e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(6); 403-413

Original Research Article

Comparative Evaluation of Dexmedetomidine and Butorphanol on Perioperative Hemodynamics, Sedation and Postoperative Analgesia for Patients Undergoing Lower Abdominal Surgery

Shashank Kumar Kanaujia[1], Avinash Kumar Yadav[2], Manoj Kumar Chaurasiya[3], Bhavya Naithani[4], Ajay Chaudhary[5]

[1]Assistant Professor, Department of Anaesthesiology, King George's Medical University, Lucknow, India
[2]Junior Resident, Department of Anaesthesiology, King George's Medical University, Lucknow, India
[3]Associate Professor, Department of Anaesthesiology, King George's Medical University, Lucknow, India
[4]Assistant Professor, Department of Plastic and Reconstructive Surgery, King George's Medical University, Lucknow, India
[5]Professor, Department of Anaesthesiology, King George's Medical University, Lucknow, India

Received: 25-03-2024 / Revised: 23-04-2024 / Accepted: 26-05-2024
Corresponding Author: Dr. Manoj Kumar Chaurasiya
Conflict of interest: Nil

Abstract:

Background: Lower abdominal surgeries may be performed under regional (spinal or epidural) or general anesthesia. The aim of our study is to compare the effectiveness of dexmedetomidine and butorphanol on perioperative hemodynamics, sedation, and postoperative analgesia for patients undergoing lower abdominal surgery.

Materials and Methods: The randomized prospective study of one year was conducted in the Department of Anesthesiology, King George's Medical University, Lucknow after getting approval from the Institutional Ethics Committee of the University and informed consent from all the patients. Total 66 patients were included in this study as per inclusion and exclusion criteria and divided into two groups: Group A [n=33]: Butorphanol was given as 0.10 mg/kg in 50 ml saline as a single dose slow infusion over 10 minutes, and Group B [n=33]: Dexmedetomidine was given as 1.5 mcg/kg in 50 ml saline as a single dose slow infusion over 10 minutes.

Result: In our study mean age in group A was 31.20±6.27 years and group B was 32.72±6.02 years, where p value was 0.321. No significant difference of ASA I and ASA II between group A and group B, where p value was 0.071 in our study. In our study there was significant difference between group A and group B in comparison of mean arterial pressure at 5 min ,10min and 24 hrs having p value of .027,.040 and .040 respectively. There was significant difference between group A and group B in comparison of VAS score at 24hrs, 48hrs, 72hrs p value were <.001, <.001 and <.001 respectively. In our study significant difference between group A and group B in comparison of Sedation score at baseline, 1 hr, 6 hrs, 12 hrs, 48 hrs and 72 hrs, the p values were <0.001, <0.001, <0.001, <0.001, 0.025 and <0.001 respectively. In our study, bradycardia was noted in 6.06% patients of group A and 3.03% patients of group B, there was no statistically significant difference between both the groups. There was significant difference between group A and group B in comparison of nausea, vomiting and constipation, where p values were 0.049, 0.031 and 0.048 respectively.

Conclusion: The present study concludes that group B (dexmedetomidine) drug has been found to have better control in heart rate, mean arterial pressure with better sedation and good postoperative analgesia as compared to group A (butorphanol) drug.

Keywords: Dexmedetomidine, Butorphanol, Perioperative Hemodynamics and Sedation, Postoperative Analgesia, Lower Abdominal Surgery.

Introduction

Lower abdominal surgeries may be performed under regional (spinal or epidural) or general anesthesia. Because of its fast initiation, superior blockade, decreased risk of infection, lower failure rates, and cost-effectiveness, the spinal blockade is still the first alternative, although it has the disadvantages of shorter block length and lesser postoperative analgesia. The most common agent used for spinal anesthesia, bupivacaine, is a local anesthetic that has a relatively limited time of operation. Many local anesthetic adjuvants have been used intrathecally to enhance and extend the efficiency of intraoperative analgesia in the postoperative phase.[1-2]

Opioids are commonly employed to provide neuraxial analgesia over systemic drugs, with the advantages of neuraxial narcotics being well-established.[1] Opioids provide the advantage of providing strong analgesia in comparison with local anesthetics and allow the patient's early ambulation by sparing sympathetic and motor nerves.

It is approximately 25 times as strong as morphine and has a low dependency on the skin. Dexmedetomidine was recently evaluated as a supplement to local anesthesia and has more of an alpha-2-adrenergic agonist than Clonidine.[4-6] The affinity for α2adrenoreceptor is about ten times higher. The analgesic effect of Dexmedetomidine is inhibited by the release of c-fiber transmitters and by hyperpolarizing post-synaptic dorsal horn neurons. [3]

Many people use butorphanol for headaches, perioperative analgesia, and musculoskeletal pain, even though it only has a 0.5% analgesic impact compared to sufentanil. Dexmedetomidine is anα-2-receptor agonist, and a study has found that dexmedetomidine infusion enhances renal function. Activation of the α-2 receptor, by inhibiting renin and antidiuretic hormone secretions, and by stopping adrenal steroidogenesis, stimulates the excretion of sodium and water. Furthermore, studies have indicated that the stimulation of the α-2 receptor increases GFR through the stimulation of atrial natriuretic peptide, leading to afferent arteriolar dilatation.[7-9]A recent study has also shown that butorphanol combined with Dexmedetomidine can be used safely and effectively in patients undergoing laparoscopic surgery with no increase in the incidence of adverse reactions.[7]

This procedure has proved to be very safe, but risks and potential complications exist as in any surgical procedure. Compared with open surgery, the safety and complication rates are similar.

