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CLINICAL COMPARATIVE STUDY BETWEEN INTRATHECAL DEXMEDETOMIDINE AND DEXAMETHASONE ON PROLONGING THE DURATION OF INTRATHECAL BLOCKADE IN LOWER LIMB ORTHOPEDIC SURGERY

By

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ABSTRACT

Background: Spinal anesthesia is safer than general anesthesia during lower limb operations; many studies have been concerned about prolonging the duration of spinal anesthesia by adding different adjuvants.

Objective: To compare the efficacy of intrathecal dexmedetomidine versus intrathecal dexamethasone in prolonging duration of spinal anesthesia, and postoperative analgesia, safety and hemodynamic stability.

Patients and methods: Our study was carried out on 60 patients of American Society of Anesthesiologists (ASA) physical status I or II, scheduled for orthopedic operation under spinal anesthesiadivided into A, B and C from March 2020 to November 2020. They were divided into 3 equal groups: Group A received 2ml bupivacaine (0.5%) and 10µg dexmedetomidine in 1ml normal saline intrathecal, Group B received 2ml bupivacaine (0.5%) and 4 mg dexamethasone in 1 ml normal saline intrathecal and Group Creceived 2ml bupivacaine (o.5%) and 1ml normal saline Intrathecal. The study was carried out at Al-Azhar University Hospitals (Al- Hussein and Sayed Galal Hospitals).

Results: The present study showed statistically significant difference (P-value <0.001) between the three groups according to time of motor and sensory regression. The regression time of block (both sensory and motor) were prolonged in A (sensory 359.50±20.32, motor 319.00±21.06) and B (sensory 199.75±18.22, motor 170.00±20.00) when compared to the C group (sensory 149.55±10.83, motor 141.00±22.09). However, the duration was longest in A group among the three groups. According to amount of analgesic consumption postoperatively, there was significant decrease in amount in A group in comparison to B and C groups. The amount is insignificantly decreased in B group in comparison to C group. Regarding safety and hemodynamic stability there was no statistically significant difference between the three groups.

Conclusion: Dexmedetomidine had prolonging the duration of spinal anesthesia more than dexamethasone and control group with statistically significant difference between the three groups and provided prolonged postoperative analgesia compared to dexamethasone and control group.

Keywords: Intrathecal dexmedetomidine, Intrathecal dexamethasone, Spinal anesthesia.

INTRODUCTION

Orthopedic surgeries are very common and lower limb fractures occur in a lot of age groups, old age specially are at high risk and have a lot of morbidity and mortality with general anesthesia. So, regional techniques have come to take an

upper hand in anesthesia over general anesthesia due to certain advantages like less chance of airway compromise and aspiration, facilitation of postoperative analgesia, benefit in some preexisting medical conditions and so on. However, postoperative pain control is a major problem because spinal anesthesia using only local anesthetics is associated with relatively short duration of action, and thus early analgesic intervention is needed in the postoperative period. A number of adjuvants, such as opioids and others have been studied to prolong the effect of spinal anesthesia. The addition of opioids to local anesthetic solution has disadvantages, such as pruritus and respiratory depression *(Guptaet al., 2011)*.

One of these additives is dexamethasone, which has been proved in many studies to prolong the duration of peripheral blocks both in animal and human studies. Dexamethasone has anti-inflammatory and analgesic action by inhibition of transmission in nociceptive C -fibers and neural discharge. When given as an additive in peripheral nerve blocks or in intrathecal anesthesia, it prolongs the duration of anesthesia *(Shalu and Ghodki, 2017)*.

Dexmedetomidine is eight times more specific and highly selective α2-adrenoreceptor agonist compared with clonidine, that making it a useful and safe adjunct in diverse clinical applications *(Ganesh and Krishnamurthy 2018)*.

The mechanism by which intrathecal α2-adrenoceptor agonists prolong the motor and sensory block of local anesthetics is by binding to presynaptic C-fibers and postsynaptic dorsal horn neurons. Their analgesic action is a result of depression of the release of C-fiber transmitters and hyperpolarization of postsynaptic dorsal horn neurons *(Nethra et al., 2015)*.

The prolongation of sensory effect may result from synergism between local anesthetic and α2-adrenoceptor agonist, while the prolongation of the motor block of spinal anesthetics may result from the binding of α2-adrenoceptor agonists to motor neurons in the dorsal horn Intrathecal α2-receptor agonists have been found to have antinociceptive action for both somatic and visceral pain *(Routray et al., 2017)*.

