IJMA

International Journal of Medical Arts

VOLUME 6, ISSUE 8, AUGUST 2024

P- ISSN: 2636-4174
E- ISSN: 2682-3780

Available online at Journal Website
https://ijma.journals.ekb.eg/
Main Subject [Anesthesiology]

Original Article

Dexmedetomidine Or Fentanyl as An Adjuvant to Single Low-Dose Bupivacaine Intrathecal Anesthesia for Management of Normal Labor Pain, A Randomized Control Study

Khaled Elsheshtawy Mahmoud Shrief *, Essam Shafiq Abd El Wahab, Ismail Mohamed Ahmed, Hany Said Ismail Ramadan

Department of Anesthesia, Intensive Care and Pain Management, Faculty of Medicine, Al-Azhar University, Cairo, Egypt.

Article information

Received: 30-07-2024

Accepted: 31-08-2024

DOI: 10.21608/ijma.2024.289107.1969.

*Corresponding author

Email: khaledshrief2@gmail.com

Citation: Shrief KEM, Abd El Wahab ES, Ahmed IM, Ramadan HIS. Dexmedetomidine or Fentanyl as an Adjuvant to Single Low-Dose bupivacaine intrathecal anesthesia for management of normal Labor Pain, A Randomized Control Study. IJMA 2024; August; 6 [8]: 4814-4821, doi: 10.21608/ijma.2024.289107.1969.

ABSTRACT

Background: To improve the quality of the analgesia, adjuvants were added to intrathecal bupivacaine. The purpose of this work was to assess the efficacy of intrathecal dexmedetomidine [DEX] and fentanyl in reducing pain during delivery, patient satisfaction, and mother's outcome.

Methods: This randomized, controlled double-blind trial had been conducted on 90 women planned for spontaneous vaginal delivery. Participants were randomized into three groups equally and obtained intrathecal block by using 3.75 mg bupivacaine in 3 ml saline in the control group, plus 20 µg fentanyl in 3 ml saline in the fentanyl group, and DEX 5 µg in 3 ml saline in DEX group. The total volume of injected in each group was equal [3 mL].

Results: Before and at the delivery time, the visual analog scale [VAS] was substantially reduced in the DEX and fentanyl groups contrasted to the control group and comparable between the DEX and fentanyl groups. After-delivery, the VAS was lower in the DEX group compared to the fentanyl and control groups at 30 minutes and 60 minutes, and in the fentanyl group compared to the control group. At 90 minutes and 120 minutes, the DEX group continued to have substantially reduced VAS scores than the other two groups, and the fentanyl group had lower scores than the control group. The sensory analgesia duration was substantially longer in the DEX group contrasted to in the fentanyl and control groups. No substantial variation existed in complications and satisfaction across all groups.

Conclusion: DEX and fentanyl are superior to control as it reduces the pain during and after delivery with higher satisfaction without causing any significant complications for mothers and neonates with superiority of DEX to fentanyl.

Keywords: Dexmedetomidine; Fentanyl; Bupivacaine; Intrathecal; Labor Pain.

INTRODUCTION

Nevertheless, the majority of women experience agonizing pain throughout labor. The pain encountered throughout deliveries mostly originates from physiological mechanisms, but psychological and social elements also contribute to its perception [1].

Throughout vaginal deliveries, the administration of medication for pain is sought to alleviate the mother's distress and accelerate the advancement of labor. As many women suffered from pain throughout delivery, effective pain management strategies are necessary to decrease pain severity. Providing suitable analgesia is crucial since pain increases the concentration of circulating catecholamine's, leading to impaired uterine perfusion [2].

Spinal anesthesia [SA] is a very successful type of anesthesia for cesarean sections and vaginal deliveries because of its convenience, greater accuracy and faster administration. This ensures that pain management throughout the perioperative period is straightforward, effective, and safe with no complications [3].

To enhance the duration of analgesia and decrease its adverse effects, combinations of various types of analgesics administered with local anesthetics have been utilized. Certain medications, including opioids, α2 agonists, neostigmine, and vasoconstrictors, have been administered as adjuvants in spinal anesthesia with the purpose of extending intraoperative and postoperative analgesia [4].