Risks include the following

- Bleeding: This procedure will lead to some blood loss, but patients rarely need a blood transfusion. You need to make your surgeon aware if you are interested in autologous blood transfusion.
- Infection: A wide range of antibiotics is treated to decrease the risk of infection following surgery. Please contact us at once if you experience signs or symptoms of infection after the procedure (fever, incision drainage, urinary hypothesis or irritation, pain, or something that may be of interest to you).[1-2]
- Tissue/organ injury: A potential intestine, vascular, spleen, liver, lung, pancreas, gallbladder, and other tissue/organ injury may be rare, but may need a further operation. Rare, but a possible risk is kidney function failure. The tissue of the cardiovascular can develop in the kidney as well.[10]
- Conversion to open surgery: If trouble occurs during this procedure, this surgical procedure can involve conversion to a standard operation. This can lead to a wider open incision norm and therefore a longer recovery time.
- Stone removal failure: it is a risk that the stone, typically due to the tallness or position of the stone, cannot be fully removed. Further care may be appropriate.[1] Of the above background, this study will be focused on the comparative evaluation of dexmedetomidine and perioperative butorphanol hemodynamics, sedation, and postoperative analgesia for patients undergoing lower abdominal surgery.

Aims and Objectives

The aim of our study is to compare the effectiveness of dexmedetomidine and butorphanol on perioperative hemodynamics, sedation, and postoperative analgesia for patients undergoing lower abdominal surgery.

Primary Objective

To estimate and compare the effectiveness of dexmedetomidine and butorphanol in peri-operatives mean arterial blood pressure.

Secondary Objective

- Effectiveness & comparison of study drug on intraoperative sedation
- Effectiveness &comparison of study drug on postoperative analgesia

Materials and Methods

The randomized prospective study of one year was conducted in the Department of Anesthesiology, King George's Medical University, Lucknow after getting approval from the Institutional Ethics Committee of the University and informed consent from all the patients. Total 66 patients were included in this study as per the inclusion and exclusion criteria and divided equally into two groups: Group A [n=33]: Butorphanol was given as 0.10 mg/kg in 50 ml saline as a single dose slow infusion over 10 minutes, and Group B [n=33]: Dexmedetomidine was given as 1.5 mcg/kg in 50 ml saline as a single dose slow infusion over 10 minutes.

Inclusion Criteria

- Patients of either sex, aged 20-60 years
- ASA grade I-II
- Lower abdominal surgery

Exclusion Criteria

- Presence of SBP 150 mmHg DBP 90 mmHg inside OT

- BMI >30 kg/m2, renal or hepatic insufficiency, neurologic, psychiatric disease, preoperative HR <45/min or on antihypertensive medication with any α2 adrenergic agonists e.g., clonidine
- Patient having bradycardia (HR ≤50 beats/minute) and heart block, arrhythmia
- Patients with diabetic mellitus.

Sample Size

66 cases (33 in each group)

The sample size formulae used are as follows:(Bernard, 5th edition) [11]

$$n = \frac{(\sigma_1^2 + \sigma_2^2 / \kappa)\,(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

Where,

n = Sample size

σ = Standard Deviation; Δ = Difference of means; κ= Ratio

$Z_{1-\alpha/2}$= Two-sided Z value

$Z_{1-\beta}$= Power

$$n = \frac{(0.04^2 + 0.06^2)/1\,(1.64 + 0.84)^2}{0.010^2}$$

$$n = \frac{(0.0052)\,(6.175)}{0.00100} = 32.55$$

So, n = 33 in each group.

Study Protocol

Patients were evaluated at the day before surgery by an anaesthesiologist. Patients were randomly assigned to receive dexmedetomidine or Butorphanol, according to sequentially numbered opaque sealed envelope.

To maintain blinding, the anaesthetist who prepared and administered the anaesthesia help in collecting data, but not involved in management or assessments. All patients were blind to the intervention. Patients received standardised care during the peri-operative period.

Once the patients were shifted to the operating room, the electrocardiogram monitoring, non-invasive blood pressure and pulse oximeter were attached and baseline vitals recorded. In group A patient, Butorphanol was given as 0.10 mg/kg in 50 ml saline as a single dose slow infusion over 10 minutes. In group B patient, Dexmedetomidine was given as 1.5 mcg/kg in 50 ml saline as a single dose slow infusion over 10 minutes.

Patients' blood pressure, Heart rate and anxiety level of were assessed using the Ramsay Sedation Score (RSS) at this point and every 5 min during intraoperative period and every hour in the postoperative period until completion of the study.

The patient positioned in the right lateral position and lumbar puncture performed under aseptic precautions using either a 23-guage or a 25-guage Quincke-Babcock spinal needle in the L3- L4 interspace. After obtaining free flow of cerebrospinal fluid, heavy bupivacaine (.5%) 3mg/kg was injected intrathecally and then patients were turned supine. Oxygen administered continuously at 5 L/min via a face mask. In both group patients, vitals recorded every 5 minutes and their anxiety level is assessed through Ramsay Sedation Score. Postoperative analgesia is assessed using VAS scale. Vasoactive drugs including mephentermine and phenylephrine was used to maintain blood pressure in the normal range according to haemodynamic responses when necessary, and atropine was used if heart rates were less than 50 beats/min.

