RESEARCH PAPER

Study of Efficacy and Safety of Dexmedetomidine and Fentanyl as Premedication Agent in Gynaecological Laparoscopic Surgeries

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ABSTRACT

Introduction: Gynaecological Laparoscopic surgeries are common these days; however, the optimal strategy for pain management remains a subject of ongoing debate. This study evaluates the comparative effects of dexmedetomidine and fentanyl on both hemodynamic stress responses and pain management in patients undergoing elective laparoscopic procedures.

Aim: The study aims to assess and compare the impact of dexmedetomidine versus fentanyl on stress response of endotracheal intubation, pain control, hemodynamic stability and any complication if occurs in patients undergoing gynaecological laparoscopic surgeries.

Materials and Methods: In this prospective, randomized, double-blinded trial, 100 adult patients of age group 18-65 years, classified as American Society of Anaesthesiologist (ASA) Grade I and II undergoing gynaecological laparoscopic surgery were randomly assigned to one of two groups: Group D (dexmedetomidine) and Group F (fentanyl), with 50 patients in each group. Group D received an intravenous (IV) loading dose of 1 μg/kg dexmedetomidine over 10 minutes prior to anesthesia induction. Group F received an intravenous (IV) loading dose of 2 μg/kg fentanyl over 2 minutes prior to anesthesia induction. Anaesthesia was induced with inj propofol 2mg/kg IV and succinylcholine 2mg/kg. Neuromuscular blockade was induced with inj Atracurium 0.5mg/kg IV. Anaesthesia was maintained with sevoflurane and O_2, Nitrous oxide (40:60) along with Atracurium 0.1-0.2 mg/kg @ 10-20 min. In operating room parameters like Heart Rate (HR), Respiratory Rate (RR), Systolic Blood Pressure (SBP), Diastolic blood pressure (DBP), Mean Arterial Pressure (MAP), SpO_2, were recorded 5 minutes after infusion of drug i.e., dexmedetomidine or fentanyl. The said parameters were again recorded after injection of induction drugs, after intubation, 1,2,3,5 minutes after intubation, just after pneumoperitoneum, and 5,10,15,30,45 and 60 minutes after pneumoperitoneum, five minutes after release of pneumoperitoneum, five and 10 minutes after extubation. Visual Analogue Scale (VAS) pain scores and Ramsay sedation scores were monitored and recorded throughout the postoperative periods. Post operative analgesic requirements within 24 hours noted. Any complication if occurred like respiratory depression, bradycardia or hypotension were then noted and treated. Residual paralysis was reversed with Inj. Glycopyrolate 8 μg/kg and Inj. Neostigmine 0.05 mg/kg IV. Patient was then extubated after thorough oral suction.

Results: Patients in Group D demonstrated superior hemodynamic stability, with reduced HR and MAP 5 minutes post-intubation and post-extubation and exhibited lower VAS pain scores during postoperative period. Patients in Group D consistently maintained higher sedation levels, predominantly within Ramsay Sedation Score (RSS) grades 4–5 and 6, signifying more profound and stable sedation than that observed in Group F, who largely remained within the RSS 2–3 range. Patients in Group D showed lower requirement of post operative analgesia in comparison to Group F.

Conclusion: Intravenous dexmedetomidine, as a premedication agent is excellent analgesic and sedative agent during gynaecological laparoscopic surgery, offers a significant advantage over fentanyl by reducing intubation stress response and surgical stress response, minimizing perioperative analgesic consumption and providing superior post operative pain control. This approach enhances overall hemodynamic stability and postoperative comfort, making it a viable option for improved perioperative management.

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Keywords: Dexmedetomidine, Fentanyl, Premedication, Gynaecological Laparoscopic Surgery, Hemodynamic Stability, Postoperative Pain.