The present work aimed to compare the effect of adding dexmedetomidine versus dexamethasone intrathecally as an adjuvant to 0.5% hyperbaric bupivacaine for prolonging the duration of spinal anesthesia, postoperative analgesiaand evaluate any possible side effects.

PATIENTS AND METHODS

This prospective randomized double blind clinical study was approved by the ethics committee in Al-Azhar University and patients' written informed consents were obtained.

The study was carried out at Al- Azhar University Hospitals (Al-Hussein and Bab El-Sharia) from March 2020 till November 2020.

This study included 60 patients of both sex, ages ranged from 20-50 years, ASA physical status I and II scheduled for lower limb orthopedic surgeries requiring spinal anesthesia. Patients were excluded from the study if they had major cardiac, respiratory, hepatic or renal diseases, hypersensitivity to used drugs,

uncontrolled diabetes, neurological or psychological disorder that may affect communication with the patient, neuromuscular disorder or drug abuse interfered with sensations or motor power of lower limbs, body mass index <30 kg per square meter, coagulopathy, or infection at the site of injection.

In pre-anesthetic room 18 G IV cannula was inserted and 10 ml/ kg crystalloid solution as a preload was started. On arrival to OR all monitors were attached (noninvasive blood pressure, pulse oximetry, and five-lead ECG), Baseline readings were recorded.

All patients were prepared for spinal anesthesia using 2 ml bupivacaine (0.5%). The patients were randomly divided into three equal groups:Group A was administered 10 μgdexmedetomidine in 1 ml saline.Group Bwas administered 4 mg dexamethasone in 1 ml saline andGroup C was administered an additional 1 ml of saline. After infiltration of the skin by 5ml lidocaine 2%, intrathecal anesthesia was administered using a 22-G spinal needle inserted into the L3–L4 space, with the patient in the sitting position with complete sterilization.. The patients were monitored for heart rate, arterial pressure, and oxygen saturation every 5 min after injection for 30 min, and then every 15 min. Sensory block was assessed using pin prick every 2 min, while the patient was supine till proper level was reached (T10 dermatome), and Bromage scale was measured to reach Bromage 3 before surgery *(Rajesh et al., 2015)*.

Any decrease in heart rate below 60/min was treated with intravenous atropine (0.01 mg/kg), and any decrease in mean arterial pressure below 20% of the basal reading was treated by fluid bolus and 5 mg intravenous increments of ephedrine. Pain postoperatively was assessed with visual analogue scale (VAS) between 0 and 10 (0 = no pain, 10 = the most severe pain). If the VAS was ≥ 3 patient received Ketolac (30 mg IV infusion) first, then VAS reassessed 15 minutes later, nalbuphine (0.15 mg/kg IV) was given if (VAS) ≥ 3 after giving Ketolac. VAS was been reassessed 15 minutes later to any rescue analgesic injection. Postoperative nausea and vomiting was managed if intolerable with ondansetron (4 mg) intravenously.

Statistical analysis: Results of the present study were statistically analyzed using SPSS version 20.0 (IBM, USA).Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage. Numerical data were compared using A one-way analysis of variance (ANOVA) test followed by Post-hoc test, while categorical data were compared using Chi-square. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value of < 0.05 was considered significant.

RESULTS

Regarding demographic data(age, sex, ASA, time of operation), there was no statistically significant difference between three groups. The findings of our study regarding male to female ratio (80%), mean of ageof patients(34.8-33.0-36.1), ASA to ASA ratio (76.67%) and mean of duration of operation (90.0-80.5-80.0) **(Table 1)**.

Table (1): Comparison between three groups according to demographic data

Groups / Demographic data	Group A *(n=20)*	Group B *(n=20)*	Group C *(n=20)*	P-value
Age (years) Mean±SD	34.80±8.88	33.80±8.70	36.10±9.68	0.726
Sex Female	4 (20.0%)	3 (15.0%)	5 (25.0%)	0.732
Male	16 (80.0%)	17 (85.0%)	15 (75.0%)	
ASA I	16 (80.0%)	15 (75.0%)	15 (75.0%)	0.911
II	4 (20.0%)	5 (25.0%)	5 (25.0%)	0.410
Weight (Kg)	79.90±9.22	79.50±7.55	76.40±10.06	0.118
Height (cm)	175.10±9.22	172.20±7.49	169.20±9.73	
Duration of operation	90.00±16.99	80.50±18.02	85.00±16.99	0.231

Regarding time of total sensory and motor block regression, there wasa statistically significant difference between three groups. The regression time of block both sensory and motor prolonged in A and B groups when compared to the C group. However, the duration was longest in A group among the three groups. This study showed that mean of time of sensory regression is (359.5-199.75-149.55) for Groups A, B and C respectively. The mean of time of motor regression is (319.0-170.0-141.0) for Groups A, B and C respectively **(Table 2)**.

