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Comprehensive evaluation of clinical efficiency of dexamethasone as a supportive agent for bupivacaine in spinal anesthesia: An original research study

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***Abstract*---**Background and Aim: In order to enhance the overall performance and efficiency of bupivacaine, several additives have been experimented by various researchers. However, each adjunctive agent has its own disadvantages and limitations. This study was conducted to evaluate the clinical efficiency of dexamethasone as a supportive agent for bupivacaine in spinal anesthesia. Materials & Methods: Total 60 patients fulfilling as per the American Society of Anesthesiologists class I and class II of either sex aged between 21 to 60 years were included in the study. All patients were studied into two groups; Group 1 patients received combination of intrathecal bupivacaine (3ml, 15mg, 0.5%) plus dexamethasone (2ml, 8mg). Group 2 patients received intrathecal bupivacaine (3ml, 15mg, 0.5%) plus saline (2ml). Spinal anesthesia was administered with standard manner at lumber space. The early onset of anesthesia along with duration of block and assessment of pain were noted carefully to investigate further. Statistical Analysis & Results: Statistical analysis was completed by SPSS software wherein P value less than 0.05 was considered significant. Out of total studied 60 patients, maximum 31 patients were in the age range of 21-30 years. Age range of 41-50 years confirmed only 6 subjects. P value was highly significant. In group one, the mean onset was 12.89 minutes while mean sensory block time was 125.54 minutes. The calculated painless period in minutes was 220.15. In group two, the mean onset was observed at 11.92 minutes while mean sensory block time was 116.02 minutes. The calculated painless period in minutes was 213.63. Two sample t- test

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evaluation of mean score and standard deviation in both the study groups showed significant *P* value for group one while non-significant *P* value for group two. Conclusion: Within the limitations of the study it was concluded that simultaneous usage of dexamethasone and bupivacaine efficiently prolongs the necessary sensory block timings. However, clinicians should consider and correlate with other critical clinical parameters before experimenting such combinations.

***Keywords*---**bupivacaine, dexamethasone, spinal anesthesia, surgery, abdomen.

Introduction

In the recent past, regional anesthesia has been increasingly used due to its advantages of potent analgesia with minimum complications like educed nausea. Prolonged duration of action is one of the prime requisite of any anesthesia shot.[1] Researchers have studied many anesthetic regimen and their combinations to maximize patient comfort. However, no such regime seems to be completely free from patient discomfort.[2,3] Studies have confirmed that local anesthesia does not offer anesthesia for more than 5-6 hours. Therefore, local anesthesia is usually avoided for major surgeries wherein prolonged duration of action is required.[4,5] In order to achieve all of the desired advantages of anesthesia, anesthetist usually increases the dose. However, increasing the drug dose has its own deleterious effects primarily toxicity. Literature has clearly demonstrated that single dose of nerve block is quite easy to attempt when compared with other available approaches.[6,7] Also, single dose block is more economical and require less attention during follow up phase. The average anesthetic coverage of local anesthesia is limited and can only be augmented by increasing the dose only up to its toxic limits. All such circumstances eventually lead to the actual necessity of potent external adjunct. In this regard, dexamethasone is one of the most popular and studied agent.[8] Chemically it is a glucocorticoid which possess anti-inflammatory and immunosuppressive properties. However, neural toxicity is still a serious concern for legitimate use of dexamethasone. It largely depends upon several factors like suitable and effective dosage and mechanism of action of dexamethasone. So, all these clinical dilemmas must be minimized and addressed at the earliest. Hence this study was conducted to evaluate the clinical efficiency of dexamethasone as a supportive agent for bupivacaine in spinal anesthesia.

Materials & Methods

This study was planned with idea of testing our predefined research hypothesis. So, the planned study was solely based on clinical trial model. Complete randomization was attempted to minimize the systematic errors like confounding, biased outcome of respondents and co- intervention. Additionally, we proceeded with blinding process. Double blinding was ensured to make balance among the participants during their follow up phases. Neither participants nor researchers were aware about the type of intervention used in this double blind clinical trial. Randomized trial study also tends to minimize the selection bias during the selection of samples.

Inclusion and Exclusion Criteria

A total of sixty cases fulfilling as per the American Society of Anesthesiologists class I & II of either sex aged between 21 to 60 years scheduled for surgery under spinal anesthesia were selected. All subjects were informed well about the intended purpose of the study. Informed consent was obtained accordingly. All patients were studied into 02 groups of 30 each.
Group 1 patients received the new treatment regime i.e.; combination of intrathecal bupivacaine (3ml, 15mg, 0.5%) plus dexamethasone (2ml, 8mg).
Group 2 patients received only standard treatment regime i.e.; intrathecal bupivacaine (3ml, 15mg, 0.5%) plus saline (2ml).

