THE EFFECT OF INTRAVENOUS VERSUS INTRA THECAL DEXAMETHASONE IN BUPIVACAINE SPINAL ANESTHESIA ON POSTDURAL PUNCTURE HEADACHE

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ABSTRACT:

Background: *Spinal anesthesia is a gold standard procedure in urologic, orthopedic, obstetric and gynecological operations. However, post dural puncture headache (PDPH) is very annoying, there is no effective preventive or treatment method for it.*

Aim of work: *This study compared the effect of IV dexamethasone versus intrathecal dexamethasone as adjuvant to bupivacaine, on prevention of PDPH.*

Methods: *A comparative, double blind, randomized prospective study was conducted on 630 patients, ASA physical status I and II, of both sexes, undergoing lower abdominal and lower limb surgeries under spinal anesthesia. Patients were randomly divided into 3 equal groups. Group 1: received bupivacaine 0.5% 3 ml and 1 ml normal saline intrathecal and 8 mg intravenous dexamethasone in 10 ml saline. Group 2: received bupivacaine 0.5% 3 ml and 4 mg (1 ml) dexamethazone intrathecal, and 10 ml normal saline intravenous. Group 3: received bupivacaine 0.5% 3ml and 1 ml normal saline intrathecal, and 10 ml normal saline intravenous.*

Results: *In Group 1, PDPH occurred in 13 patients (6.19%) in post anesthesia care unit (PACU) and in 20 patients (9.5%) within 48 hours. In group 2, PDPH occurred in 14 patients (6.6%) in PACU and 22 patients (10.4%) had PDPH within 48 hours. In group 3, 16 patients (7.6%) had PDPH in PACU and within 48 hours 21(10%) had PDPH. There was no statistically significant difference between the three groups.*

Conclusion: *Incidence of post dural puncture headache, between using intrathecal bupivacaine alone or combined with intrathecal dexamethasone (4 mg) or intravenous dexamethas-one (8 mg) was similar.*

Keywords: *Dexamethasone; Bupivacaine; Postdural Puncture Headache, intrathecal*

INTRODUCTION:

Spinal anesthesia is a popular method of anesthesia, used for many lower abdominal and lower limb surgeries. However, penetrating the meninges for local anesthetic injection into subarachnoid space may be associated with many undesirable effects[(1)]. Post dural puncture headache (PDPH) is one of the most frequent side effects of spinal anesthesia. It may be mild self-limited or severe distressing, affecting the life style of the patient. There are many studies to determine the pathogenesis and possible causes of PDPH[(2)]. But till now, the pathophysiology of PDPH is still unclear. It's supposed that Cerebrospinal fluid (CSF)

leakage through the dural puncture may lead to decreased CSF volume and pressure. However, the relationship between the low CSF pressure and volume and (PDPH) is yet unclear[(3)]. Another theory suggests that loss of CSF activates adenosine receptors which lead to vasodilatation and headache[(4)].

For PDPH, conservative measures such as hydration and bed rest should be started immediately but these measures have a history of being not very effective. Therefore, other numerous strategies have been suggested. Some are non-invasive such as giving caffeine. Others are invasive such as epidural morphine injection or to replace CSF or to seal the dural puncture site by epidural saline bolus, epidural colloid or blood patch [(5)].

Dexamethasone is widely used in anesthetic practice; as anti-inflammatory, antiemetic and analgesic. Dexamethasone has been used intra-thecal as an adjuvant to local anesthetics, and intravenously to produce analgesia and sedation, with improving the outcome of PDPH [(6)]. However, no studies have been conducted to compare between intrathecal versus intravenous dexamethasone for prevention of PDPH.

AIM OF THE WORK:

The aim of this study is to compare the effect of IV dexamethasone (8 mg) versus intrathecal dexamethasone (4 mg) as adjuvant to bupivacaine, on post dural puncture headache (PDPH), in surgeries of lower abdomen and lower limb.

PATIENTS AND METHODS:

This prospective, randomized double blind, comparative study was conducted in period between February and July 2021, after ethical committee approval. Patients included were 21-50 years age, of both genders, ASA physical status I and II, and allocated for lower abdominal or lower limb surgeries under spinal anesthesia.

Exclusion criteria were: emergency cases, patients with heart diseases, hepatic or renal insufficiency, hemodynamics instability, infection at the site of injection or systemic, coagulopathy or bleeding diathesis, neurological and muscular diseases, and surgery time > 2 hours.