Follow-up

Side effects potentially related to bradycardia and hypotension, was recorded. Bradycardia was defined as a heart rate less than 50 beats/min, and hypotension were defined as the mean arterial pressure being less than 30% from baseline or a systolic blood pressure decrease of less than 90 mm Hg for 3 min. Follow-up evaluations performed on postoperative day 1–3 (24, 48 and 72 hours after surgery).

Statistical Analysis

Data was entered in Microsoft Excel and analyzed using statistical software IBM SPSS version 21 (Chicago, IL, USA). Statistical analysis was performed using SPSS software (SPSS Inc., Chicago, IL, USA) for Windows program.

The continuous variables were evaluated by mean (standard deviation) or range value when required. The dichotomous variables were presented in number/frequency and analyzed using Chi-square or Fisher Extract test. For comparison of the means between the two groups, analysis by Student t-test, Mann-Whitney U test, and Spearman correlation with 95% confidence interval were used. A p-value of < 0.05 or 0.001 was regarded as significant.

Results

Table 1 shows that 18 (54.54%) male and 15 (45.45%) female in group A and out of 33 patients 19 (57.57%) male and 14 (42.42%) female in group B.

Table 1: Gender Distribution in both group

Gender	Group A	Group B
Male	18 (54.54%)	19 (57.57%)
Female	15 (45.45%)	14 (42.42%)

Table 2: Age distribution in group A & Group B

Age Group	Group A	Group B
20 to 30 years	9 (27.27%)	10 (30.30%)
31 to 40 years	11 (33.33%)	9 (27.27%)
40 to 50 years	7 (21.21%)	6 (18.18%)
51 to 60 years	6 (18.18%)	8 (24.24%)
Mean Age	44.52±10.27	42.42±9.11
Total	33	33

Table 2 shows that out of 33 patients of group A 9 (27.27%) patients were between 20 to 30 years, 11 (33.33%) patients were between 31 to 40 years, 7 (21.21%) patients were between 40 to 50 years, 6 (18.18%) patients were between 51 to 60 years. Out of 33 patients of group B, 10 (30.30%) patients were between 20 to 30 years, 9 (27.27%) patients were between 31 to 40 years, 6 (18.18%) patients were between 40 to 50 years, 8 (24.24%) patients were between 51 to 60 years.

Table 3: Comparison of parameters between group A & Group B

Variables	Group A	Group B	T Value	P Value
Age (Years)	31.20±6.27	32.72±6.02	-1.109	0.321
Height (cm)	164.17±6.75	164.50±7.93	-1.197	0.802
Weight (kg)	64.55±5.56	61.87±7.23	1.854	0.102
BMI (Kg/m^2)	24.00±2.75	22.90±2.71	1.798	0.153
Surgery Duration(min)	88.45±11.53	87.00±13.82	0.509	0.620

Table 3 shows that mean age in group A was 31.20±6.27 and group B was 32.72±6.02, where p value was 0.321. Mean height in group A was 164.17±6.75 cm and group B were 164.50±7.93 cm, where p value was 0.802. Mean weight in group A was 64.55±5.56 kg and group B was 61.87±7.23 kg, where p value was 0.102. Mean BMI in group A was 24.00±2.75 kg/m^2 and group B was 22.90±2.71 kg/m^2, where p value was 0.153. mean surgery duration in group A was 88.45±11.53 min and the mean surgery duration was 87.00±13.82 min, where p value was 0.620.

Table 4: Comparison of Gender Distribution between group A and group B

Variables	Group A	Group B	P Value
Male	18 (54.54%)	19 (57.57%)	0.421
Female	15 (45.45%)	14 (42.42%)	
Total	33	33	

Table 4 shows no significant difference of gender distribution between group A and group B.

Table 5: ASA grading in group A and Group B

Variables	Group A	Group B	P Value
ASA I	19 (57.57%)	24 (72.72%)	0.071
ASA II	14 (42.42%)	9 (27.27%)	

Table 5 shows that no significant difference of ASA I and ASA II between group A and group B, where p value was 0.071.

Table 6: Comparison of duration of analgesia between group A and Group B

Variables	Group A	Group B	T Value	P Value
Duration of Analgesia (min)	440.0±41.91	520.8±34.21	9.75	<0.001

Table 6 displays that duration of Analgesia in group A was 440.0±41.91 min and group B was 520.8±34.21 min, where p value was <0.001.

Table 7: Comparison of VAS score between group A and Group B

VAS score	Group A (B)	Group B (D)	T Value	P Value
VAS score1	0	0	-	-
VAS score 2	0	0	-	-
VAS score 3	0	1 (3.03%)	0.894	0.112
VAS score 4	2 (6.06%)	3 (9.09%)	0.887	0.101
VAS score 5	9 (27.27%)	15 (45.45%)	1.894	0.033
VAS score 6	12 (36.36%)	8 (24.24%)	1.457	0.044
VAS score 7	7 (21.21%)	3 (9.09%)	1.199	0.021
VAS score 8	3 (9.09%)	0	1.094	0.032
VAS score 9	0	0	-	-
VAS score 10	0	0	-	-

Table 7 illustrates that out of 33 patients of group A VAS score 4 in 2 (6.06%) patients, VAS score 5 in 9 (27.27%) patients, VAS score 6 in 12 (36.36%) patients, VAS score of 7 in 7 (21.21%) and VAS score 8 in 3 (9.09%) patients. Out of 33 patients of group B VAS score 3 in 1 (3.03%) patients, VAS score 4 in 3 (9.09%) patients, VAS score 5 in 15 (45.45%) patients, VAS score of 6 in 8 (24.24%) and VAS score 7 in 3 (9.09%) patients. In comparison of both groups significant difference in VAS score 5, VAS score 6 VAS score 7 and VAS score 8, where p value was 0.033, 0.044, 0.021, 0.032 respectively.

