Original Article

The effect of adding dexmedetomidine or dexamethasone to bupivacaine–fentanyl mixture in spinal anesthesia for cesarean section

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Abstract

Background and Aims: Many strategies are available to prevent spinal-induced hypotension in cesarean section, especially the use of a low dose of spinal anesthesia combined with adjuvants. This study investigated the effect of adding either dexmedetomidine or dexamethasone to the intrathecal bupivacaine–fentanyl mixture on the postoperative analgesia duration, after elective cesarean section.

Material and Methods: This prospective, randomized, double-blind study was conducted on 90 full-term parturients undergoing elective cesarean section, who were randomly distributed into three groups. They all received spinal anesthesia with the bupivacaine–fentanyl mixture (2.5 ml), in addition to 0.5 ml normal saline (*control group*), 5 μg dexmedetomidine dissolved in 0.5 ml normal saline (*dexmedetomidine group*), or 2 mg dexamethasone (*dexamethasone group*). The time to the first request of morphine rescue analgesia was recorded, in addition to the total dose of morphine consumed in the first 24 h after surgery, the postoperative numerical rating score (NRS), and maternal and fetal outcomes.

Results: As compared to the control group and the dexamethasone group, the use of dexmedetomidine as an additive to the bupivacaine–fentanyl mixture significantly prolonged the time to the first request of rescue analgesia, decreased postoperative morphine consumption, and decreased the pain score 4 and 6 h after surgery. There was an insignificant difference between the control and dexamethasone groups.

Conclusion: The use of dexmedetomidine as an additive to bupivacaine–fentanyl mixture in spinal anesthesia for cesarean section prolonged the postoperative analgesia and decreased the postoperative opioid consumption in comparison to the addition of dexamethasone or normal saline.

Keywords: Cesarean section, dexmedetomidine, dexamethasone, postoperative pain, spinal anesthesia

Introduction

Spinal anesthesia is commonly used in cesarean section (CS) surgery. However, it could be associated with many side effects, especially hypotension.[1] Many strategies are available to prevent spinal-induced hypotension in CS, especially the use of a low dose of spinal anesthesia associated with adjuvants.[2] Intrathecal administration of opioids allows reduction of the local anesthetic dose, potentiates analgesic potency, and minimizes potential side effects.[3,4]

Dexmedetomidine is an α2 adrenergic receptor agonist that has an analgesic effect. Although not approved by the US Food and Drug Administration (US FDA), some studies suggest that its administration via the intrathecal route can prolong the effect of postoperative analgesia.[5] It acts through

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Access this article online

Quick Response Code:

Website: https://journals.lww.com/joacp

DOI: 10.4103/joacp.joacp_396_22

How to cite this article: Ahmed SA, Lotfy HA, Mostafa TA. The effect of adding dexmedetomidine or dexamethasone to bupivacaine–fentanyl mixture in spinal anesthesia for cesarean section. J Anaesthesiol Clin Pharmacol 2024;40:82-9.

Submitted: 13-Nov-2022 **Accepted:** 20-Dec-2022 **Published:** 14-Mar-2024

a different mechanism than that of intrathecal opioids, and thus, both combined improve postoperative analgesia without increasing the side effects.[6]

Dexamethasone may have an analgesic effect through reducing the inflammatory process, blocking nociceptive C-fibers transmission, or suppressing the neural ectopic discharge. Its use as an adjuvant in peripheral nerve block prolongs postoperative analgesia.[7] It can also be used as an intrathecal adjuvant without reported complications.[8]

The authors hypothesize that the use of a low dose of dexmedetomidine or dexamethasone as an adjuvant to bupivacaine–fentanyl mixture in spinal anesthesia for patients undergoing CS may improve postoperative analgesia without inducing severe hemodynamic changes. This study was conducted to evaluate the duration of postoperative analgesia (primary outcome) and postoperative morphine consumption (secondary outcome) with the addition of dexmedetomidine or dexamethasone to bupivacaine–fentanyl in spinal anesthesia for CS.