For sample size calculation, using ***Yousefshahi et al.***[(7)] as a reference, a sample size of 630 cases was calculated, divided equally into three groups. This sample size achieves 80% power when the effect size is moderate (=0.12) and using 2 degrees of freedom Chi-Squared test with a significant level of 0.05.

Using computer generated randomization program, patients were randomly divided into three equal groups: Group 1: patients received intrathecal 3 ml bupivacaine 0. 5% +1 ml normal saline + intravenous 8 mg dexamethasone in 10 ml saline. Group 2: patients received intrathecal 3 ml bupivacaine 0. 5% + 4 mg (1 ml) dexamethasone + intravenous 10 ml normal saline. Group 3: patients received intrathecal 3 ml bupivacaine 0. 5% +1 ml normal saline + intravenous 10 ml normal saline.

Pre-anesthetic check-up, including routine investigations, was performed for all patients, with procedure explanation, and taking written informed consent. Baseline clinical values of the patients, including heart rate, systolic and diastolic blood pressures, and oxygen saturation were recorded.

Upon patients' arrival into the operating room, peripheral oxygen saturation (SpO_2), ECG, pulse rate (PR), and systolic and diastolic blood pressures were monitored one of the researchers and recorded every 5 minutes till the end of surgery. In a sitting position and with antiseptic techniques, 25 G Quincke needle was inserted intrathecally at L3–L4 or L4–L5 interspace through

midline approach. The study drugs were given by an anesthesiologist not aware of the type of medications injected. Subsequently, the patients were put in the supine position, and given oxygen 3 L/minutes by nasal prongs.

Sensory block was assessed by loss of sensation to pinprick in the midline using a 22 G blunt hypodermic needle or alcohol-soaked cotton. Time from intra thecal drug injection to the time when the patient does not feel the pinprick at T10 level was taken as time of sensory onset. The degree of motor block was assessed at the same intervals as sensory level by the modified Bromage score [8]. The onset of motor block was the time between injection and achievement of highest level of motor block.

Bradycardia (defined as HR < 60 beats/min) was treated with atropine sulfate 0.3 mg intravenous increments. Hypotension (defined as systolic blood pressure [SBP] < 20% of baseline value) was treated with 10 mg intravenous ephedrine increments and additional Ringer's lactate solution (8 ml/kg). Pain (both postoperative and PDPH) was assessed by visual analog scale (VAS) score. Incidence and severity of postdural puncture headache was evaluated within 48 hours postoperative (PO). It was diagnosed as occipital or frontal headache, aggravated by erect or sitting position, coughing, sneezing and straining, and relieved by lying flat. Severity of PDPH was evaluated and compared using VAS. Headache was treated with bed rest and good hydration. Moderate PDPH was treated with bed rest, good hydration, caffeine 300 mg I.V twice daily and oral analgesics. If headache was not relieved or PDPH was severe, invasive treatment was considered in the form of an epidural blood patch.

Statistical analysis

Recorded data were analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean ± standard deviation (SD). Qualitative data were expressed as frequency and percentage. Continuous variables were checked for normality by using Shapiro-Wilk test. One-way analysis of variance (ANOVA) was used when comparing more than two groups; followed by Post Hoc test if there was significant difference. Chi-square (x2) test was used to compare proportions between qualitative parameters. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value < 0.05 was considered statistically significant.

RESULTS

There was no statistically significant difference between the three groups as regards the demographic data (age, gender, residence, weight, height, BMI) as (table 1).

Table (1): Comparison between the three groups as regards to demographic data (age, gender, residence, weight, height, BMI)

		Group (1) (n=210)	Group (2) (n=210)	Group (3) (n=210)	P Value
Age (years)	Mean± S.D	35.09±8.753	35.61±8.712	35.61±8.116	0.764
Gender (number, %)	Male	99 (47.1%)	121(57.6%)	98(46.7%)	0.43
	Female	111 (52.9%)	89(42.4%)	112(53.3%)	
Residence (number, %)	Urban	110(52.4%)	108(51.4%)	103(49%)	0.781
	Rural	100(47.6%)	102(48.6%)	107(51%)	
Weight (Kg)	Mean± S.D	81.31±8.098	80.98±8.147	82.00±7.828	0.412
Height (cm)	Mean± S.D	167.02±5.62	167.45±6.041	167.42±6.059	0.703
BMI (kg/m^2)	Mean± S.D	29.25±3.560	28.96±3.323	29.36±3.501	0.466

Data are expressed as number & percentage; or mean & Standard deviation Using: F-One Way Analysis of Variance; x2-Chi-square test; p-value > 0.05 NS

By comparing the data of the three groups, there was no statistically significant difference between the three groups regarding **preoperative vital data** (pulse, respiratory rate, systolic blood pressure, diastolic blood pressure) (table 2)..

