



# TEN-YEAR FOLLOW-UP OF QUALITY IN REGIONAL ANESTHESIA AND ANALGESIA IN OBSTETRICS

## OBSTETRIC REGIONAL ANESTHESIA: IMPROVING QUALITY

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**ABSTRACT** – Introduction: Quality assessment of provided healthcare is becoming a standard in numerous health institutions worldwide, which is beneficial for both the patient and the institution. In order to achieve this standard, it is necessary to develop quality indicators in all segments of health-care. Postdural puncture headache is a common complication following neuraxial blocks, especially in obstetric anesthesia. If severe, it is a cause of emotional and psychological distress and must be treated by a blood patch.

**Aim:** The aim of this study was to determine whether the number of these complications is reduced when blood patch frequency is monitored and analyzed and to assess the effect of countermeasures in order to improve the quality and safety of regional anesthesia in obstetrics.

**Methods:** Before 2009 and during that year at the University Hospital Sveti Duh, there had been a large number of severe postdural puncture headaches after spinal anesthesia and epidural analgesia treated by a blood patch in 6.12% of cases. After noticing the rising number of blood patches, we decided to analyse data every year. We recorded all blood patches injected to obstetric patients within the period of nine years, from 2009 to 2018 and concurrently we introduced a set of measures to improve the quality of neuraxial blocks, such as the use of atraumatic 26 or 27-gauge pencil-point spinal needles and modern neuraxial blockade protocols. Data were collected from anesthesiology and gynecology protocols and analyzed with MedCalc software, version 18.1.2.

**Results:** The frequency of blood patch applications has been reduced from 6.12% to 0.30%, which is statistically significant. The percentage of placed epidural catheters for vaginal birth increased from 21% in 2009 to 38% in 2018. Although not statistically significant, the number of pregnant women undergoing a caesarean section is also growing, while the total number of births is falling. The proportion of caesarean sections in spinal anesthesia varies from year to year.

**Discussion:** A statistically significant decrease in the number of installed blood patches clearly indicates the positive effect of measures taken to improve quality, which could contribute to the growing interest of pregnant women in childbirth in epidural analgesia. The number of placed epidural catheters is increasing despite the decline in the total number of deliveries and the increase in the number of deliveries completed by caesarean section.

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Conclusion: Monitoring the incidence of severe post-puncture headaches treated with blood patches has shown great progress in improving the quality and safety of regional anesthesia and analgesia in our institution, so we believe that monitoring the number of blood patches could serve as an indicator of regional anesthesia and analgesia in obstetrics. Monitoring the number of blood patches shows that the frequency of post-puncture headaches does not correlate only with the type of needle or epidural catheter used for neuroaxial blocks, but is also a sensitive indicator of any deviations from the achieved standards. Furthermore, it indicates the need for careful analysis of causes in order to adopt and implement appropriate countermeasures.

Keywords: *blood patch, postdural puncture headache, quality indicators, regional anesthesia and analgesia, obstetric anesthesia*

## Introduction

Quality assessment of provided care is becoming a standard in numerous health institutions worldwide, which is beneficial for both patients and institutions. Patient monitoring is becoming not only an important element of quality improvement, but also important in decreasing costs of care and faster hospital discharge (1). Although there is no universally accepted assessment tool, certain factors indicating quality of anesthesia and postoperative recovery have been identified (2). The most commonly used quality indicators in anesthesia are postoperative pain, nausea and vomiting, emotional and psychological distress and cognitive dysfunction and dissatisfaction (2). These quality indicators refer primarily to general anesthesia, which is why there is a need to define quality indicators for regional anesthesia.

Postdural puncture headache (PDPH) is the most common complication in neuraxial anesthesia or neuraxial analgesia along with maternal hypotension during the procedure (3). According to the International Headache Society, PDPH is any headache that develops within five days from dural puncture and cannot be explained by any other cause (4). In most cases it worsens while standing or sitting and is relieved by lying down (5). It usually resolves spontaneously within two weeks (4).

There is a higher incidence of PDPH in obstetric patients because of their sex, young age, increase in intra-abdominal pressure, decline in the density of cerebrospinal fluid in pregnant women and widespread use of neuraxial anesthesia procedures in obstetrics (6). Low body mass index, use of a larger needle gauge and *traumatic* needles also increase PDPH risk. Needle gauge is considered to be the most significant factor in the development of PDPH (7). Commonly used spinal needles range from 22 to 27 G, while normally used epidural needles are 16–18 G (8).

