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Anesthesiology

"COMPARATIVE STUDY OF FENTANYL WITH PROPOFOL AND FENTANYL WITH DEXMEDETOMIDINE AS INTRAVENOUS ANAESTHETICS FOR UPPER GI ENDOSCOPY"

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ABSTRACT

Background: Upper GI endoscopic procedure requires patient's cooperation and endoscopist's satisfaction and this can be improved by intravenous sedation and analgesia.

Aim: to compare the haemodynamic effects and sedation efficacy of fentanyl with propofol and fentanyl with dexmedetomidine in patients undergoing elective diagnostic upper gastrointestinal endoscopy (UGIE).

Material and methods: A total of 60 patients undergoing UGIE were enrolled in the study. Patients were randomly divided into two groups, Group P received 1mg/kg of Propofol followed by 10-20 mg iv bolus when required and group D received an infusion of 1mcg/kg of Dexmedetomidine over 10 min, followed by 0.2-0.7mcg/kg/hr as continuous infusion.

Statistical analysis: Data analysis was done using SPSS version 16.0. p value <0.05 was considered as statistically significant.

Results: Induction time was shorter in propofol group when compared to dexmedetomidine group (0.79 min vs 10.73 min, p=0.0001). Recovery time was early in dexmedetomidine group when compared to propofol group (8.4 min vs 12 min, p=0.0001). Mean arterial pressure was significantly lower in propofol group when compared to dexmedetomidine group. Fall in heart rate was higher in dexmedetomidine when compared to propofol. Respiratory rate, Spo2 and patient satisfaction were comparable in both groups (p > 0.05).

Conclusion: Dexmedetomidine is associated with greater haemodynamic stability and faster recovery when compared to propofol. Endoscopists expressed a higher level of satisfaction with dexmedetomidine compared with propofol.

KEYWORDS : Dexmedetomidine, Propofol, Fentanyl, Mean arterial pressure, heart rate, upper GI endoscopy

INTRODUCTION

Upper GI endoscopy is the standard practice to diagnose oesophageal, Gastric and Duodenal diseases. The UGIE is an invasive procedure and usually lasts for 10min with very low complication rates. The Upper GI Endoscopy may be performed with or without conscious sedation using topical pharyngeal anaesthesia alone. But patient's tolerance to procedure and endoscopist satisfaction increases when sedation is used along with topical pharyngeal anaesthesia1. Moreover judicious use of sedation can alleviate the sympathetic response (rise in Heart rate and Systolic blood pressure) to the procedure2

Numerous agents are available for moderate sedation in endoscopy. The goals of sedation are analgesia, amnesia, immobility during the procedure, quick patient recovery to pre-procedure level of consciousness and less hemodynamic alterations4. Propofol and midazolam are the most widely used sedative medications during UGIE. Propofol is used commonly as it is characterized by rapid onset, short duration of action and rapid recovery and minor adverse effects including transient hypotension, dose dependent respiratory depression and hypoventilation. Balanced anaesthesia with short acting opioids (alfentanyl, remifentanyl and fentanyl) and midazolam is believed to reduce the risk of deep sedation and provide good analgesia. Midazolam is favoured due to its potent amnesic properties, anxiolytic effect and short elimination half-life. Dexmedetomidine is a highly selective alpha-2 adrenergic agonist with a relative high ratio of alpha-2 / alpha-1 activity when compared with Clonidine. It has been used widely for sedoanalgesia in diagnostic and therapeutic procedures, and its use is progressively increasing. It has a unique feature of lacking respiratory depression even with accidental over dosage. So it has advantage over other sedatives such as benzodiazepines, opioids and propofol as all of them cause dose dependent respiratory depression.

PATIENTS AND METHODS

The randomized prospective "Comparative study of Fentanyl with Propofol and Fentanyl with Dexmedetomidine as intravenous anaesthetics for upper GI endoscopy" was undertaken at Government General Hospital, Kurnool. The institutional ethical committee approved the study and written informed consent was obtained from all the patients before being included in the study.

