Comparative Study Between Dexmedetomidine Versus Propofol-Ketamine Versus Propofol-Fentanyl When Used for Sedation During Gastrointestinal Endoscopies

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ABSTRACT

The aim of this study is to compare Dexmedetomidine, propofol-ketamine and propofol-fentanyl for the sedation of patients undergoing upper gastrointestinal endoscopic procedures in terms of induction and recovery profiles, sedation and adverse effects, patient and endoscopist satisfaction. MATERIALS AND METHODS: After approval from hospital ethics committee a randomized comparative study was conducted in 90 patients who were undergoing upper gastrointestinal endoscopic procedures in the Department of Gastroenterology. Patients were randomized into 3 groups of 30 each by computer generated random numbers. Group 1(n=30), patients received loading dose of inj. Dexmedetomidine 1.5 µg/kg i.v infused over 10 min followed by maintenance infusion at a rate of 0.5µg/kg/hr. Group 2(n=30), patients received inj. Ketamine 0.5mg/kg i.v and inj. Propofol 1-2mg/kg i.v followed by infusion of inj. propofol 50µg/kg/min i.v as maintenance. Group 3(n=30), patients received inj. Fentanyl 1µg/kg i.v and inj. Propofol 1-2mg/kg i.v followed by infusion of inj. propofol 50µg/kg/min i.v as maintenance. All procedures were performed after achieving a sedation level of 4-5 Ramsay sedation score. RESULTS: Results were analysed by analysis of variance (ANOVA) tests. P value <0.05 was considered to be significant. There was statistically significant difference between groups with respect to the induction time and recovery time. Induction time was shorter in the ketamine-propofol group than propofol-fentanyl group and dexmedetomidine group. However recovery was faster in the propofol-fentanyl group when compared to the other groups.

CONCLUSION: Patients in Propofol Fentanyl group have early induction and faster recovery profiles with lower incidence of side effects compared to Dexmedetomidine and Ketamine Propofol groups. There by Propofol Fentanyl combination can be used as a safe sedative regimen in upper Gastrointestinal endoscopies.

INTRODUCTION

Sedation is defined as a drug-induced depression of the level of consciousness. Sedation and analgesia are integral parts of each GI endoscopy procedure. Majority of GI endoscopies are typically performed under moderate sedation with benzodiazepines alone or in combination with an opioid. The main purposes of sedation and analgesia during gastrointestinal endoscopy are to relieve patient’s discomfort, pain and anxiety, to reduce memory of the unpleasant event and to facilitate the procedure. Benzodiazepines are the most often used as sedation agents by endoscopists. Benzodiazepines do not provide analgesia and for this reason they are commonly co-administered with opioids. Fentanyl, alfentanil and remifentanil have appeared as good alternatives for GI sedation.

Propofol has rapid onset and short duration of action which makes it suitable for sedation in gastrointestinal endoscopy. It provides higher patient satisfaction. In spite of its favourable profile, due to lack of analgesic properties, large doses may be needed for maintenance of anaesthetic depth especially in prolonged procedures which can cause cardio respiratory adverse effects. Propofol requirement can be reduced with addition of adjuvants like ketamine and fentanyl.

Ketamine is N-Methyl-D-aspartate receptor antagonist, alone or in combination with other sedatives has been evaluated for sedation mainly in pediatric patients for procedural sedation and analgesia. Its use results in better quality and depth of sedation with shorter recovery times than patients sedated using benzodiazepines and opioids alone. Because pharyngeal and laryngeal reflexes are usually active, ketamine should not be used alone in diagnostic procedures of the pharynx, larynx or bronchial tree. The potential advantages of ketamine-propofol combination over ketamine alone for procedural sedation include shorter recovery time and a lower incidence of ketamine associated emesis and recovery agitation.

Dexmedetomidine, a highly selective α-2adrenergic receptor agonist with sedative and analgesic properties has the unique feature of lacking respiratory depression even with accidental over dosage giving it the advantage over other sedatives as benzodiazepines, opioids and propofol as all of them cause dose dependent respiratory depression. Its use for upper GI endoscopies showed good result.