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1. Introduction :

Laparoscopic surgery has largely replaced traditional open surgical techniques due to its benefits, including reduced invasiveness, minimised postoperative pain, early ambulation and quicker discharge times [1]. While laparoscopic procedures are employed across various gynaecological surgeries—such as Hysterectomy, Myomectomy, Tubal Ligation, Ovarian Cystectomy, Pelvic Reconstructive Surgery, etc. These procedures are particularly noted for their lower complication rates and faster recovery compared to their open counterparts. Laryngoscopy and endotracheal intubation is the gold standard for airway management during general anesthesia.Stress response, initiated by laryngoscopy and endotracheal intubation, triggers a pronounced sympathetic nervous system activation resulting in hemodynamic instability in the form of increased heart rate and blood pressure [2].

During laparoscopic surgery, the insufflation of the abdominal cavity with carbon dioxide (CO2) to achieve an intra-abdominal pressure (IAP) of 10-12 mmHg introduces significant physiological challenges [3]. This pneumoperitoneum alters respiratory and cardiovascular dynamics by increasing airway pressures, decreasing lung compliance, and elevating systemic vascular resistance, which further stimulates sympathetic responses. The magnitude of these changes is influenced by the severity and duration of surgical trauma, patient positioning, and perioperative pain management [4]. In the postoperative period, residual effects may include shoulder tip pain, hypercarbia, and transient respiratory compromise due to diaphragmatic irritation and CO2 retention.

Pain management is a crucial component of anesthesia, as inadequate control of perioperative pain can lead to increased stress response, haemodynamic instability, and delayed recovery. Effective attenuation of this response is particularly important in laparoscopic surgeries, where surgical stimuli and pneumoperitoneum further contribute to physiological stress.Fentanyl, a potent opioid analgesic, is widely used for intraoperative pain control due to its action on μ-opioid receptors in the central nervous system, thereby inhibiting nociceptive transmission and providing haemodynamic stability. Dexmedetomidine, a highly selective α2-adrenergic agonist, produces sedation and analgesia through central sympatholysis by acting on receptors in the locus coeruleus. It reduces sympathetic outflow, attenuates stress responses, and provides analgesia with minimal respiratory depression.

Aim and Objectives

The aim of this study is to compare the effects of dexmedetomidine and fentanyl on stress response, perioperative haemodynamics, and postoperative pain control in patients undergoing laparoscopic gynecological surgeries under general anesthesia. The objectives include:

- Assessing stress response during laryngoscopy, intubation, and pneumoperitoneum
- Evaluating haemodynamic stability during surgery
- Comparing recovery profile and time to extubation
- Measuring pain severity using Visual Analog Scale (VAS) postoperatively
- Evaluating sedation levels at extubation and post operative period using ramsay sedation score
- Documenting adverse effects such as nausea, vomiting, bradycardia, hypotension, and respiratory depression

2. MATERIALS AND METHOD

STUDY DESIGN

A randomized controlled trial was conducted on 100 female patients, aged 18–65 years, undergoing elective laparoscopic gynecological surgeries under general anesthesia. Patients were randomly allocated into two groups: Group D (dexmedetomidine) and Group F (fentanyl).

Inclusion criteria were patients classified as American Society of Anaesthesiologists (ASA) physical status I or II. Exclusion criteria included known allergy to study drugs, history of substance abuse, significant cardiovascular, respiratory, neurological, hepatic or renal disorders, anticipated difficult airway, haemodynamically unstable patients, ASA class III or higher and failure of laparoscopic surgeries.

Preoperative assessment was conducted a day before surgery and included detailed medical and surgical history, physical examination, systemic examination, and necessary laboratory investigations. Special attention was given to co-morbidities such as hypertension, diabetes, and respiratory diseases. Cardiovascular and respiratory evaluations were emphasized, and all patients were classified as ASA I or II. Airway assessment was performed to anticipate any difficulty in intubation or ventilation.

Written informed consent was obtained from all patients after explaining the study protocol.

METHOD

After confirming nil per oral (NBM) status, patients were taken to the operating theatre, where intravenous access was secured, intravenous fluids were started, and baseline vital parameters including heart rate (HR), mean arterial pressure (MAP), and oxygen saturation (SpO_2) were recorded. Continuous monitoring

included electrocardiography (ECG), non-invasive blood pressure (NIBP), pulse oximetry, and capnography.