Table 8: Comparison of Ramsay score between group A and Group B

Ramsay score	Group A (B)	Group B (D)	T Value	P Value
1	0	0	-	-
2	0	3 (9.09%)	1.3688	0.044
3	5 (15.15%)	8 (24.24%)	1.1425	0.111
4	11 (33.33%)	19 (57.57%)	0.9357	0.033
5	17 (51.51%)	3 (9.09%)	0.8468	0.001
6	0	0	0.7468	-

Table 8 shows that out of 33 patients of group A Ramsay score 3 in 5 (15.15%) patients, Ramsay score 4 in 11 (33.33%) patients and Ramsay score 5 in 17 (51.51%) patients. Similarly, out of 33 patients of group B, Ramsay score 2 in 3 (9.09%) patients, Ramsay score 3 in 8 (24.24%) patients, Ramsay score 4 in 19 (57.57%) patients and Ramsay score 5 in 3 (9.09%) patients. In comparison of both groups there were significant difference in Ramsay score 2, Ramsay score 4 and Ramsay score 5, where p values were 0.044, 0.033 and 0.001 respectively.

Table 9: comparison of pulse rate between group A & Group B

Pulse (Per Minute)	Group A		Group B		T Value	P Value
	Mean	SD	Mean	SD		
Base Line	80.6	9.68	79.3	7.75	0.6954	0.473
5 Min	77.7	9.67	76.9	7.76	0.8214	0.665
10 Min	76.0	9.56	76.3	7.60	1.0743	0.962
15 Min	78.1	9.68	78.2	7.43	0.9688	0.939
30 Min	77.0	9.80	76.0	7.24	0.5425	0.506
45 Min	78.77	9.87	77.2	7.67	0.4357	0.375
60 Min	77.0	9.80	75.2	7.64	0.5468	0.298
6 hr	75.3	9.44	73.8	7.08	0.6542	0.479
12 hr	77.0	9.46	76.5	7.65	1.325	0.791
24 hr	73.1	8.61	74.5	6.84	1.542	0.321
48 hr	75.6	8.66	75.1	6.84	1.021	0.854
72 hr	74.6	6.74	74.1	7.41	1.250	0.457

Table 9 shows there were no any significant difference between group A and group B in comparison of pulse rate at base line to 72 hrs.

Table 10: comparison of Systolic Blood Pressure rate between group A & Group B

Systolic Blood Pressure	Group A		Group B		T Value	P Value
	Mean	SD	Mean	SD		
Base Line	126.3	7.21	124.7	6.40	1.025	0.316
5 Min	118.7	7.28	114.8	6.30	1.532	0.016
10 Min	115.8	7.25	111.3	6.37	1.792	**0.006**
15 Min	116.9	7.23	113.4	6.33	1.547	**0.030**
30 Min	113.3	7.14	110.4	6.33	1.856	0.060
45 Min	111.8	7.07	109.2	6.36	1.596	0.094
60 Min	112.9	6.91	110.4	6.33	1.823	0.084
6 hr	113.5	6.95	112.3	5.73	1.195	0.421
12 hr	114.2	6.35	112.0	4.60	1.698	0.163
24 hr	113.2	6.31	111.8	3.54	1.664	0.142
48 hr	113.6	6.32	111.6	3.45	1.451	0.131
72 hr	113.2	5.62	111.2	3.13	1.514	0.624

Table 10 indicates there were significant difference between group A and group B in comparison of Systolic Blood Pressure at 10 min and 15 min, the p value was 0.006 and 0.030 respectively.

Table 11: Comparison of Diastolic Blood Pressure between group A & Group B

Diastolic Blood Pressure (mm/hg)	Group A		Group B		T Value	P Value
	Mean	SD	Mean	SD		
Base Line	77.67	5.57	76.6	6.65	0.644	0.544
5 Min	76.1	5.63	74.2	4.96	1.245	0.135
10 Min	74.7	5.75	73.3	5.06	1.011	0.265
15 Min	75.3	5.73	73.1	5.18	1.457	0.102
30 Min	75.7	5.68	74.3	5.29	1.199	0.316
45 Min	73.9	5.72	71.7	5.38	1.894	0.118
60 Min	73.3	5.93	70.5	5.40	1.887	0.041
6 hr	72.7	5.92	71.5	6.44	0.801	0.441
12 hr	70.9	6.18	71.7	5.92	-0.277	0.569
24 hr	71.2	6.51	72.2	5.54	-0.214	0.421
48 hr	71.0	6.10	72.1	4.65	-0.324	0.214
72 hr	70.8	6.01	72.0	4.01	-0.214	0.124

Table 11 shows there were significant difference between group A and group B in comparison of Diastolic Blood Pressure at 60 min, the p value was 0.041 respectively.

