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Effect of dexmedetomidine infusion on incidence of postoperative delirium in elderly patients undergoing total hip arthroplasty: Randomised controlled double-blinded trial

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Abstract

Background: Pediatric patients are susceptible to significant levels of stress and anxiety during the phase of perioperative. The use of sedative premedication has the potential to mitigate the levels of anxiety and emotional distress experienced by individuals. The use of dexmedetomidine and midazolam as preoperative sedatives for pediatric patients has been more prevalent in recent years. However, the impact of these sedatives on postoperative respiratory adverse events (PRAEs) remains uncertain.

Objectives and Aims: The objective of this research is to assess the effectiveness of intranasal dexmedetomidine as a premedication for general anesthesia in pediatric patients who are having adenotonsillectomy and have respiratory comorbidities.

Methods and Subjects: The present research was conducted at Tanta University Hospitals, specifically in the Department of Anesthesiology. It used a prospective double-blind randomized controlled trial (RCT) and focused on pediatric patients who were scheduled to undergo adenotonsillectomy and had a recent mild infection of upper respiratory tract.

Results: A statistically important variance was observed among the groups under study in terms of Total PRAEs. Additionally, a comparison among the two group's revealed differences in heart rate (HR), excluding the baseline HR, as well as at fifteen minutes post sedation, thirty minutes post sedation, at induction, fifteen minutes intraoperatively, and thirty minutes intraoperatively in terms of mean arterial blood pressure (MAP) measured in millimeters of mercury (mmHg).

Conclusion: The results of this research indicate that intranasal administration of dexmedetomidine might effectively induce sedation before to surgery and perhaps mitigate the risk of PRAEs.

Keywords: Dexmedetomidine, postoperative delirium, elderly, total hip arthroplasty

Introduction

Delirium is a sudden condition of confusion marked by a decrease in the capacity to concentrate, maintain, or change attention, as well as cognitive alterations such as loss of memory, disorientation, linguistic disruption, and perceptual disruption ^[1]. Postoperative delirium (POD) is a type of delirium that occurs in patients following surgical operations and anaesthesia. It often reaches its highest point within 1-3 days following the procedure ^[2].

The incidence of POD is 2-3% in general surgical population and 50-70% in high-risk patients' group ^[3, 4]. Delirium is a frequently observed postoperative consequence in older people who are undergoing significant surgical procedures associated with many risks' predictive factors in such age group including pre-existing cognitive dysfunction, poor physical condition, alcoholism, memory impairment and preexisting neurological disorders ^[5, 6].

The postoperative complication known as the POD is a significant issue that frequently results in unfavourable outcomes, such as higher death rates, longer stays in the hospital, functional disability, placement in long-term care facilities, and increased hospitalisation expenses ^[7, 8].

Regarding preventive measures of POD, many modalities have been identified including limitations of use of benzodiazepines ^[9, 10], multi modal analgesia, total intravenous anesthesia (TIVA) and avoidance of perioperative metabolic derangements (hypoxia and

hypoglycemia) [11].

Dexmedetomidine is a medication that specifically activates alpha 2 receptors in the body. It has analgesic, sedative, anxiolytic and hypotensive properties, which reduce the sympathetic responses to surgeries and stress. Furthermore, it has the added benefit of reducing the need for opioids and does not dramatically decrease respiratory drive [12].

Dexmedetomidine exhibits neuroprotective properties and has been associated with reduced stress, inflammatory response, and increased postoperative cognitive function [13, 14].

Several meta-analyses have specifically focused on the utilisation of dexmedetomidine as a preventive measure against delirium in older individuals who were admitted to the intensive care unit (ICU), without differentiating between surgical and non-surgical cases. The meta-analyses demonstrated that administering dexmedetomidine in the ICU can decrease the occurrence of delirium [15, 16]. Additional meta-analyses were conducted specifically on adult patients who were undergoing heart surgeries. Insufficient data exists about the usage of dexmedetomidine in noncardiac surgery patients during the perioperative period.

We hypothesized that intraoperative dexmedetomidine administration may decrease the frequency of POD in older individuals undergoing THA. The purpose of this work was to assess the impacts of intraoperative dexmedetomidine administration on incidence of POD in elderly individuals undergoing total hip arthroplasty.

Patients and Methods

This prospective randomised controlled double-blinded work had been performed on 70 adult individuals aged above 65 years old, both genders, body mass index (BMI) (18.5-29.9) kg/m², American Society of Anesthesiologists (ASA) I-III physical status, scheduled to undergo unilateral total hip arthroplasty. The study had been performed from October 2022 to September 2023 following permission from the Ethics Committee Tanta University Hospitals (approval code: 35848/9/22), Tanta, Egypt. All subjects submitted a well-informed written consent.