Fentanyl is a synthetic narcotic that is derived from phenyl piperidine. It is known for its high potency and quick onset of action [5]. Fentanyl is a favorable choice for alleviating the pain of labor because of its short half-life [6]. Respiratory depression, vomiting, nausea, euphoria, and sedation are common adverse effects associated with all opioids [7].

Dexmedetomidine [DEX] acts specifically as an agonist for alpha-2 adrenergic receptors [8]. DEX is often used in several medical settings for alleviating both pain and anxiety. Additionally, it has been utilized as an adjunct in

THE AIM OF THE WORK

The primary aim of this work was to assess the efficacy of intrathecal DEX and fentanyl in reducing pain during and after delivery and patient satisfaction. The secondary aim was to study the complication and adverse effect on the mother and fetus.

PATIENTS AND METHODS

This prospective, randomized, controlled double-blind trial was conducted on 90 primi- and multi –gravidae women, from 18 to 40 years old planned for spontaneous vaginal delivery. The work was performed following approval from the Ethics Committee Al-Azhar University Hospitals. The participants provided a well-informed written consent.

Cardiac, liver, or kidney diseases, allergy to local anesthetics or the studied drugs, any contraindication of regional anesthesia, and intrauterine growth retardation or fetal compromise were excluded.

Participants had been allocated into three equal group's at random parallel way.Patients received SA by 3.75 mg bupivacaine in 3 ml saline in the control group, plus 20 μg fentanyl in 3ml saline in the fentanyl group, and DEX 5 μg in 3 ml saline in DEX group. The total volume of injected in each group was equal [3 mL]. All participants had been exposed to comprehensive taking of history and gynecological examinations, and usual investigations.

A complete explanation of the study design and purpose, as well as the visual analog scale [VAS], was instructed to the mother. The study started at the active phase of labor, 4 cm cervical dilatation with at least 3 effective uterine contractions lasting for 40 to 50 sec in 10 minutes. Head presentation, no intrauterine growth retardation or death. Without any uterine scar or cephalopelvic disproportion, there was no history of coagulopathy or spinal cord deformity. All cases were done under the basic cardiac monitor, oxygen 2 L/min by nasal cannula, wide bore cannula inserted and all drugs and equipment for resuscitation were available all the time. To maintain the blind nature of the trial, anesthesiology resident [who was unaware of the study] administered drugs in accordance with instructions enclosed in a sealed envelope.

Under complete aseptic technique, an anesthesiologist administered SA to all participants using a 27 G Quincke spinal needle. The procedure was performed while the individuals were seated, targeting the L4-L5 intervertebral area. Following the observation of transparent cerebrospinal fluid flowing freely, the drugs according to the group had been injected slowly intrathecally then we changed position to supine with a slightly left lateral.

Hemodynamic monitoring including heart rate [HR], mean arterial pressure [MAP], and oxygen saturation level [SpO2] starting from baseline just before the injection then zero point [just after injection] then 5 min,15 min,30 min and 60 min finally after delivery.

The analgesic impact was monitored by the visual analog scale [0-10] at baseline before injection and then every 30 min till the time of delivery. The onset of sensory analgesia is the time needed to decrease the VAS by 2 points after injection. Postoperative pain assessment measured by VAS at 30min after delivery and 60min., 90min., and 120min. Analgesia duration is the period of time from when the block begins to when the first request for alleviation of pain occurs if VAS exceeds 5.

The complications were recorded all the time as [purities, drowsiness, allergic reaction, nausea and vomiting, any change in fetal HR and rate of instrumental delivery]. APGAR scores of neonates were also assessed at 1 min and 5 min following delivery.

Patient satisfaction with analgesics 2 hours after the surgery [1] [5: excellent; 4: good; 3: fair; 2: bad; 1: very bad].

Sample size justification

The sample size calculation was performed using G. power 3.1.9.2 [Universitat Kiel, Germany]. The sample size was calculated based on the following considerations: 0.05 α error and 95% power of the study to demonstrate a 10%increase in duration of sensory analgesia [the primary outcome] with Dexmedetomidine group than Fentanyl group [mean 181 and SD 35.43 min] and Control group [mean 152.26 and SD 21.09 min according to a previous study][11]. Two cases were added to each group to overcome dropout. Therefore, 30 patients will be allocated in each group.