Selection criteria

Inclusion criteria :

1. ASA Grade I and II
2. Age between 18 to 60 years
3. Patients coming for diagnostic elective upper GI endoscopy

Exclusion criteria :

1. Patients allergic to study drugs
2. Morbid obesity
3. Patients with comorbid conditions (diabetes mellitus, hypertention, hepatic or renal insufficiency)
4. Pregnancy
5. Emergency endoscopy

Randomization:

The patients were randomly allocated in to two groups as below:

- Group P (Propofol group; n=30) – received 1 mg/kg of loading dose of Propofol followed 10-20 mg iv bolus when it required
- Group D (Dexmedetomidine group; n=30) – received an infusion of 1 mcg/kg loading dose of Dexmedetomidine over 10min, followed by 0.2 to 0.7 mcg/kg/hr as continuous infusion.
- Inj.Fentanyl 25 mcg was administered intravenously as an adjunct to the above drugs as and when required12

Procedure

Prior to the procedure clinical history and physical examination was performed for each patient. Additionally the anaesthetic risk was assessed with the ASA classification of physical status and the patients completed a demographic questionnaire and patients were explained about the visual analogue scale (VAS) and informed consents were obtained. All patients were kept nil per oral 8-10 hours prior to the procedure. Upon arrival to the endoscopy suite monitoring like electrocardiogram (ECG), oxygen saturation of haemoglobin (SPO2) and non invasive blood pressure (NIBP) was started and continued until shifting out to the recovery area. The baseline values of heart rate, mean arterial blood pressure, oxygen saturation of haemoglobin and respiratory rate were recorded. Patients were pre-medicated with injection Glycopyrrolate 4 mcg/kg and injection Ondansetron 0.08 mg/kg intravenously. We defined the following evaluation time points as T0 = baseline, T1 = after induction, T2 = after introduction of endoscope, T3 =during procedure, T4 = after removal of endoscope, recovery. When the patient achieved a desired level of sedation of 2-4 on observer assessment alertness / sedation scale endoscope was

introduced47. Occurrence of adverse events like hypertension, hypotension, bradycardia, arrhythmias, desaturation, apnoea, gagging and retching was also recorded during the procedure. All endoscopic procedures were carried out by a single operator in prone position. During the procedure any of the adverse events were observed, recorded and treated accordingly. Oxygen desaturation was considered when Spo2 level dropped below 92% for more than 10 sec. A heart rate < 50 beats/min or a 20% decrease from the baseline was labelled as bradycardia, whereas a heart rate over 110 or an increase of more than 20% from the baseline level was considered as tachycardia. Mean arterial blood pressure level that were lower than 60 mm of Hg or 20% less than the baseline was regarded as hypotension and a mean arterial blood pressure value of over 150 mm of Hg or a 20% increase from the baseline was regarded as hypertension. The patient satisfaction regarding discomfort like pain and gagging during the procedure was assessed using the VAS in the recovery room (0 = no pain, to 10 = worst pain). Endoscopist satisfaction regarding retching and difficulty during the procedure was assessed using VAS (0 = no retching/ difficulty, to 10 = maximum retching/difficulty). Recovery from sedation was assessed using modified aldrete recovery score at 5 min after removal of endoscope and every 5 min thereafter until a discharge score of 10/10 was reached48.

Statistical analysis

Data analysis was done using SPSS version 16.0. Haemodynamics and respiratory data were evaluated using the unpaired t-test for within group comparisons. Numerical data are reported as means +/- standard deviation. Ordinal data are reported as median (interquartile range). Categorical data were analysed using Chi-square test. $P < 0.05$ was considered as significant and $P < 0.0001$ as highly significant (HS).

OBSERVATION AND RESULTS

Demographic data :

In present study 60 patients were randomized into two groups of 30 each. The mean age of the patients in propofol group was 39.26 years and in dexmedetomidine group was 39.23 years. Male / female included in our study are 20/10 and 17/13 in propofol group and dexmedetomidine group respectively. The average weight of the patients in propofol and dexmedetomidine group are 48.6 kgs and 49.13 kgs respectively. The ASA status (I/II) of the patient are similar in both propofol and dexmedetomidine group (14/16 vs 18/12). There was no statistically significant difference between the propofol and dexmedetomidine group with regard to age, gender, weight, ASA class and were comparable ($P > 0.05$). The results of demographic data are shown below in table 5.