Criteria for exclusion included a previous medical history of neurological or psychiatric disorder or stroke, as well as a history of drug, opiate or alcohol abuse, allergy to dexmedetomidine, major renal, or hepatic diseases, illiteracy and severe hearing or visual impairment which may interfere with communication, second- or third-degree heart block, sick sinus syndrome, or clinically severe sinus bradycardia, perioperative serious cardiopulmonary complication revision of previous total hip arthroplasty.

Randomization and blindness

The participants had been randomised by computer generated number into two equal groups (35 patients each) and the result of randomisation was sealed in sequentially numbered opaque envelopes. Dexmedetomidine Group (group D): received intraoperative dexmedetomidine infusion (Medrelaxmidine, ARABCOMED, Egypt, (200 µg/50 ml) in a dose of 0.3 µg/kg/hour. Control Group (group C): received equivalent volume of saline infusion. The concealment of information with regards to randomization, preparation of the drug of the study, and allocation of groups was implemented to ensure that patients, investigators involved in gathering information and

postoperative follow-up, anaesthetists, and other healthcare workers caring for patients were unaware of these details.

Throughout the study, a nurse who wasn't involved in anaesthesia or surgery prepared the medicines. These drugs were then given to the anaesthetists responsible for the patients participating in the study. This process ensured that the patients were randomly assigned to receive either dexmedetomidine or a placebo. The research medications, dexmedetomidine (200 µg/50 ml) or normal saline (50 ml), were transparent and supplied in syringes of identical size and brand.

Each recipient had been exposed to taking of history, clinical assessment, laboratory tests [full blood picture (CBC), activated partial thromboplastin time (APTT), international normalized ratio (INR), Na⁺, K⁺, liver and kidney function tests].

During the pre-anaesthetic assessment, all patients were familiarized with Visual analogue scale (VAS) [17] and confusion assessment method (CAM) [18]. Patients were not medicated prior to surgery and anaesthetists were instructed to avoid administration of benzodiazepines.

General anaesthetic technique was standardized for all patients. On arrival at operation room, intravenous (IV) cannula was established, and participants received monitoring employing non-invasive blood pressure (NIBP), ECG, pulse oximetry, bispectral index (BIS), end tidal CO₂, and temperature. An infusion of saline placebo or dexmedetomidine (0.3 µg/kg /hr) was initiated 5 minutes before induction of general anaesthesia till the end of surgery. General anesthesia had been produced by fentanyl (1 µg/kg), propofol (1.5-2 mg/kg), atracurium (0.5 mg/kg). Tracheal intubation was done 3 minutes after anaesthesia induction.

Anaesthesia was maintained using isoflurane (1-1.5%) in O₂-air (50%-50%). Incremental dosages of atracurium (0.1 mg/kg) were given as needed. Additional dose of fentanyl (0.5 µg/kg) were given as well.

Anesthetic agent was modified to keep BIS between 40-60 and alterations in mean arterial pressure (MAP) and heart rate (HR) within 20% of the preoperative base line. During surgery, lactated ringer solution at a rate of 10 ml/kg/hr was given. A decrease in MAP more than 20% below baseline level was corrected with ephedrine (10 mg) that would have been repeated once as needed. A decrease in the HR below 60 beat/min was managed with IV atropine 0.5 mg. The infusion of the drug of the study had been stopped if there were severe bradycardia, hypotension or new-onset atrioventricular blockade that didn't enhance following routine therapy, or any instances which the anaesthetist recognized necessary.

At the end of surgery, patients were extubated after reversal of muscle relaxant using neostigmine (0.05 mg/kg) and atropine (0.01 mg/kg)

Postoperatively, patient was transferred to PACU. Immediately after transfer to PACU, patients received ketorlac tromethamine (30 mg) then every 8 hours and paracetamol (1 gm) IV which repeated every 6 hours. Postoperative pain had been evaluated utilising the VAS score (0 point indicates no pain and 10 indicate maximum pain). Patients received morphine in a dose of 0.05 mg /kg if VAS score is ≥4. The time at which the initial administration of morphine after surgery occurred and the total amount of opioids administered postoperatively have been recorded. Incidence of POD in the 1st 5 days following

surgery evaluated utilising confusion assessment method (CAM) which was performed preoperatively, in PACU when the patients fulfilled the criteria for discharge from PACU to the ward, and 12 h intervals for 5 days following surgery. The CAM algorithm has four clinical criteria: (1) sudden onset and fluctuating progression; (2) lack of focus; (3) disorganised cognition; and (4) changed state of awareness. In order to diagnose delirium, it is necessary for both the first and second criteria to be present, as well as either the third or fourth criteria, or both [19]. Participants were classified as either CAM positive (indicating the presence of delirium) or CAM negative (indicating the absence of delirium). The diagnosis of delirium was verified and addressed by psychiatrist consultation.