Material and Methods

The authors first explained to the local Research Ethical Committee that intrathecal administration of dexmedetomidine and dexamethasone is safe based on previous studies,[5,8] although it is not yet approved by FDA. After obtaining approval from the Ethics Committee (approval code: 33840/06/20), the trial was registered on clinicaltrial.gov (ID: NCT04464616), after which the first patient was enrolled on July 15, 2020. The last patient was enrolled on January 20, 2021. All enrolled parturients signed an informed written consent to participate in the study.

Full-term pregnant females undergoing elective CS under spinal anesthesia were included in the study. The exclusion criteria were as follows: patients' refusal to participate in the study, body mass index (BMI) greater than 35 kg/m^2, height less than 160 cm, gestational age less than 37 weeks, and presence of diabetes mellitus or preeclampsia, eclampsia, cardiac diseases, coagulopathy, psychological or neurological disorders, allergy to the study medications, or antepartum hemorrhage.

Randomization was performed by an independent data manager who assigned the patients to their groups based on a computer-generated software of randomization. Distribution was introduced in closed opaque envelopes to divide the patients into three groups as follows.

Group I (control group): Spinal anesthesia was given by injecting 3 ml composed of 10 mg hyperbaric bupivacaine 0.5% (2 ml), 25 μg fentanyl (0.5 ml), and normal saline (0.5 ml).

Group II (dexmedetomidine group): Spinal anesthesia was given by injecting 3 ml composed of 10 mg hyperbaric bupivacaine 5% (2 ml), 25 μg fentanyl (0.5 ml), and 5 μg dexmedetomidine (preservative free) dissolved in 0.5 ml normal saline.

Group III (dexamethasone group): Spinal anesthesia was given by injecting 3 ml composed of 10 mg hyperbaric bupivacaine 5% (2 ml), 25 μg fentanyl (0.5 ml), and 2 mg preservative-free dexamethasone (0.5 ml).

All the patients were assessed preoperatively with adequate neurological examination. Intravascular access was established once the patients were admitted to the operating room. The patients were then connected to the monitor. An anesthesia resident who was not participating in the study and had no subsequent role in it helped in the preparation of the local anesthetic mixtures under complete aseptic conditions in uniform sterile syringes (3 ml in each syringe containing 2 ml of hyperbaric bupivacaine [10 mg], 0.5 ml fentanyl [25 μg], and 0.5 ml normal saline [group I], 0.5 ml normal saline containing 5 μg dexmedetomidine [group II], or 2 mg dexamethasone [group III]).

In a sitting position and under complete aseptic conditions, spinal anesthesia was performed at the level of L3–L4 or L4–L5 intervertebral spaces using a 25-gauge pencil-point spinal needle, with injection of the pre-prepared anesthetic mixture. Then, the patients were turned to supine position with left lateral uterine displacement with a starting fluid co-load consisting of 7 ml/kg of lactated Ringer's solution. Oxygen was supplied to all patients using a nasal cannula at a flow rate of 3 l/min. Maternal hypotension (systolic blood pressure less than 90 mmHg or a decrease of more than 20% from baseline) was managed by 100 μg phenylephrine and a 250 ml bolus of lactated Ringer's solution. Maternal bradycardia was managed by 0.3 mg of intravenous (IV) atropine.

Sensory blockade was assessed by pinprick test using a 27-gauge needle from caudal to cranial direction every 2 min until the sensory block reached the level of T4. Motor block was assessed by modified Bromage score[9] every 5 min until a score of 2 or 3 was reached. If the satisfactory sensory and motor blockade level was not achieved within 20 min, the patient received general anesthesia and was excluded from the study. All patients received 1 g paracetamol IV infusion every 6 h and ketorolac 30 mg IV every 12 h as routine postoperative analgesia.

An assistant nurse not participating in the study and blinded to its groups helped in obtaining and recording the measurements. The postoperative numerical rating score (NRS) of pain (metric score 0–10 for assessment of the severity of pain, where 0 = no pain and 10 = maximal pain) was evaluated immediately after surgery and then every 2 h till 8 h, and then every 4 h till 24 h. When the NRS reached 4 or more, 3 mg IV morphine was given and repeated whenever required. The time to the first request for rescue analgesia, which is the time interval from the end of the surgery till the first request of morphine, was calculated (primary outcome). The total dose of morphine consumed in the first 24 h after surgery was also recorded (secondary outcome).

