Original Article/*Özgün Araştırma*

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Can Subarachnoid Dexmedetomidine Decrease the Incidence of Post Operative Nausea and Vomiting (PONV) and Shivering with Minimal Hemodynamic Instability in Cesarean Section? A Prospective, Randomized, Double-Blinded, Controlled Study

Subaraknoid Deksmedetomidin Sezaryen Doğumda Minimal Hemodinamik İnstabilite ile Post Operatif Bulantı ve Kusma (POBK) ve Titreme İnsidansını Azaltabilir mi? Prospektif, Randomize, Çift Kör, Kontrollü Bir Çalışma

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ABSTRACT

Objective: The utilization of highly selective α-2 agonist dexmedetomidine is significantly growing as an intrathecal adjuvant in cesarean section (CS) performed under subarachnoid block.

The aim of this study was to determine whether the addition of low dose dexmedetomidine to local anesthesia for spinal anesthesia reduces perioperative nausea, vomiting and shivering in patients scheduled for lower segment cesarean section with minimal hemodynamic instability.

Methods: In this controlled prospective study, 60 parturients scheduled for elective CS (under spinal anesthesia) were equally randomized into two groups. Group D (dexmedetomidine group) received hyperbaric bupivacaine (0.5%; 10 mg) in addition to dexmedetomidine (5 µg; 0.2 mL), while Group C (control group) received normal saline for the spinal block. Hemodynamic parameters as well as the incidence of shivering, vomiting, and nausea and were recorded.

Results: There was a statistically substantial rise in block duration in Group D (218.83 ± 10.72) than in Group C (163.17 ± 9.96), with p-value <0.001. There was also a statistically substantial elevation in the patient percentage who experienced shivering in Group C (50.0%) compared to Group D (10.0%), with p-value = 0.001, and an elevation in the intensity in Group C than Group D, (p=0.005).

Conclusion: We concluded that intrathecal dexmedetomidine has no substantial impact on the prevention (occurrence) of vomiting as well as nausea throughout CS but can efficiently alleviate shivering occurrence with minimal or low hemodynamic instability.

Keywords: Bupivacaine, spinal anesthesia, dexmedetomidine, shivering, cesarean section

ÖZ

Amaç: Subaraknoid blok altında gerçekleştirilen sezaryen doğumda intratekal adjuvan olarak seçici α-2 agonisti deksmedetomidinin kullanımı önemli ölçüde artmaktadır.

Bu çalışmadaki amacımız minimal hemodinamik instabilitesi olan alt segment S planlanan hastalarda spinal anestezi için lokal anesteziğe düşük doz deksmedetomidin eklenmesinin perioperatif bulantı, kusma ve titremeyi azaltıp azaltmadığını belirlemektir.

Yöntem: Bu kontrollü prospektif çalışmada, elektif sezaryen doğum (spinal anestezi altında) planlanan 60 gebe eşit şekilde iki gruba randomize edildi. Grup D (deksmedetomidin grubu) deksmedetomidinin (5 µg; 0,2 mL) yanı sıra hiperbarik bupivakain (%0,5; 10 mg) alırken, Grup K (kontrol grubu) spinal anestezi için normal salin aldı. Hemodinamik parametrelerin yanı sıra titreme, kusma ve bulantı insidansı da kaydedildi.

Bulgular: Blok süresinde Grup D'de (218,83 ± 10,72) Grup K'ye (163,17 ± 9,96) göre istatistiksel olarak anlamlı bir artış vardı ve p değeri <0,001 idi. Grup K'de (%50,0) titreme yaşayan hasta yüzdesinde Grup D'ye (%10,0) kıyasla istatistiksel olarak anlamlı bir artış vardı; p değeri = 0,001 ve Grup K'de Grup D'ye göre titreme şiddetinde bir artış vardı (p=0,005).

Sonuç: İntratekal deksmedetomidin'in S sırasında kusmanın ve bulantının önlenmesi (oluşumu) üzerinde önemli bir etkisinin olmadığı ancak minimal hemodinamik instabilite ile titreme oluşumunu etkili bir şekilde hafifletebileceği sonucuna vardık.

