesthesiologists in the USA showed that, to prevent PDPH, 19% placed an intrathecal catheter, 12–25% used epidural saline, and 10–31% applied an epidural blood patch as a prophylactic measure [27]. The use of epidural saline is 12-25%, demonstrating that clinical experience is beneficial. In addition, prophylactic single dose epidural saline has been reported to result in a decrease in the incidence of headaches following dural puncture [28].

In our study, the epidural continuous infusion of normal saline significantly reduced the incidence of PDPH. There are numerous variables in the pathophysiology of PDPH. One explanation for the beneficial effect of intrathecal saline is that

the increase in CSF pressure may result in approximation of the dura and arachnoid at the puncture site, thus sealing the defect. The most widely assumed theory concerning the cause of PDPH is based on the notion of loss of CSF through a dural tear. CSF volume alterations may be the closest explanation for the headache mechanism. The epidural space is a potential gap surrounding the dural sheath extensions and it is located between the dura and the periosteum, lying between the vertebral canal and the fibrous extensions to the ligaments. The slim dura in this area permits access to the cerebrospinal fluid of the local anesthetic and provides a basis for epidural anesthesia. The agents given in the epidural anesthesia practice are not injected directly into the neural tissues but require diffusion from the injection spot. The lumbar injection of saline raises epidural and intrathecal pressures. The reduced leakage allows the dura to repair. However, measurements of pressures generated in the subarachnoid and epidural spaces show that despite the significant increase in epidural pressure, the increase in subarachnoid pressure maintains the differential pressure on the dura. Also, saline may induce an inflammatory reaction within the epidural space, promoting closure of the dural perforation. PDPH was seen in 7 patients in the control group, but not observed in study group. We believe that epidural saline infusion is a safe and tolerable modality that effectively reduces the frequency and violence of PDPH with mild and limited adverse events.

We observed nausea and vomiting. Nausea and vomiting occurred in one and two patients from each group, respectively. These could be secondary to maternal hypotension, which in turn causes decreased cerebral blood flow.

Limitations

The limitations of this study included the fact that it was a single-center study. The study group patients were punctured twice, once with an 18-gauge Tuohy needle and once with the 27-gauge needle, whereas control group patients were only punctured once, using the 27-gauge needle. In addition, the pain threshold of the patients may have been different, and the classification of pain is not objective.

Conclusion

We investigated a low-risk technique for the prevention of PDPH. In our study, the preservative-free normal saline infusion via an epidural catheter was infused at a rate of 2 ml/h for 24 hours. The epidural continuous infusion significantly reduced the incidence of PDPH. This current study demonstrated that the administration of epidural saline during an elective caesarean section under spinal anesthesia significantly reduced the incidence of PDPH. Further studies on larger series are needed to evaluate its safety and efficacy.

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