The onset of sensory block (time interval from intrathecal injection to reaching the sensory block at T4) was recorded in addition to the duration of sensory block (time interval from reaching the level of sensory block to T4 to the first request of postoperative rescue analgesia). The onset of motor block (time from intrathecal injection to reaching a Bromage score of 2) and the duration of motor block (time elapsed between reaching the highest Bromage score and reaching a score of 0) were recorded.

The incidence of postoperative nausea and vomiting (PONV) was graded as none (0) (no episode of nausea or vomiting), mild (1) (one episode of nausea that was resolved without treatment), moderate (2) (repeated episodes of nausea that were resolved with treatment), and severe (3) (continuous episodes of nausea or vomiting).[10] PONV was treated by administering 4 mg IV ondansetron that could be repeated. The incidence and intensity of shivering were also assessed intraoperatively and postoperatively in the recovery room using the method of Tsai and Chu as follows: 0, no shivering; 1, peripheral vasoconstriction without visible shivering; 2, muscular activity in only one muscle group; 3, muscular activity in more than one muscle group; and 4, shivering involving the whole body.[11] The maternal level of sedation was assessed in the recovery room by the 4-point scale of Filos *et al*.[12] (1 = awake and alert; 2 = somnolent, responsive to verbal stimuli; 3 = somnolent, arousable to physical stimuli; and 4 = unarousable).

The incidence of bradycardia, hypotension, or pruritis was also recorded. The Apgar score was assessed at 1 and 5 min after delivery to assess the neonatal outcome.[13] On the next day after delivery, the quality of the recovery of parturient was assessed by the obstetric quality of recovery-11score (ObsQoR-11). It is a score that is composed of multiple items with grading of each item from 0 to 10, where 0 = strongly agree and 10 = strongly disagree.[14] All the enrolled mothers and their babies underwent neurological and general examination at 2, 4, and 6 months after delivery for the presence of any neurological or other adverse disorders.

Statistical analysis

Based on a previous study,[6] sample size calculation revealed that at least 26 patients were required in each group to detect a significant change in the time to the first request of rescue analgesia of 60 min at 0.05 alpha value and 90% power of the study. To overcome the possibility of dropout cases, 30 patients were included in each group. The Statistical Package for the Social Sciences (SPSS) computer program (SPSS Inc., Chicago, IL, USA) was used in the statistical analysis of the recorded data. Categorical data were presented as numbers and frequencies (%) after analysis using the Chi-square test, while parametric data were analyzed by one-way analysis of variance (ANOVA) test and *post hoc* Tukey's honest significant difference (HSD) test and expressed as mean ± standard deviation. Kruskal–Wallis test was used for the statistical evaluation of nonparametric data, which are expressed as median and interquartile range with intergroup comparison carried out using Mann–Whitney test. The results were statistically significant when the *P*-value was less than 0.05.

Results

One hundred and seven patients were assessed for eligibility to participate in this study, 17 of which were excluded and the other 90 patients were randomly allocated to three equal groups. One patient in group I and another one in group III discontinued the intervention owing to failed spinal anesthesia [Figure 1]. The basic demographic data of the studied patients showed insignificant statistical differences among the three groups [Table 1].

The time to the first request of morphine rescue analgesia was significantly longer in group II than group I ($P < 0.0001$) and group III ($P < 0.0001$), with insignificant differences between groups I and III ($P = 0.275$). The total dose of morphine consumed in the first 24 h after surgery was significantly lower in group II compared to group I ($P < 0.0001$) and group III ($P = 0.002$), with insignificant change between groups I and III ($P = 0.172$). The NRS at 4 and 6 h after surgery was significantly lower in group II than groups I ($P = 0.007$ and 0.027, respectively) and III ($P = 0.008$ and 0.027, respectively), with insignificant difference between groups I and III ($P = 0.846$ and 0.621). However, the NRS was similar in the three groups at all other time intervals ($P = 0.971$, 0.951, 0.137, 0.155, 0.431, 0.735, and 0.708) [Table 2].

