# CONSCIOUS SEDATION IN SPINAL ANESTHESIA: A COMPARATIVE STUDY OF PROPOFOL VERSUS MIDAZOLAM

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**ABSTRACT**

**OBJECTIVE: To determine the advantages of conscious sedation in spinal anesthesia by comparing Propofol with Midazolam.**

**METHODS: The study was carried out on 60 patients undergoing various elective surgical procedures under spinal anesthesia. The patients were divided into three groups each containing 20 patients. Group A (n=20) received initial bolus of 30 mg of Propofol intravenously (IV) followed by 10 mg top ups on as-required basis. Group B (n=20) received initial bolus of 2 mg of Midazolam followed by 1 mg increments to maintain the conscious sedation. Group C (n=20) did not receive any conscious sedation (Control). The patients were interviewed through a structured questionnaire before anesthesia and 24 hours after the surgical procedure. Demographic variables were scored using descriptive statistics and results were analyzed using correlation methods.**

**RESULTS: It was revealed that in patients who were given conscious sedation, 17 patients (85%) from Midazolam group as compared to 12 patients (60%) from Propofol group were not willing to have remained wide awake during the procedure. Similarly 15 patients (75%) from Midazolam group as compared to 10 patients (50%) from Propofol group were very much comfortable being asleep during the procedure. Ten patients (50%) from the group who were not given conscious sedation remained apprehensive and uncomfortable and they very much desired to be sedated during the procedure.**

**CONCLUSION: Conscious sedation was very effective in spinal anesthesia in alleviating preoperative anxiety and apprehension. Midazolam proved to be a better agent than Propofol for the purpose.**

**KEY WORDS: Conscious sedation (MeSH), Spinal anesthesia (MeSH), Propofol (MeSH), Midazolam (MeSH).**

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## INTRODUCTION

Conscious sedation is the use of medication to minimally depress the level of consciousness in a patient while allowing the patient to continually and independently maintain a patent airway and respond appropriately to gentle physical stimulation or verbal communication, e.g. "open your eyes".

Patient arrives and leaves in a condition as close to normal as possible.[1] Consciousness is defined as a state of awareness of surroundings and alertness to events.[2] Sedation describes a depressed level of consciousness which may vary from light to deep. Conscious sedation is a controlled state of pharmacological depression of consciousness enabling treatment to be carried out and communication is maintained throughout the period of sedation besides maintaining protective reflexes. It is achieved when there is onset of slurred speech. It avoids the adverse psychological and physiological effects of stress. It reduces anxiety in frightened and agitated patients. It provides anterograde amnesia especially after Midazolam and patient is not troubled with unpleasant and frightening memories of their surgical procedure. Conscious sedation is being widely used in various diagnostic,[3,4] surgical and therapeutic procedures. Its use in spinal anesthesia is becoming increasingly popular.[5] The goals and objectives of conscious sedation are to provide a tranquil patient, free from anxiety with reduced attention, amnesia and retention of verbal communication and cooperation albeit sluggish.[6] It provides calming effect and minimizes stress. Despite the established record[7] of safety of conscious sedation, problems have occurred as one degree of sedation may progress to another depending upon the dose of the administered drug. These include hypoventilation, apnoea, airway obstruction and cardiopulmonary impairment. Appropriate agents provide safe and effective sedation and ensure greatest margin of safety. Conscious sedation may be produced by administration of various pharmacological agents by several common routes.[8-11] In this study intravenous route is adopted and Propofol is compared with Midazolam to determine the advantages of conscious sedation in spinal anesthesia.

## METHODS

It was an observational analytical study in which effects of conscious sedation in spinal anesthesia was observed and analyzed by using two different drugs for this purpose, i-e Propofol versus Midazolam. The study was initiated after taking approval from hospital ethical committee.

The study was carried out in 60 patients, above 20 years of age (majority between 40 and 50 years of age) having physical status of American Society of Anesthesiologists (ASA) i.e. ASA–I (A normal healthy patient) and ASA–II (A patient with mild systemic disease). Both male and female cases (male-42 and female-18) were randomly selected. The cases who were administered spinal anesthesia were restricted to lower abdominal, orthopaedic and perineal elective surgical procedures (Table I)

The patients were divided into three groups which were:

**Group A** (n=20) Patients who were administered Propofol for conscious sedation.

**Group B** (n=20) Patients who were administered Midazolam for conscious sedation.

**Group C** (n=20) This group did not receive any conscious sedation and was treated as a control group.

In group A, the patients were given Lignocaine 40 mg IV before Propofol to avoid pain on injection. Subsequently an initial bolus of 30 mg Propofol was administered IV followed by 10 mg top ups on as-required basis.