For induction of anesthesia, patients in Group D received an intravenous loading dose of dexmedetomidine 1 μg/kg over 10 minutes prior to induction of anesthesia, while Group F received an intravenous loading dose of fentanyl 2 μg/kg over 2 minutes prior to induction.

Intraoperative parameters including heart rate (HR), respiratory rate (RR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), oxygen saturation (SpO_2), were recorded 5 minutes after completion of study drug infusion. These parameters were subsequently recorded after administration of induction agents, immediately after intubation ,1,2,3 and 5 minutes post-intubation, immediately after creation of pneumoperitoneum, and at 5, 10, 15, 30, 45, and 60 minutes thereafter.Additional recordings were taken 5 minutes after release of pneumoperitoneum and at 5 and 10 minutes following extubation.

Ramsay Sedation Scale is calculated during extubation and post operatively by observing the patient's response to stimuli and assigning a score from 1 to 6, where 1 = anxious/agitated, 2–4 = increasing sedation, and 5–6 = deep sedation with no response to stimuli . Postoperative pain was assessed using the Visual Analog Scale (VAS), where patients rated their pain on a scale of 0 to 10, with 0indicating no pain and 10 representing severe pain.

The requirement for rescue analgesia was closely monitored, and Inj. Diclofenac 75 mg IV was administered as needed to ensure patient comfort throughout the recovery period.

Results

The comparative analysis between Group D and Group F in laparoscopic gynecological procedures highlights key differences in terms of haemodynamic stability,, analgesia, sedation profile and recovery

Demographics

There was no statistically significant difference between the two groups with respect to demographic variables such as age and sex ($p > 0.05$). Both groups were comparable in terms of ASA physical status distribution, with no statistically significant difference observed between Group D and Group F ($p > 0.05$).

HAEMODYNAMICS

Table 1. Hemodynamic and Respiratory Parameters for Group F (Fentanyl)

Time Point	**HR (Mean)**	**SBP DBP (Mean) (Mean)**	**MAP**	**SPO2**
Baseline	78	125 85	98	99
After induction agent	72	115 78	90	99
Immediately after intubation	98	140 100	113	99
1 mins post -intubation	96	138 96	110	99
2 mins post -intubation	90	136 94	108	99
3 mins post -intubation	88	132 92	105.3	99
5 mins post-intuba tion	84	130 90	103	99
Immediately after pneumoperitoneum	92	138 98	111	99
5 mins post-pneumo.	90	132 92	105	99
10 mins post-pneumo.	88	128 88	101	99
15 mins post-pneu	86	125 85	98	99

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30 mins post-pneumo.	84	122 82	95	99
45 mins post-pneumo.	83	120 80	93	99
60 mins post-pneumo.	82	118 78	91	99
5 mins after release	80	120 80	93	99
5 mins after extubation	86.05	138 95	109	99

Time Point	**HR (Mean)**	**SBP DBP (Mean) (Mean)**	**MAP**	**SPO2**
10 mins after extubation	88	135 92	106	99

Table 2. Hemodynamic and Respiratory Parameters for Group D (Dexmedetomidine)

Time Point	**HR (Mean)**	**SBP DBP (Mean) (Mean)**	**MAP**	**Spo2**
Baseline	75	120 80	93	99
After induction agent	70	110 75	87	99

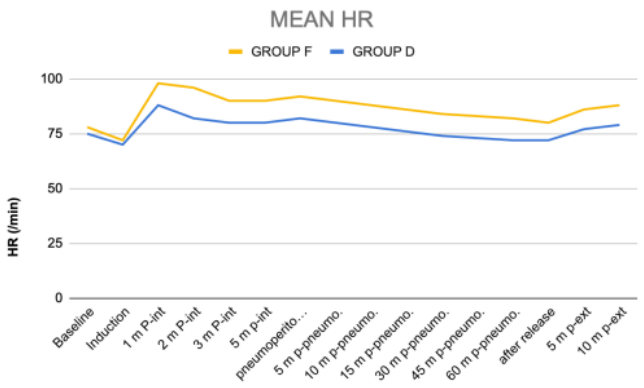
Immediate 88 130 90 103 99 ly after intubation