Characteristics	Group 'P'	Group 'D'	'p' value
Age(years)	39.26 +/- 14.19	39.23 +/- 12.02	0.99
Male / female	20 / 10	17 / 13	0.425
Weight (kg)	48.6 +/- 7.12	49.13 +/- 7.48	0.77
ASA class (I / II)	14 / 16	18 / 12	0.30

Onset of sedation :

In present study the onset of sedation (Time to achieve OAAS score of 2-4) was 0.79 +/- 0.23 min in propofol group and 10.72 +/- 1.41 min in dexmedetomidine group and it was rapid in propofol group and statistically highly significant as $p = 0.0001$. Duration of procedure in propofol group and dexmedetomidine group was 6.45 +/- 1.90 min and 7.10 +/- 2.01 min respectively and were comparable as $p > 0.05$.

In present study the patient's satisfaction assessed by visual analogue scale was 1.63 +/- 0.80 and 1.4 +/- 0.72 in propofol group and dexmedetomidine group respectively and were comparable as $p > 0.05$. The endoscopist satisfaction assessed by visual analogue scale was 1.82 +/- 0.92 and 0.9 +/- 0.60 in propofol group and dexmedetomidine group respectively. The endoscopist satisfaction was higher in dexmedetomidine group and it was statistically highly significant as $p = 0.0001$. Willingness to undergo similar procedure in future was significantly higher in dexmedetomidine group when compared to propofol group (96.6% vs 76.6%, $p = 0.02$) The results are shown in table 6 given below.

Recovery from sedation:

In present study recovery time (time taken to achieve modified aldrete recovery score of 9-10) was 12 +/- 2.28 min and 8.4 +/- 2.01 min in propofol group and dexmedetomidine group respectively. Recovery was faster in dexmedetomidine group when compared to propofol group and it was statistically highly significant as $p = 0.0001$. the results are shown in table 6 given below.

	Group 'P'	Group 'D'	P value
Time to achieve OAAS of 2-4 (min)	0.79 +/- 0.23	10.73 +/- 1.41	0.0001 (HS)
Duration of procedure (Min)	6.45 +/- 1.90	7.10 +/- 2.01	0.20
Recovery time (MAS of 10/10) (Min)	12.0 +/- 2.28	8.4 +/- 1.30	0.0001 (HS)
Willingness to undergo similar procedure in future (n)	23 (76.6)	29 (96.60)	0.02 (S)
Patient satisfaction(VAS)	1.63 +/- 0.80	1.40 +/- 0.72	0.246
Endoscopist satisfaction(VAS)	1.82 +/- 0.92	0.90 +/- 0.60	0.0001 (HS)

Table 6: Subjects and procedural characteristics

Hemodynamic monitoring :

During procedure hemodynamics are monitored and recorded as
T0 - Baseline value
T1 - After adequate sedation (OAAS of 2-4)
T2 - Immediately after insertion of endoscopy
T3 - During endoscopy
T4 - After removal of endoscopy
Recovery - in the recovery room

Baseline hemodynamic parameters:

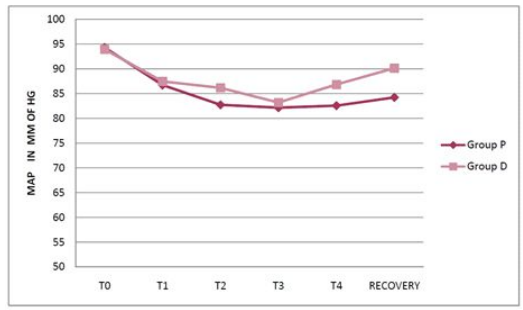
In present study baseline mean arterial pressure in propofol and dexmedetomidine group were 94.30 +/- 9.46 mm of Hg and 93.93 +/- 9.19 mm of Hg respectively. Baseline heart rate in propofol and dexmedetomidine group were 91.26 and 88.03 respectively. Baseline respiratory rate in propofol and dexmedetomidine group were 14.86 +/- 2.20 and 15.13 +/- 1.40 respectively. In our study there was no statistically significant difference in baseline hemodynamic parameters like mean arterial pressure, heart rate, respiratory rate between propofol and dexmedetomidine group and were comparable as $p > 0.05$. The results are shown in table-7 given below.