The primary outcome was the incidence of POD in the 1st five days after surgery. The secondary outcomes were postoperative pain score in the 1st 24 hours postoperatively, postoperative opioid consumption, postoperative sedation score, length of hospital stay and adverse effects.

Sample Size Calculation

The sample size and power analysis were computed utilising the Epi-Info software statistical tool developed by the World Health Organisation and the Centres for Disease Control and Prevention, Atlanta, Georgia, USA version 2002. The criteria employed for calculating the sample size have been as follows: The study has a 95% confidence level and 80% statistical power. The prevalence of delirium in geriatric individuals after major non-cardiac surgery is substantial

with an average of 40% and we expected to reduce it to 10% in the treatment group. The sample size depending on the previously mentioned criteria was found at $N > 33$ in each group. The researcher raised the sample size to 35 to compensate for dropout cases.

Statistical analysis

The statistical analysis was conducted using SPSS v26 software (IBM Inc., Chicago, IL, USA). The normality of the data distribution was assessed using the Shapiro-Wilks test and histograms. The mean and standard deviation (SD) of the quantitative parametric variables was displayed and contrasted between both groups using an unpaired Student's t-test. The quantitative non-parametric data were reported using the median and interquartile range (IQR) and were analysed using the Mann Whitney-test. The qualitative variables were displayed as frequencies and percentages (%) and were analysed using the Chi-square test or Fisher's exact test, as appropriate. A two tailed P value < 0.05 was considered statistically significant.

Results

A total of 78 individuals were evaluated for their suitability, with five patients not meeting the specified requirements and three patients declining to take part in the study. The remaining 70 individuals were assigned randomly to two groups, with 35 individuals in each group. Statistical analysis was conducted on all 70 individuals that were followed up. Figure 1.

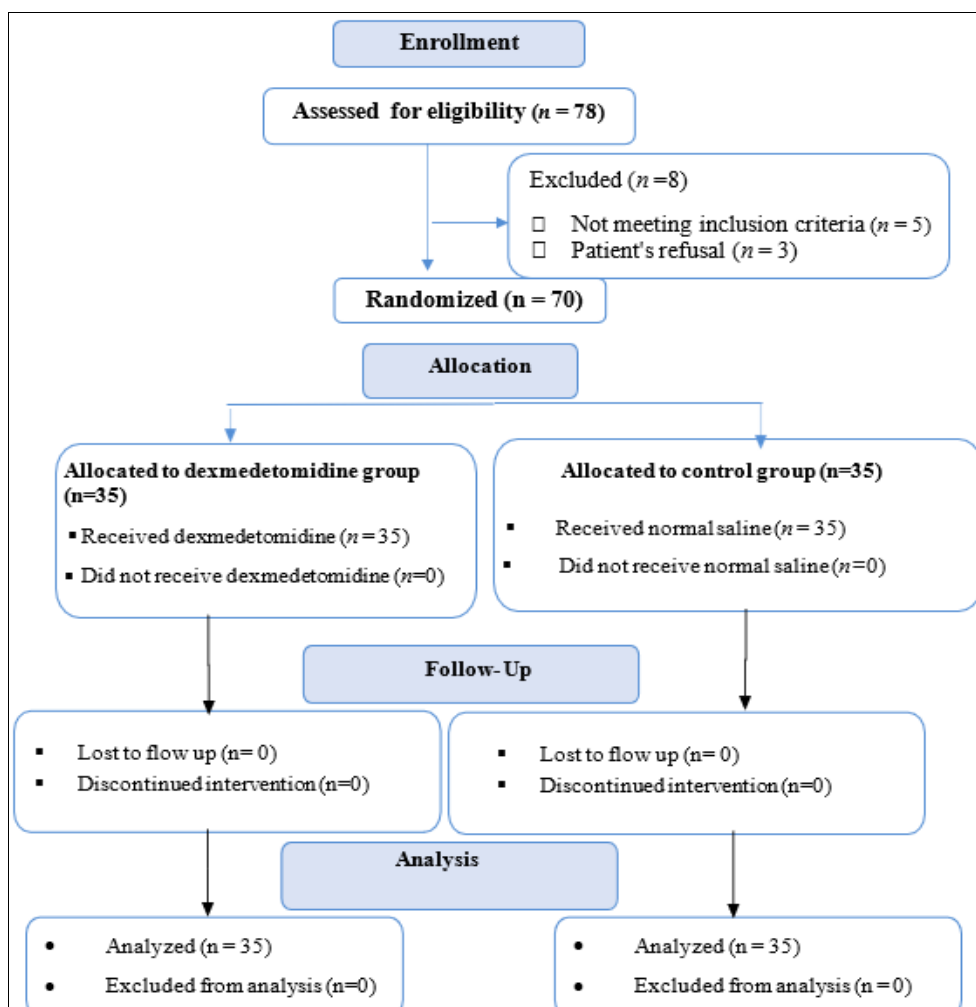


Fig 1: CONSORT flow diagram of the participants

No statistically substantial variation was existed among dexmedetomidine group and control group as regard age, sex, BMI and ASA physical status, surgery' duration, intraoperative blood loss and number of transfused packed