Table 12: Comparison of Mean Arterial Pressure between Group A & Group B

MAP (mm/hg)	Group A		Group B		T Value	P Value
	Mean	SD	Mean	SD		
Base Line	93.7	5.34	92.5	5.39	0.010	0.314
5 Min	90.3	5.35	87.7	4.24	1.564	0.027
10 Min	88.4	5.36	85.9	4.37	1.624	0.042
15 Min	89.2	5.35	86.5	4.31	1.589	0.040
30 Min	88.2	5.26	86.2	4.54	1.632	0.108
45 Min	87.2	5.62	85.8	4.41	1.632	0.118
60 Min	86.9	5.12	85.6	3.89	1.521	0.121
6 hr	86.5	5.01	85.3	4.20	1.111	0.215
12 hr	86.5	5.30	84.2	4.55	1.625	0.073
24 hr	86.5	5.40	83.9	4.53	1.712	0.040
48 hr	85.7	5.55	84.2	5.52	1.742	0.243
72 hr	85.2	5.50	85.0	4.03	0.754	0.950

Table 12 shows there were significant difference between group A and group B in comparison of Mean Arterial Pressure at 5 min, 10 min, 15 min and 24 hrs, the p value was 0.027, 0.042, 0.040 and 0.040 respectively.

Table 13: Comparison of Sedation score between Group A & Group B

Sedation score	Group A		Group B		T Value	P Value
	Mean	SD	Mean	SD		
Base Line	1.80	0.607	2.8	0.36	9.321	<0.001
1 hr	1.25	0.438	2.4	0.54	-10254	<0.001
6 hr	1.17	0.384	1.8	0.38	-7.212	<0.001
12 hr	1.15	0.361	1.5	0.50	-3.652	<0.001
24 hr	1.10	0.303	1.1	0.38	-1.121	0.333
48 hr	0.97	0.158	1.1	0.30	-2.312	0.025
72 hr	0.62	0.490	1.0	0.00	4.785	<0.001

Table 13 displays there were significant difference between group A and group B in comparison of Sedation score at baseline, 1 hr, 6 hrs, 12 hrs, 48 hrs and 72 hrs, the p values were<0.001, <0.001, <0.001, <0.001, 0.025 and <0.001 respectively.

Table 14: Comparison of VAS score between Group A& Group B

VAS score	Group A		Group B		T Value	P Value
	Mean	SD	Mean	SD		
Base Line	0.00	0.00	0.00	0.00	-	-
6 hr	0.00	0.00	0.00	0.00	-	-
12 hr	0.95	0.50	0.72	0.45	2.021	0.048
24 hr	1.82	0.63	1.00	0.00	8.125	<0.001
48 hr	2.37	0.63	1.15	0.36	10.635	<0.001
72 hr	2.75	0.54	1.87	0.68	6.314	<0.001

Table 14 illustrates there were significant difference between group A and group B in comparison of VAS score at 24 hrs, 48 hrs and 72 hrs, the p values were<0.001, <0.001 and <0.001 respectively.

Table 15: Comparison of Bradycardia and Hypotension evidence between Group A& Group B

Complication	Group A N (%)	Group B N (%)	P Value
Evidence of Bradycardia	2 (6.06%)	1 (3.03%)	0.155
Evidence of Hypotension	3 (9.09)	1 (3.03)	0.055

Table 15 shows that out of 33 patients of each group, evidence of Bradycardia in 2 (6.06%) patients of group A and 1 (3.03%) patients of group B, there is no any significant difference between (p-0.155) both groups. Similarly, out of 33 patients of each groups, evidence of hypotension in 3 (9.09) patients of group A and 1 (3.03%) patients of group B, there is no any significant difference (p-0.055) between both groups.

Table 16: Comparison of side effects between Group A & Group B

Complication	Group A N (%)	Group B N (%)	P Value
Dry Mouth	1 (3.03%)	0	NS
Nausea	3 (9.09%)	1 (3.03%)	0.049
Pruritus	0	0	NS
Vomiting	2 (6.06%)	0	0.031
Dizziness	1 (3.03%)	0	NS
Constipation	3 (9.09%)	1 (3.03%)	0.048
Total	33	33	-

Table 16 describes that out of 33 patients of group A Dry mouth in 1 (3.03%) patient, Nausea in 3 (9.09%) patients, Vomiting in 2 (6.06%) patients, Dizziness in 1 (3.03%) patients and Constipation in 3 (9.09%) patients. Similarly, out of 33 patients of group B, Nausea in 1 (3.03%) patient, and Constipation 1 (3.03%) patients. There was significant difference between group A and group B in comparison of Nausea, Vomiting and Constipation, where p values were 0.049, 0.031 and 0.048 respectively.

Discussion

In our study 54.54% were male and 45.45% female in group A and 57.57% male and 42.42% female in group B. In our study mean age in group A was 31.20±6.27 and group B was 32.72±6.02, where p value was 0.321. Mean height in group A was 164.17±6.75 cm and group B was 164.50±7.93 cm, where p value was 0.802. Mean weight in group A was 64.55±5.56 kg and group B was 61.87±7.23 kg, where p value was 0.102. Mean BMI in group A was 24.00±2.75 kg/m2 and group B was 22.90±2.71 kg/m2, where p value was 0.153. mean surgery duration in group A was 88.45±11.53 min and mean surgery duration was 87.00±13.82 min, where p value was 0.620 all parameters were com-

parable and not statistically significant in consonance with Thomas, S. M. et al.[12] who also reported no significant difference between age and weight in both groups. With respect to demographic profile of the subjects of this study, Group B (dexmedetomidine) and Group A (butorphanol) were statistically comparable in terms of number of patients, age, weight, gender, ASA status and duration of surgery. The study's observed demographic statistics agreed with those of Ahmad Waqar Khan et al.[13] who evaluated intravenous dexmedetomidine (1 µg/kg IV) versus butorphanol (30 µg/kg IV) and found no significant difference in demographic profile of the subjects.

