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Association of Propofol Vs Midazolam in Adverse Effect for Sedation during ERCP

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Abstract

Endoscopic Retrograde Cholangiopancreatography (ERCP): This is an invasive, diagnostic and therapeutic procedure for biliary and pancreatic disorders that requires adequate sedation to provide patient comfort and successful completion of the procedure. Two frequently used sedatives, midazolam and propofol, have different pharmacological properties and the selection of which remains controversial. This study aimed to check association between Propofol and Midazolam regarding adverse events in ERCP patients. A prospective observational study was conducted in a private clinical setting over four months, after ethics approval. The patients were convenience sampled, and 100 were randomly assigned equally to two groups – Propofol (n=50) and Midazolam (n=50) – age range of 18-90 years. Data was generated on modified proforma which included demographics, risk factors, sedation, recovery and postoperative safety and analysed with SPSS 27 and MS Excel using Chi-square. Baseline characteristics were comparable between the groups, and both propofol and midazolam were shown to be relatively safe sedatives used during ERCP with the

majority of the patients having no major side effects. The two drugs did have some differences in toxicities. Patients treated with midazolam had a higher percentage without complications and patients treated with propofol had higher incidences of hypotension and hypoxia.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a complex diagnosis and treatment tool and extremely essential in the treatment of pancreatic and bile duct issues[1]. Sedation is required to provide comfort to patients, cooperation and endoscopic success due to its invasive nature and the resultant discomfort related to the extended periods of endoscopic manipulation. The issue of the sedative agent that should be used has been a debatable one. The most popular sedatives like benzodiazepines like midazolam have always been used but propofol has become an extremely strong alternative because of its pharmacokinetic benefits[2]. This discourse is not just an academic exercise, but it has a direct effect on patient safety, recovery, and overall results, especially to the elderly or otherwise who have a lot of other health complications. In conscious sedation, Midazolam is a popular option since it helps in the reduction of anxiety levels, causes individuals to forget, as well as fall asleep. It is safer because of flumazenil, a particular antagonist capable of overturning its effects in case of oversedation. Nonetheless, midazolam is linked to a long period of recovery, accumulation of sedation in the presence of long surgery and different levels of patient satisfaction. Propofol on the other hand is a highly rapid acting hypnotic medication which is fast acting as well as fast. It provides a better quality of sedation, faster recovery and patient and endoscopist satisfaction[3]. Prevelance of ECRP and endocholedocholithiasis is 47% in local literature[4].

It possesses certain disadvantages that include narrow therapeutic index, respiratory depression, and the absence of a reversal agent. The role of midazolam versus propofol is thus a compromise between effectiveness and safety and we still need evidence-based advice. This clinical dilemma has been addressed by a number of comparative studies. Jung et al. conducted a randomized controlled trial where propofol and midazolam were compared in the patients who were undergoing an ERCP. They indicated that propofol was better than midazolam since it treated 97.5 percent of patients as opposed to 80 percent of patients. Propofol group took a much shorter time to recover and researchers as well as the patients felt that propofol was a better sedation agent. Interestingly, no significant changes in the cardiopulmonary parameters were observed, however, one patient experienced transient apnea, and close monitoring is necessary[5].

The article by Han and colleagues concentrates on the elderly patients (more than 80 years old) who are subjected to therapeutic ERCP, a patient population that is highly sensitive to the impact of the sedation. This was a prospective comparative trial, where the study participants underwent either midazolam and fentanyl or propofol and fentanyl and administered by trained nurses following the non- anesthesiologist guideline. The study did not identify any radical variances in safety outcomes such as hypoxia, hypotension, or bradycardia in the two categories. Similar scores were also found in patient satisfaction and the endoscopist. However, the propofol group had much shorter recovery times, which shows that propofol has an advantage in terms of recovery profile. The results of these studies are that propofol may be safely administered in extremely elderly patients with careful consideration[6]. Combination therapies have been studied by other researchers. In, Angsuwatcharakon et al. examined the cocktail regimen involving propofol and midazolam and meperidine. This was to reduce the total propofol administered and eliminate the possibilities of over sedation. It showed that cocktail group had a faster recovery and patient satisfaction than the standard sedation group, but showed that the cocktail group had a higher incidence of transient desaturation. Even though these episodes were fixed