Statistical analysis

The statistical analysis was conducted utilizing SPSS v27 [IBM©, Chicago, IL, USA]. The normality of the data distribution was assessed using the Shapiro-Wilks test and histograms. Quantitative parametric variables were reported as mean and standard deviation [SD] and received analysis utilizing ANOVA [F] test with post hoc test [Tukey]. Quantitative non-parametric variables were reported as the median and interquartile range [IQR] and received analysis utilizing the Kruskal-Wallis test with the Mann Whitney-test to contrast each group. Qualitative parameters were reported as frequency and percentage and received analysis utilizing the Chi-square test. A two-tailed P value < 0.05 was deemed statistically significant.

RESULTS

A total of 109 participants had been evaluated for eligibility in this research. Out of these, twelve participants didn't meet the criteria, and seven individuals declined to take part in the study. The remaining individuals were assigned at random to three equal groups, with 30 participants in each. The follow-up and statistical analysis were conducted on all allocated participants [Figure 1].

Demographic data and cervix diameter were insignificantly varied among all groups [Table 1]. HR, MAP, and SpO_2 measurements were insignificantly varied across all groups [Figure 2].

VAS score was insignificantly varied at baseline between among three groups and was substantially various among three groups at 0, 30min, 60min, 90min, 180min, 210min, at delivery, 30 min, 60 min, 90 min, and 120 min after delivery [P value <0.05].VAS score was significantly lower at 0, 30min, 60min, 90min, 180min, and 210min in the DEX group and fentanyl group contrasted to the control group [P value <0.05] and insignificantly various among fentanyl group and DEX group. VAS score was substantially reduced at delivery in the DEX group and fentanyl group contrasted to in the control group and the DEX group contrasted to fentanyl group [P value <0.05]. VAS score was significantly lower at 30 min, 60 min, 90min and 120 min. after delivery in the DEX group than the fentanyl group and control group and was significantly lower in the fentanyl group than the control group [P value <0.05] [Table 2].

The onset of sensory analgesia was substantially reduced in the fentanyl group contrasted to DEX group and control group [P value<0.05] and insignificantly various among the control group and the DEX group. Sensory analgesia duration was substantially higher in the DEX group and fentanyl group contrasted to control group and in the DEX group than fentanyl group after delivery [P value <0.001]. APGAR score was insignificantly various across all groups [Table 3].

Nausea, pruritus and itching, hypotension instrumental delivery, motor block, and patient satisfaction were insignificant across all groups [Table 4].

DISCUSSION

Over the years, labor analgesia has progressed towards minimizing or eliminating motor blockade and avoiding any adverse effects on the progress of labor and maternal or fetal outcomes [12]. Various adjuvants were included into regional anesthesia with the objective of prolonging the duration of effect and reducing the necessary dosage, resulting in a substantial decrease in pain following surgery. Opioids are commonly used in intrathecal space for labor analgesia with or without local anesthetics [13]. Administering adjuvant in small dosages provides effective pain alleviation while reducing the risk of systemic adverse effects [14-17]. The addition of a small amount of fentanyl to spinal anesthetic may result in a rapid onset of action and improved surgical block, along with faster recovery of motor functions. This allows for early discharge of the patient [18]. DEX has a higher affinity to α2 adrenoreceptors resulting in its heightened efficacy as an effective drug in analgesia and sedation [19].

In the present study, HR, MAP, and SpO_2 measurements were insignificantly different among DEX, fentanyl, and control groups. In line with our results, **Verma *et al.*** [20] found that HR, and blood pressure were comparable among DEX, and fentanyl groups at baseline and after combined spinal-epidural anesthesia till the time of vaginal delivery. Also, **Jain *et al.*** [21] showed that HR, and MAP were insignificantly different between DEX, and fentanyl groups in vaginal labor. Additionally, **Khosravi *et al.*** [22] noted that in cesarean sections, HR, MAP, and SpO_2 measurements were insignificantly different between DEX, and fentanyl group.