No significant difference of ASA I and ASA II between group A and group B, where p value was 0.071 in our study. In our study there was significant difference between group A and group B in comparison of mean arterial pressure at 5 min ,10min and 24 hrs having p value of .027,.040 and .040 respectively. In our study intravenous infusion of dexmedetomidine causes less fall in mean arterial pressure with better intraoperative hemodynamic stability as compare to intravenous infusion of butorphanol. Kondavagilu SR et al. [14] in 2017 who found that low dose intravenous dexmedetomidine (0.5µg/kg) attenuated the haemodynamic response similar to high dose intravenous dexmedetomidine (1µg/kg) as compared to normal saline taken as placebo. In their study, mean pressures and heart rate increased significantly at skull pin insertion in the placebo group but not in the groups in which intravenous dexmedetomidine was given. In our study significant difference between group A and group B in comparison of systolic blood pressure at 10 min and 15 min p value were .006 and .030 respectively. Jakkola et al. [15] observed a significantly increased diastolic blood pressure (increase of 20mmhg) in control group and a reduced diastolic blood pressure in dexmedetomidine group compared to baseline. In our study out of 33 patients of each group, evidence of hypotension in 3(9.09%) patients of group A and 1 patient (3.03%) of group B, there is no any significant difference between both groups. There was a fall in heart rate after infusion of dexmedetomidine. In our study out of 33 patients of each group, evidence of bradycardia in 2(6.06%) patients of group A and 1 (3.03%) patients of group B, showing no significant difference between both the groups.

Prasad SR et al. [16] conducted a study in 2012 to compare the haemodynamic parameters and efficacy of sedation between intravenous dexmedetomidine (0.5 µg/kg/hr) and fentanyl (1µg/kg/hr) in pediatric cardiac surgical patients. They found a decrease in heart rate in both the groups which was less than 10 to 15% of baseline and did not require any intervention. This finding is similar to our study in which there was a decrease in heart rate in both the groups which was statistically significant and clinically insignificant. In a study comparing intravenous butorphanol (25 µg/kg i.v.) with fentanyl (2 µg/kg i.v.) in patients having laparoscopic operations, Drs. Bhavna, H. Sojitra, Deepali L. Patel, et al. [17] found that the mean intra-operative HR, SBP, DBP, and MAP remained lower in the butorphanol group.

The treatment of pain after surgery is central to the care of postoperative pain. Pain during post operative period was measured using visual analogue scale.In our study out of 33 patients of group A VAS score 4 in 2 (6.06%) patients, VAS score 5 in 9 (27.27%) patients, VAS score 6 in 12 (36.36%) patients, VAS score of 7 in 7 (21.21%) and VAS score 8 in 3 (9.09%) patients. Out of 33 patients of group B VAS score 3 in 1 (3.03%) patient, VAS score 4 in 3 (9.09%) patients, VAS score 5 in 15 (45.45%) patients, VAS score of 6 in 8 (24.24%) and VAS score 7 in 3 (9.09%) patients. In comparison of both groups significant difference in VAS score 5, 6, 7, 8 where p values were 0.033, 0.044, 0.021, 0.032 respectively. Incidence of postoperative pain was less with no requirement of rescue analgesia in patients receiving intravenous dexmedetomidine than in patient receiving intravenous butorphanol. There was significant difference between group A and group B in comparison of VAS score at 24hrs, 48hrs, 72hrs p value were <.001, <.001 and <.001 respectively. Zhu et al. [18] in his meta-analysis evaluates the efficacy and safety regarding usage of butorphanol in patient-controlled analgesia, on the basis postoperative VAS score, postoperative RSS, and adverse events between the butorphanol and non-butorphanol groups. He concluded that butorphanol may be used in PCA as a successful postoperative analgesia and is also associated with lower side effects. Hall JE et al. [19] observed both 0.2 and 0.6-mcg/kg/hr infusions of dexmedetomidine (small and moderate doses) produced significant sedation that resolved two hours after terminating the infusions as compared with placebo. Zhang et al. [7] found that dexmedetomidine was more effective than sufentanil for maternal labor sedation, and the analgesic and sedative effects of dexmedetomidine in the high-dose group were better than those in the low-dose group. In a study by Liu et al. [20] found that the addition of dexmedetomidine combined with butorphanol to the basic postoperative analgesia regimen enhanced the analgesic effect without increasing the adverse reactions in patients, which suggested that dexmedetomidine combined with butorphanol is not only effective in postoperative analgesia and sedation but also safe in puerperium after a cesarean section.