RBCs. The incidence of POD was substantially greater in control group contrasted to dexmedetomidine group, ($p=0.004$). Table 1

Table 1: Demographic data, duration of surgery, intraoperative blood loss and transfusion, incidence of POD in the two studied groups

		Dexmedetomidine group(n=35)	Control group (n=35)	P
Age (years)		69.69 ± 5.22	69.63 ± 4.69	0.962
Sex	Male	19 (54.3%)	21 (60%)	0.629
	Female	16 (45.7%)	14 (40%)	
BMI (kg/m ²)		27.0(25.0 – 28.0)	27.70(25.0 – 29.0)	0.465
ASA classification	I	5(14.3%)	6(17.1%)	0.800
	II	23(65.7%)	24(68.6%)	
	III	7(20%)	5(14.3%)	
Duration of surgery (hours)		2.50(2.43-3.0)	2.50(2.45-3.0)	0.777
Intraoperative blood loss (ml)		350.0(300.0-400.0)	350.0(300.0-400.0)	0.868
Intraoperative blood transfusion	No	27(77.1%)	24(68.6%)	0.787
	One unit	7(20.0%)	10(28.6%)	
	2 unit	1(2.9%)	1(2.9%)	
Incidence of POD		3(8.6%)	13(37.1%)	0.004*

Data are presented as mean ± SD or frequency (%). BMI: Body mass index, ASA: American Society of Anaesthesiologists, POD: Postoperative delirium.

Number of patients developed +Ve CAM test was substantially greater in control group contrasted to dexmedetomidine group at 12 hrs postoperatively, day 1 (morning and evening) and evening of day 2

postoperatively. Postoperative RAAS on PACU admission, at 12h, day1 evening, day 2 (morning and evening) and day 3 evening were substantially decreased in dexmedetomidine group contrasted to control group ($p<0.05$). Table 2

Table 2: Postoperative CAM and RAAS changes in both groups

		Dexmedetomidine group(n=35)	Control group (n=35)	P
CAM				
Day 0	PACU	3(8.6%)	8(22.9%)	0.101
	12 hr.	2(2.7%)	11(31.4%)	0.006*
Day 1	Morning	2(5.7%)	9(25.7%)	0.022*
	Evening	2(5.7%)	9(25.7%)	
Day 2	Morning	1(2.9%)	6(17.1%)	0.106
	Evening	0(0.0%)	8(22.9%)	0.005*
Day 3	Morning	0(0.0%)	1(2.9%)	1.000
	Evening	0(0.0%)	4(11.4%)	0.114
Day 4	Morning	0(0.0%)	2(5.7%)	0.493
	Evening	0(0.0%)	0(0.0%)	--
Day 5	Morning	0(0.0%)	0(0.0%)	--
	Evening	0(0.0%)	0(0.0%)	--
RAAS				
Day 0	PACU	-1.0 (-2.0 – -1.0)	0.0 (-1.0 – 0.0)	<0.001*
	12 hr.	0.0 (0.0 – 0.50)	0.0 (-1.0 – 0.0)	<0.001*
Day 1	Morning	0.0 (0.0 – 0.0)	0.0 (-0.5 – 0.0)	0.763
	Evening	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.049*
Day 2	Morning	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.047*
	Evening	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.006*
Day 3	Morning	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.079
	Evening	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.041*
Day 4	Morning	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	0.317
	Evening	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	1.000
Day 5	Morning	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	--
	Evening	0.0 (0.0 – 0.0)	0.0 (0.0 – 0.0)	--

Data are presented as frequency (%) or median (IQR). *Significant p value < 0.05, CAM: Complementary and alternative medicine, RAAS: renin-angiotensin-aldosterone system, PACU: Post Anesthesia Care Unit.

In dexmedetomidine group and control group, the median postoperative VAS scores at 6 h, 12 h and 24 h postoperatively were insignificantly different as compared to the median postoperative VAS score on admission to

PACU of the same group. The median postoperative VAS scores in dexmedetomidine group were significantly decreased as contrasted to control group on admission to PACU, at 6 h, 12 h and 24 h postoperatively. Table 3

Table 3: Postoperative VAS score changes in both groups

	Dexmedetomidine group(n=35)	Control group (n=35)	P
PACU admission	2.0 (2.0 – 2.0)	3.0 (3.0 – 4.0)	<0.001*
6 h	2.0 (2.0 – 3.0)	3.0 (2.0 – 4.0)	0.032*
12 h	2.0 (1.0 – 3.0)	3.0 (2.0 – 3.0)	0.040*
24 h	2.0 (2.0 – 3.0)	3.0 (2.0 – 4.0)	0.013*
P ₀	>0.05*		

Data are presented as median (IQR). *Significant p value < 0.05, p₀: p value for comparing between PACU and each other periods within the same group. VAS: visual analogue score, PACU: Post Anesthesia Care Unit.