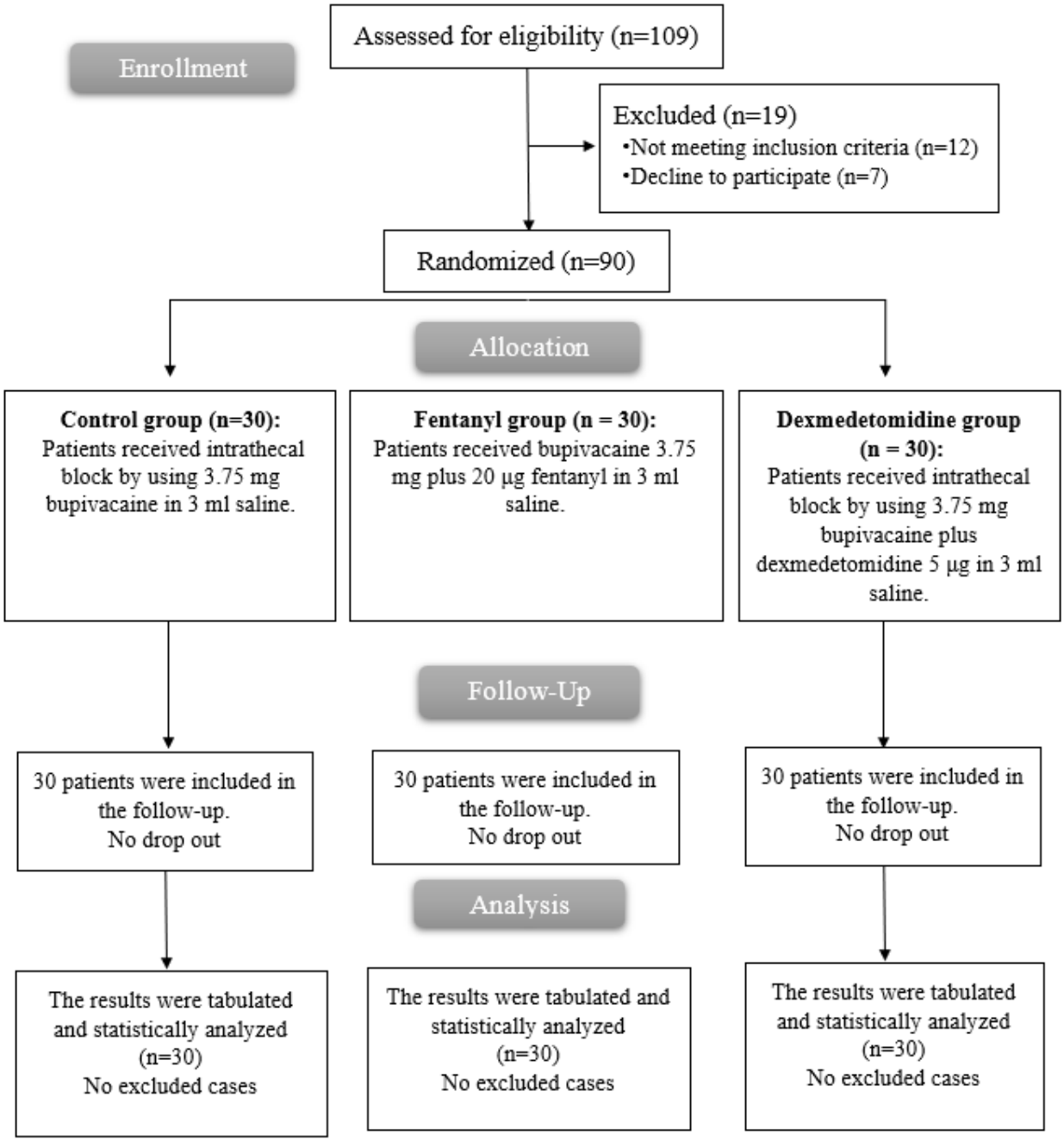
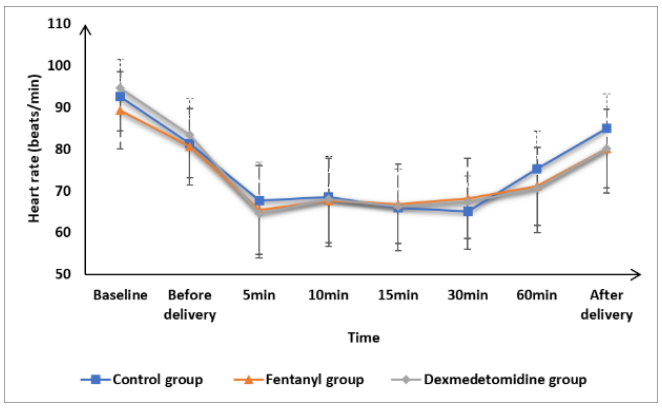