In our study out of 33 patients of group A Ramsay score 3 in 5 (15.15%) patients, Ramsay score 4 in 11 (33.33%) patients and Ramsay score 5 in 17 (51.51%) patients. In group B out of 33 patients of

group B, Ramsay score 2 in 3 (9.09%) patients, Ramsay score 3 in 8 (24.24%) patients, Ramsay score 4 in 19 (57.57%) patients and Ramsay score 5 in 3 (9.09%) patients. In comparison of both groups there were significant difference in Ramsay score 2, 4 & 5, where p values were 0.044, 0.033 and 0.001 respectively. The Ramsay sedation score was significantly higher in Group A as compared to Group B drugs with a statistically significant difference between the two groups. Our findings were similar to observations by Vidhya N, Prakash V et al. [21] who found sedation scores to be higher in butorphanol (20 µg/kg) group when comparing with nalbuphine (100 µg/kg). Sebastian B et al. [22] conducted a study in 2017 to compare intravenous dexmedetomidine at 0.75 mcg/kg and 0.5 mcg/kg with placebo (normal saline). They reported sedation scores were more with intravenous dexmedetomidine group than normal saline. In the study by Eid MD et al. [23] the median sedation score was founded to be higher in Dexmedetomidine group as compared to Buprenorphine group. In their study was no difference in median sedation score in between Bupivacaine and combination of Bupivacaine with Dexmedetomidine. In our study significant difference between group A and group B in comparison of Sedation score at baseline, 1 hr, 6 hrs, 12 hrs, 48 hrs and 72 hrs, the p values were <0.001, <0.001, <0.001, <0.001, 0.025 and <0.001 respectively. Elshafeey A et al. [24] conducted a study in 2020 to compare the efficacy of intranasal dexmedetomidine (2 mcg/kg) versus intranasal ketamine (5 mcg/kg) for anxiolysis and sedation before pediatric general anaesthesia, 30 min before procedure. They reported there was statistically significant sedation in group dexmedetomidine as compared to group ketamine. In the study of Liu et al. [20] they found that dexmedetomidine combined with butorphanol can improve the sedative effects (according to the Ramsay score) in continuous analgesia after a cesarean section, and the analgesic and sedative effects of dexmedetomidine in the high dose group are better than those in the low-dose group, which is consistent with the findings of Zhang et al. [7] found that dexmedetomidine was more effective than sufentanil for maternal labor sedation, and the analgesic and sedative effects of dexmedetomidine in the high-dose group were better than those in the low-dose group. We had also looked for the adverse events taking place in intravenous dexmedetomidine and intravenous infusion of butorphanol and found that incidence of nausea, vomiting and constipation was more common in group A(butorphanol) as compared to group B (dexmedetomidine). In our study out of 33 patients of each group, evidence of bradycardia in 2 (6.06%) patients of group A and 1 (3.03%) patients of group B, there was no statistically significant difference between both the groups. In our study group A Dry mouth in 1 (3.03%) patient, Nausea in 3 (9.09%) patients, Vomiting in 2 (6.06%) patients, Dizziness in 1 (3.03%) patients and Constipation in 3 (9.09%) patients. out of 33 patients of group B, Nausea in 1 (3.03%) patient, and Constipation 1 (3.03%) patients. There was significant difference between group A and group B in comparison of nausea, vomiting and constipation, where p values were 0.049, 0.031 and 0.048 respectively. In respect of side effect Jasleen Kaur et al. [25] shows similar result as nausea, constipation and somnolence side effect was more in butorphanol group as compared to fentanyl when used as epidural adjuvants.

Limitation

There were several limitations in our study. Sample size of 66 for such a specifically important study was comparatively moderate. Larger sample size and multicentric analysis with high precision and accuracy may be recommended for a more reliable interpretation of results. Our study includes a prospective longitudinal randomized approach that lack control group. We could have measured the parameters in much shorter interval of time. Assessment of sedation was done using the Ramsay sedation scale (RSS) score which is subjective and prone to bias. Results were limited to a single tertiary centre that may not be generalized for all settings.

Conclusion

In relation to mean heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) in the current study, we found that the butorphanol group exhibited a greater reduction in these parameters when compared to group B receiving dexmedetomidine. Regarding sedation levels, our findings indicate that patients in the dexmedetomidine group achieved Ramsay sedation scores of 3 and 4, whereas the butorphanol group achieved scores of 4 and 5. Additionally, with respect to postoperative analgesia, patients in the dexmedetomidine group reported a visual analog scale (VAS) score of 5, while those in the butorphanol group reported a VAS score of 6. Less complications were found in dexmedetomidine group in comparison to butorphanol group. So, in our study, group B(dexmedetomidine) drug has been found to have better control in HR, MAP with better sedation and good postoperative analgesia as compared to group A(butorphanol) drug.

References

1. Christiansson L. Update on adjuvants in regional anaesthesia. Period Biol. 2009; 61:161-70.
2. Chaney MA. Side effects of intrathecal and epidural opioids. Can J Anaesth. 1995; 42:891-903.