Table (2): Comparison between three groups regarding time of sensory and motor block regression

Groups / Sensory and Motor block	Group A *(n=20)*	Group B *(n=20)*	Group C *(n=20)*	ANOVA p-value	Post HOC		
					P1	P2	P3
Sensory block (min)							
Mean±SD	359.50±20.32	199.75±18.22	149.55±10.83	<0.001	<0.001	<0.001	0.001
Motor block (min)							
Mean±SD	319.00±21.00	170.00±20.00	141.00±22.09	<0.001	<0.001	<0.001	<0. 05

P1: Comparison between Group A and Group B, P2: Comparison between Group A and Group, P3: Comparison between Group B and Group C

Regarding time of request of first analgesic, there was a statistically significant difference between three groups. The requirement of analgesia significantly delayed in A group in comparison to B and C groups. C group was the earliest group in requirement of analgesia. Mean of first time of analgesia request was (293.5-178.4-125.0) for Groups A, B and C respectively **(Table 3)**.

Table (3): Comparison between three groups according to time of request of first analgesic

Groups / Time of request of first analgesic	Group A *(n=20)*	Group B *(n=20)*	Group C *(n=20)*	ANOVA p-value	Post HOC		
					P1	P2	P3
Mean±SD	293.50±15.57	178.40±19.26	125.00±17.47	<0.001	<0.001	<0.001	<0.001

P1: Comparison between Group A and Group B, P2: Comparison between Group A and Group C, P3: Comparison between Group B and Group C

There was a statistically significant difference between three groups regarding total amount of analgesic consumption there was significant decrease in amount in A group in comparison to B and C groups. The amount insignificantly decreased in B group in comparison to C group. This study showed that mean of number of analgesic injections were (1.9-3.45-3.0) for Groups A, B and C respectively **(Table 4)**.

Table (4): Comparison between three groups according to total amount of analgesic consumption

Groups / Total amount of analgesic use	Group A *(n=20)*	Group B *(n=20)*	Group C *(n=20)*	ANOVA p-value	Post HOC		
					P1	P1	P1
Mean±SD	1.90±0.45	3.45±0.51	3.50±0.51	<0.001	<0.001	<0.001	0.758

P1: Comparison between Group A and Group B, P2: Comparison between Group A and Group, P3: Comparison between Group B and Group C

According to patient's opinion toward pain control, there was a statistically significant difference between three groups. Number of patients with complete satisfaction was more in A group (65%) in comparison to B group (40%) and C group (15%) only **(Table 5)**.

Table (5): Comparison between three groups according to pain control satisfaction

Groups / Pain control satisfaction	Group A *(n=20)*	Group B *(n=20)*	Group C *(n=20)*	ANOVA p-value
No satisfaction	*1 (5.0%)*	*7 (35.0%)*	*10 (50.0%)*	<0. 01
Partial satisfaction	*6 (30.0%)*	*5 (25.0%)*	*7 (35.0%)*	
Complete satisfaction	*13 (65.0%)*	*8 (40.0%)*	*3 (15.0%)*	

There was no statistically significant difference between three groups as regard the required doses of atropine and ephedrine. In our study, we used atropine 3 times for group A, 1 time for B and no time for C group. Regarding ephedrine, we used it 2 times for A, 1 time for B and 2 times for C group **(Table 6)**.

Table (6): Comparison between three groups according to doses of atropine and ephedrine required

Groups / Drugs	Group A *(n=20)*	Group B *(n=20)*	Group C *(n=20)*	ANOVA p-value
Atropine	*3 (15.0%)*	*1 (5.0%)*	*0 (0.0%)*	0.153
Ephedrine	*2 (10.0%)*	*1 (5.0%)*	*2 (10.0%)*	0.804

There was no statistically significant difference between three groups as regards times of bradycardia and hypotension. In our study, bradicardia occurred 3 times for group A, 1 time for B and no time for C group. Regarding hypotension we faced it 2 times for A, 1 time for B and 2 times for C group **(Table 7)**.