Anahtar sözcükler: Bupivakain, spinal anestezi, deksmedetomidin, titreme, sezaryen doğum

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INTRODUCTION

The most frequently utilized anesthetic technique for lower section cesarean section (LSCS) is subarachnoid anesthesia with hyperbaric bupivacaine (0.5%). It is required to block the T4 dermatome in order to conduct a cesarean section (CS) without causing maternal distress. This elevated level is frequently accompanied by hypotension along with diminished uteroplacental perfusion. Decreasing local anesthetic agent volume to prevent hypotension conveys with it the risk of a shorter action duration and, consequently, decreased postoperative analgesia (1).

Dexmedetomidine is a highly selective α-2 adrenoreceptor agonist binding to a transmembrane G protein-binding receptor. Prior research indicated that it could be combined with local anesthetics in subarachnoid anesthesia to minimize the time required for the onset of the block, lessen the severity of pain after surgery, lengthen the duration of the block, in addition to reducing postoperative utilization of analgesics (2).

Despite the fact that subarachnoid anesthesia in CS is less dangerous compared to general anesthesia, it continues to pose a significant threat to the safety of fetal as well as maternal life. These adverse effects involve primarily shivering, bradycardia, vomiting, hypotension, and nausea (1).

If patients experience vomiting as well as nausea during the procedure, stomach contents may be inadvertently inhaled into the airways, inducing life-threatening aspiration pneumonia (3).

Shivering is a prevalent complication of subarachnoid anesthesia, which leads to dissatisfaction and discomfort for CS patients. According to a meta-analysis of 21 studies, the average shivering incidence after neuraxial anesthesia was 55% (4).

Electrocardiogram monitoring as well as pulse oximetry, can be compromised by shivering. Moreover, it can quadruple oxygen demand and carbon dioxide (CO_2) production as well as may play an integral part in wound pain intensification, delayed recovery, unit discharge, and delayed healing of wounds. Consequently, preventing shivering is plausible and could lead to improved perioperative outcomes (4).

This study aimed to determine intrathecal dexmedetomidine's impact on spinal anesthesia adverse reactions in CS.

MATERIAL and METHODS

The current prospective randomized controlled study was approved by the University Hospital's Ethics Committee approved (FMASU R 120/ 2021 on 28/5/2021). It also was registered at Clinical Trial Registry ClinicalTrials.gov Identifier: (NCT05892705). All participants provided written informed consent.

Sample size was calculated using STATA program, setting the type-1 error (α) at 0.05 and the power (1-β) at 0.8. Result from previous study showed that 7.7% of Dexmedetomidine group cases had shivering, while among placebo group 35.8% had shivering (5). Calculation according to these values produced a sample size of 30 cases in each group (60 total), taking in account 20% drop out rate.

Inclusion criteria include medically free pregnant female from 18 to 35 years old, undergoing elective, LSCS with body mass index less than 40, consenting for subarachnoid anesthesia, coagulation profile is within normal ranges.

Exclusion criteria include emergency LSCS, patient refusal enrollment in the study, allergy to the medications, coagulopathy or anticoagulation drugs, and fetal or maternal comorbidities.

The study recruited 60 obstetric subjects who fulfilled all inclusion criteria. Subjects were equally randomized into two groups (30 cases per group), namely Group C (Control group) and Group D (dexmedetomidine group).

Intrathecally, Group D received dexmedetomidine (5 μg), along with hyperbaric bupivacaine (0.5%; 10 mg). Group C patients received normal saline (0.2 mL) in addition to hyperbaric bupivacaine (0.5%; 10 mg).

Each patient underwent a standard preoperative evaluation, which includes laboratory investigations, clinical examination, as well as complete history taking.

All the patients were preloaded with lactated Ringer's solution (10 mL kg^{-1}) utilizing an 18 gauge intravenous cannula. Cases were monitored with five leads electrocardiography, non-invasive blood pressure (for recording diastolic, systolic, and mean blood pressure) at particular time points, temperature, as well as pulse oximetry.

Local anesthetic (in the form of lidocaine 3 mL; 2%) at the spinal injection site was administrated utilizing the sterile technique. Administration of the subarachnoid block was done in the seated position via a paramedian or midline approach at L3- L4/L4-L5 space (with a 27-G Quincke needle).

For Group D, (100 μg mL^{-1}) preservative-free dexmedetomidine was loaded into a 100-U insulin syringe (1 μg U^{-1}), as well as 5 U to the (2 mL; 10 mg) of hyperbaric bupivacaine (0.5%). For group C, normal saline was loaded into a 100-U insulin syringe, in addition to 5 U mixed with (2 mL; 10 mg) of hyperbaric bupivacaine (0.5%). Subjects were positioned supine with left uterine displacement immediately.

