An Observational Study to Compare Propofol with Midazolam plus Fentanyl Combination for Sedation in Gastrointestinal Endoscopies at Tertiary care Hospital in Katihar, Bihar

Authors

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Abstract

Objective & Aim: In gastrointestinal (GI) endoscopy, Propofol has revolutionised sedation practices as it can be easily titrated and has a rapid recovery profile. This observational real-world study was initiated specially in patients who were undergoing GI endoscopy sedation to compare efficacy and safety of propofol with midazolam and fentanyl combination.

Methods: 80 patients who are admired at Katihar medical college and hospital and scheduled for gastrointestinal endoscopy process were recruited for this real world observational study. Patients was divided in two groups which contains either Group A (propofol alone) or Group B (combination of midazolam plus fentanyl). Efficacy was measured by the parameters like depth of sedation (Ramsays sedation scale), time of onset of sedation, amnesia and early recovery of sedation (Modified Aldrete Score). Cardiovascular and respiratory parameters were used to evaluate safety parameters. Adverse events like hypotension, hypoxia and bradycardia were recorded. For statistical analysis, PSPP software was used.

Result: With a mean RSS of 4.9, A group patients were more deeply sedated compared to 3.2 of the B group. At ten minutes after the end of the procedure, full recovery (Aldrete score 10) was seen in 73.33% of the patients of the A group compared to 50% of the B group which was insignificant. Significant haemodynamic changes (hypotension) had observed in A group as compared to B group. Few statistically non-significant respiratory complications were seen in both the groups.

Conclusion: Both the groups present with almost same efficacy and safe.

Keywords: Propofol, Midazolam plus Fentanyl Combination, GI endoscopy sedation.

Introduction

In gastrointestinal (GI) endoscopy, Propofol has revolutionised sedation practices as it can be easily titrated and has a rapid recovery profile. Relieve anxiety, diminish memory of the discomfort or pain is the main purpose of sedation in these patients. The drugs chosen for sedation should provide a rapid return to clear headedness on completion of procedure and also ease of titration to the desired level of sedation. Propofol has largely replaced the traditional use of benzodiazepines gained overall popularity as the sedative agent of choice[1-3]
This observational real-world study was initiated specially in patients who were undergoing GI endoscopy sedation to compare efficacy and safety of propofol with midazolam and fentanyl combination.

**Methods**
This study was conducted at Katihar Medical college and hospital, Bihar over a six-month period, after departmental review board approval. Patients informed consent was obtain before the procedure begins.

The endoscopic procedures included were endoscopic ultrasound (EUS), oesophagogastroduodenoscopy (OGD scope), colonoscopy and endoscopic retrograde cholangiopancreatography (ERCP). Any patients who were under 18 years of age were excluded from the study. The other exclusion criteria include patients with active GI bleeding, pregnancy, allergic to egg or soya beans, mechanically ventilated patients and those with difficult airway.

80 patients who are admired at DMCH and scheduled for gastrointestinal endoscopy process were recruited for this real world observational study. Patients was divided in two groups which contains either Group A (propofol alone) or Group B (combination of midazolam plus fentanyl).

Efficacy was measured by the parameters like depth of sedation (Ramsays sedation scale), time of onset of sedation, amnesia and early recovery of sedation (Modified Aldrete Score). Heart rate (HR), diastolic blood pressure (DBP), systolic blood pressure (SBP), respiratory rate (RR) mean arterial pressure (MAP) and oxygen saturation (SpO2) were measured every five minutes till the end of procedure. Cardiovascular and respiratory parameters were used to evaluate safety parameters. Adverse events like hypotension, hypoxia and Bradycardia were recorded.

Qualitative data was assessed by Chi square test and by Fisher's Exact test represented by using mean ± SD and analyses between the groups were done by using unpaired t-test and Chi square test. For statistical analysis, PSPP software was used.

**Results**
The demographic data of 80 patients who were studied in our trial was illustrated in Table 1. It was observed that the demographic details are matching with each other and almost identical in both the groups.

### Table 1: Demographic characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>B Group (Mean± SD)</th>
<th>A Group (Mean± SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Yrs )</td>
<td>52.67 ± 18.21</td>
<td>53.1± 18.14</td>
<td>0.729</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>64.34 ± 10.22</td>
<td>65.07±12.09</td>
<td>0.631</td>
</tr>
<tr>
<td>Duration of procedure (min)</td>
<td>25.32± 14.29</td>
<td>22.41± 15.29</td>
<td>0.285</td>
</tr>
</tbody>
</table>

* P < 0.05 significant, B Group - Midazolam + Fentanyl, A Group - Propofol

63.3 mg was the mean induction dose of propofol in group A and 2.48mg and 129 μg of midazolam and fentanyl was the mean dose in group B. 47.22 seconds was the mean onset time of action of group A as compare to group B which was 86.28 seconds and the dissonance was statistically significant. Fentanyl 173μg and midazolam 3.25 mg was total mean dose for maintenance required in Group B and 180.83 mg (6 mg/kg/hr) was total mean dose for maintenance required in Group A.

