

Efficacy of Epidural Dexamethasone for Prevention of Post Dural Puncture Headache: A Randomized Controlled Trial

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Author's Contribution

All the authors contributed equally to this work; they designed the article, did data collection, did a thorough search, analyzed the data, wrote, reviewed and approved the final form of this manuscript.

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ABSTRACT

Objective: To evaluate the efficacy of epidural dexamethasone for prevention of post dural puncture headache.

Study Design: Randomized Controlled Trial

Place and Duration: Department of anaesthesia Holy Family, hospital, Rawalpindi from January 2017 to September 2017, in a period of nine months.

Methodology: The patients were selected from general, orthopedic, urology, and gynecology services. In study group an intervention was made through a prophylactic dose of epidural dexamethasone injection in a dose of (2 ml, 8 mg) and in control group 2 ml normal saline was injected at the time of anesthesia along with standard spinal anesthesia. The anesthesia was administered between third and fourth vertebral spaces L3 and L4 in sitting position. The dose of anesthetic was standardized at 75mg Lidocaine 5% and 25mg Fentanyl, which was administered using a 25-gauge disposable needle. The incidence of a headache was the main outcome of the study and it was measured in first 24 hours, 72 hours and 7 days after spinal anesthesia.

Results: The mean age in the intervention group was 32.18 ± 5.64 years, and control group it was 31.63 ± 6.24 years. It was observed that 3 (5.56%) patients in intervention group and 7 (12.96%) patients in control group had post dural puncture headache. The rate of a headache was significantly higher in control group after 72 hours of operation. The rate of post dural puncture headache after 7 days was significantly greater (20.37% versus 38.89%, p-value < 0.05) in control group. The comparison of mean VAS scores of pain at 24 hours and 72 hours showed that mean pain score was significantly (p-value < 0.05) lower in the intervention group. There was no statistically significant (p-value > 0.05) difference in the mean value of pain score after 7 days.

Conclusions: It was observed that epidural administration of dexamethasone during spinal anesthesia is effective and useful in preventing headaches. So intravenous epidural dexamethasone is suggested for prevention of headaches in patients who undergo spinal anesthesia.

Key Words: Post dural Puncture headache, Epidural dexamethasone, spinal analgesia.

Introduction

One of the major complications of lumbar puncture is post dural puncture headache (PDPH). The pain starts in the forehead and occipital region and covers a head or a diffuse headache is the clinical indication of PDPH. The symptoms of pain are fluctuating and become worse in standing position and become better in

lying down position. It has some other complication including stiffness of the neck, hearing loss, tinnitus, photophobia and nausea which is very distressing for the patient. ¹

There are many causes of post dural puncture which results in a headache. The lumbar puncture can be due to diagnostic

purposes, for spinal anaesthesia or dural puncture in the process of epidural anaesthesia. PDPH is a common complication of spinal anaesthesia in obstetric and younger patients. It can be a temporary complication lasting from hours to many weeks with very severe presentation even some time unbearable. It starts within 24 to 48 hours of dural puncture and resolves in few days to weeks. Major factors contributing to incidence and severity of PDPH include patients age and size of dural puncture.² The needle used for spinal anaesthesia make a puncture in the dura and the leakage of cerebrospinal fluid from the breach is the reason of post dural puncture headache.³ The physical phenomenon behind the PDPH can be explained as with the leakage of cerebrospinal fluid caused by piercing of needle in durameter drops the pressure which causes the PDPH. The cushioning effect of the fluid disappears and tension is applied directly to the cranial nerves. The onset of post dural puncture headache varies from 24 hours to seven days.⁴

The PDPH occurrence after dural puncture is instantaneous, 66% patients starts PDPH within 48% and about 90% patients starts PDPH within 72 hours. The incidence of post dural puncture headache increases considerably with repeated dural punctures. The incidence has been noted decreased with the used of small gauze needle.⁵

In spinal anesthesia local anesthetics are used to block the spinal nerves by injecting local anesthetic into the subarachnoid space. Spinal anesthesia being easy to perform is the most commonly used method for nerve blocking in obstetrics and gynecology, orthopedic and urologic operations. There are many complications associated with spinal anesthesia like infection or neurotoxic effect on central nervous system, headache and backache.^{6,7} The prevalence of PDPH varies with respect to different condition like obesity and pregnancy, the incidence is higher in obese and pregnant women.⁸

Literature have shown significant reduction in incidence of PDPH among the patients who were given prophylactic intervention of dexamethasone in comparison to control group like in a single-blinded randomized control trial, the incidence of PDPH was found to be significantly lower compared with controls at 24 hours (2.5% vs 12.5%; $p = 0.016$) and at one-week post dural puncture (11.3% vs 32.5%; $p = 0.001$) respectively.⁹

This present study was planned to assess the efficacy of prophylactic epidural injection of dexamethasone in comparison to control group for prevention of post dural puncture headache and injection site backache after spinal anesthesia.