The duration of sensory block was significantly lower in groups I and III than group II ($P < 0.0001$), with no

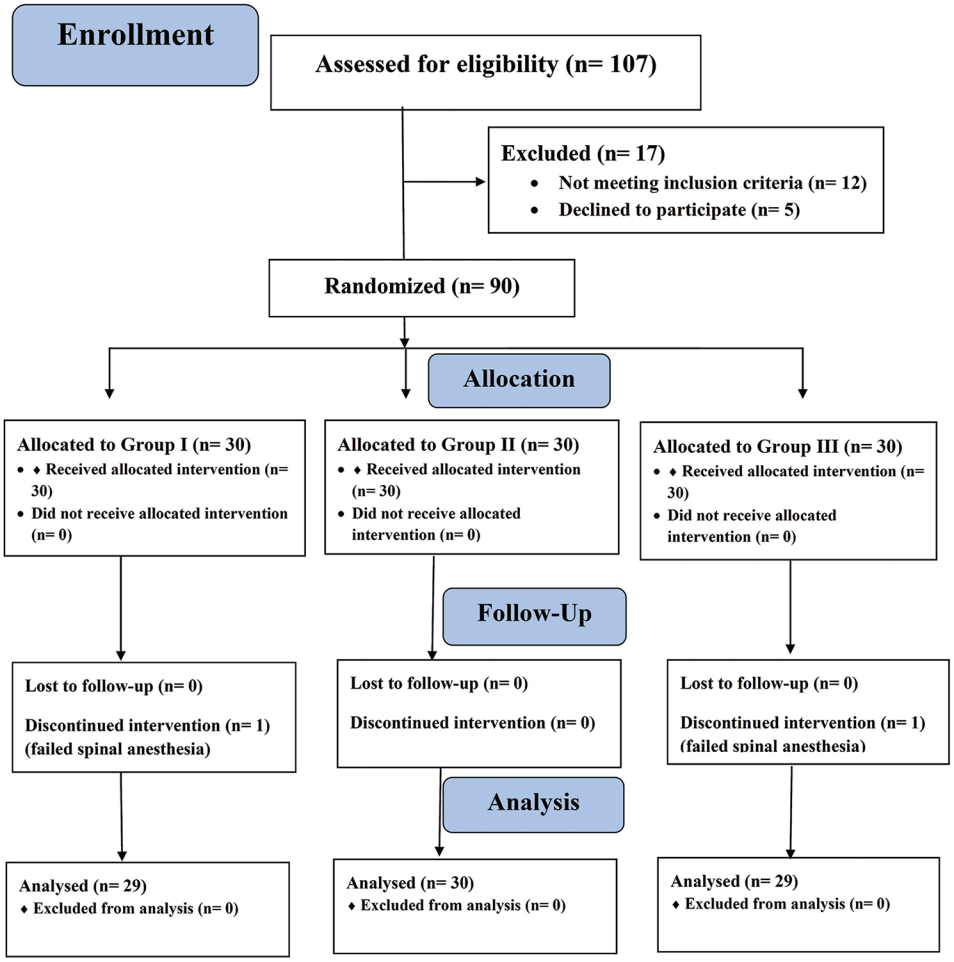

Figure 1: CONSORT flow chart of the study

Table 1: Demographic data of the study groups

	Group I (*n*=29 parturients)	Group II (*n*=30 parturients)	Group III (*n*=29 parturients)	*P*
Age (years)	26.97±3.77	28.23±4.30	29.07±4.30	0.155
BMI (kg/m^2)	30.65±2.04	31.27±1.66	31.34±1.59	0.272
Gravidity				
Primigravida	15 (51.72%)	16 (53.33%)	16 (55.17%)	0.966
Multigravida	14 (48.28%)	14 (46.67%)	13 (44.83%)	
Gestational age (weeks)	38.03±1.08	38.10±1.15	38.10±1.14	0.966
Duration of surgery (min)	37.72±6.30	38.93±6.07	39.10±5.80	0.640

BMI=body mass index, SD=standard deviation. Group I (control group), group II (intrathecal dexmedetomidine), group III (intrathecal dexamethasone). Data are presented as mean±SD or number (%). P value represents comparison among the three groups

difference between groups I and III (P = 0.071). On the other hand, the difference in onset of sensory and motor blocks and duration of motor block was statistically insignificant among the three studied groups (P = 0.934, 0.692, and 0.590, respectively) [Table 3].