PDPH is a particular problem in patients who are new mothers and for whom lying down to eliminate headache is not an option, seeing as they have a new role. PDPHs frequently do not respond to symptomatic treatment by fluid administration, caffeine, acetaminophen and non-steroidal anti-inflammatory drugs or mild opioids. Prior to 2009 and during that year at the University Hospital Sveti Duh, traumatic needles ranging from 22 to 26 G were used for the application of spinal anesthesia (SA). Considering the fact that a relatively large number of blood patches (BPs) after SA and epidural analgesia (EPA) has been observed, suggesting a large number of PDPHs in 2009, we introduced specific measures in order to improve the quality of regional anesthesia and analgesia. These measures included applying atraumatic pencil-point spinal needles with a larger gauge number, use of quality epidural kits with soft-tip catheters as well as improving technical skills by learning through practice. Since then, needle gauge for SA that has usually been used is 26 or 27 G and the needle type is pencil-point. The aim of this study was to prospectively examine the adherence to adopted protocols and the success of applying improvement measures to reduce complications of SA and EPA using BP frequency as a quality indicator.

## Methods

In this prospective research we recorded all BPs that obstetric patients were injected with, collecting data from anesthesia protocols of the Department of Anesthesiology, Reanimatology and Intensive Care Medicine and data from gynecology delivery protocols of the Department of Gynecology and Obstetrics at the University Hospital Sveti Duh in Zagreb during a period of ten years, from 2009 to 2018. Recorded data include the annual number of births, number of

C-sections, number of SA for C-sections, number of epidural anesthesia for C-sections, number of epidural analgesia for vaginal delivery and the number of BPs injected per year for treating PDPH following either spinal or epidural anesthesia. All specified pieces of information are regularly recorded in our anesthesia protocols by every anesthesiologist performing these procedures and are regularly monitored. Normally, every obstetric patient whose headache does not go away within 48 hours from conservative treatment receives a BP injection. The data was statistically analyzed using the MedCalc software, version 18.1.2. BP placement

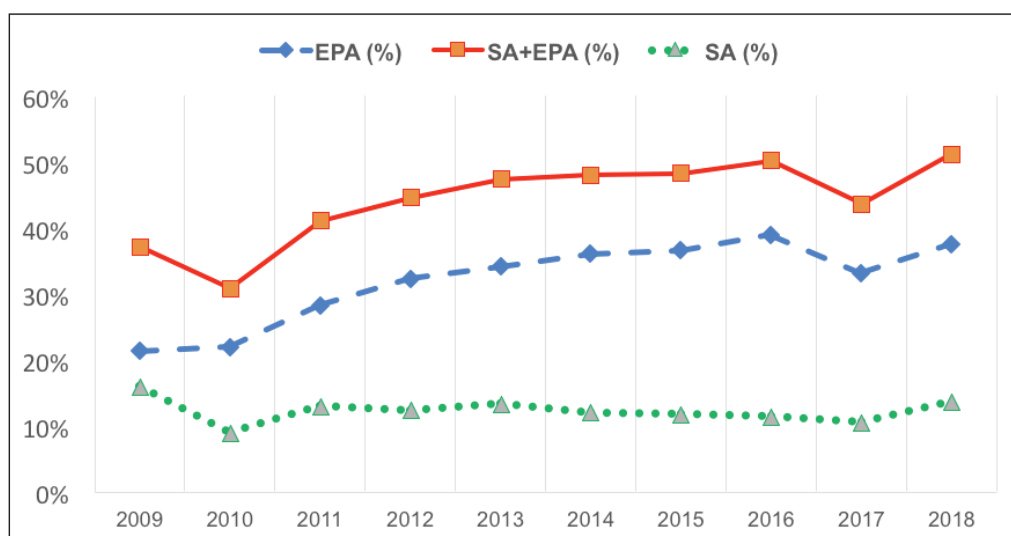
was reported as an actual count as well as incidence, with a 95% CI after both SA and EPA, and separately after SA and after EPA. The results are presented in tables and charts.

