# Effect of fentanyl, dexmedetomidine, and esmolol on pressor response during laparoscopic cholecystectomy

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***Introduction*** Laparoscopic surgery has many beneficial effects but the creation of pneumoperitoneum (PNP) may be associated with significant hemodynamic changes.

***Aim of the work*** Primary outcome: to compare opioids and nonopioids in controlling pressor response during laparoscopy. Secondary outcome: to compare the efficacy of dexmedetomidine (Dex) and esmolol in the same situation.

***Patients and methods*** Ninety patients undergoing laparoscopic cholecystectomy were randomly divided into three equal groups; group F: received fentanyl 1 μg/kg 10 min before induction and then 0.4 μg/kg/h throughout the PNP, group D: received Dex 1 μg/kg 10 min before induction and then 0.5 μg/kg/h throughout the PNP, group E: received esmolol 1 mg/kg 10 min before induction and then 0.5 mg/kg/h throughout the PNP. Hemodynamics mainly mean heart rate (MHR) and mean arterial pressure (MAP) were recorded at a specific time. Postoperative visual analog scale, time to first request of postoperative analgesia, number of patients who required postoperative analgesia, and postoperative analgesic consumption were recorded. Perioperative sedation score and blood glucose and postoperative complications, for example, bradycardia, hypotension, nausea, and vomiting were recorded. Time of discharge from the postanesthesia care unit (PACU) and hospital stay time were recorded.

***Results*** Group D showed better hemodynamic (MHR, MAP) stability and pain control than group E and much better than group F. Sedation score was higher in group D than other two groups after infusion of test drug only. The incidence of nausea and vomiting were higher in group F than group E and nausea was higher in group D than group E. Ondanosterone use was higher group F than other two groups. PACU stay time was longer in group D than other two groups.

***Conclusion*** Nonopioids (Dex and esmolol) were superior to fentanyl for attenuation of pressor response to intubation and PNP. Apart from nausea and longer PACU stay, Dex was superior to esmolol in controlling hemodynamics with better pain control.

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## Introduction

Laparoscopic surgeries has several surgical benefits with lower cost. Laryngoscopy, intubation, and pneumoperitoneum (PNP) are associated with sympathetic effects such as the rise of blood pressure, heart rate, and cardiac output reduction due to PNP and increase of systemic and pulmonary vascular resistances. Abdominal insufflations also causes ventilatory and respiratory changes [1].

Dexmedetomidine (Dex) is an α2 agonist, approved by the Food and Drug Administration as an ICU sedative in 1991; it also possesses anesthetic, hypnotic, analgesic, and anxiolytic properties. In addition, it blunts the sympathetic mediated pressor responses [2].

Esmolol is an ultrashort-acting β1-receptor antagonist, known to blunt pressor responses to noxious stimuli [3].

Kataria *et al.* [4] examined the efficacy of Dex and fentanyl on pressor response and PNP in laparoscopic cholecystectomy. Vaswani *et al.* [5] compared the effect of Dex and fentanyl on hemodynamic response in patients undergoing elective laparoscopic surgery.

## Aim of the work

Primary outcome: to evaluate whether nonopioid drugs (Dex and esmolol) or fentanyl is more efficient in controlling pressor response to intubation and PNP during laparoscopic cholecystectomy. The secondary outcome: to compare the efficacy of Dex and esmolol in suppressing stress response during laparoscopic cholecystectomy.

## Patients and methods

After approval from the Anesthesia and Intensive Care department and from local ethics committee, and informed written consent from each patient, this study was conducted at the El-Hussein University Hospital in the period from May 2018 to October 2018.

Ninety patients of both sexes, aged between 21 and 60 years old, with American Society of Anesthesiologist

physical status I and II who are scheduled for elective laparoscopic cholecystectomy were included in this study.

Exclusion criteria included, patient's refusal, BMI of more than 35 $kgm^2$, pregnant, lactating, and menstruating women, hepatic, renal and cardiac insufficiency, diabetics, history of chronic pain, alcohol or drug abuse, psychiatric disease, allergy to the studied drugs, contraindication to any of the study drugs, and inability to assess pain or using patient-controlled analgesia device.

Patients were fasted for 8 h with chance to drink clear fluid up to 2 h before surgery.