3. Wu CL, Cohen SR, Richman JM, Rowlingson AJ, CourpasGE, Cheung K. Efficacy of post-operative patient-controlled and continuous infusion epidural analgesia with opioids: A meta-analysis. Anaesthesiology 2005; 103(5): 1079-88.
4. Soumya Samal, P. Rani, Chandrasekar LJ and Saubhagya Kumar Jena. Intrathecal Buprenorphine or intrathecal Dexmedetomidine for postoperative analgesia: A comparative study. The Health Agenda, Volume 2. Issue 1. January, 2014.
5. Al-Ghanem SM, Massad IM, Al-Mustafa MM, Al-Zaben KR, Qudaista IY, Qatawneh AM et al. Effect of Adding Dexmedetomidine versus Fentanyl to Intrathecal Bupivacaine on Spinal Block Characteristics in Gynaecological Procedures: A Double Blinded Controlled Study. American Journal of Applied Sciences 2009; 6 (5):882-87.
6. Kanazi GE, Aouad MT, Jabbour-Khoury SI, Al Jazzar MD, Alameddine MM, Al-Yamman R et al. Effect of low-dose dexmedetomidine or clonidine on the characteristics of bupivacaine spinal block. Acta Anaesthesia Scand 200 50(2):222-27.
7. Zhang XK, Chen QH, Wang WX, Hu Q. Evaluation of dexmedetomidine combination with sufentanil or butorphanol for postoperative analgesia patients undergoing laparoscopic resection of gastrointestinal tumors: a quasi-experimental trial. Medicine (Baltimore). (2016)95:e5604.
8. Lipp M, Daublander M, Lanz E. Intrathecal buprenorphine for postoperative analgesia - a clinical double blinded study. Anaesthesist 1987; 36(5):233-38.
9. Dixit S. Postoperative analgesia after cesarean section: an experience wit intrathecal buprenorphine. Indian Journal of Anaethesia 2007; 51(6): 515-18.
10. Safiya IS, Kiran M. Intrathecal buprenorphine for postoperative analgesia: / prospective randomized double blinded study. J Anaesth Clin Pharmacol 2010 26(1):35-38.
11. Bernard R. Rosner. Fundamentals of Biostatistics. 5th Edition. S.Chand (G/L) & Company Ltd; 1999.
12. Thomas, S. M., Tailor, R., Kanabar.P.,Chauhan, D., & Shah, A. (2022). An observational study to compare the efficacy of dexmedetomidine versus butorphanol for balanced anaesthesia and postoperative analgesia in patients undergoing laparoscopic surgery. International Journal of Health Sciences, 6(S3), 1861-1873.
13. Ahmad Waqar Khan, Dheeraj Saxena, Juhi Saran et al. Comparison of Hemodynamic Response Among IV Butorphanol and Dexmedetomidine as a Premedication in Laparoscopic Cholecystectomy. Indian J AnesthAnalg. 2019;6(5 P-II):1715-1721.
14. Kondavagilu SR, Pujari VS, Chadalawada MVR, Bevinguddaiah Y. Low dose dexmedetomidine attenuates haemodynamic responses to skull pin holder application. Anesth Essays Res 2017;11:57-61.
15. Jaakola, Marja-Leena. "Dexmedetomidine premedication before intravenous regional anesthesia in minor outpatient hand surgery." Journal of clinical anesthesia 6.3 (1994): 204-211.
16. Prasad SR, Simha PP, Jagadeesh AM. Comparative study between dexmedetomidine and fentanyl for sedation during mechanical ventilation in postoperative pediatric cardiac surgical patients. Indian J Anaesth 2012;56:547-52.
17. Bhavna H. Sojitra, Dr. Deepali L Patel, Dr. Pragna Vachharajani, "Comparison of Butorphanol Versus Fentanyl on Intraoperative Anaesthesia Course and Post-Op Recovery Characteristic in Patient Undergoing Laparoscopic Surgery", International Journal of Science and Research (IJSR), Volume 7 Issue 2, February 2018, 425-429.
18. Zhihua Zhu and Wenyu Zhang: Efficacy and Safety of Butorphanol Use in Patient-Controlled Analgesia: A Meta-Analysis. Volume 2021, Article ID 5530441, 9.
19. Hall JE, Uhrich TD, Barney JA, Arain SR, Ebert TJ. Sedative, amnestic, and analgesic properties of small-dose dexmedetomidine infusions. Anesth Analg. 2000:90:699-705.
20. Liu H, Wang Y, Li F, Ren W and Yuan L (2022) Analgesic and Sedative Effects of Different Doses of Dexmedetomidine Combined with Butorphanol in Continuous Analgesia after a Cesarean Section. Front. Surg. 9:896536.
21. Vidhya N, Prakash V, Irshad B, Kumar VS. Comparative efficacy of butorphanol versus nalbuphine for balanced anaesthesia and postoperative analgesia in patients undergoing laparoscopic surgery. Indian J Clin Anaesth. 2019;6:143-7.
22. Sebastian, Bon, Anand T. Talikoti, and Dinesh Krishnamurthy. Attenuation of haemodynamic responses to laryngoscopy and endotracheal intubation with intravenous dexmedetomidine: A comparison between two doses. Indian journal of anaesthesia 61.1 (2017): 48.
23. Hala EA Eid, Mohamed AS, Hend Y. Dose-related prolongation of hyperbaric bupivacaine spinal anaesthesia by dexmedetomidine. Ain Shams Journal of Anesthesiology 2011; 4(2): 83-95.
24. Elshafeey A, Youssef G, Elsalam E, Saleh M, Mahrose R. Comparative study between intranasal dexmedetomidine and intranasal ketamine as a premedication for anxiolysis and sedation before pediatric general anaesthesia.

Ain Shams Journal of Anesthesiology (2020) 12:51.
25. Kaur J, Bajwa SJ. Comparison of epidural butorphanol and fentanyl as adjuvants in the lower abdominal surgery: A randomized clinical study. Saudi J Anaesth. 2014 Apr;8(2):167-7.