With a mean RSS of 4.9, A group patients were more deeply sedated compared to 3.2 of the B group. At ten minutes after the end of the procedure, full recovery (Aldrete score 10) was seen in 73.33% of the patients of the A group compared to 50% of the B group which was insignificant. In A soup it has been observed that the time to awaken the patients was 2.51 min which was was significantly more compared to 0.09 min in the B group. Recovery time in B
group was 11.5 min which was almost same in with A group (13.3 mins) and also was not significant (Table-2).

Table 2: Comparison of efficacy between the two groups

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>B Group (Mean± SD)</th>
<th>A Group (Mean± SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset of sedation (s)</td>
<td>86.28 ± 40.98</td>
<td>47.22 ± 25.61</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Ramsays Sedation Scale</td>
<td>3.2 ±1.21</td>
<td>4.9± 1.53</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Awakening (Min)</td>
<td>0.09±0.24</td>
<td>2.51± 2.21</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Recovery Time (min)</td>
<td>11.5± 8</td>
<td>10.3± 5</td>
<td>0.48</td>
</tr>
<tr>
<td>Endoscopist Satisfaction (VAS %)</td>
<td>80.67±10.73</td>
<td>77.5± 11.95</td>
<td>0.28</td>
</tr>
</tbody>
</table>

* P<0.05 is significant B Group - Midazolam+Fentanyl, A Group - Propofol, VAS - Visual analogue scale

In A group of patients 47.2% had hypotension which was statistically significant. Severe hypotension was found in 6 patients whereas moderate hypotension observed in 13 patients. Bradycardia <50 /min or ECG changes was not observed with any patients. in the B group 11.3%

Table 3: Comparison of safety parameters

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>B Group (Mean± SD)</th>
<th>A Group (Mean± SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP % decrease over baseline</td>
<td>11.03 ± 8.52</td>
<td>23.26 ± 13.06</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>HR % decrease over baseline</td>
<td>7.65 ± 8.45</td>
<td>6.37 ± 6.42</td>
<td>0.51</td>
</tr>
<tr>
<td>RR % decrease over baseline</td>
<td>20.03 ± 18.47</td>
<td>10.95 ± 15.45</td>
<td>0.043*</td>
</tr>
<tr>
<td>Saturation % decrease over baseline</td>
<td>1.37 ± 3.22</td>
<td>1.83 ± 5.62</td>
<td>0.69</td>
</tr>
</tbody>
</table>

*P<0.05 is significant, B Group - Midazolam + Fentanyl, B Group - Propofol; SBP - Systolic blood pressure, HR- Heart rate, RR- Respiratory rate

Discussion

Topical anaesthesia or its combination with sedation are the alternative two process used in anaesthetic management in gastro intestinal endoscopies. Propofol has a favourable pharmacokinetic profile due to its short-acting anaesthetic profile and also had a rapid induction of sedation, equivalent levels of amnesia and faster recovery in comparison to the benzodiazepines and opioids. For conscious sedation during GI endoscopy Midazolam is commonly used in synergy with opioid fentanyl as it is a benzodiazepine depressant of the central nervous system. This combination has some limitations like a lingering sedative effects that delay discharge, delay of onset of action and prolonged recovery, and morbidity as a result of respiratory depression. This is the main reason for which further study is required for optimal propofol administration methods for gastrointestinal procedures.

In a study done by Christopher N, operating conditions, quality of sedation, and recovery profiles were similar in intermittent bolus injections, target controlled infusion and conventional syringe infusion\(^4\). Propofol has a narrow therapeutic window and absence of a reversal agent can lead to over sedation and
therefore does not have analgesic properties\cite{5}. Combining a low dose of propofol with opioid analgesic and or benzodiazepine propofol sedation was proposed as a method that would provide safe and effective sedation reduce complications\cite{6,7}.

68 % of midazolam group were amnesic compared to 14 % of the propofol group was shown in K.W Patterson et al. study, which was almost similar findings as our study\cite{8}. Like our findings, the depth of sedation was greater, mean time to sedation was significantly faster and also these patients recovered faster as observed in other study\cite{9}. As per observation found by T.W. Weherman et al, propofol group achieved full recovery after 19 +/- 8 min compared to 29 +/- 8 min in the midazolam group\cite{10}. In our study this was different may because of usage of higher dose of both the therapies.

With sedation in both groups (80.67% B vs 75.57% in A group), the endoscopists were very satisfied which was similar findings with Eszter Sego et al\cite{11}. There were several limitations like sample size, use of older process of measuring amnesia and so many other high-tech diagnostic tools were not used. But despite that our trials brings similar finding with several other studies done in various other hospitals.

Conclusion
Both the groups present with almost same efficacy and safe. Respiratory complications and Haemodynamic variations are seen with both groups.

References