Sensory blockade assessment was done utilizing the pinprick method (through a 25-gauge needle) every 2 minutes (min) until the maximum level was reached and, subsequently, every 60 min interval until two-segment block regression took place. The motor blockade evaluation was done at the same time intervals utilizing a modified Bromage scale (6).

Side effects such as shivering, bradycardia, hypotension, and vomiting were documented and examined.

The intensity of shivering was assessed utilizing a five-point scale validated by Crossley and Mahajan, where 4= shivering in the whole body, 3=muscular activity in more than one group of muscles, 2=muscular activity in only one group of muscles, 1=peripheral or piloerection vasoconstriction without notable shivering, and 0=no shivering (4).

Shivering incidence, as well as intensity, were documented every 15 min throughout the procedure and in the recovery room.

Neonatal outcome was assessed based on the score of APGAR at 1st and 5th-min post delivery by the attending pediatrician.

Effect of subarachnoid dexmedetomidine on hemodynamic parameters will be measured.

Effect of subarachnoid dexmedetomidine on the incidence of post-operative nausea and vomiting and shivering will be observed.

Statistical Package and Analysis

Data analysis was carried out utilizing the 21st version of the SPSS software (Chicago-Illinois, USA as well as Microsoft® Excel 2016 (Microsoft-Seattle-WA-USA). Expression of quantitative data was done as ranges, standard deviations, and mean, whereas qualitative data were expressed as percentages and numbers. The comparison between groups (regarding qualitative data) was made utilizing the Chi-square test, whereas the independent t-test was utilized for quantitative data. Additionally, 5% was the accepted error margin, while 95% was the confidence interval. The p-value was considered significant at the level of <0.05.

Shapiro wilk's test was used to evaluate normal distribution of continuous data. Mean, standard deviation (± SD), and range was used for parametric numerical data, while median and interquartile range (IQR) was used for non-parametric numerical data. To test the homogeneity of variance, we used Levene's test, if it was not significant then the variances were homogeneous and we used student t test, while if Levene's Test was significant (variances are different), we used Welch's t-test (instead of Student's t-test).

RESULTS

There are no statistically substantial differences between both groups in terms of gestational age, body mass index, height, weight, and age (Table I).

There are no discernible differences between both groups with respect to block level. In contrast, there was a statistically substantial elevation in the block duration in Group D than in Group C, with a p-value <0.001 (Table II).

There are no substantial differences between both groups concerning maternal heart rate (at various measurement times) as well as SBP (at various measurement times), DBP (at various measurement times) and MBP (at various measurement times) (Table IV, V, VI).

There are no substantial difference between both groups regarding temperature (at various measurement times) nor neonatal data (Table VII, VIII).

Table I. Comparisons Between Group C and Group D Concerning Demographics as Well as the Studied Patients' Characteristics

		Group C	Group D	Test value	p-value	Sig.
		n=30	n=30			
Age (years)	Mean ± SD	27.80 ± 2.51	26.57 ± 2.84	1.783•	0.080	NS
	Range	22 – 35	21 – 30			
Weight (kg)	Mean ± SD	84.50 ± 12.52	83.17 ± 10.87	0.441•	0.661	NS
	Range	65 – 110	66 – 105			
Height (cm)	Mean ± SD	171.40 ± 6.49	169.17 ± 7.65	1.219•	0.228	NS
	Range	160 – 188	157 – 188			
Body Mass Index ($kg\ m^{-2}$)	Mean ± SD	28.72 ± 3.72	29.17 ± 4.42	-0.432•	0.667	NS
	Range	25.1 – 37.83	25.01 – 39.26			
GA (weeks)	Mean ± SD	37.90 ± 1.09	38.00 ± 1.17	-0.341•	0.734	NS
	Range	37 – 40	37 – 40			

p>0.05=non significant (NS); p<0.05=significant (S); p<0.01=highly significant (HS), Grup C (Control Group), Group D (Dexmedetomidine Group) **•:** Independent t-test, **SD:** Standard deviation, **n:** Number, **GA:** Gestational age.

Finally, there are no significant differences between both groups concerning vomiting and nausea, with a p-value=0.519. In contrast, substantial elevation was detected in the percentage of patients who experienced shivering in Group C (50.0%) than in Group D (10.0%) with a p-value=0.001. There is also a substantial elevation in the intensity in Group C than in Group D, with a p-value=0.005.