Patients passing inclusion criteria were evaluated by medical history, examination, and laboratory investigations: [complete blood count, renal function tests, (serum creatinine and blood urea), liver function tests (alanine transaminase, aspartate transaminase), international normalized ratio, prothrombin time, partial thromboplastin time, blood glucose 'fasting, 2 h postprandial' and chest radiography]. ECG was done for patients above 40 years old. All doses are based on ideal body weight.

In the operating room, routine monitoring (ECG, noninvasive blood pressure, pulse oximetry, and ed-tidal $CO_2$) were displayed continuously and 18 G intravenous cannula was inserted to all patients.

Before induction of anesthesia, 90 patients were randomly divided by a sealed envelope into three equal groups (30 patients each):

(1) Fentanyl group (group F): received fentanyl (Sunny Pharmaceutical, Egypt under license of Hameln Pharmaceuticals, Germany), loading dose 1.0 μg/kg over 10 min before induction of anesthesia followed by continuous infusion of 0.4 μg/kg/h throughout the PNP.
(2) Dex group (group D): received Dex (Hospira Inc., Lake Forest, Illinois, USA) loading dose 1 μg/kg over 10 min before induction of anesthesia followed by continuous infusion of 0.5 μg/kg/h throughout the PNP.
(3) Esmolol group (group E): received esmolol (ET255117GB 0711 India, Lot 7G 604A), loading dose 1 mg/kg before induction over a period of 10 min and maintenance 0.5 mg/kg/h throughout the PNP.

The study drugs were prepared by an anesthesiologist not involved in the study and infused with a syringe pump (Injectomat Agilia Fresenius Kabi, Le Grand Chemin, Brezins, France) and prepared as follows: about 2 ml (200 μg) of Dex was diluted in 48 ml of normal saline to make 50 ml (concentration 4 μg/ml). About 4 ml (200 μg) of fentanyl was diluted in 46 ml normal saline to make 50 ml (concentration 4 μg/ml). About 20 ml (200 mg) of esmolol was diluted in 30 ml of normal saline to make 50 ml (concentration 4 mg/ml).

After preoxygenation for 5 min with 100% oxygen, anesthesia was induced with propofol 2 mg/kg intravenous and atracurium 0.5 mg/kg slowly intravenous followed by insertion of an appropriate size endotracheal tube.

Anesthesia was maintained by volume-controlled ventilation (maintain end-tidal $CO_2$ around 35–40 mmHg), isoflurane (1.15%) in 100% oxygen. Neuromuscular blockade was maintained with atracurium (0.15 mg/kg) intravenous every 20 min. Intra-abdominal pressure was maintained to 14 mmHg throughout the laparoscopic procedure.

At the end of surgery, isoflurane and infusion of fentanyl, Dex, and esmolol were discontinued. Reversal of muscle relaxant was done by neostigmine (0.05 mg/kg) and atropine sulfate (0.01–0.02 mg/kg) intravenous, followed by extubation after taking good regular tidal volume. Duration of surgery and anesthesia were recorded.

The patient was then transferred to the postanesthesia care unit (PACU).

The MHR and MAP were recorded before induction of anesthesia (T0), after a loading dose of the studied drugs (T1), after induction of anesthesia (T2), after intubation (T3), then every 15 min during PNP (T4, T5, T6, T7), 5 min after release of PNP (T8), and 15 min postoperatively (T9).

Postoperative pain was assessed using visual analog scale (VAS) at 20 and 60 min after recovery (V1, V2, respectively) and then at 6 h after recovery (V3).

Time to the first request of analgesia, total number of patients who required postoperative analgesia, number of patients who required postoperative analgesia (ketorolac and pethidine) and average postoperative total analgesic consumption (ketorolac and pethidine) were recorded.

Sedation was assessed using the modified Ramsay sedation score preoperatively (S0), 10 min after

infusion of study drugs and before induction of anesthesia (S1), and half hour postoperatively (S2).

Random blood glucose level was recorded before induction of anesthesia (G0), half hour after start of anesthesia (G1), and after recovery (G2).

Complications during first 24 h were recorded including the postoperative nausea and vomiting (treated with ondansetron 0.1 mg/kg), and incidence of hypotension and bradycardia were recorded.

Time of discharge from PACU (min) and hospital stay time (h) were recorded.

