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Comparative Evaluation Between Propofol And Ketamine-Midazolam As Procedural Sedative Agent For Ease Of Induction Of Spinal Anesthesia In Patients Undergoing Abdominal Surgeries

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Abstract

Procedural sedation is not a routine during neuraxial blocks, but it is advisable that anesthesiologists should provide their blocks comfortably. Sedation also alleviates anxiety thereby reducing autonomic fluctuations and eases induction of spinal anaesthesia and improves its quality. All American Society of Anesthesiologists Physical Status-1 patients aged between 20 years to 60 years, undergoing elective surgeries under spinal anaesthesia, who can understand and willing to give consent will be included. In our study, there is no hemodynamic variation among the two groups as we had used bolus doses of propofol and ketamine itself has positive inotropic effects. However, one patient had airway obstruction due to tongue fall once sedated and was managed with nasopharyngeal airway in Group A. This can be attributed to deeper plane of sedation due to administration of high dose of propofol as the patient's BMI was high.

Keyword: Propofol, ketamine, midazolam

Introduction

Patient positioning during any procedure is very important, sometimes it is difficult for some patients to optimally flex their hips and knees making traditional position for induction of spinal anaesthesia difficult. There may be difficulty in positioning due to anxiety, pain and discomfort also. Providing procedural sedation has shown promising results in overcoming these problems. There is an evolving trend towards the judicious implementation of sedation during regional anesthesia providing increased patient's comfort and satisfaction [1, 2].
Procedural sedation is not a routine during neuraxial blocks, but it is advisable that

anesthesiologists should provide their blocks comfortably. Sedation also alleviates anxiety thereby reducing autonomic fluctuations and eases induction of spinal anaesthesia and improves its quality. In the past, there are limited studies in evaluating these procedural agents as sedatives for ease of induction of spinal anesthesia. In our study, we are comparing propofol and ketamine-Midazolam as procedural sedative agents before administration of spinal anesthesia in patients undergoing lower abdominal surgeries [3, 4].

Materials and Methods

Inclusion Criteria

All American Society of Anesthesiologists Physical Status-1 patients aged between 20 years to 60 years, undergoing elective surgeries under spinal anaesthesia, who can understand and willing to give consent will be included.

Exclusion Criteria

1. Obese patients BMI≥ 30.
2. Patients having any spinal deformity.
3. Patients having history of allergy to the study drugs and local anaesthetics.
4. Patients with history suggestive of GERD.
5. Patients having coagulation abnormalities, Bleeding diathesis.
6. Patients with hemodynamic instability/fixed output cardiac disorder.
7. Patients who are having features suggestive of raised ICP.

Randomisation

Patients will be randomly allocated by a computer generated randomisation into 2 groups:

Group A: Sedation with Propofol.

Group B: Sedation with Ketamine-Midazolam.

A detailed pre anaesthetic check was done on the day prior to the surgery and eligible patients were included in the study. Patient were kept fasting overnight prior to surgery and were premedicated with Tab Ranitidine 150mg on the night prior to surgery.
In operation theatre, Patients were shifted to OT after standard pre check of workstation and other equipments, basal vital parameters will be noted (Heart rate, bp spo2, Respiratory rate). Good flowing IV cannula will be secured.
In GROUP A, the patients will receive inj. Propofol 0.7mg/kg IV with increments of 20mg Till they achieve Ramsay sedation score of 4 along with oxygen via venti mask at 6-8ltr/min.
In Group B, the patients will receive inj. Ketamine 0.5mg/kg and Inj midazolam 0.02mg/kg IV along with increments of inj. Ketamine 10mg till they achieve Ramsay sedation score of 4 along with oxygen via venti mask at 6-8ltr/min.
Time to achieve Ramsay score 4 was noted and considered as onset of sedation.
All patients were maintained on spontaneous Respiration.
Any unexpected fall in saturation with sedation was recorded and treated according to standard protocol. Patient were placed with their back parallel to edge of the operating table, thighs flexed into the abdomen with neck flexed to allow the forehead to be as close as possible to knees with the help of an assistant in OT.

Under all aseptic precautions, using landmark technique, desired space for insertion of spinal needle was identified. Ease of identification of space will be assessed using ordinal scale as: easy, difficult or impossible to palpate the lumbar spinous processes, while the patient was positioned after receiving procedural sedative agent or without it according to the group allocated and it will be noted. Later, spinal anaesthesia was performed by introducing the 25G quincke spinal needle into preferred interspinous space until tactile sensation was felt. Correct placement of spinal needle into the subarachnoid space was judged by appearance of cerebrospinal fluid (CSF) in the hub of the needle. When there was no CSF in the needle hub or there was only a small amount of CSF with poor flow, the needle was rotated clockwise 90° and would wait for 5 seconds. The sequence of rotation was continued for another 3-quadrant rotation of 90° and wait 5 seconds after each rotation. Despite this maneuver, if there was absence of CSF or its free flow, the needle would be further advanced approximately by 2 mm. The number of times for needle re-directions and bony contacts will be documented.