with extra oxygen and didn't need the scope to be taken out, the results show how important it is to find the right balance between effectiveness and safety when combining agents[7]. Kim et al. compare midazolam with propofol and midazolam. The combination regimen had led to faster induction, faster recovery and improved patient compliance without raising bad event rates. This was also possible because of the synergistic effect of taking less dose of each drug and thus reducing the chances of problems. The assumption made in this paper that combining two or more drugs can be a more effective form of sedation is justified since it aids in taking advantage of the pluses of each drug. All in all, these researches demonstrate that propofol is better in recovery and quality of sedation, whereas midazolam is safer. The selection of an agent is to be made separately, considering the demographics of the patient, comorbidity, and the complexity of the procedure[8].

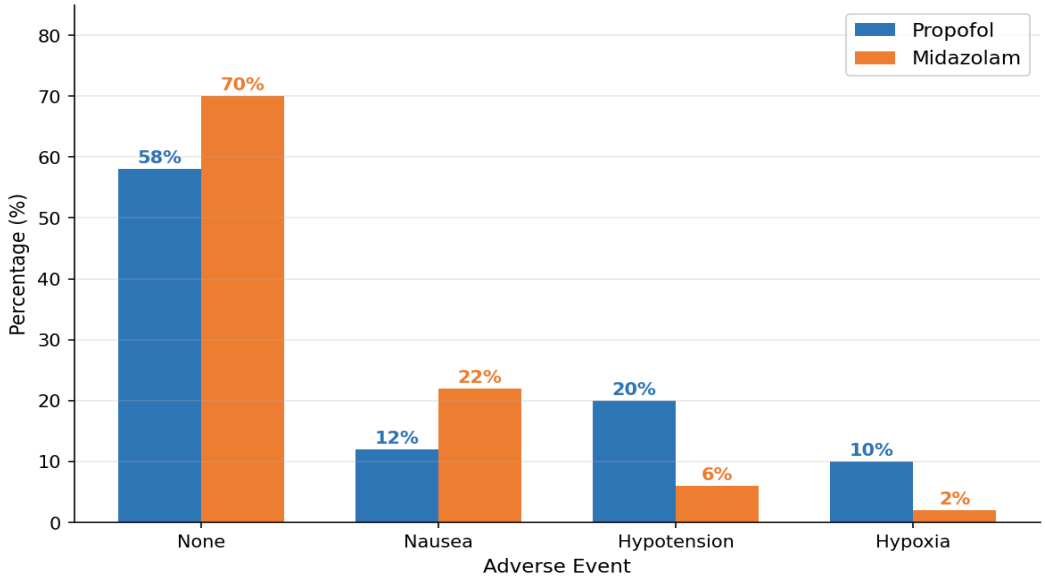
Evidence-based decisions are implemented with the help of combinations of structured assessment tools and composite scoring systems. The study is a project that aims at offering feasible recommendations on how the sedation plans employed in ERCP may be enhanced in relation to a broad research performa, and literature. It will contribute to the current discussion and improve patient care in such a complicated clinical case by conducting a systematic comparison of propofol and midazolam.

METHODOLOGY

In this study prospective observational design was adopted as per literature[9]. Private sector, Hospital of Islamabad were used for the clinical settings of this study. Sample size was 100. Convenience sampling technique were used for this study duration of the study was approximately 8 months. Data was collected through a slight modified pre-designed Performa. Reference point for data collection was the time of patient discharge from operation theatre. Data analysis was done through SPSS 27th version and M.S EXCEL 2021. Descriptive statistics, Chi square test were used for statistical analysis.