The scales of PONV, intraoperative shivering, postoperative shivering, and perioperative sedation were similar in the three groups (P = 0.1133, 0.627, 0.072, and 0.904, respectively). The incidence of hypotension, bradycardia, and pruritis was statistically insignificant in the studied groups (P = 0.899, 0.667, and 0.134, respectively) [Table 4]. The difference in neonatal outcome, including 1- and 5-min Apgar scores, was statistically insignificant among the three groups (P = 0.921 and 0.961) [Table 4].

Furthermore, the ObsQoR-11 revealed statistically significant higher overall score in group II compared to groups I and III (P < 0.0001), with insignificant difference between the overall scores of groups I and group III (P = 0.92) [Table 5].

Table 2: Postoperative analgesia in the studied groups

	Group I (*n*=29 parturients)	Group II (*n*=30 parturients)	Group III (*n*=29 parturients)	*P*	*P*1	*P*2	*P*3
Time to first request of rescue analgesia (min)	280.34±44.19	422.00±66.77	299.66±38.03	<0.0001*	<0.0001*	0.275	<0.0001*
Postoperative 24 h morphine consumption (mg)	10.03±3.03	6.70±2.91	9.00±2.66	<0.0001*	<0.0001*	0.172	0.002*
NRS							
Immediately postoperative	1 (0-2)	1 (0-2)	1 (0-2)	0.971	-	-	-
2 h	2 (0-3)	1 (0-3)	1 (0-3)	0.951	-	-	-
4 h	4 (1-6)	3 (0-6)	4 (1-6)	0.0140*	0.007*	0.846	0.027*
6 h	4 (1-6)	3 (0-6)	4 (1-6)	0.0141*	0.008*	0.621	0.027*
8 h	3 (1-6)	4 (1-6)	3 (1-5)	0.137	-	-	-
12 h	3 (1-5)	4 (2-6)	3 (1-5)	0.155	-	-	-
16 h	2 (0-5)	3 (0-5)	2 (0-5)	0.431	-	-	-
20 h	2 (0-4)	2 (0-4)	2 (0-4)	0.735	-	-	-
24 h	1 (0-3)	1 (0-3)	1 (0-3)	0.708	-	-	-

*NRS=numerical rating score, SD=standard deviation. Group I (control group), group II (intrathecal dexmedetomidine), group III (intrathecal dexamethasone). Data are presented as mean±SD or median and interquartile range. NRS (metric score 0-10 for assessment of the severity of pain, where 0=no pain and 10=maximal pain). P value represents comparison among the three groups. P1 represents comparison between groups I and II, P2 represents comparison between groups I and III, P3 represents comparison between groups II and III. *Significant change*

Table 3: Criteria of spinal anesthesia in the studied groups

	Group I (*n*=29 parturients)	Group II (*n*=30 parturients)	Group III (*n*=29 parturients)	*P*	*P*1	*P*2	*P*3
Onset of sensory block (min)	4.52±1.38	4.47±1.55	4.38±1.37	0.934	-	-	-
Duration of sensory block (min)	306.03±44.21	451.83±68.74	326.72±41.47	<0.0001*	<0.0001*	0.071	<0.0001*
Onset of motor block (min)	6.90±1.47	6.80±1.27	6.59±1.49	0.692	-	-	-
Duration of motor block (min)	133.45±36.57	142.67±34.93	136.55±33.52	0.590	-	-	-

*SD=standard deviation. Group I (control group), group II (intrathecal dexmedetomidine), group III (intrathecal dexamethasone). Data are presented as mean±SD. P value represents comparison among the three groups. P1 represents comparison between groups I and II, P2 represents comparison between groups I and III, P3 represents comparison between groups II and III. *Significant change*