Number of patients developed hypoactive delirium was substantially lower in dexmedetomidine group contrasted to control group ($p=0.011$). The delirium' duration was insignificantly various among the two groups under the study. The median (IQR) time to first postoperative

morphine administration was significantly longer in dexmedetomidine group than control group ($p<0.001$). The median total dose of postoperative morphine consumption was substantially prolonged in control group contrasted to in dexmedetomidine group ($p<0.001$). Table 4

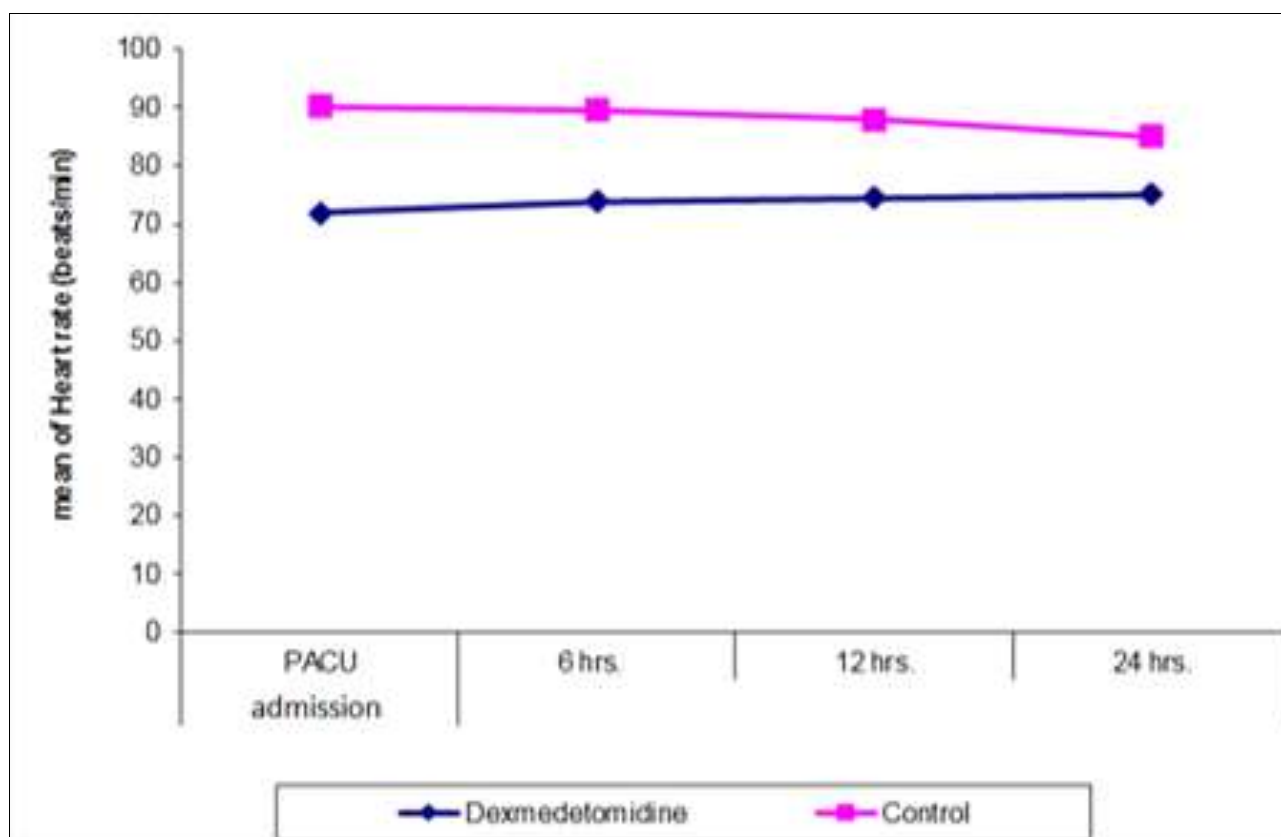
Table 4: Types and duration of delirium, time to first postoperative morphine administration and total dose of postoperative morphine consumption in both groups

	Dexmedetomidine group (n=35)	Control group (n=35)	P
Hyperactive	0(0.0%)	1(2.9%)	0.314
Hypo active	2(5.7%)	10(28.5%)	0.011*
Mixed	1(2.9%)	2(5.7%)	0.555
Duration of Delirium	36.0(30.0-42.0)	60.0(36.0-72.0)	0.146
Time to first postoperative morphine administration (hours)	11.0(8.0-15.50)	6.0(0.25-7.0)	<0.001*
Total dose of opioids (mg)	12.0(10.0-15.50)	20.0(15.0-25.0)	<0.001*