Methodology

This randomized controlled trial study was conducted after taking approval from hospital ethics committee. This study was conducted in the department of anaesthesia, Holy Family, hospital, Rawalpindi from January 2017 to September 2017 in a period of nine months. The patients were selected from general, orthopedic, urology, and gynecology services. The patients in both groups were briefly described in the study and informed written consent was taken from all the patient.

A total sample of 108 patients including 54 patient in the intervention group and 54 in control group. The sample size was calculated by using WHO sample size calculator with 5% level of significance, 80% power of test and incidence of a headache after spinal anesthesia in intervention group 2.5% and in control group 12.5%.⁶

The patients included in the study were of age between 18 to 40 years and all were in ASA class 1 or class 2 on the basis of American Society of Anesthesiology. The patients with confounding variables like headache disorders and patients contraindicated to steroid use were excluded from the study to control the confounding effect of these variables on PDPH. All the patients qualifying for the inclusion in the study were randomly allocated to two group with the help of random number tables. Patients were kept blinded by the treatment they were given that is dexamethasone or normal saline. The anesthesiologist involved in the procedure had knowledge regarding the medication used. The doctor who evaluated patient's outcome was blinded by the intervention or placebo given to the patient. One anesthesiologist was involved in all the procedure of spinal anesthesia and it was made sure that procedure should be performed only from single try but if it was not successful then that patient was excluded from the study. Similarly, patients undergoing 2nd anesthetic during the study period were also excluded.

Both the groups received the same standard spinal anesthesia by the single anesthesiologist. In study group an intervention was made through a prophylactic dose of epidural dexamethasone injection in a dose of (2 ml, 8 mg) and in control group 2 ml normal saline was injected at the time of anesthesia along with standard spinal anesthesia. The anesthesia was administered between third and fourth vertebral spaces L3 and L4 in sitting position. The dose of anesthetic was standardized at 75mg Lidocaine 5% and 25mg Fentanyl, which was administered using a 25-gauge disposable needle. The incidence of a headache was the main outcome of the study and it was measured in first 24 hours, 72 hours and 7 days after spinal

anesthesia. The outcome was measured by interviewing the patients at these three-time points. The intensity of a headache was evaluated with the help of ten-point visual analog scale (VAS) ranging from 0 to 10. Where 0 showing no pain and 10 indicating maximum worst pain. The intensity of pain was also measured at 24 hours, 72 hours and 7 days after spinal anesthesia.

The collected data was managed and analyzed through SPSS v 21. Descriptive statistics were used to calculate mean and standard deviation for quantitative variables and frequency with a percentage for qualitative variables. Chi-square test was used to compare the incidence of a headache after 24 hours and after one week. The intensity of a headache on the basis of VAS was compared between both the groups. P-value < 0.05 was considered significant.

Results

In this study, a total of 108 patients were included consisting on 54 patients in both intervention and control group. The mean age in the intervention group was 32.18 ± 5.64 years, and control group it was 31.63 ± 6.24 years. Majority 21 (38.89%) of the patients in intervention group have primary education followed by 13 (24.07%) in secondary and 11 (20.37%) in intermediate education group. In control group, most 26 (48.15%) of the patients had primary followed by 11 (20.37%) patients having secondary education level. In our study sample, 5 (9.26%) patients in intervention group and 4 (7.41%) patients in control group were uneducated. In the intervention group, main bulk 19 (35.19%) of the patients were having private job followed by 15 (27.78%) patients having govt. job and in control group, most 18 (33.33%) of the patients had govt. job followed by 16 (29.63%) patients having a private job. Similarly, 12 (22.22%) patients in intervention group and 14 (25.93%) patients in control group were not doing any job.

Our whole sample size was collected from three different departments most of the patients in the intervention group was taken from general surgery department followed by gynecology department from where 20 (37.04%) patients and 10 (18.52%) patients were taken from the orthopedic department. The control group consisted on 27 (50.0%) patients from general surgery department, 16 (29.63%) patients from gynecology and 11 (20.37%) patients were selected from the orthopedic department as elaborated in (Table I).