CHARACTERISTICS	GROUP 'P'	GROUP 'D'	'P' value
Baseline MAP (mm of Hg)	94.30 +/- 9.46	93.93 +/- 9.19	0.87
Baseline HR (bpm)	91.26 +/- 13.85	88.03 +/- 18.18	0.44
Baseline RR (bpm)	14.86 +/- 2.20	15.13 +/- 1.40	0.57
Baseline SPO2 (%)	98.4 +/- 1.37	98.6 +/- 1.09	0.53

Table 7: Baseline hemodynamic parameters

Mean Arterial Pressure (MAP):

In present study, at the end of the procedure mean arterial pressure was significantly lower in propofol group when compared to dexmedetomidine group (84.23 +/- 9.97 mm of Hg vs 90.13 +/- 7.17 mm of Hg, $p = 0.01$). In our study Eight (26.6%) patients in propofol group and three (10%) patients in Dexmedetomidine group developed hypotension. All episodes of hypotension were treated with 100-200 ml of crystalloid boluses in both groups. None of the patients in either group required vasopressors for correction of hypotension. The mean arterial pressure variations are shown in table-8 and graph-5 given below.

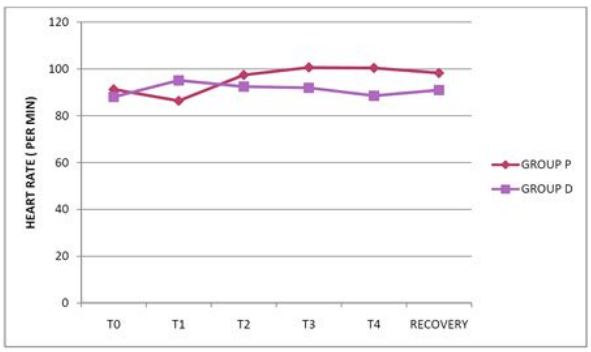


Graph 5 : Mean arterial pressure(MAP) variations

Heart Rate (HR):

In study heart rate variations were significant in Dexmedetomidine group when compared with Propofol group at various levels (T1, T3 and T4) during endoscopy ($p < 0.05$). Three (10%) patients in Dexmedetomidine group developed bradycardia. Among three

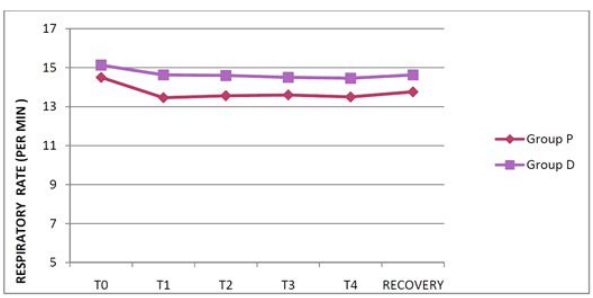
patients one patient required inj.Atropine 0.06 mg iv for correction of bradycardia. In remaining two patients it was corrected with 100-200 ml of crystalloid boluses. In our study Seven (23.3%) patients in propofol group and Six (20%) patients in Dexmedetomidine group developed tachycardia during the procedure. The incidence of bradycardia and tachycardia were comparable between propofol and dexmedetomidine group ($p > 0.05$). The heart rate variations are shown in table-9 and graph-6 given below.



Graph 6 : Heart rate variations

Respiratory Rate (RR) :

In our study patients in propofol group showed significant fall in respiratory rate when compared to dexmedetomidine group at various levels during the procedure ($p < 0.05$). In our study Two (6%) patients in propofol group developed desaturation (< 92%) and was corrected with oxygenation with nasal cannula (3 lt/min). No patients were required external manipulation of airway or supraglottic airway or tracheal intubation for hypoxemia. No patients in dexmedetomidine group developed hypoventilation or desaturation. The heart rate variations were shown in table-10 and graph-7 given below.



Graph 7: Respiratory rate variations

Adverse events:

In the present study adverse events like tachycardia, hypotension, bradycardia, arrhythmias, gag and discomfort and desaturation were comparable between propofol and dexmedetomidine group and there was no significant difference as $p > 0.05$. Adverse events are shown in table-11 given below.