1 mins post-intubation	84	128 88	101	99
2 mins post-intubation	82	124 86	99	99
3 mins post-intubation	80	122 82	95	99
5 mins post-intubation	78	120 80	93	99
Immediately after pneumoperitoneum	82	128 88	101	99
5 mins post-pneumo.	80	122 82	95	99
10 mins post-pneumo.	78	118 78	91	99
15 mins post-pneumo.	76	115 75	88	99

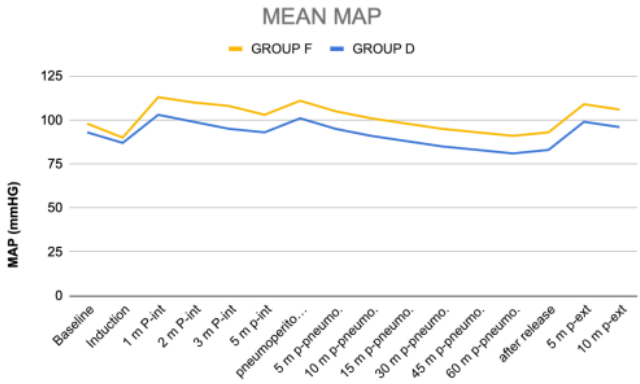
30 mins post-pneumo.	74	112 72	85	99
45 mins post-pneumo.	73	110 70	83.33	99
60 mins post-pneumo.	72	108 68	81.33	99
5 mins after release	72	110 70	83.33	99

Time Point	**HR (Mea**	**SBP DBP**	**MAP**	**Spo2**
	n)	**(Mean) (Mean)**		
5 mins after extubation	77.07	128 85	99.33	99
10 mins after extubation	79	125 82	96.33	99

Both HR and MAP decreased significantly in Group D (Figs. 2, 3) at 5 min post extubation (77.07 *vs*. 86.05 beats/min; $p = 0.021$ and 90.63 *vs*. 98.1 mmHg; $p = 0.022$).

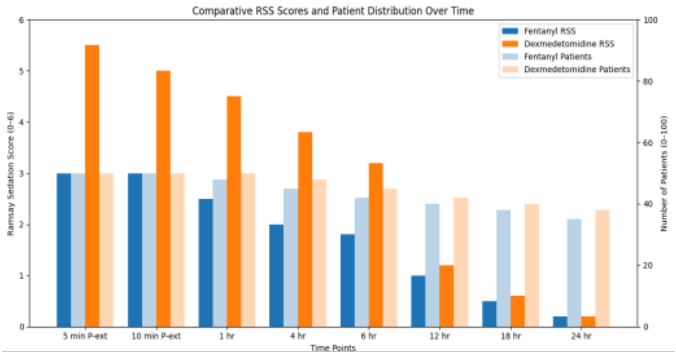


*F I G U R E 1.. Comparison between the two studied groups according to HR (beats/min). *: Statistically significant at $p \leq 0.05$; HR, heart rate; P-Int, post-intubation; m p-pneumoperitoneum P-Ext, post-extubation.*



FI G U RE 2. Comparison between the two studied groups according to MAP (mmHg).: Statistically significant at p ≤0.05; MAP, mean arterial pressure; P-Int, post-intubation; m p-pneumoperitoneum,P-Ext, post extubation.*

Ramsay sedation score



The comparative analysis of Ramsay Sedation Scores (RSS) across various post operative intervals reveal a distinct distribution pattern between Group F (fentanyl) and Group D (dexmedetomidine). Patients in Group D consistently maintained higher sedation levels, predominantly within RSS grades 4–5 , signifying more profound and stable sedation than that observed in Group F. Conversely, Group F largely remained within the RSS 2–3 range throughout the postoperative timeline , indicative of lighter sedation levels. This disparity was most pronounced during the extubation and post-recovery phases, wherein

dexmedetomidine provided superior quality of sedation. These data underscore the enhanced sedative efficacy and perioperative stability afforded by dexmedetomidine relative to fentanyl.