## Results

In the observed period, the annual number of births gradually decreased from 3500 births in 2009 to 2747 births in 2018. The number of C-sections in the last three years has increased, but without statistical significance (Table 1). The percentage of demands for EPA for vaginal births has risen from 21% in 2009 to

*Table 1* Number of births, method of delivery—rate of caesarean sections (C-sections) and use of spinal anesthesia (SA) for caesarean section

Year	Births	C-sections	Vaginal births	SA for CS	Rate of CS	95% CI No of CS	Rate of CS under SA
2009	3500	693	2807	556	19.80%	0.185–0.211	80.23%
2010	3485	674	2811	311	19.34%	0.180–0.207	46.14%
2011	3185	627	2558	414	19.69%	0.183–0.211	66.03%
2012	3133	597	2536	387	19.06%	0.177–0.204	64.82%
2013	3054	566	2488	408	18.53%	0.172–0.199	72.08%
2014	3027	596	2431	363	19.69%	0.183–0.211	60.91%
2015	2795	592	2207	329	21.18%	0.197–0.227	55.57%
2016	2761	573	2188	315	20.75%	0.192–0.223	54.97%
2017	2723	606	2115	286	22.25%	0.207–0.238	47.19%
2018	2747	631	2116	376	22.97%	0.214–0.245	59.59%



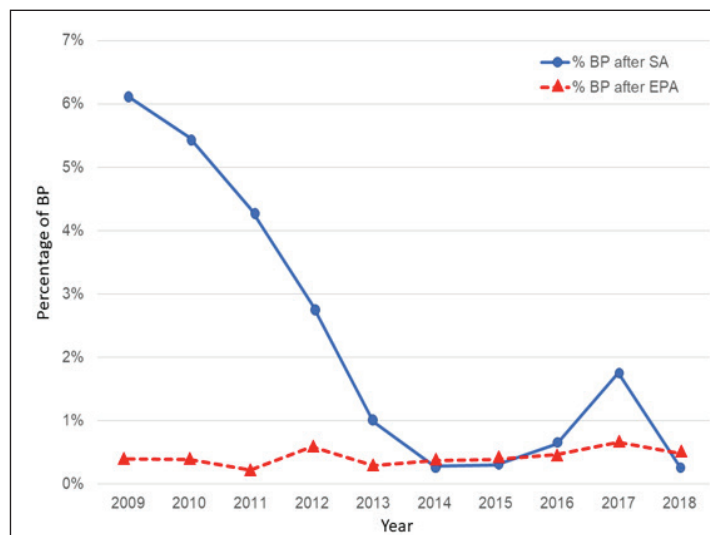
*Figure 1* Percentage of EPA and SA in a ten-year period (2009–2018)

38% in 2018 (Figure 1). The percentage of C-sections under SA is highly variable in the observed period and changes almost every year with statistical significance. The overall number of placed BPs, including BPs after EPA and after SA, decreased in the period from 2009 to 2018 with statistical significance (95% CI). In 2009, the percentage of women who received SA for C-sections and had to receive BP as therapy for PDPH was 6.12% and it gradually decreased through

the years to 0.27% in 2018 (Table 3). During 2016 and 2017, the number of BPs applied after SA increased again. A statistically significant decrease in the number of placed BPs after SA and EPA was observed in the period from 2012 to 2015, and the increase that occurs again in 2017 is statistically significant, with a 95% CI. However, if we observe the incidence of BP only after SA, a statistically significant decrease occurs in 2013. Unlike BP frequency after SA, the incidence

*Table 2 Number of placed epidural catheters (EPA), total number of neuraxial procedures including spinal anesthesia and epidural analgesia and anesthesia (SA+EPA), and number of total blood patches placed after spinal and epidural blocks (BPs after EPA+SA)*

Year	EPA	SA+EPA	BPs	% of BPs after EPA +SA	95% CI for BP (EPA+SA)
2009	746	1302	37	2.84%	1.9%–3.7%
2010	763	1074	20	1.86%	1.1%–2.7%
2011	898	1312	20	1.52%	0.9%–2.2%
2012	1013	1400	17	1.21%	0.6%–1.8%
2013	1042	1450	7	0.48%	0.1%–0.8%
2014	1092	1455	5	0.34%	0.0%–0.6%
2015	1023	1352	5	0.37%	0.0%–0.7%
2016	1074	1389	7	0.50%	0.1%–0.9%
2017	905	1191	11	0.92%	0.4%–1.5%
2018	1033	1409	6	0.43%	0.1%–0.8%