Thus, considering all the above-mentioned manipulations, each attempt was considered as a failed attempt if there was no CSF in the hub, despite advancement, three redirections coupled with 360 maneuver of the needle.

Appearance of free flow of CSF confirmed a successful needle insertion and the study was complete whenever the subarachnoid space was confirmed by observation of free flow of CSF. Thus the time duration from the time of insertion of needle in first attempt till appearance of CSF was noted as time to induce spinal anaesthesia, the number of attempts was also noted.

Patient's comfortability during the procedure was analysed by an independent observer using 10cm VAS scale (10cm denotes maximal comfort while 0cm denotes minimal comfort).

Patient satisfaction score was recorded in a subjective scale of 0-100.Additional data including any adverse or notable events was documented.

All the data were compiled and analysed by appropriate statistical methods and these Results were obtained.

Results

Totally 60 patients were enrolled in the study and there were no dropouts.

There was no significant differences among two groups in terms of Ease to identify space.

Time to induce spinal was comparatively longer in group A.

Number of attempts were significantly higher in group A.

Partient satisfaction and patient comfort were both significantly higher in Group B tha Group A.

Both the groups were comparable in terms of hemodynamics.

However, 1 patient in group A had airway obstruction once sedated which was managed using nasopharyngeal airway.

Table 1: Demographic data

Parameters	**Group**		**p value**
	A (n = 30)	**B (n = 30)**	
Age (Years)	36.13 ± 13.28	39.43 ± 12.85	0.351[1]
Gender			0.292[2]
Male	10 (33.3%)	14 (46.7%)	
Female	20 (66.7%)	16 (53.3%)	
BMI (Kg/m²)	26.79 ± 2.76	25.80 ± 2.69	0.117[1]

Table 2: Outcome

Ease To Identify Space			0.197[2]
Easy	22 (73.3%)	26 (86.7%)	
Difficult	8 (26.7%)	4 (13.3%)	
Time to Induce Spinal (Seconds)***	35.53 ± 15.39	16.17 ± 8.69	0.009[1]
Number of Spinal Attempts***	1.63 ± 1.00	1.07 ± 0.25	0.002[1]
More Than 1 Attempt (Yes)***	12 (40.0%)	2 (6.7%)	0.002[2]
Patient Comfort Score***	7.50 ± 1.61	9.17 ± 0.59	<0.001[1]
Patient Satisfaction Score***	77.50 ± 13.50	95.33 ± 7.30	<0.001[1]
Onset of Sedation (Seconds)	72.40 ± 13.53	67.20 ± 11.27	0.078[1]

Discussion

Subarachnoid block procedure, though well-explained to the well-premedicated patients preoperatively, exposure to the new operation room environment and its people, positioning for spinal procedure and the fear of pain during spinal needle insertion result in procedural discomfort. VR Hemanth kumar et al. [5] conducted a study on 90 patients and found that Ketamine in the dose of 0.3 mg/kg provided sufficient sedation for allaying procedural discomfort due to sedation, less positional difficulty, early verbal response, no hallucinations, no recall of performance of procedure, and good patient satisfaction.

We obtained similar results in our study, however the patient comfort and satisfaction was significantly higher in patients sedated with Ketamine-midazolam than propofol.

In our study, the time taken to induce spinal anaesthesia was longer in patients who were sedated with propofol compared to ketamine-midazolam group. This can be attributed to the lack of analgesic property of propofol which in turn increased the time and number of attempts. In our study, repeated bolus doses of propofol was required to maintain Ramsay sedation score of 4.instead of bolus doses, infusion of propofol would have been a better choice to maintain a steady concentration.

The number of attempts were significantly higher in patients who received propofol than ketamine midazolam as the patients would move while spinal needle is pricked due to pain in former.

Most anesthesiologists may omit the procedural sedation to avoid drug side effects.

Bagchi et al. [6] found that the MAP and HR were significantly lower in patients receiving Propofol than Midazolam for sedation in spinal anaesthesia.

In our study, there is no hemodynamic variation among the two groups as we had used bolus doses of propofol and ketamine itself has positive inotropic effects. However, one patient had airway obstruction due to tongue fall once sedated and was managed with nasopharyngeal airway in Group A. This can be attributed to deeper plane of sedation due to administration of high dose of propofol as the patient's BMI was high [7].

None of the patients had any respiratory depression, hallucinations, delirium or behavioral changes as we had used lower doses of sedative agents and addition of midazolam as supported by the study conducted by Serkan Sener et al. [8] who Co administered midazolam with ketamine and found that midazolam significantly reduces the incidence of recovery agitation after ketamine procedural sedation and analgesia in ED adults.

Conclusion

Ketamine-midazolam provides better comfort and satisfaction to the patients when used as procedural sedative agent compared to propofol. It also eases the induction of spinal anaesthesia by reducing multiple attempts and time to induce spinal anaesthesia when compared to propofol.

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