Figure [1]: CONSORT flowchart of the enrolled patients

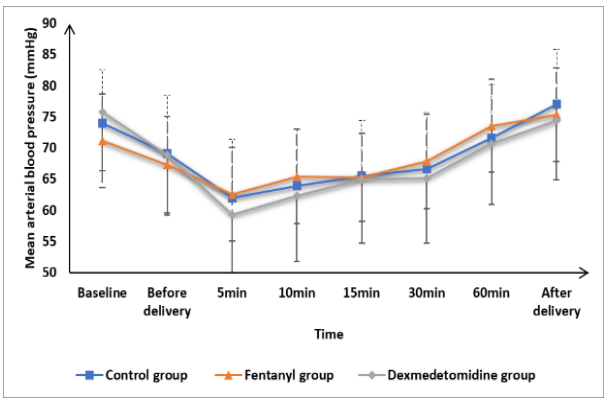
Table [1]: Demographic data and cervix diameter of the studied groups

		Control group [n=30]	Fentanyl group [n=30]	Dexmedetomidine group [n=30]	P value
Age [years]		27.5 ± 6.67	29.2 ± 6.21	27.1 ± 4.38	0.330
Weight [kg]		75.2 ± 15.63	77.9 ± 17.03	81.7 ± 12.98	0.257
Height [cm]		160.6 ± 5.93	163.5 ± 7.17	162.5 ± 6.95	0.251
BMI		29.3 ± 6.54	29.2 ± 6.94	31.1 ± 5.48	0.434
ASA physical status	**I**	25 [83.33%]	27 [90%]	26 [86.67%]	0.749
	II	5 [16.67%]	3 [10%]	4 [13.33%]	
Cervix diameter [cm]		4.5 ± 1	4.2 ± 0.93	4.1 ± 1.02	0.288

Data are presented as mean ± SD or frequency [%], ASA: American Society of Anesthesiologists.



[A]



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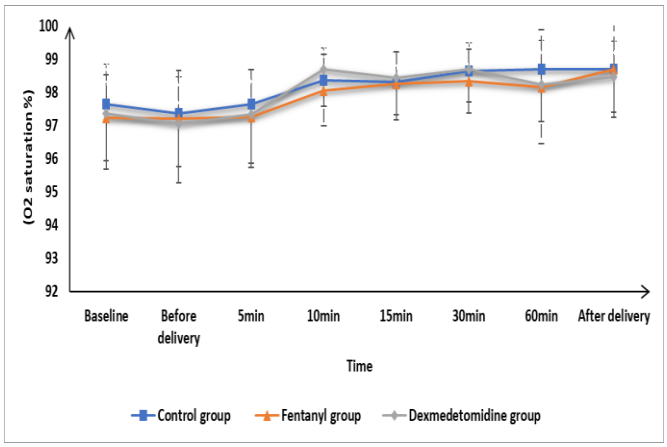

[C]

Figure [2]: [A] Heart rate, [B] mean arterial blood pressure and [C] SpO_2 of the studied groups