Hypotension was defined as a 20% decrease of baseline MAP and was treated by rapid intravenous administration of 10 ml/kg of lactated Ringer's solution but if not successful ephedrine (3 mg) intravenous was given. Bradycardia was defined as a heart rate (HR) of less than or equal to 59 bpm and was treated by atropine (0.01 mg/kg).

#### Visual analog scale

VAS is a subjective assessment of pain. The VAS is a straight, 10 cm line, which can either be vertical or horizontal, where the left end indicates no pain, while the other end denotes the worst tolerable pain. A patient determines their intensity of pain (mm), by making a single point on the line [6].

The day before surgery, the patients were familiarized with the standard VAS for pain assessment.

#### Analgesic regimen

Postoperative pain management started as soon as the patient experience pain. At a VAS of more than or equal to 4, ketorolac (30 mg intramuscular) was given. Reassessment of the pain after 10 min, if the VAS is more than or equal to 4, pethidine (1 mg/kg intravenous) was given to the patient.

Modified Ramsay sedation score: The score consists of the following six grades:

1=Anxious or agitated and restless or both.
2=Cooperative, oriented, and tranquil.
3=Drowsy but responds to commands.
4=Asleep, brisk response to light glabellar tap or loud auditory stimulus.
5=Asleep, sluggish response to light glabellar tap or loud auditory stimulus.
6=Asleep and unarousable.

Sedation score of greater than 3 was considered as undesirable. The patient was discharged from the recovery room after a score of less than or equal to 3 [7].

#### Statistical analysis

SPSS, version 17 program (SPSS Inc., Chicago, Illinois, USA), was used to enter data and statistical analysis. Data were presented as mean±SD, number, and percent. Comparison between the three groups was performed using analysis of variance test for parametric data; post-hoc test was done if analysis of variance test was significant, $\chi^2$ for number (%), and median and range for scores. A $P$ value of less than 0.05 was considered as statistically significant.

## Results

The three groups were comparable regarding demographic data and duration of surgery (Table 1).

The MHR was significantly lower ($P<0.05$) in group D in comparison to both group F and group E at all study times. In group D, there was no significant increase ($P>0.05$) in MHR compared with preoperative value at all times of the study, while in both group F and group E, it was significantly increased ($P>0.05$) at T3, T4, T6, T7 but it was significantly increased ($P<0.05$) in group F only at T5, T8, T9 (Fig. 1).

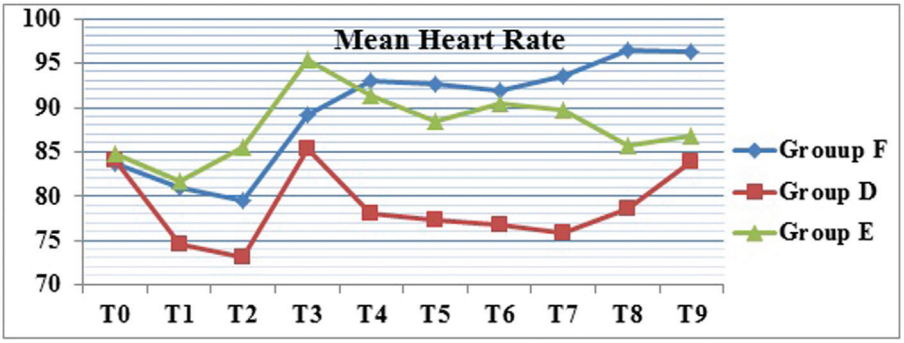
The MAP was significantly lower ($P<0.05$) in group D compared with both group F and group E at all study times. In group D, there was no significant increase ($P>0.05$) in MAP compared with preoperative values at all times of the study, while in both group F and group E, it was significantly increased ($P<0.05$) at T3, T4, T5, and T6, but at T7, it was increased in group E only and it was significantly increased ($P<0.05$) in group F only at T8 and T9 (Fig. 2).