Table II. Comparisons Between Group C and Group D in Terms of Block Level and Duration

		Group C	Group D	Test value	p-value	Sig.
		n=30	n=30			
Duration of block (min)	Mean ± SD	163.17 ± 9.96	218.83 ± 10.72	20.839•	<0.001	HS
	Range	140 – 180	200 – 240			
Level of block	T3 - T4	18 (60.0%)	15 (50.0%)	0.606*	0.436	NS
	T5 - T6	12 (40.0%)	15 (50.0%)			

p>0.05=non significant (NS); p<0.05=significant (S); p<0.01=highly significant (HS)
•: Independent t-test; ***:** Chi-square test; **n:** Number, Grup C (Control Group), Group D (Dexmedetomidine Group).

Table III. Comparisons Between Group C and Group D Concerning Maternal Heart Rate (beat min^{-1})

Maternal HR (beat min^{-1})		Group C	Group D	Test value•	p-value	Sig.
		n=30	n=30			
Baseline	Mean ± SD	93.27 ± 5.76	93.50 ± 7.63	-0.134	0.894	NS
	Range	79 – 106	79 – 107			
2 min	Mean ± SD	95.43 ± 6.54	91.73 ± 11.67	1.514	0.135	NS
	Range	78 – 105	55 – 106			
4 min	Mean ± SD	91.23 ± 6.39	88.30 ± 11.91	1.189	0.239	NS
	Range	76 – 103	53 – 103			
6 min	Mean ± SD	83.23 ± 6.39	81.70 ± 11.89	0.622	0.536	NS
	Range	68 – 95	46 – 96			
8 min	Mean ± SD	84.23 ± 6.39	84.47 ± 10.54	-0.104	0.918	NS
	Range	69 – 96	48 – 100			
10 min	Mean ± SD	86.40 ± 6.00	86.97 ± 8.98	-0.287	0.775	NS
	Range	70 – 97	70 – 115			
15 min	Mean ± SD	85.17 ± 5.53	86.33 ± 7.01	-0.715	0.477	NS
	Range	70 – 95	70 – 98			
20 min	Mean ± SD	91.27 ± 5.87	93.07 ± 6.52	-1.124	0.266	NS
	Range	76 – 103	76 – 103			
25 min	Mean ± SD	95.60 ± 5.30	93.17 ± 5.80	1.697	0.095	NS
	Range	84 – 106	79 – 103			
30 min	Mean ± SD	92.57 ± 6.13	94.07 ± 6.52	-0.918	0.362	NS
	Range	77 – 104	77 – 104			
35 min	Mean ± SD	88.87 ± 6.20	91.10 ± 6.32	-1.383	0.172	NS
	Range	73 – 101	73 – 102			
40 min	Mean ± SD	86.87 ± 6.20	89.10 ± 6.32	-1.383	0.172	NS
	Range	71 –99	71 – 100			
50 min	Mean ± SD	87.60 ± 6.07	89.47 ± 6.03	-1.194	0.237	NS
	Range	71 – 100	72 – 99			

p>0.05=non significant (NS); p<0.05=significant (S); p<0.01=highly significant (HS)
•: Independent t-test, **n:** Number, **Min:** Minutes, **HR:** Heart rate, Grup C (Control Group), Group D (Dexmedetomidine Group).

Table IV. Comparisons Between Group C and Group D with Respect to Systolic Blood Pressure (mmHg)