The comparison of the frequency of a headache was done at 24 hours, 72 hours and 7 days and it was observed that 3

(5.56%) patients in intervention group and 7 (12.96%) patients in control group had post dural puncture headache but this difference was not statistically significant (p-value > 0.05). The rate of a headache was significantly higher in control group after 72 hours of operation with 7 (12.96%) patients in intervention group and 16 (29.63%) patients in control group showing a significantly lower rate of a headache with use of epidural dexamethasone after 72 hours of operation. Similarly, the rate of post dural puncture headache after 7 days was significantly greater (20.37% versus 38.89%, p-value < 0.05) in control group as compared to the intervention group. So the use of epidural dexamethasone significantly decreases the post dural puncture headache as elaborated in (table II).

Characteristics	Intervention Group		Control Group	
	Frequency	%	Frequency	%
Age of the patients				
Mean \pm SD	32.18 \pm 5.64		31.63 \pm 6.24	
Gender of patients				
Male	24	44.44%	22	40.74%
Female	30	55.56%	32	59.26%
Educational status of the patients				
Uneducated	5	9.26%	4	7.41%
Primary	21	38.89%	26	48.15%
Secondary	13	24.07%	11	20.37%
Intermediate	11	20.37%	8	14.81%
Graduate	4	7.41%	5	9.26%
Job status of the patients				
Govt. Job	15	27.78%	18	33.33%
Private Job	19	35.19%	16	29.63%
House wife	8	14.81%	6	11.11%
Job less	12	22.22%	14	25.93%
Frequency of Patients from different departments				
General Surgery	24	44.44%	27	50.00%
Orthopedic	10	18.52%	11	20.37%
Gynecology	20	37.04%	16	29.63%

Headache	Intervention Group		Control Group		P-value
	Frequency	%	Frequency	%	
24 hours	3	5.56%	7	12.96%	0.184
72 hours	7	12.96%	16	29.63%	0.034
7 days	11	20.37%	21	38.89%	0.019

The comparison of mean VAS scores of pain at 24 hours showed that mean pain score was significantly (p-value < 0.05) lower

in the intervention group with a mean value of 2.8 ± 1.5 as compared with the control group having a mean value of 3.5 ± 1.9 . The mean pain score on the basis of VAS was significantly (p -value < 0.05) lower after 72 hours with mean VAS score value of 3.5 ± 2.6 in the intervention group as compared to control group whose mean pain score value was 4.8 ± 2.9 . There was no statistically significant (p -value > 0.05) difference in the mean value of pain score after 7 days as elaborated in (table III).

Table III: Comparison of mean pain score between both groups at 24hr, 72hr and 7 days

Headache	Intervention Group	Control Group	P-value
	Mean \pm SD	Mean \pm SD	
24 hours	2.8 ± 1.5	3.5 ± 1.9	0.036
72 hours	3.5 ± 2.6	4.8 ± 2.9	0.016
7 days	4.6 ± 2.7	5.4 ± 3.1	0.156

Discussion

The incidence of post dural puncture headache is a major drawback of spinal anesthesia and the anesthesiologists have been wearisome to reduce the incidence of PDPH. For this purpose, the reduction of the size of the needle used for spinal anesthesia showed a direct and significant impact on PDPH in previous studies. The incidence has been noted up to 40% with a 22g needle and around 25% with a 25g needle. The incidence reduced significantly between 2-12% by using a 26g and $< 2\%$ with use of 29g or smaller needle but the use of smaller size needle have very high chances of failure due to technical difficulties.^{10, 11}

Post dural puncture headache is an adverse effect of spinal anesthesia due to puncture of dura mater. PDPH starts in the frontal region and spreads out with the passage of time and become generalized. In some patients this pain extent to neck or shoulders. The PDPH may be worsening due to coughing or straining because it raises the intracranial pressure. In some patients, it might have neck stiffness, photophobia, nausea/vomiting, dizziness or tinnitus as comorbid condition along with PDPH.¹²

In parturient, post dural puncture headache is a significant cause of morbidity. Although PDPH is a very common complication of spinal anesthesia and very frequently faced by anesthesiologists but its management is still controversial and has no standard protocol. Most of the anesthesiologists yet follow the conventional method of treatment for its management like strict bed rest and intense hydration, although these methods have almost no evidence of effectiveness. The methods which have proved efficient in different randomized

control trials like gabapentin and ACTH are not in common use for management of PDPH.^{13, 14, 15}

Lumber puncture with a needle used for administration of anesthetics is the cause of post dural puncture headache. In PDPH a pin starts in the head and increases with time in the beginning till some hours, its intensity enhances with patients upright position and decreases when lying down. This pain usually settles down abruptly within five to seven days. Many interventions are in practice to prevent a headache after spinal anesthesia. These interventions include methods used before, during or immediately after lumbar puncture. But these interventions are not in common use because of uncertainties of their clinical effectiveness, especially regarding drug treatments.¹⁶