**Table 1 Demographic data and duration of surgery**

| | Group F ($N$=30) | Group D ($N$=30) | Group E ($N$=30) | $P$ value |
|---|---|---|---|---|
| Age (years) | 45.5±8.3 | 44.4±7.9 | 44.9±8.6 | 0.842 |
| Sex (female/male) | 24 (60)/ 16 (40) | 26 (65)/ 14 (35) | 22 (55)/ 18 (45) | 0.659 |
| BMI (kg/m$^2$) | 27.7±3.7 | 28.2±3.5 | 28.4±3.8 | 0.749 |
| ASA physical status (ASA I/ASA II) | 30 (75)/ 10 (25) | 32 (80)/8 (20) | 28 (70)/ 12 (30) | 0.587 |
| Duration of surgery (min) | 45.3±3.2 | 47.1±3.3 | 46.3±3.4 | 0.113 |

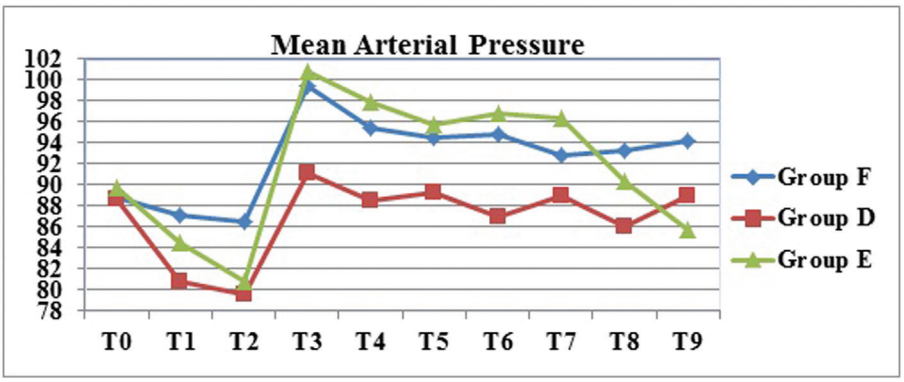
Data are represented as mean±SD and $n$ (%). ASA, American Society of Anesthesiologists; group D, dexmedetomidine group; group E, esmolol group; group F, fentanyl group. $P$ value more than 0.05, statistically not significant; $P$ value less than 0.05, statistically significant.

**Figure 1**




Mean heart rate among groups.

**Figure 2**




Mean arterial pressure among groups.

VAS was lower in group D than the other two groups at all postoperative times of the study but without significant differences (Table 2).

Time to first request of postoperative analgesia (min) was significantly longer in group D than the other two groups. Number of patients who required postoperative analgesia, and who required ketorolac or pethidine and average ketorolac (mg) and pethidine (mg) consumption were significantly lower in group D than group E and much lower than group F (Table 3, Fig. 3).

Sedation scores were comparable among the three groups at S0 and S2 but it was significantly higher in group D than the other two groups at S1 (Table 4).

Regarding blood glucose level (mg/dl), there were no significant differences among groups at all study times (Table 5).

The incidence of nausea and vomiting were significantly higher in group F than group E ($P<0.001$, 0.024, respectively) and nausea was significantly higher in group D than group E ($P=0.024$). Ondansetron use was significantly higher in group F than the other two groups ($P=0.011$, 0.011, respectively). There was no significant differences ($P>0.05$) regarding incidence of hypotension and bradycardia among groups (Fig. 4).

PACU stay time (min) was significantly longer in group D than both group F and group E ($P<0.001$, $<0.001$, respectively) and it was also significantly longer in group E than group F ($P=0.02$), while hospital stay time (h) showed no significant difference among groups ($P>0.05$) (Table 6).

## Discussion

Laryngoscopy and tracheal intubation are associated with sympathetic stimulation, which may cause a rise in blood pressure and HR and laparoscopy requires creation of PNP, with an elevation of intra-abdominal pressure that may cause a rise in plasma level of epinephrine, norepinephrine, and renin activity. Renin–angiotensin–aldosterone system activation leads to various hemodynamic changes such as decreased cardiac output, increased arterial pressure, and elevated pulmonary and systemic vascular resistance [8].