SBP (mmHg)		Group C	Group D	Test value•	p-value	Sig.
		n=30	n=30			
Baseline	Mean ± SD	129.03 ± 5.20	126.10 ± 9.23	1.516	0.135	NS
	Range	120 – 140	110 – 140			
2 min	Mean ± SD	122.30 ± 4.39	120.20 ± 7.18	1.366	0.177	NS
	Range	114 – 132	105 – 130			
4 min	Mean ± SD	117.27 ± 3.85	119.30 ± 5.18	-1.725	0.090	NS
	Range	110 – 125	103 – 128			
6 min	Mean ± SD	113.87 ± 4.81	111.03 ± 8.09	1.649	0.105	NS
	Range	100 – 124	89 – 127			
8 min	Mean ± SD	114.67 ± 5.77	111.77 ± 7.80	1.636	0.107	NS
	Range	100 – 122	91 – 126			
10 min	Mean ± SD	116.70 ± 5.06	114.20 ± 5.68	1.801	0.077	NS
	Range	100 – 125	105 – 125			
15 min	Mean ± SD	117.50 ± 6.42	115.07 ± 4.90	1.651	0.104	NS
	Range	100 – 128	105 – 125			
20 min	Mean ± SD	119.97 ± 4.28	119.10 ± 4.57	0.759	0.451	NS
	Range	110 – 127	110 – 128			
25 min	Mean ± SD	124.53 ± 5.09	122.87 ± 6.88	1.066	0.291	NS
	Range	115 – 133	110 – 134			
30 min	Mean ± SD	125.07 ± 4.04	122.87 ± 6.88	1.510	0.137	NS
	Range	116 – 133	110 – 134			
35 min	Mean ± SD	123.37 ± 4.02	121.20 ± 6.87	1.492	0.141	NS
	Range	115 – 132	109 – 133			
40 min	Mean ± SD	121.67 ± 4.79	120.00 ± 6.73	1.105	0.274	NS
	Range	110 – 130	108 – 130			
50 min	Mean ± SD	120.20 ± 5.03	118.60 ± 6.40	1.076	0.286	NS
	Range	109 – 129	107 – 130			

p>0.05=non significant (NS); p<0.05=significant (S); p<0.01=highly significant (HS)
•: Independent t-test, **n:** Number, **Min:** Minutes, **SBP:** Systolic blood pressure, Grup C (Control Group), Group D (Dexmedetomidine Group).

Table V. Comparisons Between Group C and Group D in Terms of Diastolic Blood Pressure (mmHg)

DBP (mmHg)		Group C	Group D	Test value•	p-value	Sig.
		n=30	n=30			
Baseline	Mean ± SD	80.90 ± 6.56	78.67 ± 6.06	1.370	0.176	NS
	Range	69 – 90	68 – 90			
2 min	Mean ± SD	73.23 ± 6.38	73.33 ± 9.29	-0.049	0.961	NS
	Range	60 – 84	50 – 88			
4 min	Mean ± SD	69.43 ± 7.56	71.53 ± 6.52	-1.152	0.254	NS
	Range	50 – 80	60 – 80			
6 min	Mean ± SD	68.23 ± 7.36	71.00 ± 6.08	-1.587	0.118	NS
	Range	50 – 79	59 – 79			
8 min	Mean ± SD	70.10 ± 7.64	72.73 ± 6.29	-1.457	0.151	NS
	Range	52 – 81	61 – 81			

Table V. Cont.

DBP (mmHg)		Group C	Group D	Test value•	p-value	Sig.
		n=30	n=30			
10 min	Mean ± SD	71.20 ± 3.85	72.40 ± 4.84	-1.063	0.292	NS
	Range	63 – 77	65 – 82			
15 min	Mean ± SD	73.70 ± 4.06	71.63 ± 5.08	1.740	0.087	NS
	Range	64 – 82	60 – 80			
20 min	Mean ± SD	73.17 ± 4.54	72.83 ± 5.32	0.261	0.795	NS
	Range	64 – 84	60 – 80			
25 min	Mean ± SD	77.10 ± 4.37	76.07 ± 5.60	0.797	0.429	NS
	Range	68 – 88	66 – 88			
30 min	Mean ± SD	72.70 ± 4.06	71.63 ± 5.08	0.898	0.373	NS
	Range	63 – 81	60 – 80			
35 min	Mean ± SD	73.93 ± 4.08	73.50 ± 4.43	0.394	0.695	NS
	Range	64 – 82	61 – 81			
40 min	Mean ± SD	74.00 ± 3.96	72.47 ± 4.25	1.447	0.153	NS
	Range	64 – 82	62 – 82			
50 min	Mean ± SD	75.47 ± 3.88	73.73 ± 3.90	1.724	0.090	NS
	Range	65 – 83	65 – 83			

p>0.05=non significant (NS); p<0.05=significant (S); p<0.01=highly significant (HS)
•: Independent t-test, **n:** Number, **Min:** Minutes, **DBP:** Diastolic blood pressure, Grup C (Control Group), Group D (Dexmedetomidine Group).