Table 2: VAS score of the studied groups

	Control group [n=30]	Fentanyl Group [n=30]	Dexmedetomidine Group [n=30]	P value	Post hoc
Baseline	8[6 - 8]	8[6 - 8]	8[7 - 8.75]	0.780	
0 min.	5[3 - 6]	3[2 - 5]	3[2 - 4]	**<0.001***	P1=**0.004***; P2<**0.001*** P3=0.472
30min	4[3 - 6]	3[3 - 4]	4[2 - 4]	**0.009***	P1=**0.012***; P2=**0.005*** P3=0.758
60min	4[3 - 5.75]	4[1.25 - 5]	4[2 - 5]	**0.037***	P1=**0.046***; P2=**0.016*** P3=0.678
90min	4.5[3 - 6]	4[2.25 - 5]	4[2.25 - 5]	**0.007***	P1=**0.009*** ; P2=**0.004*** P3=0.782
180min	4[4 - 5]	3.5[3 - 5]	4[3 - 5]	**0.003***	P1=**0.004*** ; P2=**0.002*** P3=0.838
210min	5[4.25 - 5]	5[4 - 6]	4.5[3 - 5]	**<0.001***	P1<**0.001***; P2<**0.001*** P3=0.843
At delivery	6.5[6 - 8]	5.5[5 - 6]	4[3 - 5]	**<0.001***	P1=**0.021***; P2<**0.001*** P3=**0.005***
After delivery					
30min	6.5[5 - 7]	5.5[3 –6.75]	3[3 - 5.75]	**<0.001***	P1=**0.009*** ; P2<**0.001*** P3=**0.017***
60min	6[6 - 7]	5[4 - 6]	3[3 - 6]	**<0.001***	P1=**0.008***; P2<**0.001*** P3=**0.043***
90min	6[5.25 - 8]	5.5[5 - 7]	4.5[3 - 6]	**<0.001***	P1=**0.045*** ; P2<**0.001*** P3=**0.020***
120min	5[5- 6]	5[3 - 6]	3[2 - 4]	**<0.001***	P1=**0.034***; P2<**0.001*** P3=**0.011***

Data are presented as median [IQR], P1: P value between the control group and fentanyl group, P2: P value between the control group and DEX group, and P3: P value between fentanyl group and DEX group. VAS: Visual analog score.

Table [3]: Onset and duration of sensory analgesia

	Control group [n=30]	Fentanyl Group [n=30]	Dexmedetomidine Group [n=30]	P	Post Hoc
Onset of sensory analgesia[min]	4.3 ± 1.11	3.1 ± 1.4	4.1 ± 1.17	**0.001***	**P1<0.001*;** P2=0.50 **P3=0.005***
Duration of sensory analgesia[min]	96.2 ± 7.66	111.1 ± 7.84	155.3 ± 14.98	**<0.001***	**P1<0.001* ; P2<0.001* P3<0.001***
APGAR after 1 min	7.8 ± 0.87	8.1 ± 0.83	8.5 ± 1.22	0.072	
APGAR after 5 min	8.1 ± 0.98	8.5 ± 1.22	8.4 ± 1.16	0.343	

Data are presented as mean ± SD or frequency [%].

Table [4]: Complications and patient satisfaction of the studied group

		Control group [n=30]	Fentanyl group [n=30]	Dexmedetomidine group [n=30]	P
Nausea		4 [13.33%]	3 [10%]	4 [13.33%]	0.902
Pruritus and itching		1 [3.33%]	7 [23.33%]	3 [10%]	0.055
Fatal bradycardia		3 [10%]	3 [10%]	7 [23.33%]	0.237
Hypotension		5 [16.67%]	6 [20%]	7 [23.33%]	0.812
Instrumental delivery		1 [3.33%]	2 [6.67%]	1 [3.33%]	0.770
Motor block		1 [3.33%]	0 [0%]	2 [6.67%]	0.355
Patient Satisfaction	**Excellent**	18 [60%]	21 [70%]	25 [83.33%]	0.140
	Good	10 [33.33%]	9 [30%]	5 [16.67%]	
	Fair	2 [6.67%]	0 [0%]	0 [0%]	
	Bad	0 [0%]	0 [0%]	0 [0%]	
	Very Bad	0 [0%]	0 [0%]	0 [0%]	

In this study, both the DEX and fentanyl were more effective than the control group in reducing pain at various time points. DEX was generally more effective than fentanyl, particularly at delivery and in the post-delivery period.