Table (7): Comparison between three groups according to times of bradycardia and hypotension

Groups / Vital data	Group A *(n=20)*	Group B *(n=20)*	Group C *(n=20)*	ANOVA p-value
Bradycardia	*3 (15.0%)*	*1 (5.0%)*	*0 (0.0%)*	0.153
Hypotension	*2 (10.0%)*	*1 (5.0%)*	*2 (10.0%)*	0.804

DISCUSSION

In this study, there was a significant prolongation of duration of spinal anesthesia with dexmedetomidine and dexamethasone with more effective postoperative analgesia; however dexmedetomidine is associated with the longest duration of anesthesia and most effective postoperative analgesia. Dexmedetomidine added to intrathecal bupivacaine was associated with a longer duration of the sensory blockade compared with addition of dexamethasone in lower limb orthopedic surgeries under spinal anesthesia. In addition, it caused longer duration of motor block. Meanwhile, addition of dexamethasone prolonged duration of sensory block. Postoperatively, dexmedetomidine produced longer duration of analgesia. Frequency of adverse events was limited in all groups.

Dexmedetomidine's ability to prolong sensory and motor blockade could be explained by being a highly selective α 2-adrenergic receptor agonist. In addition, it has a sedative, analgesic, perioperative sympatholytic, and hemodynamic-stabilizing property. Moreover, it has the advantage of no respiratory depression. In the spinal cord, it activates α 2-adrenergic receptors in the neurons of the superficial dorsal horn. It directly reduces pain transmission by reducing the release of pronociceptive transmitter, substance P, and glutamate from primary afferent terminals, and by hyperpolarizing spinal interneurons by G-protein-mediated activation of potassium channels. The possible explanation of the effect of

adding dexmedetomidine to intrathecal bupivacaine lies in its synergistic effect being selective α 2-adrenergic receptor agonist, which binds to the presynaptic C-fibers and postsynaptic dorsal horn neurons. Thus, it produces analgesia by depressing the release of C-fiber transmitters, hyperpolarization of postsynaptic dorsal horn neurons; whereas bupivacaine as a local anesthetic acts by blocking sodium channels *(Gupta et al., 2011)*.

The study results went in line with the study conducted by *(Shukla et al., 2011)* who compared dexmedetomidine versus magnesium sulfate added to intrathecal bupivacaine, and found that dexmedetomidine shortened the onset and prolonged the duration of spinal anesthesia. Another study proved superiority of intrathecal dexmedetomidine in comparison with clonidine and fentanyl, it provided prolonged motor and sensory block and reduced demand of additional analgesics *(Solanki et al., 2013)*. The current study results were in agreement with the studies comparing clonidine and dexmedetomidine in different doses as adjuncts to bupivacaine which found the duration of sensory and motor block to be prolonged with dexmedetomidine compared with clonidine. Postoperative analgesia was comparable in these two groups and superior compared to bupivacaine alone *(Al-Mustafa et al., 2013)*. Dexmedetomidine was tried as an adjunct to spinal bupivacaine through the intravenous route. It was found to prolong sensory and motor block with a good sedative effect *(Kaya et al., 2010)*. Compared with midazolam, intravenous dexmedetomidine had prolonged sensory block and longer time to first request for postoperative analgesia, whereas duration of motor block was similar *(Reddy et al., 2013)*. Similarly, premedication with intravenous dexmedetomidine is better than clonidine to provide intraoperative sedation and postoperative analgesia during bupivacaine spinal anesthesia for orthopedic lower limb surgery *(Bajwa et al., 2011)*.

The previously mentioned studies as well as the current study confirmed safety and hemodynamic stability of dexmedetomidine, whether administered intravenously or intrathecally as an adjuvant to spinal bupivacaine anesthesia.

In this study, dexamethasone was found to prolong the sensory blockade and prolong the time to first call for analgesia when added to intrathecal bupivacaine compared with bupivacaine alone. Intrathecal dexamethasone as an analgesic could be explained by influencing prostaglandin production. The results of the current study regarding dexamethasone went in line with a study conducted by Bani-Hashem who reported an increase in the duration of sensory block associated with the addition of intrathecal dexamethasone *(Bani-Hashem et al., 2011)*.

The study results showed that adding dexmedetomidine to intrathecal bupivacaine prolonged the sensory blockade duration by more than100% compared with bupivacaine alone, although the sensory blockade duration was prolonged by 33.3% when adding dexamethasone to intrathecal bupivacaine. The cost effectiveness of dexmedetomidine versus dexamethasone is an issue of conflict, as tangible cost of

dexmedetomidine is higher than dexamethasone. Yet, the intangible costs (hospital stay, wound infection, ICU stay if needed, antibiotics …. etc.) need to be considered in drug selection.