Table VI. Comparisons Between Group C and Group D as Regards Mean Arterial Blood Pressure (mmHg)

MBP (mmHg)		Group C	Group D	Test value•	p-value	Sig.
		n=30	n=30			
Baseline	Mean ± SD	97.00 ± 4.90	94.73 ± 5.28	1.724	0.090	NS
	Range	89 – 106	84 – 107			
2 min	Mean ± SD	89.47 ± 4.70	87.53 ± 8.65	1.076	0.287	NS
	Range	80 – 96	62 – 102			
4 min	Mean ± SD	84.57 ± 6.04	85.43 ± 5.95	-0.560	0.578	NS
	Range	70 – 93	70 – 95			
6 min	Mean ± SD	83.27 ± 5.98	84.27 ± 5.76	-.660-	0.512	NS
	Range	69 – 92	69 – 92			
8 min	Mean ± SD	84.57 ± 5.58	85.80 ± 5.42	-.869-	0.389	NS
	Range	70 – 93	70 – 93			
10 min	Mean ± SD	85.07 ± 3.38	86.37 ± 2.81	-1.619-	0.111	NS
	Range	75 – 91	80 – 92			
15 min	Mean ± SD	87.67 ± 3.22	86.07 ± 3.44	1.859	0.068	NS
	Range	78 – 94	78 – 92			
20 min	Mean ± SD	88.67 ± 3.29	88.10 ± 3.62	0.634	0.529	NS
	Range	82 – 95	81 – 94			
25 min	Mean ± SD	95.27 ± 3.57	93.53 ± 4.44	1.666	0.101	NS
	Range	87 – 105	86 – 102			
30 min	Mean ± SD	87.67 ± 3.22	86.07 ± 3.44	1.859	0.068	NS
	Range	78 – 94	78 – 92			

Table VI. Cont.

MBP (mmHg)		Group C	Group D	Test value•	p-value	Sig.
		n=30	n=30			
35 min	Mean ± SD	89.43 ± 2.99	87.93 ± 3.82	1.693	0.096	NS
	Range	80 – 95	76 – 94			
40 min	Mean ± SD	87.00 ± 3.25	86.77 ± 4.23	0.240	0.812	NS
	Range	75 – 93	72 – 93			
50 min	Mean ± SD	86.83 ± 3.34	85.70 ± 4.40	1.124	0.266	NS
	Range	75 – 93	70 – 92			

p>0.05=non significant (NS); p<0.05=significant (S); p<0.01=highly significant (HS)
•: Independent t-test, **n:** Number, **Min:** Minutes, **MBP:** Mean Blood Pressure, Grup C (Control Group), Group D (Dexmedetomidine Group).

Table VII. Comparisons Between Group C and Group D with Respect to Temperature

Temperature		Group C	Group D	Test value•	p-value	Sig.
		n=30	n=30			
Baseline	Mean ± SD	36.97 ± 0.19	36.98 ± 0.20	-0.066	0.948	NS
	Range	36.6 – 37.3	36.6 – 37.3			
2 min	Mean ± SD	36.87 ± 0.19	36.88 ± 0.20	-0.066	0.948	NS
	Range	36.5 – 37.2	36.5 – 37.2			
4 min	Mean ± SD	36.77 ± 0.19	36.78 ± 0.20	-0.066	0.948	NS
	Range	36.4 – 37.1	36.4 – 37.1			
6 min	Mean ± SD	36.97 ± 0.19	36.98 ± 0.20	-0.066	0.948	NS
	Range	36.6 – 37.3	36.6 – 37.3			
8 min	Mean ± SD	37.07 ± 0.19	37.08 ± 0.20	-0.066	0.948	NS
	Range	36.7 – 37.4	36.7 – 37.4			
10 min	Mean ± SD	37.25 ± 0.20	37.17 ± 0.19	1.715	0.092	NS
	Range	36.9 – 37.6	36.8 – 37.5			
15 min	Mean ± SD	37.35 ± 0.20	37.27 ± 0.19	1.715	0.092	NS
	Range	37 – 37.7	36.9 – 37.6			
20 min	Mean ± SD	37.23 ± 0.19	37.17 ± 0.19	1.286	0.204	NS
	Range	36.9 – 37.6	36.8 – 37.5			
25 min	Mean ± SD	37.13 ± 0.17	37.07 ± 0.19	1.407	0.165	NS
	Range	36.8 – 37.5	36.7 – 37.4			
30 min	Mean ± SD	37.02 ± 0.16	36.97 ± 0.19	1.174	0.245	NS
	Range	36.7 – 37.4	36.6 – 37.3			
35 min	Mean ± SD	36.94 ± 0.17	36.87 ± 0.19	1.578	0.120	NS
	Range	36.6 – 37.3	36.5 – 37.2			
40 min	Mean ± SD	36.75 ± 0.18	36.67 ± 0.19	1.712	0.092	NS
	Range	36.4 – 37.1	36.3 – 37			
50 min	Mean ± SD	36.94 ± 0.17	36.87 ± 0.19	1.507	0.137	NS
	Range	36.6 – 37.3	36.5 – 37.2			

p>0.05=non significant (NS); p<0.05=significant (S); p<0.01=highly significant (HS)
•: Independent t-test, **n:** Number, **Min:** Minutes, Grup C (Control Group), Group D (Dexmedetomidine Group).