Considering the complications of propofol-ketamine-fentanyl when used alone the present study was designed to evaluate the efficacy of various sedation combinations like Propofol Ketamine Propofol Fentanyl aiming to reach adequate sedation with advantage of lesser side effects of individual drugs when used at optimal doses. Also these drug combinations were compared to dexmedetomidine to evaluate its efficacy. The drug combinations are compared in terms of time to induction, time to recovery, efficacy, and safety, as well as patient and endoscopist satisfaction.

AIMS AND OBJECTIVES

The aim of this study is to compare

Dexmedetomidine, propofol-ketamine and propofol-fentanyl for the sedation of patients undergoing upper gastrointestinal endoscopic procedures in terms of induction and recovery profiles, sedation and adverse effects, patient and endoscopist satisfaction.
tient and endoscopist satisfaction. The parameters compared were 'Induction and recovery time, Haemodynamic variables (HR, MAP), Respiratory parameters (RR, SP02), Effectiveness of sedation (RSS Score), Patient satisfaction (1-10), Endoscopist satisfaction (1-10), and sedation related side effects.

MATERIALS AND METHODS

After approval from hospital ethics committee a randomized comparative study was conducted in 90 patients who were undergoing upper gastrointestinal endoscopies in the Department of Gastroenterology, King George Hospital, Andhra Medical College November 2013 to August 2015.

Inclusion criteria includes: Age 18-50 years. Patients belonging to ASA grade I and grade II, Patients who gave informed consent. Exclusion criteria are Age<18 years ASA III, IV, V classification, Unregulated hypertension, Allergic reaction to planned medication in patients medical history, Asthmatic history, hypovolemia, severe bradycardia (HR<50/min) or related bradyarrythmias. Impaired liver and renal function.

After placement of intravenous cannula infusion of Ringer lactate was started. All patients received inj. glycopyrrolate 0.2 mg, inj. midazolam 0.02 mg/kg and Lidocaine 10% was sprayed into the pharynx to achieve pharyngeal anesthesia. Supplemental oxygen was administered to all patients at rate 4 l/min. All procedures were performed after achieving a sedation level of 4-5 Ramsay sedation score14. Patients were randomized into 3 groups of 30 each by computer generated random numbers.

Group 1 (n=30), patients received loading dose of inj. Dexametomidine 1.5 µg/kg.v infused over 10 min followed by maintenance infusion at a rate of 0.5 µg/kg/hr.

Group 2 (n=30), patients received inj ketamine 0.5 mg/kg i.v and inj. Propofol 1-2 mg/kg.v followed by infusion of inj. propofol 50 µg/kg/min i.v.as maintenance.

Group 3 (n=30), patients received inj. fentanyl 1 µg/kg i.v and inj. Propofol 1-2 mg/kg.v followed by infusion of inj. propofol 50 µg/kg/min i.v as maintenance.

Failure to reach the acceptable level of sedation (Ramsay sedation score of 4-5) to perform the endoscopy was treated with increase in the rate of maintenance infusion of the study drug. Intravenous fentanyl 0.5-1 µg/kg was given in divided doses as rescue analgesia for unwanted movements hindering endoscopic procedure which could not be achieved with increasing the infusion rate of maintenance drug.

Monitoring include: Heart rate, Mean arterial pressure, Respiratory rate, SpO2 and Ramsay sedation score were continuously monitored and at recovery after the patient achieved 9-10 points on Aldrete Recovery Scale Score(T4). 15

Patient satisfaction was recorded (where 1=worst medical experience he ever had, while 10=best medical experience he had). Endoscopist satisfaction (where 1=worst method of sedation, while 10=best method of sedation and he would like to have it as regular method of sedation in his practice. The incidence of post operative nausea and vomiting (PONV), agitation, movement were recorded and managed accordingly.

STATISTICAL ANALYSIS: Statistical analysis of present study was conducted, using the Mean, standard error, Chi-square, Linear Correlation Coefficient and Analysis of variance (ANOVA) tests.

OBSERVATIONS AND RESULTS

Ninety patients were included in this study.