We took care of precise selection of cases to study as minor factors can also lead to data degradation. Patients free from any hyper-allergic conditions were included in the study. All patients falling under ASA grade III and IV were excluded from the study. Also, patients with history of myocardial infarction, uncontrolled diabetes and hematological disorders were not entertained anyways. Any kind of malnourished or obese condition was excluded. Spinal anesthesia was administered preferably at L3-L4 or L4-L5 region through midline approach using a 25G Quincke spinal needle. The initial onset of sensory blockade along with duration of block and assessment of pain were recorded comprehensively to analyze further. Patient's personal details were kept confidential. All related risks and benefits were explained in detail to all participating patients. Statistical analysis was conducted by SPSS software in which *P* value less than 0.05 was considered significant.

Statistical analysis and results

Statistical analysis was attempted by statistical software Statistical Package for the Social Sciences Series 22 (SPSS). The chief endeavor was to estimate and obtain *P* values, mean, standard deviation, chi- square test, standard error and 95% CI. Table 1 shows about distribution of patients into two study groups according to regimes. Table 2 and Graph 1 demonstrates that out of 60 studied patients, males were 38 and females were 22. Maximum 31 patients were seen in the age range of 21-30 years. Age range of 31-40 years reported 17 subjects. Age range of 41-50 years demonstrated only 6 subjects. *P* value was extremely significant here (0.01). Table 3 shows data about statistical details including mean, standard deviation, *P* value for group I [n=30]. Mean onset was noticed at 12.89 minutes while mean sensory block time was 125.54 minutes. The recorded painless period in minutes was 220.15. *P* value was highly significant for sensory block time, it was 0.01. Table 4 shows data about statistical details including mean, standard deviation, *P* value for group II [n=30]. Mean onset was observed at 11.92 minutes while mean sensory block time was 116.02 minutes. The measured painless period in minutes was 213.63. *P* value was not significant for any of the studied parameters. The associated standard error showed a sensible range of 0.204-0.647. Table 5 and Graph 2 illustrates about two sample t- test evaluation of mean score and standard deviation in both the study groups. The comparative *P* value was 0.005 for group one (Significant) while it was 0.287 for group two (Non-Significant).

Table 1: Distribution of patients into two study groups according to regimes

Groups	Group I [New]	Group II [Standard]	Mode
Regime	Bupivacaine-Dexamethasone	*Bupivacaine-Saline*	Intrathecal
Number	30	30	Intrathecal

Table 2: Age & gender wise distribution of patients

Age Group (Years)	Male	Female	Total	P value
21-30	20	11	31	0.08
31-40	10	7	17	0.20
41-50	4	2	6	0.01*
51-60	4	2	6	0.50
Total	38	22	60	*Significant

Table 3: Statistical details including mean, standard deviation, *p* value for group I [n=30]

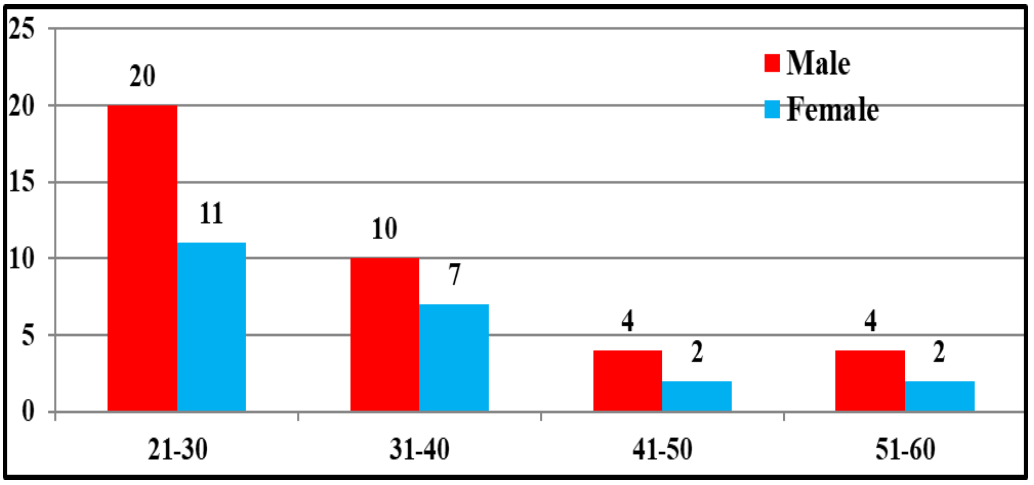
Parameters	Mean	Std. Deviation	Std. Error	95% CI	Pearson Chi-Square Value	df	Level of Significance (p value)
Onset (Minutes)	12.89	0.212	0.290	1.63	1.033	1.0	0.30
Sensory Block Time (Minutes)	125.54	0.337	0.035	1.45	2.928	1.0	0.01*
Painless period (Minutes)	220.15	0.928	0.435	1.34	1.837	2.0	0.08

Table 4: Statistical details including mean, standard deviation, *p* value group II [n=30]