Postoperative analgesic consumption

As shown (Table 3), The time to the first analgesic request was longer in Group D than in Group F . Both findings were statistically insignificant. The total dose of postoperative Diclofenac consumption in 24 h was significantly less in Group D (2.49 *vs*. 3.98 mg; $p = 0.003$), yet not clinically significant. However, the percentage of patients who did not need any postoperative analgesic was significantly higher in Group D than in Group F ($p = 0.031$).

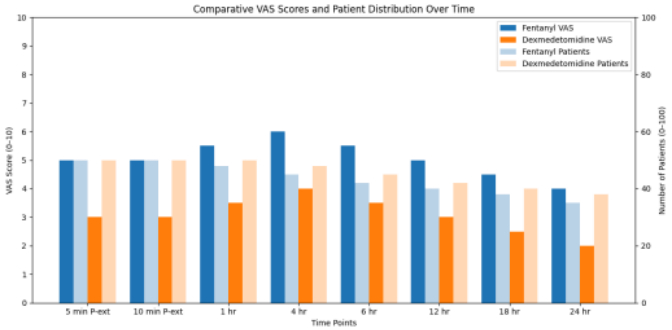
Parameter	Group D (n=50)	Group F (n=50)
Time to 1st request (min)	50 ± 46.8	30 ± 56.5
Analgesic requested once (No. %)	2 (4.9%)	5 (9.8%)
Analgesic requested twice (No. %)	5 (9.8%)	8 (17.1%)

Statistically significant at $p \leq 0.05$.

TABLE 3. Comparison between the two studied groups according to postoperative analgesic consumption.

Visual analogue scale

The VAS pain score recordings showed persistent lower values in Group D than in Group F at all time intervals(24 hours) , with a significant decrease upon arrival into the PACU ($p = 0.002$), at 60 min, and until 6 h postoperatively with a p value < 0.001 at 120 min postoperatively .



FI G U RE 4. Comparison between the two studied groups according to VAS. *******: *Statistically significant at $p \leq 0.05$. VAS, visual analogue scale.*

4. Discussion

Gynaecological laparoscopic surgeries have become the standard of care, offering advantages like reduced invasiveness, minimal postoperative pain, and faster recovery compared to traditional open techniques. However, the procedure introduces physiological stress, notably from the creation of pneumoperitoneum, which involves insufflation of carbon dioxide to achieve an intra-abdominal pressure of 10-12mmHg. This pneumoperitoneum alters respiratory and cardiovascular physiology by increasing intra-abdominal pressure, leading to elevated systemic vascular resistance and changes in heart rate and blood pressure, which necessitates effective perioperative management to ensure hemodynamic stability.

The stress response is further exacerbated during laryngoscopy, endotracheal intubation, and extubation, which trigger a pronounced sympathetic activation characterized by tachycardia and hypertension. Various premedication agents have been employed to attenuate this hemodynamic response, including Opioids: Sufentanil, Alfentanil, Remifentanil; Beta-Blockers: Esmolol, Metoprolol, Propranolol, Labetalol, Atenolol; Alpha-2 Adrenergic Agonists: Clonidine; Calcium Channel Blockers: Nifedipine, Verapamil, Diltiazem; Vasodilators: Sodium Nitroprusside, Nitroglycerine, Hydralazine; and Local Anesthetics: Lignocaine (Lidocaine).

Fentanyl

Fentanyl is a potent, fully synthetic opioid analgesic, chemically classified as a phenylpiperidine derivative. Due to its high lipophilicity, it rapidly crosses the blood-brain barrier, resulting in a rapid onset of analgesia, typically within 2–3 minutes after intravenous administration. Its mechanism of action centers on acting as a selective agonist primarily on the μ-opioid receptors (MOR) located throughout the central nervous system. Activation of these receptors leads to neuronal hyperpolarization and inhibition of nociceptive signal transmission by decreasing the release of excitatory neurotransmitters. This action produces profound analgesia, sedation, and helps provide hemodynamic stability. Because of its rapid redistribution from the brain to muscle and fat, the drug has a relatively short duration of action following a single bolus dose.