Adverse events	Group 'P'	Group 'D'	P value
Tachycardia (n)	7 (23.3%)	6 (20%)	0.754
Bradycardia (n)	0	3 (10%)	0.755
Hypotension (n)	8 (26.6%)	3 (10%)	0.095
Gag & discomfort (n)	15 (50%)	10 (33.3%)	0.190
Fall in spo2 (n)	2 (6%)	0	0.150

Table 11 : Comparison of adverse events

DISCUSSION

The aim of the study was to compare the efficacy and safety of Dexmedetomidine with Propofol as sole sedoanalgesic in patients undergoing upper GI endoscopy. The present study revealed that Dexmedetomidine is safer as it is associated with least hemodynamic perturbations and is more effective as rate of desired sedation achieved was higher than Propofol. Dexmedetomidine use was also associated with faster recovery and higher level of endoscopist satisfaction as compared to propofol.

The dose regimen of both Propofol and Dexmedetomidine used in our study were similar to that used by Samson, et al12. Group D patients received 1 mcg/kg dexmedetomidine iv over 10 min followed by 0.2-0.7 mcg/kg/hr as continuous infusion until an appropriate sedation was achieved. Group P patient received 1 mg/kg propofol iv bolus followed by 10-20 mg as intermittent bolus depending upon requirement. In both groups inj fentanyl was given 0.5 mcg/kg iv bolus as and when required. The longer induction time with dexmedetomidine was due to the slow infusion over 10 min to avoid undesirable hemodynamic changes that occur with faster infusion. At lower doses the dominant action of alpha-2 agonists is sympatholysis mediated by the alpha-2A adrenergic receptor subtype. At higher doses of alpha-2 agonists such as those achieved by rapid iv administration, hypotension dominates by activation of alpha-2B adrenoreceptors located on smooth muscle cells in resistance vessels. It is therefore recommended that loading boluses of dexmedetomidine be administered slowly. Propofol has advantages over standard agents used for conscious sedation (benzodiazepines and opiates). The advantages of propofol are rapid onset of action, early recovery, less patient discomfort and less nausea and vomiting. A number of small randomized controlled trials have evaluated the efficacy of the propofol for gastrointestinal endoscopy compared to traditional sedative agents with varying results. A 2005 meta analysis of 12 RCT's summarized the potential benefits of propofol sedation during gastrointestinal endoscopy by comparing the cardiopulmonary complications like hypoxia, hypotension, arrhythmias and apnoea between propofol and other traditional sedative agents.

In study fentanyl was given in both group of patients at a dose of 0.5 mcg/kg iv bolus to reduce the total dose of propofol and to improve the sedative efficacy of dexmedetomidine. In their study Lera dos Santos ME et al5 used fentanyl 1mcg/kg iv and was associated with deep sedation.

Onset of sedation :

In present study the onset of sedation was rapid in propofol group when compared to dexmedetomidine group (0.79 min vs 10.73 min) and it was statistically highly significant ($P = 0.0001$). The late onset of action in dexmedetomidine was due to infusion of loading dose over 10 min to avoid cardiovascular complications. Samson et al12 in their study showed the similar finding with regards to onset of action. The duration of endoscopic procedure were similar in both propofol and dexmedetomidine group (6.45 min vs 7.10 min) and there was no statistically significant difference regarding duration of the procedure ($p = 0.20$).

Hemodynamic changes

Mean arterial pressure (MAP) :

In present study there was no significant difference in baseline mean arterial pressure between propofol and dexmedetomidine. Mean arterial pressure was significantly lower in propofol group at the end of the procedure when compared to dexmedetomidine group (84.23 mm of Hg vs 90.13 mm of Hg, $p = 0.01$). This finding could be due to narrow therapeutic window of propofol. In present study eight (26.6%) patients in propofol group and three (10%) patients in dexmedetomidine group developed hypotension. All episodes of hypotension in both group were treated with 100-200 ml of crystalloid boluses. No patients in either group required vasopressors for correction of hypotension. Similar episodes of hypotension were observed with propofol in previous studies conducted by Samson et al12 .