Table 4: Maternal complication and Apgar score in the three study groups

	Group I (*n*=29 parturients)	Group II (*n*=30 parturients)	Group III (*n*=29 parturients)	*P*
PONV scale	2 (0-3)	1.5 (0-3)	1 (0-3)	0.1133
Intraoperative shivering scale	2 (0-3)	1 (0-3)	1 (0-3)	0.627
Postoperative shivering scale	1 (0-3)	1 (0-3)	1 (0-3)	0.072
Perioperative sedation scale	1 (1-3)	1 (1-3)	2 (1-3)	0.904
Hypotension, *n* (%)	9 (30.03%)	11 (36.67%)	10 (34.48%)	0.899
Bradycardia, *n* (%)	6 (20.69%)	8 (26.67%)	9 (30.03%)	0.667
Pruritis, *n* (%)	9 (30.03%)	3 (10%)	7 (24.14%)	0.134
1 min Apgar score	9 (7-10)	9 (7-10)	9 (7-10)	0.921
5 min Apgar score	10 (8-10)	10 (8-10)	10 (8-10)	0.961

PONV=postoperative nausea and vomiting. Group I (control group), group II (intrathecal dexmedetomidine), group III (intrathecal dexamethasone). Data are presented as median and interquartile range or number (%). P value represents comparison among the three groups

No neurological disorders or any other adverse disorders were found during the long-term follow-up of the enrolled patients and their babies.

Discussion

This study revealed that the addition of low-dose dexmedetomidine to bupivacaine–fentanyl mixture in intrathecal anesthesia for pregnant females scheduled for elective CS, compared to the addition of dexamethasone or normal saline, prolonged postoperative analgesia, decreased postoperative morphine consumption, improved postoperative analgesia, and improved maternal recovery, with insignificant effects on PONV, shivering, incidence of complications, sedation, and Apgar score.

Postoperative pain after CS can lead to increased opioid consumption, delayed functional recovery, psychological disturbances, and development of chronic postpartum pain.[15-17] This is in line with the first recommendations of

Table 5: ObsQoR-11 in the studied groups

	Group I (*n*=29 parturients)	Group II (*n*=30 parturients)	Group III (*n*=29 parturients)	*P*	*P*1	*P*2	*P*3
I have moderate pain	3 (0-10)	7 (1-10)	3 (0-10)	<0.0001*	<0.0001*	0.833	<0.0001*
I have severe pain	5 (0-10)	8 (1-10)	5 (0-10)	0.001*	0.0007*	0.971	0.0006*
I had N&V	8 (2-10)	8 (1-10)	8 (2-10)	0.990	-	-	-
I have been feeling dizzy	5 (0-9)	8 (0-10)	6 (1-9)	0.0008*	0.0009*	0.392	0.009*
I had shivering	5 (0-10)	8 (1-10)	5 (0-10)	<0.0001*	0.0001*	0.914	0.0001*
I have been comfortable	3 (0-10)	7 (1-10)	4 (0-10)	0.02*	0.006*	0.421	0.04*
I am able to mobilize independently	4 (0-10)	4 (0-10)	5 (0-10)	0.470	-	-	-
I can hold baby without assistance	4 (0-10)	8 (0-10)	4 (0-9)	<0.0001*	0.0002*	>0.99	0.0001*
I can feed/nurse my baby without assistance	4 (0-10)	8 (1-10)	4 (0-10)	<0.0001*	0.0005*	0.423	<0.0001*
I can look after my personal hygiene/toilet	5 (0-10)	7 (1-10)	5 (0-10)	0.002*	0.004*	0.842	0.002*
I feel in control	5 (0-10)	8 (0-10)	5 (0-9)	0.001*	0.008*	0.601	0.002*
Total	54 (36-76)	79 (60-90)	53 (40-75)	<0.0001*	<0.0001*	0.930	<0.0001*

*N and V=nausea and vomiting, ObsQoR-11=obstetric quality of recovery-11score. Group I (control group), group II (intrathecal dexmedetomidine), group III (intrathecal dexamethasone). Data are presented as median and interquartile range. P value represents comparison among the three groups. P1 represents comparison between groups I and II, P2 represents comparison between groups I and III, P3 represents comparison between groups II and III. *Significant change*