Table (2): Comparison between three groups as regard to patient's preoperative vital signs

	Group (1) (n=210)	Group (2) (n=210)	Group (3) (n=210)	P Value
Pulse (beats/min) Mean± S.D	76.52±10.639	77.08±10.559	76.20±10.127	0.688
Respiratory Rate (breath/min) Mean± S.D	15.74±2.633	15.97±2.402	16.09±2.523	0.355
Systolic Blood pressure (mmHg) Mean± S.D	123.43±7.199	123.31±7.246	123.69±7.143	0.857
Diastolic Blood pressure (mmHg) Mean± S.D	76.43±6.642	75.93±6.552	76.38±6.507	0.896

Intraoperative data of the three groups, there was a statistically significant difference as regards onset of sensory block (P value < 0.05). Post_hoc test shows significant difference between groups 1&2, 1&3, 2&3. Duration of pain free period was also significant (P value < 0.05). Post_hoc test shows significant difference between groups 1&3, 2&3 but not statistically different between groups 1&2. While there was no statistically significant difference between the three groups regarding duration of sensory block (P > 0.05) (table 3)

Table (3): Comparison between three groups as regard to patient's onset time and duration of sensory block and pain-free period (minutes)

	Group (1) (n=210)	Group (2) (n=210)	Group (3) (n=210)	P Value
Onset time Mean± S.D	5.63 ±0.99	6.37±1.08 ¶	7.995±1.47 ¥ €	0.0001*
Duration of Sensory Block Mean± S.D	97.28±7.216	97.28±7.632	98.17±7.588	0.373
Duration of pain-Free period Mean± S.D	247.57±63.37	244.433±55.001	240.30±55.77 ¥ €	0.001*

Using: F-One Way Analysis of Variance; p-value > 0.05 NS. Post hoc test: ¶ significant between groups 1&2, ¥ significant between groups 1&3 € significant between groups 2&3

Data as pulse, RR, SBP, DBP were recorded at time 0 (was immediately after intra-thecal injection), 1 (was after 30 minutes), 2 (after 60 minutes), 3 (after 90 minutes of time zero). By comparing the data of the three groups (all recorded data were within normal range), there was no statistically significant difference between the three groups regarding vital signs at different time intervals (table 4).

Table (4): Comparison between three groups as regard to patient's vital signs at different time intervals

	Group (1) (n=210)	Group (2) (n=210)	Group (3) (n=210)	P Value
Pulse (beats/min) Mean± S.D	84.35±8.887	85.34±8.852	84.86±8.528	0.511
Respiratory Rate (breath/min)	15.95±2.69	16.23±2.61	15.85±2.49	0.295

Mean± S.D				
Systolic Blood pressure (mmHg) Mean± S.D	123.60±7.308	123.31±6.839	123.52±7.431	0.914
Diastolic Blood pressure (mmHg) Mean± S.D	76.71±6.647	75.90±6.518	76.62±6.598	0.388

Data are expressed as mean & Standard deviation. Using: F-One Way Analysis of Variance; x2-Chi-square test; p-value > 0.05 NS

Regarding adverse effects, there was no statistically significant difference between the three groups (P > 0.05) (table 5).