*Figure 2 Number of blood patches after spinal anesthesia and after epidural analgesia and anesthesia in a ten-year period (2009–2018)*

Table 3 Number of blood patches in relation to spinal anesthesia (BPs after SA) or epidural anesthesia and analgesia (BPs after EPA)

Year	BPs after SA	% BPs after SA	95% CI for BP after SA	BPs after EPA	% BPs after EPA	95% CI for BP after EPA
2009	34	6.12%	4.1%–8.1%	3	0.40%	-0.1%–0.9%
2010	17	5.47%	2.9%–8.0%	3	0.39%	-0.1%–0.5%
2011	18	4.35%	2.4%–6.3%	2	0.22%	-0.1%–0.8%
2012	11	2.84%	1.2%–4.5%	6	0.59%	0.1%–1.1%
2013	4	0.98%	0.0%–1.9%	3	0.29%	0.0%–0.6%
2014	1	0.28%	-0.3%–0.8%	4	0.37%	0.0%–0.7%
2015	1	0.30%	-0.3%–0.9%	4	0.39%	0.0%–0.8%
2016	2	0.63%	-0.2%–1.5%	5	0.47%	0.1%–0.9%
2017	5	1.75%	0.2%–3.3%	6	0.66%	0.1%–1.2%
2018	1	0.27%	-0.3%–0.8%	5	0.48%	0.1%–0.9%

of BP placement after EPA remains stable throughout the observed period. Although not statistically significant, there is a slight increase in the number of BPs after EPA in 2017 (Figure 1, Table 3).

## Discussion

In 2009, a relatively large number of PDPHs was observed at our institution. Therefore, improvement measures were introduced in 2010, such as applying atraumatic spinal needles with a larger gauge number and the use of better epidural kits with soft-tip catheters as well as new, contemporary neuraxial blockade protocols. The introduction of these measures has resulted in a significant decrease in the frequency of this complication and the statistic is now comparable to centers of excellence. However, we did not record mild PDPH that subsided on conservative therapy. Most mild headaches are frequently not reported to the anesthesiologist, which makes these headaches more difficult to routinely track. BP is an indicator of severe headache that does not subside on symptomatic analgesic therapy and reduced ambulation, which is why the overall number of PDPHs is likely double the number of BPs. The incidence of PDPH after both SA and EPA, according to a study conducted at 30 institutions by the Society for Obstetric Anesthesia and Perinatology, is 0.7%, and 55.7% of those that required epidural blood patch (BP), meaning that 0.39% of women who received neuraxial anesthesia also re-

ceived BP. Unfortunately, the incidence of PDPH after EPA was not tracked separately in the cited report (9). Other studies that observed the incidence of PDPH came up with similar results. Accidental dural puncture occurs in around one out of a hundred epidurals in obstetric anesthesia where the majority of patients develop PDPH. The incidence of BP following SA is around one out of 500 in the obstetric population (10). Therefore, it is estimated that the overall number of PDPHs is double the number of those treated by BP (9).

Compared to the results of the aforementioned study where the incidence of BP placement after both SA and EPA was 0.39%, in 2009, the incidence was 6.1% at our hospital, which is statistically significantly higher. It is evident that the introduced measures led to significant improvement with only 0.27% of BPs after SA in 2018. The incidence of PDPH is also influenced by the number of puncture attempts. It is possible that due to a slower flow of the CSF through a smaller-gauge needle, or because of the anatomical characteristics of the lumbar part of the spine, the position of the needle tip in the spinal space remains undetected and consequently, multiple punctures are performed. In this context, the experience and manual skills of an anesthesiologist are crucial. Although not statistically significant, the increase in BP placements after SA in 2017 is a sign that our anesthesiologists did not strictly follow the agreed measures. Alternatively, the cause of



this increase could be the increase in the number of residents who are still in the process of learning necessary skills and consequently, the quality of regional anesthesia has a downward tendency. This may also be related to anesthesia staff fluctuations in recent times, caused by migrations of our highly trained doctors to other countries, among other factors.