Table 1: Age in years, weight in kilograms, sex distribution and endoscopy time in the three groups.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in yrs</td>
<td>35.7±10.7</td>
<td>41.3±10.9</td>
<td>37.9±10.5</td>
<td>0.1</td>
</tr>
<tr>
<td>Weight in kgs</td>
<td>56.3±6.1</td>
<td>54.5±6.1</td>
<td>56.4±6.7</td>
<td>0.4</td>
</tr>
<tr>
<td>Sex Ratio M/F</td>
<td>18/12</td>
<td>17/13</td>
<td>17/13</td>
<td>0.9</td>
</tr>
<tr>
<td>Endoscopy time</td>
<td>13.3±3.7</td>
<td>13.1±4.0</td>
<td>13.8±4.2</td>
<td>0.7</td>
</tr>
</tbody>
</table>

p>0.05

Their demographic data showed no statistically significant difference (p>0.05) between the groups with respect to age, sex, and weight. The duration of endoscopy was comparable in all the groups with no statistically significant difference (p>0.05)(Table 1, Figure 1).

Table 2: Induction and recovery time in minutes.

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Induction time</td>
<td>10.5±2.4</td>
<td>2.1±0.7</td>
<td>2.8±1.0</td>
<td>0.001</td>
</tr>
<tr>
<td>Recovery time</td>
<td>14.0±4.0</td>
<td>12±3.3</td>
<td>7.6±2.2</td>
<td>0.001</td>
</tr>
</tbody>
</table>

p>0.05

There was a highly statistically significant difference (p<0.001) between groups with respect to the induction time and recovery time. Induction time was shorter in group 2 (2.1±0.7) than group 3 (2.8±1.0) and group 1 (10.5±2.4). Recovery was faster with group 3(7.6±2.2) when compared to group 2 (12±3.3) and group 1 (14.0±4.0)(Table 2, Figure 2).

Table 3: Heart rate in beats per min.

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>T0</td>
<td>72±6.7</td>
<td>70.8±6.9</td>
<td>72±7.0</td>
<td>0.7</td>
</tr>
<tr>
<td>T1</td>
<td>59.8±5.5</td>
<td>74.5±6.7</td>
<td>69.2±5.1</td>
<td>0.001</td>
</tr>
<tr>
<td>T2</td>
<td>66.9±4.6</td>
<td>69.2±5.1</td>
<td>67±4.2</td>
<td>0.11</td>
</tr>
<tr>
<td>T3</td>
<td>67±4.2</td>
<td>69.2±5.1</td>
<td>66.9±4.6</td>
<td>0.11</td>
</tr>
<tr>
<td>T4</td>
<td>68.0±5.0</td>
<td>69.4±6.9</td>
<td>70.8±6.8</td>
<td>0.2</td>
</tr>
</tbody>
</table>

p>0.05

There was an highly statistically significant difference (p<0.001) in heart rate between the groups, during T1 (at induction). Heart rate was higher in group 2 (74.5±6.7 bpm) when compared to group 3 (69.2±5.1 bpm) and group 1 (59.8±5.6 bpm). No statistically significant difference was seen among the groups during T2, T3 intervals.(Table 3)

Table 4: sedation score(score 1 to 6).

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1</td>
<td>4.0±0.6</td>
<td>4.1±0.8</td>
<td>4.0±0.6</td>
<td>0.8</td>
</tr>
<tr>
<td>T2</td>
<td>3.8±0.6</td>
<td>3.7±0.5</td>
<td>3.7±0.6</td>
<td>0.8</td>
</tr>
<tr>
<td>T3</td>
<td>3.7±0.6</td>
<td>3.7±0.6</td>
<td>3.7±0.5</td>
<td>0.8</td>
</tr>
</tbody>
</table>

p>0.05

There was no statistically significant difference among the 3 groups at T1, T2 and T3 interval. All the patients in the three groups were satisfactorily sedated (RSS score 4-5) with mean of 4.0±0.6 in group 1, 4.1±0.8 in group 2 and 4.0±0.6 in group 3. (Table 4,)
In regard to patient satisfaction, the patients in group 3 were more satisfied compared to those in groups 1 and 2. The p value is 0.001 showing highly significant patient satisfaction score in group 3 with mean and standard deviation 8.1±0.8 compared to that in group 1 (7.4±0.8) and group 2 (7.7±0.8). From the endoscopist’s perspective the satisfaction score was higher with p value <0.001 in group 3 with mean and standard deviation of 8.0±0.7 compared to group 1 (7.1±0.6) and group 2 (7.4±0.9) (Table 5).

Table 5: Patient and endoscopist satisfaction (Score from 1 to 10).