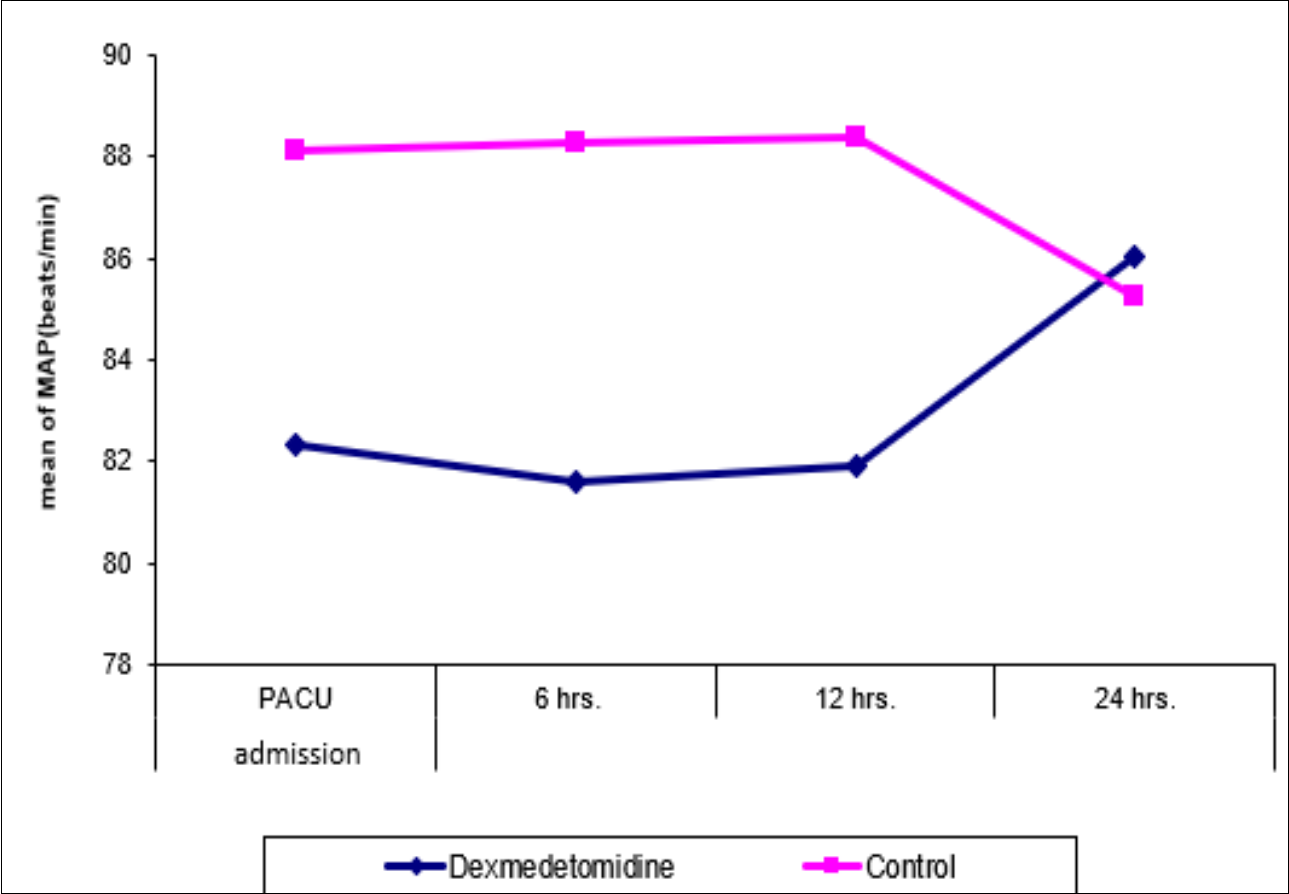
Data are presented as frequency (%) or median (IQR). Significant p value < 0.05.

Postoperative HR, MAP and O₂ saturation at 6 h, 12 h, 24 h postoperatively were insignificantly different as compared to HR and MAP value on admission to PACU of the same group, while HR were substantially decreased in