**Table 2 Postoperative visual analog scale among groups**

| | Group F (*N*=30) | | Group D (*N*=30) | | Group E (*N*=30) | | |
|---|---|---|---|---|---|---|---|
| Time | Median | Range | Median | Range | Median | Range | *P* value |
| At 20 min postoperative (V1) | 3 | 2–5 | 1 | 1–2 | 3 | 2–4 | 0.475 |
| At 60 min postoperative (V2) | 5 | 4–7 | 3 | 2–5 | 5 | 3–8 | 0.581 |
| At 6 h postoperative (V3) | 3 | 2–6 | 2 | 1–4 | 4 | 2–7 | 0.621 |

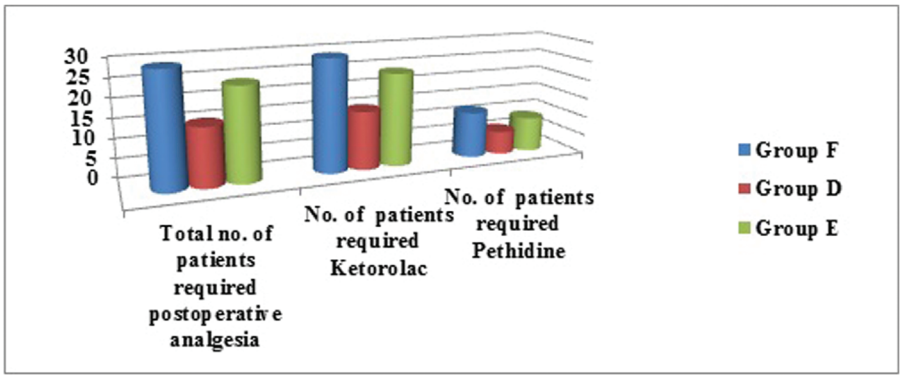
Group D, dexmedetomidine group; group E, esmolol group; group F, fentanyl group. *P* value more than 0.05, statistically not significant; *P* value less than 0.05, statistically significant.

**Table 3 Time to first request of analgesia (min) and average analgesic consumption (ketorolac, pethidine) among groups**

| | Group F (*N*=30) | Group D (*N*=30) | Group E (*N*=30) | *P* value |
|---|---|---|---|---|
| Time to first request of postoperative analgesia (min) | 61.1±25. 7 | 194.3±91.3 | 120±50.4 | <0.001 |
| | Group F vs. group D | Group F vs. group E | Group D vs. group E | |
| | <0.001 | <0.001 | <0.001 | |
| Average ketorolac consumption (mg) | 878±50.4 | 270±14.9 | 450±27.3 | <0.001 |
| | Group F vs. group D | Group F vs. group E | Group D vs. group E | |
| | <0.001 | <0.001 | <0.001 | |
| Average pethidine consumption (mg) | 840±45.7 | 420±22,6 | 630±33.5 | <0.001 |
| | Group F vs. group D | Group F vs. group E | Group D vs. group E | |
| | <0.001 | <0.001 | <0.001 | |

Data are represented as mean±SD. Group D, dexmedetomidine group; group E, esmolol group; group F, fentanyl group. *P* value more than 0.05, statistically not significant; *P* value less than 0.05, statistically significant.

**Figure 3**




Total number of patients who required postoperative analgesia and the number of patients who required postoperative ketorolac and pethidine among groups.

**Table 4 Modified Ramsay sedation score among groups**

| | Group F (*N*=30) | Group D (*N*=30) | Group E (*N*=30) | *P* value |
|---|---|---|---|---|
| Preoperative (S0) | 2.33±0.62 | 2.38±0.65 | 2.35±0.59 | 0.952 |
| After study drug (S1) | 2.38±0.63 | 2.74±0.74 | 2.33±0.52 | 0.029 [?] |
| | Group F vs. group D | Group F vs. group E | Group D vs. group E | |
| | 0.047 [?] | 0.739 | 0.016 [?] | |
| Postoperative (S2) | 2.38±0.52 | 2.52±0.64 | 2.30±0.44 | 0.284 |

Data are represented as mean±SD. Group D, dexmedetomidine group; group E, esmolol group; group F, fentanyl group. *P* value more than 0.05, statistically not significant; *P* value less than 0.05, statistically significant.

Gupta *et al.* [9] estimated the blood glucose during Dex and fentanyl premedication for laparoscopic cholecystectomy. Neil and Patel [10] examined the effect of Dex and fentanyl on hemodynamic response during laparoscopic surgery. Srivastava *et al.* [3] examined the effect of Dex and esmolol on hemodynamic responses during laparoscopic cholecystectomy.