Table VIII. Comparisons Between Group C and Group D as Regards Neonatal Data

Neonatal data		Group C n=30	Group D n=30	Test value	p-value	Sig.
Weight (g)	Mean ± SD	2911.00 ± 424.32	2922.00 ± 432.13	-0.099•	0.921	NS
	Range	2000 – 3700	2000 – 3700			
Heart rate (beats min_{-1})	Mean ± SD	147.73 ± 12.11	144.40 ± 10.55	1.137•	0.260	NS
	Range	124 – 180	125 – 170			
SBP (mmHg)	Mean ± SD	73.73 ± 7.71	77.40 ± 10.64	-1.529•	0.132	NS
	Range	60 – 90	56 – 95			
DBP (mmHg)	Mean ± SD	46.77 ± 8.50	47.37 ± 9.26	-0.261•	0.795	NS
	Range	31– 60	32 – 61			
Apgar score 1 min	Median (IQR)	7 (7-8)	8 (7-8)	-1.650*	0.099	NS
	Range	4 – 10	5 – 10			
Apgar score 5 min	Median (IQR)	9 (9 – 10)	9 (9 – 10)	-0.475*	0.634	NS
	Range	6 – 10	8 – 10			

p>0.05=non significant (NS); p<0.05=significant (S); p<0.01=highly significant (HS)
•: Independent t-test; ***:** Mann-Whitney test, **n:** Number, **G:** grams, **SBP:** Systolic blood pressure, **DBP:** Diastolic blood pressure, **Min:** Minutes, Grup C (Control Group), Group D (Dexmedetomidine Group).

Table IX. Comparisons Between Group C and Group D with Respect to Nausea and Vomiting as Well As Shivering and Intensity

		Group C	Group D	Test value*	p-value	Sig.
Nausea and vomiting	No	23 (76.7%)	25 (83.3%)	0.417	0.519	NS
	Yes	7 (23.3%)	5 (16.7%)			
Shivering	No	15 (50.0%)	27 (90.0%)	11.429	0.001	HS
	Yes	15 (50.0%)	3 (10.0%)			
Intensity	0	15 (50.0%)	27 (90.0%)	12.714	0.005	HS
	1	3 (10.0%)	1 (3.3%)			
	2	5 (16.7%)	2 (6.7%)			
	3	7 (23.3%)	0 (0.0%)			

p>0.05=non significant (NS); p<0.05=significant (S); p<0.01=highly significant (HS)
***:** Chi-square test, Grup C (Control Group), Group D (Dexmedetomidine Group).

DISCUSSION

Shivering is distressing for patients. In addition, it may result in physiological changes like the production of CO_2 as well as elevated tissue oxygen consumption, resulting in elevated cardiac output and minute ventilation (7). In an obstetric setting, it also hinders the monitoring of patients and the mother's ability to cradle the infant.

Spinal anesthesia hinders thermoregulatory mechanisms by suppressing vasoconstricting tone, which has a major role in the regulation of temperature. In addition, spinal anesthesia causes core heat redistribution from the trunk (below block level) to peripheral tissues (8). These factors increase patients' susceptibility to shivering and hypothermia. Furthermore, postoperative vomiting and nausea following spinal anesthesia for CS are prevalent and cause distress. Vomiting and nausea are controlled by two distinct medulla units, the vomiting center and the chemoreceptor trigger zone (9).

Neuraxial adjuvants are utilized to enhance or extend analgesia as well as minimize adverse effects linked to normal or elevated concentrations of a single local anesthetic agent. Numerous pharmacological interventions, such as ketamine, pethidine, doxapram, clonidine, and tramadol, have been examined for the treatment and eliminating shivering (5).