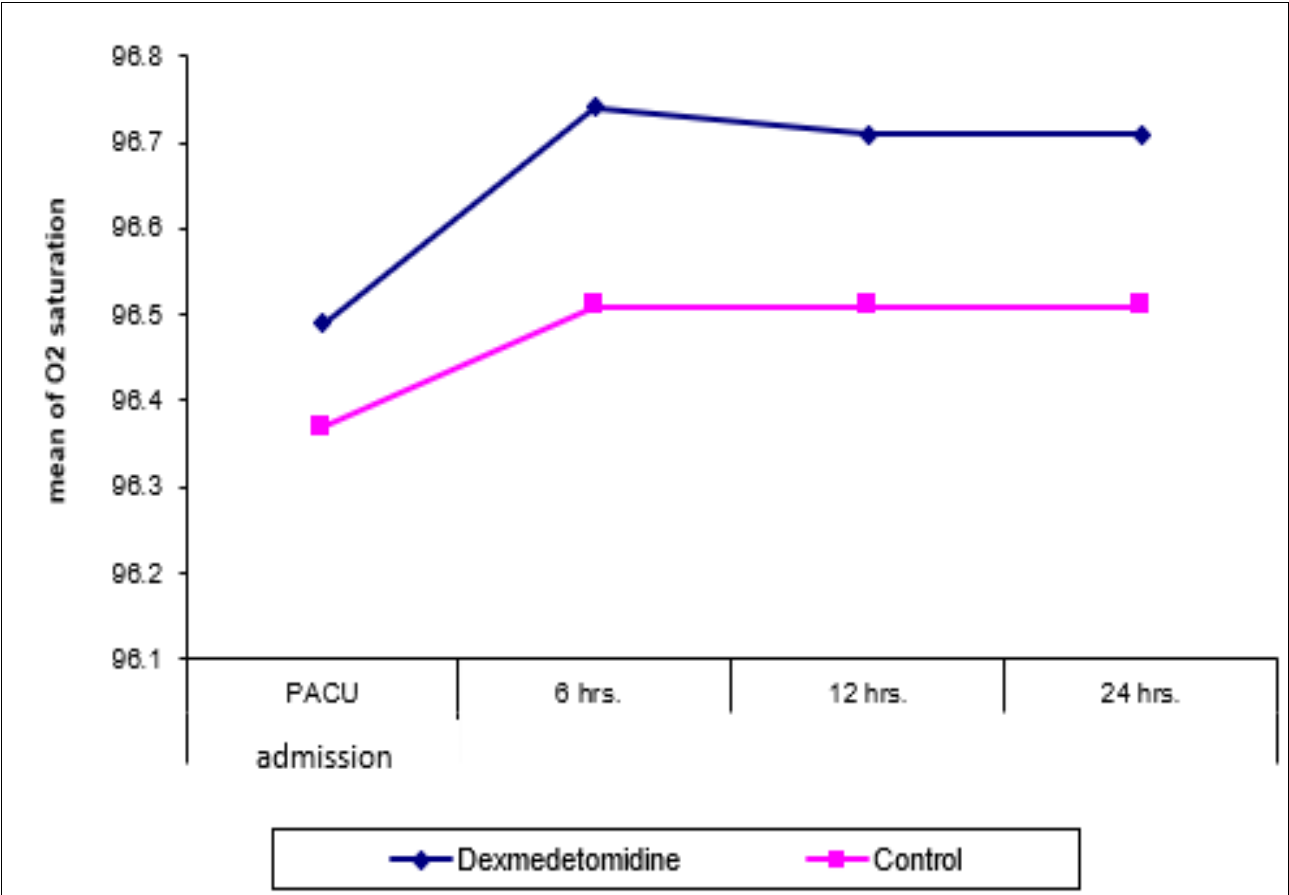
dexmedetomidine group contrasted to control group on admission to PACU, at 6 h, 12 h and 24 h postoperatively. Figure 2.



(A)



(B)



(C)

Fig 2: Postoperative (A) heart rate (beats/min), (B) mean arterial blood Pressure (mmHg) and (C) postoperative O₂ saturation (%) changes in both groups

There was insignificantly different between the studied groups regarding length of hospital stay and adverse effects.

Table 5.

Table 5: Length of hospital stay and adverse effects in both groups.

		Dexmedetomidine group (n=35)	Control group (n=35)	P
Length of hospital stay (d)		6.0(6.0 – 6.0)	6.0(6.0 – 6.0)	0.235
Adverse effects	Hypotension	8 (22.9%)	7 (20.0%)	0.771
	Bradycardia	5 (14.3%)	1 (2.9%)	0.088

Data are presented as frequency (%) or median (IQR).

Discussion

The findings of our work showed that dexmedetomidine group had lower incidence of POD in the 1st 5 days postoperatively, lower postoperative VAS score, lower postoperative morphine consumption and longer time to 1st postoperative morphine administration than the control group. The duration of delirium, length of hospital stays, and the incidence of adverse effects were insignificantly different among both groups.

Regarding frequency of POD, our results showed that the frequency of POD and the number of patients developed hypoactive delirium were substantially greater in control group contrasted to dexmedetomidine group. However, the duration of delirium was insignificantly various among the two studied groups. Our results matched with Xuan *et al.* [20] who reported that the frequency of POD was significantly decreased in the dexmedetomidine group contrasted to the placebo group. Moreover, Yan C and Ti-jun D [21] reported that Administering dexmedetomidine intravenously not only decreases the occurrence and duration of POD, but also reduces the time of hospitalisation in older patients who have undergone total hip arthroplasty.