The current study showed that MHR was significantly lower in the Dex group compared with both fentanyl and esmolol groups at all study times. In the Dex group, there

was no significant increase in MHR compared with the preoperative value at all times of the study, while in both fentanyl and esmolol groups, it was significantly increased after intubation, during all PNP periods except at 30 min, but it was increased in the fentanyl group only after release of PNP and at 15 min postoperatively. Kataria *et al.* [4] observed that HR in the Dex group was significantly decreased after start of infusion of Dex, and decreased more after induction, but it increased to near baseline after intubation and then there was significant increase during PNP which returned to baseline at about 30–45 min after creation of PNP. In the fentanyl group, there was insignificant decrease in HR after fentanyl infusion which became significant after induction and but it increased significantly after intubation and HR remained above the baseline after creation of PNP till the end of PNP. In both Dex and fentanyl groups, HR remained above baseline during postoperative period until 45 min and then returned to baseline at about 60 min postoperatively. Srivastava *et al.* [3] showed that there was a significant decrease in HR in the Dex group after administration of the study drugs. Intubation and PNP caused significant increase in HR in the esmolol group, compared with preoperative values; however, this increase was not seen in the Dex group.

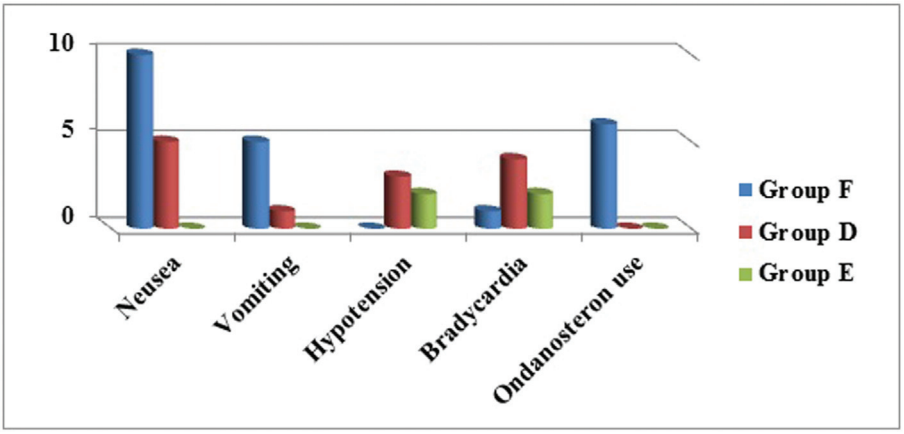
The present study demonstrated that MAP was significantly lower in the Dex group compared with both fentanyl and esmolol group at all study times. In the Dex group, there was no significant increase in MAP compared with preoperative value at all times of the study, while in both fentanyl and esmolol groups, it was significantly increased after intubation, during all PNP periods except at 60 min where it was increased in the esmolol group only, but it was significantly increased in the fentanyl group only at 15 min postoperatively. Kataria *et al.* [4] observed that there was a significant decrease in MAP after infusion of Dex, and decreased more after induction; however,

**Table 5 Blood glucose level (mg/dl) among groups**

| | Group F (*N*=30) | Group D (*N*=30) | Group E (*N*=30) | *P* value |
|---|---|---|---|---|
| Baseline (before induction of anesthesia) (G0) | 88.2±19.7 | 87.6±21.1 | 88.9±19.9 | 0.969 |
| Half hour after start of anesthesia (G1) | 114.7±16.1 | 123.2±14.1 | 117.7±15.1 | 0.093 |
| After 2.5 h postoperatively (G2) | 124.3±25.3 | 116.5±21.3 | 126.3±24.4 | 0.245 |

Data are represented as mean±SD. Group D, dexmedetomidine group; group E, esmolol group; group F, fentanyl group. *P* value more than 0.05, statistically not significant; *P* value less than 0.05, statistically significant.

**Figure 4**




Incidence of side effects among groups.