Our results came in agreement with, **Jain *et al.*** [21] noted that the pain score was substantially reduced in the DEX group than fentanyl group.

Also, **Khosravi *et al.*** [22] noticed that the pain score was substantially reduced in the DEX group contrasted to fentanyl group in cesarean section.

Additionally, **Ismail *et al.*** [23] stated that the pain score was substantially reduced in the DEX and fentanyl groups contrasted to in the control group and substantially reduced in the DEX group contrasted to in the fentanyl group in lower limb amputation.

Moreover, **Ezz *et al.*** [24] illustrated that the first VAS measurements were similar across the DEX and control groups, however the following records revealed substantially greater VAS scores in the control group compared to the DEX group.

Consistent with our findings, **Li *et al.*** [11] revealed that the onset of the blockade was substantially faster in the DEX group contrasted with the control and fentanyl groups in cesarean section. Duration of analgesia was substantially higher in the DEX group compared to in the control group.

In the current work, the onset of sensory analgesia was substantially reduced in the fentanyl group contrasted to DEX group and control group and insignificantly different between the control group and the DEX group. Duration of sensory analgesia was substantially higher in the DEX group and fentanyl group contrasted to control group and in the DEX group than fentanyl group after delivery.

In agreement with our results, **Jain *et al.*** [21] noticed that the duration of sensory analgesia was substantially higher in the DEX group contrasted to the fentanyl group after delivery however the onset of analgesia was substantially reduced in the DEX group contrasted to the fentanyl group.

Also, **Khosravi *et al.*** [22] noted that the analgesia duration was substantially higher in the DEX group contrasted to in the fentanyl group after delivery.

Additionally, **Ismail *et al*.** [23] revealed that the analgesia duration is prolonged in the DEX group than fentanyl and control group.

Also, **Ezz *et al*.** [24] showed that the analgesia onset was faster, and the duration of analgesia was prolonged in the DEX group contrasted to in the control group.

Moreover, **Sun *et al.*** [25] found that the duration of sensory analgesia in cesarean sections was substantially greater in the DEX group and fentanyl group contrasted to control group and in the DEX group contrasted to fentanyl group.

Our results revealed that nausea, pruritus and itching, hypotension, instrumental delivery, motor block, and patient satisfaction were insignificant among the three groups.

In line with our findings, **Verma *et al.*** [20] revealed that in active labor, nausea, and hypotension were insignificantly different between fentanyl and DEX groups. However, pruritus was the notable side effect with fentanyl which was significantly higher than the DEX group. Itching occurs due to several mechanisms. Firstly, fentanyl activates central opioid receptors in the brain and spinal cord, which may indirectly cause itching, potentially through the modulation of immune or inflammatory responses in the skin.

Although less likely than other opioids to induce histamine release, fentanyl can still trigger this reaction, leading to vasodilation and increased blood vessel permeability, causing itchiness. Additionally, fentanyl may influence the peripheral nervous system, altering the sensation of itch. Furthermore, opioids like fentanyl can disrupt neurotransmitter balance in the central nervous system, contributing to itching sensations [26].

Our results came in agreement with **Jain *et al.*** [21] who revealed that that nausea, hypotension, and instrumental delivery, were insignificantly different DEX and fentanyl groups.

Also, **Khosravi *et al.*** [22] found that the incidence of complications of nausea and hypotension was insignificant variation among DEX and fentanyl groups.

Additionally, **Gupta et al.** [27] illustrated that subjects in both the DEX and fentanyl groups did not show any complications, including nausea, pruritus, itching, sedation, and hypotension.

Limitations were relatively small in the sample size. It was conducted at a single center. The follow-up of patients was limited to a relatively short period. Further studies comparing other adjuvants are recommended.

Conclusions

DEX and fentanyl are superior to control as it reduces the pain during and after delivery with higher satisfaction without causing any significant complications for mothers and neonates with superiority of DEX to fentanyl.

Financial support and sponsorship:

Nil

Conflict of Interest:

Nil

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IJMA

International Journal of Medical Arts

VOLUME 6, ISSUE 8, AUGUST 2024

P- ISSN: 2636-4174
E- ISSN: 2682-3780