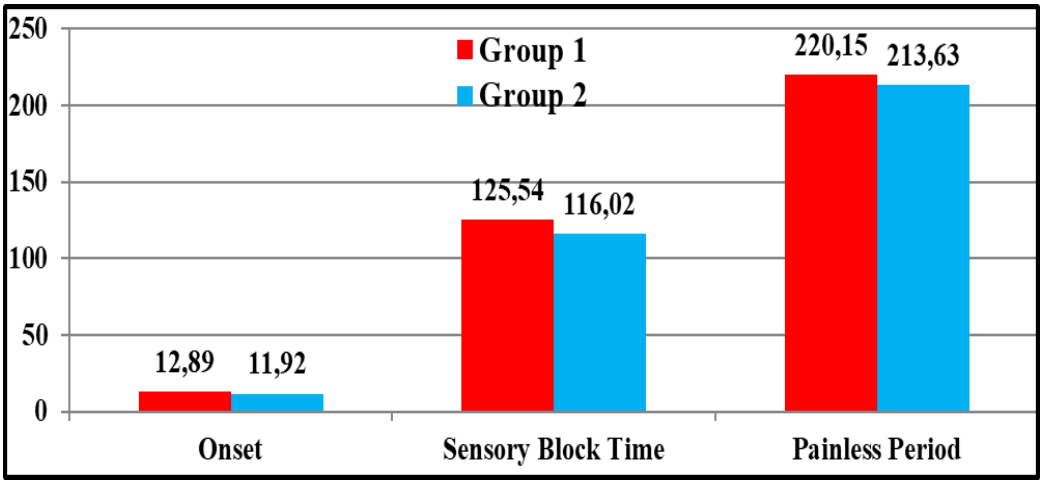
Parameters	Mean	Std. Deviation	Std. Error	95% CI	Pearson Chi-Square Value	df	Level of Significance (p value)
Onset (Minutes)	11.92	0.938	0.647	1.39	1.435	1.0	0.50
Sensory Block Time (Minutes)	116.02	0.038	0.204	1.93	2.288	1.0	0.10
Painless period (Minutes)	213.63	0.331	0.251	1.94	2.947	2.0	0.20

Table 5: Two sample t- test assessment of mean score and standard deviation in both the study groups

Parameters	Group I		Group II	
	Mean Score	SD	Mean Score	SD
Onset	12.89	0.212	11.92	0.938
Sensory Block Time	125.54	0.337	116.02	0.038
Painless Period	220.15	0.928	213.63	0.331
P-value	0.005 (Significant)		0. 287 (Non-Significant)	



Graph 1: Age & gender wise allocation of patients



Graph 2: Two sample t- test estimation of mean score and standard deviation in both the study groups

Discussion

Inadequate control of pain during follow up period remains the principal problem after interventional therapies. For optimal and satisfactory control of pain,

anesthetist must be aware of various factors like patients parameters (age, weight, gender), physiology of drug and extent or depth of surgery.[9] Additionally, the level of depression and anxiety must also be considered while deciding the dose of anesthetic agent for a particular age and sex.[10] Researchers have experimented various drugs to enhance the performance of the anesthesia. The popularly used adjuncts are epinephrine, opioids and ketamine. All of them have demonstrated different outcomes in terms of post operative anesthesia and analgesia.[11,12] Bupivacaine is one of the extensively used and popular anesthetic agents used during various surgical procedures. Bupivacaine is a mostly available by its trade name Anawin. Mostly it is available with the small mixed amount of epinephrine to enhance its duration of action.[13] As reported by most of the researchers, duration of action of bupivacaine ranges between 2 to 8 hours. Bupivacaine must be avoided in cases of known hypersensitivity. Dexamethasone is chemically a corticosteroid with known anti-inflammatory property.[14] In the recent time dexamethasone has been used for managing severe cases of covid-19 and other chronic infections. In a recent randomized clinical trial conducted in United States, controlled combination of dexamethasone and bupivacaine has been shown to control pain during orthopedic and abdominal surgeries.[15] Researchers like Quesada and Ferré also agreed that addition of dexamethasone adjunct to bupivacaine undoubtedly improves its onset of action and working time.[16,17] Yayik and colleagues studied and compared the dexamethasone plus bupivacaine with solo bupivacaine. Their results were very exacting since the experimented combination showed improved clinical performance.[18] Guay and associates studied the effect of dexamethasone on bupivacaine during spinal anesthesia. Their study results were highly comparable and significant. They also state that clinical doses of Dexamethasone with Bupivacaine must be altered as per the patient's demographic and clinical parameters.[19]

Conclusion

For effective and efficient spinal anesthesia, several clinical trials have been conducted by the researchers. All such clinical trials have their own limitations and ethical issues. Within the limitations of the study, we concluded that clinical use of dexamethasone with bupivacaine alters its behavior and efficiencies particularly in cases of abdominal surgeries attempted under spinal anesthesia. This clinical trial clearly shows that concomitant usage of dexamethasone and bupivacaine efficiently prolongs the required sensory block timings. However, anesthetist must consider and correlate with other crucial clinical factors before trying such combinations.

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