**Table 6 Postanesthesia care unit stay time (min) and hospital stay time (h)**

| | Group F | Group D | Group E | *P* value |
|---|---|---|---|---|
| PACU stay time (min) | 10.0±2.6 | 15.5±3.3 | 11.8±3.2 | < 0.001 |
| | Group F vs. group D | Group F vs. group E | Group D vs. group E | |
| | <0.001 | 0.02 | <0.001 | |
| Hospital stay time (h) | 19.8±3.3 | 21.3±3. 7 | 20±3.6 | 0.210 |

Data are represented as mean±SD. Group D, dexmedetomidine group; group E, esmolol group; group F, fentanyl group; PACU, postanesthesia care unit. *P* value more than 0.05, statistically not significant; *P* value less than 0.05, statistically significant.

after intubation, it increased a little bit but still significantly decreased below baseline and it still so throughout the PNP till the end of the surgery. In the fentanyl group, MAP significantly decreased after infusion of fentanyl, and it decreased more after induction and then it increased after intubation but still significantly decreased below baseline. MAP elevated above the baseline after PNP and remained above baseline till the end of the surgery. Postoperatively, MAP remained below baseline in the Dex group but above the baseline in the fentanyl group till 60 min after completion of the surgery. Srivastava *et al.* [3] showed that MAP were significantly lower in the Dex group compared with the esmolol group after intubation, at all time observations of PNP, post-PNP and postoperative period. There was no significant increase in MAP in the Dex group, compared with preoperative values at all time of PNP, while it was a significantly increased in the esmolol group during all PNP periods except at 30 min.

The current study demonstrated that postoperative VAS was lower in the Dex group than the other two groups at all study times but with no significant differences. Kataria *et al.* [4] observed that the mean VAS score in PACU at 15, 30, 45, 60 min was higher in the fentanyl group than in the Dex group.

The present study showed that the time to first request of postoperative analgesia was significantly longer in the Dex group than the other two groups. The number of patients who required postoperative analgesia and who required ketorolac or pethidine and average ketorolac (mg) and pethidine (mg) consumption were significantly lower in the Dex group than the other two groups. Neil and Patel [10] demonstrated that the mean duration of adequate postoperative analgesia was significantly higher in the Dex group (81.3 min compared with 41.9 min) in the fentanyl group.

The current study demonstrated that sedation scores were comparable among the three groups in the preoperative and postoperative values but it was higher in the Dex group than the other two groups after starting infusion of the study drugs. Kataria *et al.* [4] observed that the sedation score was comparable in both Dex and fentanyl groups. Srivastava *et al.* [3] showed that after infusion of the study drug, the sedation score was significantly higher in the Dex group compared with the esmolol group ($P$=0.001), while there was no significant difference in postoperative period ($P$=0.073).

Regarding blood glucose level (mg/dl) in the present study, there were no significant differences among groups including baseline, intra-, and postoperative values. Gupta *et al.* [9] demonstrated that the blood glucose concentration increased during and after surgery in both fentanyl (114.7±27, 121.3±25, respectively) and Dex groups (123.2±14, 114.6±21, respectively) ($P$=0.53, 0.43, respectively).

The current study showed that the incidence of nausea was significantly higher in the fentanyl group than the esmolol group and in the Dex group than the esmolol group. The incidence of vomiting was significantly higher in the fentanyl group than the esmolol group. Ondansetron use was significantly higher in the fentanyl group than both Dex and esmolol groups. There were no significant differences regarding the incidence of hypotension and bradycardia among groups. Vaswani *et al.* [5] observed that postoperative nausea and vomiting were found in two (6.7%) patients in the Dex group and three (10%) patients in the fentanyl group while bradycardia was observed in one (3.3%) patient in the Dex group only. Neil and Patel [10] observed that two (6.6%) patients developed bradycardia 10 min postextubation in the Dex group only; none of the patients developed hypotension in both groups and nausea and vomiting were observed in two (6.6%) patients in the Dex group and three (10%) patients in the fentanyl group.

The current study showed that, PACU stay time (min) was significantly longer in the Dex group than both fentanyl and esmolol groups ($P$<0.001,<0.001, respectively) and it was also significantly longer in group E than group F ($P$=0.02), while hospital stay time (h) showed no significant difference among groups ($P$>0.05).

## Conclusion

Nonopioids (Dex and esmolol) were superior to opioids (fentanyl) for attenuation of stress response to intubation and PNP. Apart from nausea and longer PACU stay, Dex was superior to esmolol with better control of hemodynamics (HR, MAP), less VAS, less number of patients required postoperative analgesia, less ketorolac, and pethidine consumption and longer time to first request of analgesia with no complications.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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