<table>
<thead>
<tr>
<th>Group</th>
<th>Patient satisfaction</th>
<th>Endoscopist satisfaction</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>7.4±0.8</td>
<td>7.1±0.6</td>
<td>0.004</td>
</tr>
<tr>
<td>Group 2</td>
<td>7.7±0.8</td>
<td>7.4±0.9</td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td>8.1±0.8</td>
<td>8.0±0.7</td>
<td>0.001</td>
</tr>
</tbody>
</table>

p<0.05

In this study, rescue analgesic doses of inj.fentanyl 0.5-1µg/kg iv was given in 6 cases (20%) each in group 2 and group 3 and compared to 12 cases (40%) in group 1.(Table 6)

Table 6: Rescue analgesia (n=30).

<table>
<thead>
<tr>
<th>Group</th>
<th>Rescue analgesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>12 (40%)</td>
</tr>
<tr>
<td>Group 2</td>
<td>6(20%)</td>
</tr>
<tr>
<td>Group 3</td>
<td>6(20%)</td>
</tr>
</tbody>
</table>

In this study, the incidence of movement of patients during procedure was 6 cases (20%) in group 1, 3 cases (10%) in group 3 and 2 cases (7%) in group 2.Post operative nausea and vomiting occurred in two patients (7%) each in group 1 and 3 and in three patients (10%) in group 2. Agitation occurred only in three patients (10%) in group 2. (Table 7)

Table 7: Sedation related side effects.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Movement</td>
<td>6(20%)</td>
<td>2(7%)</td>
<td>3(10%)</td>
</tr>
<tr>
<td>PONV</td>
<td>2(7%)</td>
<td>3(10%)</td>
<td>2(7%)</td>
</tr>
<tr>
<td>Agitation</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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DISCUSSION:
The present study was done to compare Dexmedetomidine, propofol- ketamine and propofol-fentanyl for the sedation of patients undergoing upper gastrointestinal endoscopic procedures in terms of induction and recovery profiles, sedation and adverse effects, patient and endoscopist satisfaction.

The combination of ketamine and propofol more properly known as ketofol has many advantages in outpatient procedures like gastrointestinal endoscopies. The opposing physiological effects of these drugs suggest a potential for synergy.26

Considering the complications of propofol, ketamine, fentanyl when used solely the present study was designed to evaluate the efficacy of various sedation combinations aiming to reach a state of sedation which meets the patient and endoscopists satisfaction together with the least cardiopulmonary affection and adverse effects of individual drugs. Also these combinations were compared to dexmedetomidine to evaluate its efficacy.

Goal of this study was to provide an adequate level of sedation while minimizing pain and anxiety, minimizing unwanted patient movement during procedure the adverse drug-related events, and maintaining a stable cardiovascular and respiratory status. Continuous infusion technique was used in this study to maintain a steady state sedation level.

Their demographic data showed no statistically significant differences (p>0.05) between the groups with respect to age, sex, and weight. The duration of endoscopy was comparable in all the groups with no statistically significant difference (p>0.05).

Induction of sedation was calculated as time to achieve Ramsay sedation score 4-5 that is adequate to perform endoscopy. The induction of sedation was faster in patients receiving ketamine-propofol (2.1±0.7 min) compared to dexmedetomidine (10.5±2.4 min) and propofol-fentanyl (2.8±1.0 min). In a study done by Ashraf S.Hasanain and his colleagues in 2014 comparing dexmedetomidine and propofol for sedation during gastrointestinal endoscopies they found higher induction time with dexmedetomidine (10.51±1.75min) than with propofol (3.17±0.72min) that is similar to the present study. Lera dos santos ME et al performed a study with propofol-fentanyl for gastrointestinal endoscopy, they observed mean induction time value 2.63±1.6 min which is similar to the present study.

Recovery time was calculated as time to achieve alderete score of >9 after completion of endoscopy procedure. Recovery was faster with propofol-fentanyl (7.6±2.2 min) when compared to ketamine propofol (12±3.3 min) and dexmedetomidine (14±4.0 min).20Rham Hasanein and his colleagues also observed shorter recovery time in patients who received propofol fentanyl (9.4±2.3 min) compared to those who received ketamine propofol (11.5±2.59 min). In a study by Ramakiran et al comparing propofol, dexmedetomidine and ketamine in outpatient ERCP observed that time for attaining modified alderete score >9 was 16.6±3.18 min with dexmedetomidine, 7.5±3.2 min with propofol and 10±4.17 min for ketamine.29 The recovery time of the dexmedetomidine group was significantly prolonged which could be attributed to the pharmacological profile of dexmedetomidine, that is similar to the present study.