PROSPECT guidelines for elective CS, which implemented the strategies required to minimize systemic opioid use and developed stratified post-discharge opioid prescription practices to reduce unnecessary opioid usage after CS.[18]

Intrathecal administration of dexmedetomidine started to gain interest despite not being approved by the FDA.[19] The exact mechanism of action is not known. However, it may cause hyperpolarization of postsynaptic dorsal horn neurons in the substantia gelatinosa, and this modulates the antinociception. This may also be caused by the binding of dexmedetomidine to the presynaptic C-fibers, which results in decreased nociceptive transmission.[20] This is in agreement with the study of Xia *et al*.[21] and Liu *et al*.[22] who demonstrated that intrathecal administration of dexmedetomidine potentiated hyperbaric bupivacaine antinociception in spinal anesthesia for patients scheduled for CS.

The study of Qi *et al*.[23] and the meta-analysis of Liu *et al*.[22] revealed that the addition of dexmedetomidine to spinal anesthesia for CS prolonged the duration of postoperative analgesia and did not affect motor block and the incidence of complications.[23] The two clinical studies of Bi *et al*.[24,25] found that the use of dexmedetomidine as an additive to local anesthetics in spinal anesthesia for women undergoing CS prolonged postoperative analgesia and decreased postoperative analgesic consumption.

Intrathecal administration of dexamethasone may improve the analgesic effect through its anti-inflammatory effect and blocking of transmission in the nociceptive C-fibers.[26] Tkachenko and Pyasetska[27] suggested that intrathecal administration of 4 mg dexamethasone as an additive to local anesthetic in spinal anesthesia for elective CS significantly decreased the incidence of hypotension, nausea and vomiting, and shivering. Moreover, the results of this study oppose the results of Abdel-Aleem *et al*.[28] and El-Shourbagy *et al*.,[29] who concluded that the use of dexamethasone as a local anesthetic adjuvant in spinal anesthesia can prolong the duration of sensory and motor block and decrease the incidence of PONV.

The quality of recovery was much improved with the use of intrathecal dexmedetomidine, which agreed with the results of Li *et al*.,[30] who conducted a randomized study to evaluate the efficacy and safety of intrathecal dexmedetomidine in pregnant females scheduled for CS.

The results of the current clinical study may be limited due to the use of a single dose of bupivacaine, fentanyl, dexmedetomidine, and dexamethasone. The study does not evaluate the addition of dexmedetomidine or dexamethasone alone to hyperbaric bupivacaine. The little sample size also adds to the study limitations.

Conclusions

It can be concluded that the addition of dexmedetomidine in comparison to either dexamethasone or normal saline to a mixture of bupivacaine–fentanyl during spinal anesthesia for patients undergoing elective CS significantly prolonged the time to the first request of morphine rescue analgesia, improved the postoperative pain score, and decreased postoperative morphine consumption, without any significant difference between the addition of dexamethasone and normal saline.

This study ensured how different additives to spinal anesthesia enhance the quality and effectiveness of postoperative analgesia after CS. This study presented how enhanced recovery after anesthesia could be achieved, especially prolonged

postoperative analgesia, which was one of the important recommendations of guidelines of obstetric anesthesia, by adding a combination of different additives to intrathecal bupivacaine.

These combinations could decrease the incidence of intraoperative hypotension related to spinal anesthesia in CS by decreasing the doses of intrathecal bupivacaine, enhance sensory block of combined additives and local anesthetics, and provide effective and prolonged postoperative analgesia without maternal and fetal side effects, aiming for best maternal and fetal recovery profile.

Acknowledgements

We would like to acknowledge all the members of the Department of Anesthesia and intensive care, Faculty of Medicine, Tanta University.

Authors' contributions

Sameh Ahmed contributed to the study concepts, clinical studies, data acquisition, statistical analysis, and manuscript editing and review. *Hashem lofty* performed definition of intellectual content, literature research, data analysis, and manuscript preparation and review. *Tarek Mostafa* contributed to the study concepts, design, definition of intellectual content, clinical studies, experimental studies, data acquisition, data analysis, manuscript review, and acted as guarantor.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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