A COMPARATIVE STUDY ON EFFECT OF FENTANYL WITH PROPOFOL AND FENTANYL WITH DEXMEDETOMIDINE AS INTRAVENOUS ANAESTHETICS FOR UPPER GI ENDOSCOPY

Sankula Kalyan[1], Gunna Shantiraj[2]

[1]Assistant Professor, Department of Anaesthesiology, Viswabharathi Medical College, Kurnool, Andhra Pradesh.
[2]Associate Professor, Department of Anaesthesiology, Viswabharathi Medical College, Kurnool, Andhra Pradesh.

ABSTRACT

BACKGROUND

Routine upper GI endoscopy is the standard practice to diagnose oesophageal, gastric and duodenal diseases. 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 anaesthesia.[1] The present study is 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).

MATERIALS AND METHODS

This is a randomized prospective comparative study. It was undertaken at Viswabharathi Hospital, Kurnool among 60 patients during the period of October 2014 to October 2016.

RESULTS

The patients were assigned into two groups of 30 each. Group P (n=30) received Propofol to achieve desired level of sedation and Group D (n=30) received Dexmedetomidine. There was statistically significant difference between groups with regard to induction time, recovery time and endoscopist satisfaction ($p < 0.05$). Induction time was shorter in propofol group when compared to dexmedetomidine group (0.79 min vs 10.73 min, $p=0.0001$). Endoscopist satisfaction is also significantly higher in dexmedetomidine group when compared to propofol group (0.9 vs. 1.82, $p =0.0001$).

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.

KEYWORDS

Upper GI endoscopy, fentanyl, propofol, dexmedetomidine.

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BACKGROUND

The development of upper gastrointestinal endoscopy (UGIE) has greatly expanded the diagnostic and therapeutic capabilities of gastroenterologists. 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 anaesthesia.[1] Moreover judicious use of sedation can alleviate the sympathetic response (rise in Heart rate and Systolic blood pressure) to the procedure.[2] Numerous agents are available for moderate sedation in endoscopy. Sedation practices may vary from country to country and from hospital to hospital that could influence the endoscopists attitude.[3] The goals of sedation are analgesia, amnesia, immobility during the procedure, quick patient recovery to pre-procedure level of consciousness and less hemodynamic alterations.[4] Propofol is used commonly as it is a powerful sedative characterized by rapid onset, short duration of action and rapid recovery and also it causes mild analgesia and minor adverse effects including transient hypotension, dose dependent respiratory depression and hypoventilation. Balanced anaesthesia with short acting opioids (alfentanil, remifentanil and fentanyl) and midazolam is believed to reduce the risk of deep sedation and provide good analgesia. 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. The present study is to compare effect of fentanyl with propofol and fentanyl with

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Corresponding Author:
Dr. G. Shantiraj,
Flat No. 309, MS 9,
Priya Towers, Deva Nagar,
Kurnool- 518002, Andhra Pradesh.
E-mail: shantirajgunna123@gmail.com
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Dexmedetomidine as intravenous anaesthetics for upper GI endoscopy.

Aims and Objectives

To compare the hemodynamic effects and sedation efficacy of fentanyl with propofol and fentanyl with dexmedetomidine in patients undergoing elective diagnostic upper gastrointestinal endoscopy (UGIE).

The Haemodynamic Parameters Include

Heart rate (HR), Noninvasive blood pressure (NIBP) Respiratory rate (RR) and Oxygen saturation (Spo2).

Other Parameters Compared are-

Onset of sedation, Recovery time, Patient's satisfaction, Endoscopist satisfaction and Adverse events.

MATERIALS AND METHODS

Source of Data

60 patients who got admitted to Viswabharathi Hospital, Kurnool for upper GI endoscopy during the period of October 2014 to October 2016.

Inclusion Criteria

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

Exclusion Criteria

- ASA Grade III and IV
- Age less than 18 years and more than 60 years
- Patients allergic to study drugs
- Morbid obesity
- Baseline SpO2 <90%
- Mechanically ventilated patients
- Patients with comorbid conditions (diabetes mellitus, hypertension, hepatic or renal insufficiency)
- Patients who had difficulty in communication (due to language problem or deafness)
- Pregnancy
- Emergency endoscopy

Methodology

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 required.[5]

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 noninvasive 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. 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 introduced.[6] 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 reached.[7]

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).

RESULTS

Demographic Data

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.

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

Table 1

Subjects and Procedural Characteristics

	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 2

Baseline hemodynamic parameters: 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.

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 3

Mean Arterial Pressure (MAP): In our study Eight (26.6%) patients in propofol group and three (10%) patients in Dexmedetomidine group developed hypotension

Time	Group 'D'	Group 'P'	P value
T0	93.93 ± 9.19	94.30 ± 9.46	0.87
T1	87.46 ± 8.86	86.73 ± 9.31	0.75
T2	86.16 ± 9.74	82.73 ± 9.77	0.17
T3	83.20 ± 10.17	82.16 ± 11.11	0.70
T4	86.83 ± 8.96	82.56 ± 10.01	0.08
Recovery	90.13 ± 7.17	84.23 ± 9.97	0.01 (S)

Table 4

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.

Time	Group 'P'	Group 'D'	P value
T0	91.26 ± 13.85	88.03 ± 18.18	0.44
T1	86.36 ± 13.13	95.10 ± 13.19	0.01 (S)
T2	97.40 ± 13.95	92.43 ± 15.05	0.18
T3	100.63 ± 13.94	91.93 ± 18.44	0.04 (S)
T4	100.4 ± 13.31	88.56 ± 21.01	0.01 (S)
Recovery	98.23 ± 11.78	90.96 ± 16.28	0.05

Table 5

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).

Time	Group 'P'	Group 'D'	P value
T0	14.50 ± 1.59	15.13 ± 1.40	0.108
T1	13.46 ± 1.35	14.63 ± 0.99	0.0003 (S)
T2	13.56 ± 1.19	14.60 ± 1.06	0.0007 (S)
T3	13.60 ± 1.00	14.50 ± 1.30	0.0039 (S)
T4	13.50 ± 0.97	14.46 ± 1.10	0.0007 (S)
Recovery	13.76 ± 1.04	14.63 ± 1.15	0.0032 (S)

Table 6

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.

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 7

DISCUSSION

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 al[5] in their study showed the similar finding with regards to onset of action.

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). In present study eight (26.6%)

patients in propofol group and three (10%) patients in dexmedetomidine group developed hypotension. Similar episodes of hypotension were observed with propofol in previous studies conducted by Samson et al.[5]

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 al[8] and Muller et al[9]

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 (3 lt/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 al[10] and Sethi et al[8] showed that dexmedetomidine has no effect on respiratory centre and our study results correlate with these studies with regards to respiratory rate variations.

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 al,[5] Damiraran et al,[11] Takimoto et al[12] Sethi et al[8] and Vazquez-Rata et al,[13] reported significantly high rate of endoscopist satisfaction in dexmedetomidine group.

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 al[13] and Samson et al[5] (7.7 Min. vs. 12.7 Min., P <0.05).

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 al[5] 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 to propofol.

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