Table (5): Comparison between three groups as regard to patient's incidence of adverse events

Incidence of Adverse Events	Group (1) (n=210)		Group (2) (n=210)		Group (3) (n=210)		P Value	
	No.	%	No.	%	No.	%		
No	170	81	178	84.8	182	86.7		0.493
Hypotension	5	2.4	5	2.4	8	3.8	0.598	
Bradycardia	7	3.3	6	2.9	6	2.9	0.947	
Nausea and Vomiting	14	6.7	9	4.3	9	4.3	0.439	
Shivering	14	6.7	12	5.7	5	2.4	0.103	

Using: x2-Chi-square test; p-value > 0.05 NS

There was no statistically significant difference between the three groups regarding PDPH in recovery, within 48 hours (P > 0.05) (table 6)

Table (6): Comparison between three groups as regard to patient's PDPH

PDPH	Group (1) (n=210)		Group (2) (n=210)		Group (3) (n=210)		P Value
	No.	%	No.	%	No.	%	
In recovery (120 minutes)	13	6.19	14	6.6	16	7.6	0.84
Within 48 hours	20	9.5	22	10.4	21	10	0.949

Data are expressed as number & percentage Using: x2-Chi-square test; p-value > 0.05 NS

There was no statistically significant difference between the three groups regarding vital signs (within 48 hours) (pulse, respiratory rate, systolic blood pressure, diastolic blood pressure). (table 7)

Table (7): Comparison between three groups as regards to patient's vital signs (within 48 hours)

	Group (1) (n=210)	Group (2) (n=210)	Group (3) (n=210)	P Value
Pulse				
Mean± S.D	86.00±14.601	85.24±14.947	84.37±15.571	0.538
Respiratory Rate				
Mean± S.D	16.9±2.57	17.04±2.73	16.76±2.39	0.523
Systolic Blood pressure				
Mean± S.D	123.43±7.199	123.31±7.246	123.69±7.143	0.857
Diastolic Blood pressure				
Mean± S.D	76.43±6.642	76.43±6.543	76.38±6.507	0.996

Data are expressed as mean & Standard deviation Using: F-One Way Analysis of Variance; x2-Chi-square test; p-value > 0.05 NS

DISCUSSION:

Effective postoperative pain control is an essential component of the care of the surgical patient. Inadequate pain control may result in increased morbidity or mortality, Spinal anesthesia is the most commonly used technique for lower abdominal and lower limb surgeries as it is very economic and easy to administer. It reduces mortality rate associated with lower abdominal and lower limb surgeries by sixteen times when compared with general anesthesia. Spinal anesthesia avoids the risks of general anesthesia such as aspiration of gastric contents, difficulty with airway management[9].

Post-Dural Puncture Headache (PDPH) is a common problem after a deliberate puncture of the dura-arachnoid for purposes of diagnosis, therapy, spinal anesthesia, or unintentionally during epidural procedures. It affects the daily life of patients with marked restriction of their physical activities[10].

The factors that can affect the incidence of PDPH include age, gender, pregnancy, history of PDPH, shape of needle tip, size of needle, needle orientation to dura matter and number of lumbar punctures. The association between needle size and type with incidence of PDPH was described as 75% for 16-18 G needles, 30% for 22 G Quinke needles and reduced to 0.37% for 27 G pencil point needles [11].

The results of the present study were different in comparison to the study of ***Khraise et al.***[12], the findings revealed that the most influential factors affecting PDPH incidence in obstetrical patients were repeated puncture attempt and presence of tension headache prior to the spinal anesthesia. Furthermore, age, weight, previous history of spinal anesthesia and PDPH, presence of preeclampsia, migraine, sinusitis, needle type and caffeine withdrawal did not predispose the women to PDPH.

Epidural and intrathecal steroids are used to reduce chronic pain [13]. Intrathecal dexamethasone increased duration of sensory block and postoperative analgesia. Although intrathecal dexamethasone is used to control chronic pain[14].

In a prospective study of ***El-Shourbagy et al.*** [15], intrathecal 8 mg dexamethasone and hyperbaric bupivacaine provided statically significant more duration of analgesia as compared to hyperbaric bupivacaine alone, significantly prolonged sensory block compared with intrathecal bupivacaine alone, and the motor block duration was significantly prolonged when compared with control group; There was no effects on the onset time of sensory block.

Findings of ***Bani-Hashem et al.***[14] study are in agreement with the present study. It included 50 patients scheduled for orthopedic surgery under spinal anesthesia. Patients were randomly allocated to receive hyperbaric bupivacaine with normal saline (control group) or hyperbaric bupivacaine plus dexamethasone (case group) intrathecally. Duration of sensory block in dexamethasone group was significantly higher than in the control group.