Pathophysiology of PDPH is not yet clear, many drug options have been used as prophylactic treatment for a headache in clinical practice, for example EBP is used because it blocks CSF leakage, some postural positions are also recommended for prevention or reducing intensity of PDPH, such as prone position allows a seal to form over the dura by reducing pressure in subarachnoid space. Increased hydration improves the CSF production.¹⁷

The main purpose of prophylactic used of drugs is to decrease the frequency of PDPH in patients undergoing spinal anesthesia, and to decrease the intensity of a headache as much as possible, to avoid the requirement of the therapeutic option after its occurrence. Thus this method of prophylactic use of drugs improves the quality of life and significantly reduces the hospital stay with a decline in chances of adverse events overall.

The results of this present study showed that the post dural headache was most common in age interval of the thirties with an average age also lying in this interval. This fact has also been discussed in previous studies. The lesser incidence of PDPH in an elderly individual is due to decrease in the elasticity of cranial structures, which occurs as a normal aging process, and also a reduction in overall pain sensitivity. Similarly, the incidence of PDPH was higher in female patients as compared to male patients. This is supported by other studies in the literature which have shown almost double chances of PDPH among females as compared to males.^{18, 19}

Post dural puncture headache usually occurs for few days ranging from three to seven days. But this period is miserable and requires early intervention and treatment. These interventions used for PDPH include drug therapy and invasive approaches. A wide range of miserable emotional reactions are associated with PDPH, which may consist of tears due to pain,

the panic condition of the patients and anger. So the discussion about risk and complications with the patients become very important before the procedure. In obstetric patients, PDPH is more unfortunate because they expect to take care of the baby and happiness due the newborn. And in this condition, these patients have higher chances of depression and anxiety. It is important to counsel the patients regarding the reason of a headache, expected time course and treatment options for PDPH.²⁰

According to the results of this present study 5.56% patients in intervention group and 12.96% patients in control group had post-dural puncture headache but this difference was not statistically significant (p -value > 0.05). The rate of a headache was significantly higher in control group (29.63% vs. 12.96%) after 72 hours of operation as compared to the intervention group with use of epidural dexamethasone. Similarly, the rate of post dural puncture headache after 7 days was significantly greater (20.37% versus 38.89%, p -value < 0.05) in control group as compared to the intervention group. So the use of epidural dexamethasone significantly decreases the post-dural puncture headache.

The prophylactic use of dexamethasone for PDPH is controversial due to variation in its results but most of the studies have concluded that dexamethasone has better results to decrease the incidence of PDPH. It was observed in another study that administration of dexamethasone significantly decreases the intensity of PDPH, without affecting the incidence of PDPH.²¹

In another randomized controlled trial study, it was found that the incidence of PDPH was significantly lower in dexamethasone group at 24 hours (2.5% vs. 12.5%) as compared to control group. In the same study, the post dural puncture headache was significantly lower (11.3% vs 32.5%; $p = 0.001$) in the intervention group as compared to control group.²² Similarly Yousafshashi et al. also found significantly (p -value = 0.046) reduced incidence of PDPH after 24 hours in dexamethasone group.²³

Post dural puncture headache has very severe and miserable presentation so should be treated seriously. Even though it is not a fatal and self-limiting disease and its postural nature prevents the patients from performing routine activities. Along with all these complications of PDPH, it increases the hospital stay and eventually the cost as well. It might be associated with auditory and visual disturbances, nausea, vomiting and cranial nerve palsy. These patients require psychological support and therapeutic measures. Preventive measures that decrease the

incidence of PDPH such as smaller size needle, atraumatic needle and parallel direction of needle bevel in relation to dural fibers should always be considered. Several prophylactic measures are available including pharmacological and interventional measures. Once PDPH has occurred its management is very important and epidural blood patch is considered the best method till the date, but in severe conditions, surgical closure is an option which should be taken as the option of last resort.

Conclusion

In conclusion, it was observed that epidural administration of dexamethasone during spinal anesthesia is effective and useful in preventing headaches that follow this anesthetic procedure. Taking into consideration the results of this research, intravenous dexamethasone is suggested for prevention of headaches in patients who undergo spinal anesthesia. The results of this study revealed that the use of dexamethasone significantly reduces the incidence of pain at 24 hours, 72 hours and after 7 days. Similarly, the intensity of pain on the basis of VAS score was also significantly reduced at 24 hours and 72 hours with the use of dexamethasone preventive dose.

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