Dexmedetomidine

Dexmedetomidine is a highly selective α2-adrenergic agonist. Its primary mechanism involves central sympatholysis, achieved by acting on α2-adrenergic receptors, most notably those concentrated in the locus coeruleus. By decreasing sympathetic outflow from the central nervous system, dexmedetomidine effectively attenuates the surgical and intubation-related stress responses. This central action provides a unique combination of sedation and analgesia with the significant advantage of causing minimal to no respiratory depression, thereby enhancing overall perioperative stability and patient comfort.

Hemodynamic Stability

The comparative analysis of hemodynamic parameters indicates that dexmedetomidine (Group D) provided superior stability compared to fentanyl (Group F). Dexmedetomidine, a selective α2-adrenergic agonist, attenuates the sympathetic stress response, which is crucial during events such as endotracheal intubation and pneumoperitoneum. Group D showed a significant reduction in

both Heart Rate (HR) and Mean Arterial Pressure (MAP) following extubation (HR: 77.07 *vs*. 86.05 beats/min, $p = 0.021$; MAP: 90.63 *vs*. 98.1 mmHg, $p = 0.022$), reflecting better control of the stress response in the critical post-operative period. Throughout the intraoperative course, Group D consistently maintained lower HR and MAP values compared to Group F, aligning with findings that dexmedetomidine better controlled hemodynamic changes during elective laparoscopic surgeries.

Amnesia and RSS Scores

Regarding sedation, the analysis of Ramsay Sedation Scores (RSS) demonstrated that Group D patients maintained consistently higher and more profound sedation levels, predominantly falling within RSS grades 4–6. In contrast, Group F patients largely remained in the RSS 2–3 range, indicative of a lighter state of sedation. This disparity underscores the enhanced. sedative efficacy of dexmedetomidine over fentanyl in the postoperative setting, with the superior quality of sedation in Group D being most evident during the extubation and post-recovery phases.

Analgesia and the Visual Analog Scale (VAS)

Perioperative pain management was significantly more effective in the dexmedetomidine group. Group D exhibited consistently lower Visual Analog Scale (VAS) pain scores across all recorded time intervals post-operatively. Specifically, a significant decrease in VAS scores was observed in Group D upon arrival into the PACU ($p = 0.002$), at 60 minutes, and throughout the duration until 4 hours postoperatively, including a p value of < 0.001 at 120 minutes. Group D patients had a lower mean total postoperative Diclofenac consumption over 24 hours (2.49 ± 2.27 mg *vs*. 3.98 ± 2.35 mg; $p = 0.003$). Furthermore, a significantly higher percentage of patients in Group D did not require any postoperative analgesic .

Recovery

Recovery parameters indicated a prolonged time to first analgesic request in Group D (50 ± 46.8 minutes) compared to Group F (30 ± 56.5 minutes), although this outcome was statistically non-significant ($p = 0.203$). Crucially, Group D demonstrated a superior recovery profile, characterized by more profound and sustained sedation (RSS 4–6) during the post-extubation phase, which underscores the enhanced analgesic and sedative effects of dexmedetomidine relative to the lighter sedation of Group F (RSS 2–3).

5. Conclusion

The findings of this prospective, randomized trial establish the superior efficacy of intravenous dexmedetomidine compared to fentanyl as a premedication agent in gynaecological laparoscopic surgeries. Dexmedetomidine provided enhanced hemodynamic stability throughout the perioperative period, significantly attenuating the sympathetic stress response associated with both endotracheal intubation and extubation, as evidenced by better-controlled heart rate and mean arterial pressure compared to the fentanyl group. Furthermore, dexmedetomidine conferred robust postoperative benefits, demonstrated by consistently lower Visual Analogue Scale pain scores for up to four hours post-surgery and a significant reduction in the requirement for rescue analgesia over 24 hours, with a greater proportion of patients requiring no postoperative medication. Collectively, the superior control over hemodynamic stress, combined with the profound and stable quality of perioperative sedation and reduced analgesic consumption, confirms that dexmedetomidine offers a distinctly advantageous pharmacological profile for optimizing perioperative management and enhancing patient comfort during elective gynaecological laparoscopic procedures.

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