RESULTS

Figure 1: Adverse Events by Sedation Group (Bar Chart)



Chi-Square = 9.039 p = 0.029

Adverse Events by Sedation Group

There was a significant difference in the adverse event profiles of the two groups. Hypotension was more common in the Propofol group (20% vs 6% in the Midazolam group, n=10, n=3). Propofol, on the other hand, was associated with minimal nausea

(n=6, 12%) while Midazolam was associated with higher incidence of nausea (n=11, 22%). There was a higher rate of hypoxia in the Propofol group (10%, n=5) than Midazolam (2%, n=1). The numbers of adverse events were zero in 29 (58%) patients receiving Propofol and 35 (70%) patients receiving Midazolam.

Recovery Parameters

Table 1: Summery of All Statistical Test.

Variable	Category	Propofol (n=50)	Midazolam (n=50)	Total (n=100)
Gender	Male	26 (52%)	26 (52%)	52 (52%)
	Female	24 (48%)	24 (48%)	48 (48%)
Age Group (years)	18–30	0 (0%)	1 (2%)	1 (1%)
	31–40	6 (12%)	6 (12%)	12 (12%)
	41–50	14 (28%)	11 (22%)	25 (25%)
	51–60	18 (36%)	20 (40%)	38 (38%)
	61–70	8 (16%)	8 (16%)	16 (16%)
	71–80	4 (8%)	4 (8%)	8 (8%)
ASA Status	I	7 (14%)	4 (8%)	11 (11%)
	II	27 (54%)	28 (56%)	55 (55%)
	III	10 (20%)	11 (22%)	21 (21%)
	IV	6 (12%)	7 (14%)	13 (13%)
Adverse Events	None	29 (58%)	35 (70%)	64 (64%)
	Nausea	6 (12%)	11 (22%)	17 (17%)
	Hypotension	10 (20%)	3 (6%)	13 (13%)
	Hypoxia	5 (10%)	1 (2%)	6 (6%)

100 patients (50 in the Propofol group and 50 in the Midazolam group) were included in the study. Demographic and clinical profile of the participants were similar in both groups. There were almost equal numbers in both sexes, 52% male and 48% female. Likewise, age distribution and ASA status at baseline were similar, showing good baseline comparability of the study groups.

A statistically significant difference was found between the Propofol and Midazolam groups for adverse events ($\chi^2 = 9.039$, $p = 0.029$). There were more patients in the Midazolam group without adverse events (70%) than in the Propofol group (58%). Patients on Midazolam (22%) had more nausea than those on Propofol (12%). The rate of clinically significant hypotension (20% vs. 6%) and hypoxia (10% vs. 2%) was higher in patients in the Propofol group than in those in the Midazolam group. Based on these results the overall safety profile of Midazolam was more favorable, especially in terms of cardiovascular and respiratory adverse events.

Moreover, statistically significant differences also were noted in recovery parameters – time to eye opening (p 0.001), time to obey commands ($p < 0.001$), and GCS score

at 30 minutes (p = 0.019). This suggests that there were significant differences in recovery characteristics between the two treatment groups. However, from the available summary table, it is not possible to determine if one of these drugs resulted in a quicker recovery as no medicine-specific median or mean values are provided for these variables.

From currently available evidence, it seems that Midazolam was the drug of choice in terms of safety, with a greater percentage of patients with no adverse events and a lower incidence of hypotension and hypoxia. However, definitive conclusions about overall superiority must await the recovery outcome values of both groups, since recovery time and postoperative consciousness are important factors that influence the clinical effectiveness.

CONCLUSION

Finally, propofol and midazolam were determined to be generally safe sedative agents for ERCP and most patients did not have adverse events. The negative effect profiles were, however, different for the two drugs. Midazolam was linked to an increased percentage of patients that did not present with any complications and a reduced number of serious cardiorespiratory events, while propofol was linked to increased rates of hypotension and hypoxia. The nausea was more common with midazolam, but was a less serious side effect than the cardiorespiratory side effects reported with propofol. Selection of sedative agent for ERCP must therefore be made based on an individual patient's characteristics and comorbidities and should be carefully monitored, especially if propofol is used.

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