The relative number of BPs following EPA was relatively stable in the observed period, despite the fact that the number of placed epidural catheters increased. This means that the quality of epidural analgesia remained unchanged, although improvement was expected because of increased experience of our anesthesiologists. The increased number of BPs following EPA in 2017, albeit not statistically significant, could also be the result of a higher number of residents who also perform EPA as well as the introduction of other less experienced staff. Further EPA quality improvement could probably be achieved by placing epidural catheters under ultrasound control, either by ultrasound pre-procedural imaging or real-time ultrasound guidance of the procedure, or by using other new techniques for epidural space detection (11). A study conducted on 108 patients showed lower failure of epidural space detection, fewer cases of multiple attempts and a shorter time for identifying the epidural space using the Epidrum technique for epidural space detection (12). In this way, we could reduce the number of failed epidural space detections in the future and reduce accidental dural punctures. The proportion of C-sections in overall deliveries at our hospital remained relatively stable, ranging from 19 to 22%. Nevertheless, there was a trend of growth in the frequency of C-sections during the observed period, albeit not statistically significant. It is in accordance with the increase in the frequency of C-sections in the world (13). The percentage of C-sections in SA varies in the observed period. It could be an indicator of certain inconsistencies in the decisions made by gynecology and anesthesiology staff and the degree of defensibility of those decisions, as there is a trend of increase in C-sections which are considered urgent, causing a decrease in C-sections performed in regional anesthesia.

From the obtained results it is also evident that the number of placed epidural catheters is increasing in spite of the reduced number of births. The increase in demands for EPA can be attributed to lower frequency of complications following regional anesthesia

and analgesia due to improved anesthesiologists' skills and technique, better informed pregnant women and increased availability of the service at the global level and at our institution. Therefore, if the number of complications after anesthesia is reduced, patient satisfaction is expected to increase, and the same goes for the interest in this type of anesthesia and analgesia. Through our ten years of monitoring the complications of regional anesthesia and analgesia in obstetrics, BP has emerged as a useful and comprehensive quality indicator. The features of a good quality indicator, in addition to its reliability, sensitivity and specificity, should include easy and quick detection, possibility of continuous monitoring and also provide some form of feedback to healthcare providers in order to improve future care. Providing information about patient safety is considered to be one of the most important characteristics of a quality indicator (14). Other authors also agree that registries and incident reporting with root cause analysis are crucial to improvement processes (15). If we took traditional quality indicators (postoperative pain, nausea and vomiting, emotional and psychological distress, cognitive dysfunction and dissatisfaction) and the characteristics that a quality indicator should have and applied them to neuraxial anesthesia in obstetrics, we could say that severe PDPH is the most common complication that causes prolonged post-delivery hospitalization. As it should be treated by BP, the frequency of BP is a parameter that can easily be tracked and is suitable as a quality indicator for continuous monitoring of obstetric regional anesthesia and analgesia. It is reliable because it is directly related to anesthesia. It is a parameter that reflects the safety of the neuraxial block and greatly influences patient experience. Furthermore, reporting the number of BPs provides feedback to a clinician and could lead to improvement actions. Therefore, BP could be used as a quality indicator in obstetric regional anesthesia and analgesia and possibly in neuraxial anesthesia in general.

## Conclusion

PDPH is a common complication in neuraxial anesthesia and analgesia, in obstetric patients in particular. About half of PDPHs are severe and require treatment with BP. According to our ten-year follow-up of quality improvement measures in obstetric regional anesthesia, BP frequency seems to be a valuable indicator of quality of clinical practice in obstetric neuraxi-

al anesthesia and analgesia. A relatively high frequency of BP application during and before 2009 was a warning that a set of improvement measures should be introduced. Following the introduction of standardized protocols and large-gauge spinal needles, the relative frequency of BP decreased from 6.1 to 0.3%. Since the high frequency of BP, because of the fact it is an invasive procedure, it can easily be tracked through anesthesia protocols, and it is a reliable parameter, suitable for continuous monitoring of the quality of regional anesthesia. It is directly related to anesthesia practice, reflects the safety of neuraxial blocks and influences patient experience as well as the cost of healthcare. Our study has also shown that BP frequency even responds to small changes in the structure of healthcare providers and their commitment to standardized algorithms. In our prospective study it was proven to be a good tool for detecting the need to introduce improvement measures and for monitoring the effect of those measures. Therefore, we conclude that the incidence of BP applications can be used as a reliable, sensitive and specific quality indicator in obstetric neuraxial anesthesia and analgesia.

Authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Sažetak

## DESET GODINA PRAĆENJA KVALITETE U REGIONALNOJ OPSTETRIČKOJ ANESTEZIJI

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Uvod: Procjena kvalitete pružene zdravstvene usluge postaje standard u zemljama diljem svijeta što doprinosi dobrobiti pacijenata i većoj konkurentnosti i ugledu institucija u kojima se pruža zdravstvena skrb. Kako bi se razvio visok standard pružanja zdravstvene usluge, potrebno je razvijati indikatore kvalitete u svim segmentima zdravstvene skrbi. Postpunkcijska glavobolja česta je komplikacija neuroaksijalnih blokova, osobito u opstetričkoj anesteziji. Ukoliko je jakog intenziteta, može dovesti do emocionalnih i psiholoških poteškoća mladih majki i mora se liječiti krvnom zakrpom.

Cilj: Cilj ovog istraživanja bio je utvrditi može li se praćenjem broja postavljenih krvnih zakrpa smanjiti učestalost komplikacija i procjenjivati učinak uvedenih protumjera, odnosno poboljšanje kvalitete i sigurnosti regionalne anestezije u opstetriciji.

Metode: Prije 2009. i tijekom te godine u Kliničkoj bolnici "Sveti Duh" primijećen je velik broj postpunkcijskih glavobolja nakon spinalne i epiduralne anestezije koje su zahtijevale primjenu krvne zakrpe u čak 6,12% slučajeva. Nakon što smo primijetili sve veći broj krvnih zakrpa, odlučili smo analizirati ove podatke svake godine. U razdoblju od 2009. do 2018., bilježili smo sve krvne zakrpe ubrizgane pacijenticama i istodobno smo uveli niz mjera za poboljšanje kvalitete neuroaksijalnih blokova, kao što je korištenje atraumatskih i gala promjera 26 ili 27G „pencil point“ vrha i suvremene protokole neuraksijalne blokade. Podatci su prikupljeni iz anestezioloških i ginekoloških protokola i analizirani programom MedCalc software, version 18.1.2.

Rezultati: Učestalost postavljanja krvne zakrpe smanjila se sa 6,12% na 0,30% što je statistički značajno. Postotak postavljenih epiduralnih katetera za vaginalni porođaj narastao je s 21% u 2009. i na 38% u 2018. godini. Iako nije statistički značajno, raste i broj trudnica podvrgnutih carskom rezu dok istovremeno pada ukupni broj porođaja. Udio carskih rezova u spinalnoj anesteziji varira iz godine u godinu.

Rasprava: Statistički značajan pad u broju postavljenih krvnih zakrpa jasno ukazuje na pozitivan učinak poduzetih mjera u svrhu poboljšanja kvalitete što bi moglo doprinijeti i sve većoj zainteresiranosti trudnica za porođaj u epiduralnoj analgeziji. Broj postavljenih epiduralnih katetera raste unatoč padu ukupnog broja porođaja i rastu broja porođaja dovršenih carskim rezom.

Zaključak: Praćenjem pojavnosti težih oblika postpunkcijskih glavobolja liječenih krvnom zakrpom vidljiv je veliki napredak u poboljšanju kvalitete i sigurnosti regionalne anestezije i analgezije u našoj ustanovi, stoga smatramo da bi praćenje broja krvnih zakrpa moglo poslužiti kao indikator kvalitete regionalne anestezije i analgezije u opstetriciji. Praćenjem broja krvnih zakrpa uočava se da učestalost postpunkcijskih glavobolja ne korelira samo sa vrstom igle ili epiduralnog katetera koji se koriste za neuroaksijalne blokove već je osjetljiv pokazatelj bilo kojih odstupanja od dosegnutih standarda te ukazuje na potrebu pomne analize uzroka kako bi se usvojilo i provelo odgovarajuće protumjere.

Ključne riječi: *krvna zakrpa, postpunkcijska glavobolja, indikatori kvalitete, regionalna anestezija i analgezija, opstetrička anestezija*