Pethidine can most effectively prevent shivering, although its action mechanism is not well-defined. The major concern is that, with concomitant use of other anesthetics, it can cause respiratory depression as well as a documented higher postoperative nausea and vomiting incidence (4). Ketamine is associated with a higher incidence of hallucinations, hypertension, and tachycardia. Tramadol is associated with nausea,

vomiting, and dizziness. Clonidine is linked to sedation and hypotension (10). In contrast, dexmedetomidine is a short-acting α2 mimetic with a diminished hypotensive impact as well as an additional sedative impact. Activating these receptors in the spinal cord as well as the brain decreases sympathetic tone and lowers the endocrine response.

Numerous antiemetics have been shown to reduce perioperative vomiting and nausea. The intravenous administration of droperidol as well as metoclopramide, decreases intraoperative nausea incidence throughout cesarean delivery (11). These medications have negative adverse effects. Droperidol has the potential to induce dysphoria and extrapyramidal symptoms (12). Metoclopramide may exacerbate tachycardia induced by stress (13). In this setting, 5-HT3 antagonists (ondansetron, granisetron) also reduce nausea (3). Although these medications have a low incidence of adverse effects, the high cost may discourage their usage.

The search for drugs that sufficiently improve thermoregulatory tolerance without causing undesirable side effects is an ongoing endeavor. We aimed to investigate intrathecal dexmedetomidine as an adjuvant to bupivacaine in spinal anesthesia to reduce trembling, with the expectation that its side effects will be minimal and may also reduce vomiting and nausea.

In this randomized controlled trial, the results obtained supported our hypotheses that the addition of dexmedetomidine to spinal anesthesia for CS substantially decreased shivering incidence (p=0.001), with a 50% elevation in Group C compared to only a 10% elevation in Group D. We discovered that it had a negligible effect on vomiting (p=0.005). Intrathecal dexmedetomidine hinders the body's thermoregulatory center by probably hindering the transmission of body temperature information at the spinal cord level, thereby decreasing shivering incidence during CS.

Consistent with our results, Wang et al. conducted a meta-analysis of 4 Randomized controlled trials (RCTs) and illustrated that intrathecal dexmedetomidine substantially decreased shivering incidence during CS (3). Furthermore, dexmedetomidine did not elevate vomiting and nausea incidence during CS. Consistent with our findings, Usta et al. reported that dexmedetomidine infusion (we utilized the intrathecal route) perioperatively substantially decreased shivering linked to spinal anesthesia during minor surgical procedures without any significant adverse effect perioperatively (14).

The results of a meta-analysis conducted by Zhang et al. on 24 RCTs support our findings (15). They discovered that dexmedetomidine as a neuraxial adjuvant was statistically effective in perioperative shivering prevention. Additionally, dexmedetomidine could enhance the block characteristics. However, they recommend considering the possibility of bradycardia. In addition, they found no evidence of an elevated risk of other complications, including hypotension and vomiting/nausea.

Our findings concur with Li et al., who confirmed that dexmedetomidine does not substantially decrease vomiting and nausea incidence during CS (16). Therefore, intrathecal dexmedetomidine does not impact vomiting and nausea incidence during CS. Unexpectedly, significant hypotension was observed when the intravenous (IV) route was utilized (11).

In 2008, Konakci et al. illustrated that elevated epidural doses administered dexmedetomidine caused demyelination in rabbits (17). Zhang et al. in 2013 evaluated intrathecal dexmedetomidine's safety and neurotoxic potential in vivio and in vitro in mice (15). In addition to its effect on prolonging analgesia, they discovered that dexmedetomidine possesses neuroprotective properties, particularly against the neurotoxicity caused by local anesthetics.

Our investigation has limitations. First, only 5µg of dexmedetomidine was administered. Further research is required to evaluate various intrathecal dexmedetomidine doses. A potential second limitation of our study is the relatively small sample size. A larger sample size is required for more precise results. Furthermore, we did not investigate the safety of dexmedetomidine in neonates. Therefore, further research is recommended.

CONCLUSION

To conclude, the addition of intrathecal dexmedetomidine to hyperbaric bupivacaine in spinal anesthesia for CS did not significantly decrease the incidence nor severity of postoperative nausea and vomiting, although it decreased the incidence and severity of shivering.

AUTHOR CONTRIBUTIONS

Conception or design of the work: ME
Data collection: HE, ME
Data analysis and interpretation: HE, ME
Drafting the article: SMSER
Critical revision of the article: ME
The author (ME, SMSER, HE) reviewed the results and approved the final version of the manuscript.

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