On the other side, Hong *et al.* [22] reported that on the first postoperative day, the incidence of delirium was marginally reduced in patients administered dexmedetomidine compared to those who received placebos. However, while the addition of dexmedetomidine to analgesia decreased the likelihood of delirium by approximately 33%, the observed difference did not reach statistical significance.

The positive impacts of dexmedetomidine on lowering POD can be attributed to its ability to alleviate surgery-induced neuroinflammatory processes and potentially provide neuroprotective properties [23]. Dexmedetomidine has been found to have the ability to suppress cerebral inflammatory responses and decrease the generation of peripheral serum TNF- α , as demonstrated in preclinical experimental models [24].

Furthermore, it should be noted that Dexmedetomidine possesses analgesic properties, resulting in a reduction of the intensity of postoperative pain in individuals who are administered Dexmedetomidine. Furthermore, the pain-relieving impact of dexmedetomidine may reduce the need for opioids, thereby lowering the occurrence of delirium. This is significant because opioids have been associated with the onset of delirium [25]. Due to the fact that acute pain plays a major role in causing delirium, it is possible that the analgesic effects of Dexmedetomidine may have helped decrease delirium among individuals who received treatment. Dexmedetomidine may maintain neural connection by creating a sleep-like electroencephalography pattern and a non-rapid eye movement sleep-like state. As a result, sleep quality is enhanced. Severe pain and low sleep quality are significant risk factors for POD, and the improvements generated by dexmedetomidine in both pain

and sleep quality may have led to a decrease in delirium [26]. Regarding postoperative pain, our results revealed that administration of dexmedetomidine was correlated with lower postoperative pain scores, lower postoperative consumption of morphine and longer time to first postoperative morphine administration. The beneficial effects of dexmedetomidine administration on postoperative analgesia and opioid consumption were proved by Hong *et al.* [22] who reported that the dexmedetomidine group experienced reduced levels of pain severity at rest and during movement compared to the placebo group over the initial 5 days following the surgery. As well, Abdelzaam *et al.* [25] reported that VAS was substantially decreased in the dexmedetomidine group immediately postoperative and up to 4 hours when contrasted to control group. On the contrary, Yan C and Ti-jun D [21] stated that no statistically substantial variation was existed in VAS scores among the dexmedetomidine group and control group at rest and motion on days 1, 2, and 3 after surgery.

As regards the reported hemodynamics in our study, dexmedetomidine group had lower postoperative HR and MAP as compared to the control group. Liu *et al.* [27] concluded that compared to normal saline group, a substantial reduce in MAP was existed in the dexmedetomidine group at many time points, including incision in skin, end of operation, and from extubation until 30 min following extubation. However, a few differences existed in the changes in HR compared to the normal saline group throughout the entire perioperative period. On the other side Abdelzaam *et al.* [25] reported that regarding HR and MAP postoperatively, no significant variations were existed in measurements among dexmedetomidine, control and haloperidol groups.

Regarding postoperative RAAS score, it was substantially decreased in dexmedetomidine group than control group on PACU admission, at 12h, day1 evening, day2(morning and evening) and day 3 evening. Our results agreed with Liu *et al.* [27] reported that based on the Riker Sedation-agitated Scale, dexmedetomidine substantially alleviated emergency agitation or delirium contrasted to normal saline group. On the contrary Hong *et al.* [22] reported that The RAAS scores of patients receiving dexmedetomidine and placebo were comparable over the initial 5 days after surgery.

Our current work revealed, no statistically substantial variation was existed between the studied groups as regard length of hospital stay and incidence of adverse effects (hypotension and bradycardia). Our results supported by Hong *et al.* [22] and Liu *et al.* [27] reported that no statistically substantial variation was existed between dexmedetomidine and placebo groups regarding length of hospital stay. On the contrary, Yan C and Ti-jun D [21] and Lv and Gu [28] reported that the average length of hospital stay in dexmedetomidine group was substantially decreased contrasted to that in control group.

Limitations of this study including that small sample size and lack of ability to undertake long-term patient follow-up. The impact of dexmedetomidine on people undergoing neuraxial anaesthesia are uncertain. This study was conducted on individuals over 65 years of age and data in younger patients could not be evaluated. Additionally, the study did not compare different doses of dexmedetomidine, nor other drugs known to reduce POD.

Conclusions

Administration of intraoperative dexmedetomidine provided lower incidence of POD, lower post operative pain score, lower total dose of post operative consumption of morphine and longer time to first postoperative morphine administration compared the control group with no significant variation in duration of delirium and incidence of adverse effects between the two studied groups.

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Conflict of Interest: Nil

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