Heart Rate (HR):

In present study heart rate variations were significant in dexmedetomidine group of patients when compared to propofol group of patients at various levels (T1, T3 and T4) during endoscopic procedure. The similar fall in heart rate was also observed with dexmedetomidine in previous studies conducted by Sethi et al13 and Muller et al7. In present study three (10%) patients in dexmedetomidine group showed significant bradycardia.One patient required Inj.Atropine and two patient required 100-200 ml of crystalloid fluid boluses for the correction of bradycardia. Our study correlates with previous study conducted by Samson et al12. Seven (23.3%) patients in propofol group and Six (20%) patients in dexmedetomidine group developed tachycardia in our study during endoscopy.

Respiratory Rate (RR) and oxygen saturation (Spo2) :

In the present study there were significant respiratory rate variations between propofol and dexmedetomidine group. Propofol acts on respiratory centre and causes respiratory depression and

hypoventilation. Two (6%) patients in propofol group showed significant desaturation (Spo2 < 92%) and was treated with oxygenation by nasal cannula (3lt/min). None of the patients in dexmedetomidine group showed hypoventilation and desaturation as it has no effect on respiratory centre. In previous studies conducted by Takimoto et al9 and Sethi et al13 showed that dexmedetomidine has no effect on respiratory centre and our study results correlate with these studies with regards to respiratory rate variations. No patient in either group required external airway manipulations or supra glottic airway or bag and mask ventilation or endotracheal intubation.

The desired sedation level was significantly higher in the dexmedetomidine group when compared to propofol group. Similarly Takimoto et al9 reported significantly higher rate of effective sedation in the dexmedetomidine group compared with the midazolam or propofol groups undergoing endoscopic mucosal dissection of gastric tumours.

Patient's and endoscopist satisfaction :

In present study both patient's and endoscopist satisfaction were assessed by using Visual Analogue Scale (VAS) in the recovery room after complete recovery that is after achievement of Modified Aldrete Recovery Score of 9-10. Endoscopist satisfaction was significantly higher in dexmedetomidine group when compared to propofol group (P = 0.0001) due to decreased rate of movement and gag reflex during procedure. Similarly Samson et al12, Damiraran et al6, Vazquez-Rata et al8, Sethi et al12 and Takimoto et al9 reported significantly high rate of endoscopist satisfaction in dexmedetomidine group. There was no significant difference in patient satisfaction between dexmedetomidine and propofol group (P = 0.246). Willingness to undergo similar procedure in the future was higher in dexmedetomidine group (96.6%) when compared to propofol group (76.6%) and was statistically significant (p = 0.02)

Recovery time:

In present study recovery was faster in dexmedetomidine group (8.4 min) when compared to propofol (12 min) and it was statistically highly significant (p = 0.0001). Our study results were in line with those reported in studies by Vazquez-Reta et al8 and Samson et al12 (7.7 Min Vs 12.7 Min, P < 0.05). Though all sedative drugs are safe to use during upper GI endoscopy the importance of vigilant monitoring by a trained nurse or anaesthetist cannot be ignored. Sedative induced hypotension can be prevented by pre-hydration with 100-200 ml intravenous fluid just prior to administration of upper GI endoscopy. Dexmedetomidine as sole sedative is superior to propofol in terms of safety and recovery time and endoscopist satisfaction. The use of propofol was associated with hypotensive episodes that can be prevented by prehydration.

Adverse events:

Both dexmedetomidine and propofol were similar with regard to adverse events like hypotension, tachycardia, bradycardia, significant desaturation and arrhythmias. In present study Seven (23.3%) patients in propofol group and Six (20%) patients in dexmedetomidine group developed tachycardia (p > 0.05). Eight (26.6%) patients in propofol group and three (10%) patients in dexmedetomidine group developed hypotension (p > 0.05).

Three (10%) patients in dexmedetomidine group showed significant bradycardia. Two (6%) patients in propofol group showed desaturation (Spo2 < 92%). Similar adverse events were reported by Samson et al12 in their study.

CONCLUSION

Use of Dexmedetomidine was associated with greater haemodynamic stability and faster recovery when compared to propofol. Endoscopists expressed a higher level of satisfaction with dexmedetomidine compared with propofol.

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