The heart rate was calculated at induction, 5 min after insertion of endoscope and recovery. The heart rate during T1 (at induction) was higher in patients receiving ketamine-propofol (74.5±6.7bmp) compared to propofol-fentanyl (69.2±5.1bpm) and dexmedetomidine (59.8±5.6 bmp). No statistically significant difference was seen among the groups during T2, T3 intervals. Ketamine causes central sympathetic stimulation and suppression of baroreceptors causing increasing in heart rate and mean arterial pressures. This explains the higher heart rate in the ketamine propofol group.20

The mean arterial pressure in all the groups was stable throughout the procedure. Addition of propofol to ketamine in ketamine propofol group might have blunted the sympathomimetic response of ketamine which would increase the mean arterial pressure.16

There was no statistically significant difference observed with respect to respiratory rate and oxygen saturation percentage in all the groups (p>0.05).21

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There was no statistically significant difference observed with respect to respiratory rate and oxygen saturation percentage in all the groups (p>0.05).21
tients receiving dexmedetomidine(20%), compared to patients receiving propofol fentanyl(10%) and ketamine propofol(7%).

Post operative nausea and vomiting was higher in patients receiving ketamine propofol (10%) compared to 7% each in dexmedetomidine and propofol fentanyl group. Agitation occurred only in three patients (10%) in ketamine propofol group. 19,22

In this study, rescue analgesic doses of inj .fentanyl 0.5-1µg/kg iv was given in 6 cases (20%) each in ketamine propofol group and propofol fentanyl group compared to 12 cases(40%)in dexmedetomidine group. Rescue analgesia with fentanyl was needed in 30% patients of Group Dexamethomidine compared to 17.63% patients of group propofol as observed by Tomar GS and singh ET al.21.

SUMMARY
A comparative study was conducted in 90 patients of age 18-50 years,of ASA 1 and 2 scheduled to undergo gastro intestinal endoscopies. The patients were assigned into three groups of 30 each. Group 1(n=30), patients received loading dose of inj.Dexmedetomidine 1.5 µg/kg i.v infused over 10 min followed by maintenance infusion at a rate of 0.5µg/kg/hr. Group 2(n=30),patients received inj ketamine 0.5mg/kg l.v and inj.Propofol1-2 mg/kg.v followed by infusion of inj.propofol 50µg/kg/min l.v as maintenance. Group 3(n=30), patients received inj fentanyl 1µg/kg i.v and inj.Propofol1-2 mg/kg.v followed by infusion of inj.propofol 50µg/kg/min i.v as maintenance.

There was a statistically significant difference between groups with respect to the induction time and recovery time. Induction time was shorter in ketamine propofol group than propofol fentanyl group and dexmedetomidine group. However recovery was faster in propofol fentanyl group when compared to other groups.

The heart rate was comparable at all intervals in the three groups except at T1 interval where the heart rate was significantly higher in ketamine propofol group.

The mean arterial pressure,respiratory rate and Oxygen saturation percentage were comparable in all the three groups.RSS score of 4-5 was maintained at the time of insertion of endoscope(T1 interval).

Patient satisfaction and endoscopist satisfaction was more in the patients who received propofol fentanyl than those who are given ketamine propofol and dexmedetomidine.

The incidence of movement during procedure and rescue analgesia requirement was higher in dexmedetomidine group. Post operative nausea and vomiting occurred in two patients (7%) each in dexmedetomidine group and propofol-fentanyl group and in three patients (10%) in ketamine –propofol group. Agitation occurred in three patients (10%) in ketamine-propofol group only.

CONCLUSION:
Patients in Propofol Fentanyl group have early induction and faster recovery profiles with lower incidence of side effects compared to Dexamethomidine and Ketamine Propofol groups. There by Propofol Fentanyl combination can be used as a safe sedative regimen in upper Gastrointestinal endoscopies.

REFERENCES