On the contrary to our study, there was no significant difference in motor block regression to Bromage 0 between the dexamethasone group and control (normal saline) group *(Nashwa et al., 2014).*

CONCLUSION

Addition of dexmedetomidine to intrathecal bupivacaine prolonged the duration of sensory and motor block, and prolongs postoperative analgesia compared with dexamethasone when added to intrathecal bupivacaine, with effective hemodynamic stability and limited frequency of adverse events in all groups.

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دراسة عملية للمقارنة بين حقن الديكسمتيدوميدين والديكساميثازون تحت الام العنكبوتية في اطالة زمن التخدير النصفي في جراحات عظام الطرف السفلي

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خلفية البحث: نظرا لسرعة إنتهاء مفعول التخدير النصفي، فقد أخذت الأبحاث في التطور للوصول إلى أقصى مدة ممكنة للتخدير النصفي وذلك عن طريق إضافة بعض المواد إلى المخدر النصفي والتي كان من ضمنها عقاري الديكسمتيدوميدين والديكساميثازون محل الدراسة الحالية.

الهدف من البحث: تقييم فعالية كلا من الديكساميثازون والديكسمتيدوميدين في إطالة زمن التخدير النصفي عند حقنهما تحت الأم العنكبوتية، وكذلك تقييم الاعراض الجانبية لكل منهما.

المرضي وطرق البحث: هذه الدراسة تم تنفيذها على 60 من المرضى الذين حضروا إلى مستشفى باب الشعرية والحسين الجامعي (مستشفيات جامعة الازهر) للقيام بجراحة عظام غير طارئة بالطرف السفلي. وقد تم أخذ التاريخ المرضي لجميع الحالات وانتقاء الحالات التي تدخل ضمن المجموعة الأولى أو الثانية ضمن تقييم الجمعية الأمريكية للتخدير، وذلك في الفترة من مارس الى نوفمبر 2020.

وقد تم تقسيم المرضى إلى ثلاث مجموعات متساوية: المجموعة الأولى تم إعطائها 10 ميكروجرام من عقار الديكسمتيدوميدين مع 2 مل من المخدر النصفي,والمجموعة الثانيه تم إعطائها 4 مللي جرام من عقار الديكساميثازون مع 2 مل من المخدر النصفي,والمجموعة الثالثة تم إعطائها 1 مل محلول ملحي طبيعي مع 2 مل من المخدر النصفي.

نتـــائج البحـــث: لـــم يكـــن هنـــاك فرقـــا إحصـــائيا بـــين المجموعـــات الثلاثـــة فيمـــا يتعلـــق بـــالعمر والنـــوع ومـــدة الجراحـــة، وكـــان الفـــرق الإحصـــائي فـــي وقـــت التخـــدير للأعصـــاب الحســـية الـــذي كـــان فـــي المجموعـــة الأولـــى (359.5) وفـــي المجموعـــة الثانيـــة (199.75) والمجموعـــة الثالثـــة (149.55)، وكـــذلك وقـــت تخـــدير الاعصـــاب الحركيـــة الـــذي كـــان للمجموعـــة الأولـــى (319) وللمجموعـــة الثانيـــة (170) وللثالثـــة (141). كمـــا لـــوحظ انخفـــاض عـــدد مـــرات الحاجـــة إلـــى المســـكنات بعـــد إجـــراء العمليـــة الجراحيـــة مـــع المجموعـــة الأولـــى عنـــه مـــع الثانيـــة والمجموعـــة الثالثـــة. وبالإشـــارة إلـــي الأعـــراض الجانبيـــة فلـــم يوجـــد فـــرق إحصـــائي بـــين الـــثلاث مجموعـــات مـــن حيـــث إنخفـــاض ضـــغط الدم وإنخفاض عدد نبضات القلب، والاحساس بالقيء، وكذلك القيء.

الاســـتنتاج: اضـــافة عقـــار الديكســـميتيدوميدين تحـــت الأم العنكبوتيـــة مـــع المخـــدر النصـــفي يزيـــد زمـــن التخـــدير الحســـي والحركـــي لاعصـــاب الطـــرفين الســـفليين، كمـــا يقلـــل الحاجـــة إلـــى المســـكنات بعـــد العمليـــات الجراحيـــة مقارنـــة بعقـــار الديكســـاميثازون، مـــع الحفـــاظ علـــى إســـتقرار العلامـــات الحيويـــة للمـــريض وعـــدم زيـــادة الأعـــراض الجانبية في أي من المجموعات عن الاخرى.

الكلمـــات الدالـــة: الديكســـميتيدوميدين تحـــت الأم العنكبوتيـــة، الديكســـاميثازون تحـــت الأم العنكبوتية، التخدير النصفي.