As regards PDPH, the current study revealed that there was no statistically significant difference between groups. ***Yang et al.*** [16], found that incidence of PDPH was significantly less in dexamethasone group than control group in first 24 h postoperatively, this may be due to the different sample size as the study was on pregnant women . However, there was no significant difference (P< 0.05) between them in the first 7 postoperative days. ***Noyan et al.*** [17] **and** ***Alam et al.*** [18] found that hydrocortisone could resolve PDPH symptoms. ***Yousefshahi et al.***[7] reported that prophylactic intraoperative intravenous 8 mg dexamethasone, after umbilical cord

ligation, increased the severity and incidence of PDPH. On the other hand, ***Hamzei et al.*** [19] found that 8 mg dexamethasone significantly reduced the incidence of PDPH in the first 24 h and first week after spinal anesthesia. In the study of Yousefshahi and his colleagues, four different anesthesiologists (not the same anesthesiologist) performed the dural puncture and attempted punctures more than once in some participants, and the study of ***Hamzei and his colleagues*** [19], was a single-blind, not a double-blind design. The above-mentioned points in ***Yousefshahi's*** [7] ***and Hamzei's*** [19] studies may have led to the inconsistent effects of dexamethasone on PDPH. Yet the study by ***Doroudian et al.*** [20] has shown that application of dexamethasone has been associated with lower intensity of postoperative headache in spinal anesthesia.

Conclusion:

This study has shown that prophylactic administration of dexamethasone either intravenous or intraathecal with spinal anesthesia did not affect the incidence of PDPH.

Recommendation:

More well-designed trials with different doses of dexamethasone and objective indexes assessing the severity of headaches are needed to verify these results.

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تأثير حقن الوريد مقابل حقن تحت الام العنكبوتية لعقار ديكساميثازون في التخدير النخاعي بوبيفاكايين على صداع ثقب الجافية

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الخلفية: التخدير النخاعي هو إجراء معياري ذهبي في عمليات المسالك البولية وجراحة العظام والتوليد وأمراض النساء. ومع ذلك ، فإن صداع ما بعد ثقب الجافية مزعج للغاية ، ولا توجد طريقة وقائيةأو علاجية فعالة له.

هدف العمل: قارنت هذه الدراسة بين تأثير ديكساميثازون كمساعد بوبيفاكين عن طريق حقن الوريد او تحت العنكبوتية ، على الوقاية من صداع ثقب الام العنكبوتية بعد التخدير النصفي

الطرق: تم إجراء دراسة استباقية عشوائية مزدوجة التعمية على ٦٣٠ مريضاً من فئة الجسدية ١ و ٢ من كلا الجنسين ، خضعوا لعمليات جراحية في أسفل البطن والأطراف السفلية تحت التخدير النخاعي. تم تقسيم المرضى بشكل عشوائي إلى ٣ مجموعات متساوية. المجموعة ١: تلقى بوبيفاكايين ٠.٥٪ ٣ مل و ١ مل محلول ملحي عادي داخل القراب و ٨ ملغ ديكساميثازون في الوريد في محلول ملحي ١٠ مل. المجموعة ٢: تلقى بوبيفاكايين ٠.٥٪ ٣ مل و ٤ ملجم (١ مل) ديكساميثازون داخل القراب ، و ١٠ مل محلول ملحي في الوريد. المجموعة ٣: تلقى بوبيفاكايين ٠.٥٪ ٣ مل و ١ مل محلول ملحي عادي داخل القراب ، و ١٠ مل محلول ملحي في الوريد.

النتائج: في المجموعة ١ ، حدث في ١٣ مريضًا (٦.١٩٪) في وحدة رعاية ما بعد التخدير مريضًا (٩.٥٪) في غضون ٤٨ ساعة. في المجموعة الثانية ، حدث في ١٤ مريضًا (٦.٦٪) في PACU و ٢٢ مريضًا (١٠.٤٪) كان لديهم في غضون ٤٨ ساعة. في المجموعة ٣ ، كان لدى ١٦ مريضًا (٧.٦٪) في وفي غضون ٤٨ ساعة كان لدى ٢١ (١٠٪) صداع. لم يكن هناك فرق معتد به إحصائيا بين المجموعات الثلاث.

الاستنتاج: ان حدوث صداع بعد ثقب الجافية ، بين استخدام بوبيفاكايين داخل القراب وحده أو مع ديكساميثازون داخل القراب (٤ ملغ) أو ديكساميثازون في الوريد (٨ ملغ) كان متشابهًا.