In group B, the patients were given an initial bolus of 2 mg of Midazolam followed by 1 mg increments to maintain the conscious sedation. The end point of conscious sedation in both groups A and B was the slurring of speech, preservation of eye opening response to verbal command being sedated at the same time.

Absolute calm and tranquility was ensured throughout the surgical procedure. All the patients were reassured and briefed about the procedure of spinal anesthesia and surgery. The patients were clearly informed whether they were going to be sedated or would remain wide awake during the procedure. All the patients were preloaded with one litre of Ringers lactate and given 10 mg of injection Maxolon IV. A local infiltration of 2 ml of 1% plain Lignocaine was given and spinal anesthesia was administered in lying position with 25 gauge spinal needle using 2 ml of 0.75% hyperbaric Bupivacaine in each case. Non invasive blood pressures, $O_2$ saturations and ECGs were monitored throughout the procedure. A questionnaire was completed for each patient. In this the comments and responses of the patient at the time of preanesthetic assessment were documented followed by another question – answer session 24 hours after the surgical procedure. Patients with extremes of ages, having psychological / emotional disturbances, those who did not have dense spinal block, and those who developed significant hypotension and incidence of vomiting were excluded from the study.

Descriptive statistics were used to describe the data. Moreover, frequencies and percentages of demographic variables were computed, data was analyzed using statistical package for social sciences (SPSS) version 17.

## RESULTS

This study gave us some very interesting results and quite a few important observations. It was revealed that in patients who were given conscious sedation, 17 patients (85%) from Midazolam group as compared to 12 patients (60%) from Propofol group were not willing to have remained wide awake during the procedure. Similarly 15 patients (75%) from Midazolam group as compared to 10 patients (50%) from Propofol group were very much comfortable being asleep during the procedure. Ten patients (50%) from the group who were not given conscious sedation remained apprehensive and uncomfortable and they desired to be sedated during the procedure (Table II, III and IV).

**TABLE I: VARIETY OF SURGICAL PROCEDURES**

| Indications | Frequency | Percentage |
|---|---|---|
| Hernia / Hydrocele | 15 | 25 |
| Orthopaedic Surgery | 07 | 11.7 |
| Apppendicectomy | 10 | 16.7 |
| Ovarian Tumours and Mass | 03 | 5 |
| Tubal ligation | 05 | 8.3 |
| Vaginal hysterectomy | 05 | 8.3 |
| Perineal Surgery | 15 | 25 |
| Total | 60 | 100 |

**TABLE II: GROUP A: PATIENTS GIVEN CONSCIOUS SEDATION WITH PROPOFOL (n=20)**

| | | Very much | | Slightly | | No | |
|---|---|---|---|---|---|---|---|
| | | Frequency | % age | Frequency | % age | Frequency | % age |
| 1 | Were you comfortable being asleep during procedure? | 10 | 50 | 06 | 30 | 04 | 20 |
| 2 | Do you wish that it would have been better if you had remained wide awake during procedure? | 02 | 10 | 06 | 30 | 12 | 60 |

**TABLE III: GROUP B: PATIENTS GIVEN CONSCIOUS SEDATION WITH MIDAZOLAM (n=20)**

| | | Very much | | Slightly | | No | |
|---|---|---|---|---|---|---|---|
| | | Frequency | % age | Frequency | % age | Frequency | % age |
| 1 | Were you comfortable being asleep during procedure? | 15 | 75 | 03 | 15 | 02 | 10 |
| 2 | Do you wish that it would have been better if you had remained wide awake during procedure? | 0 | 0 | 03 | 15 | 17 | 85 |

**TABLE IV: GROUP C: PATIENTS NOT GIVEN ANY CONSCIOUS SEDATION (n=20)**

| | | Very much | | Slightly | | No | |
|---|---|---|---|---|---|---|---|
| | | Frequency | % age | Frequency | % age | Frequency | % age |
| 1 | Were you comfortable being asleep during procedure? | 10 | 50 | 02 | 10 | 08 | 40 |
| 2 | Do you wish that it would have been better if you had remained wide awake during procedure? | 10 | 50 | 02 | 10 | 08 | 40 |

## DISCUSSION

During surgery under spinal anesthesia unpleasant sensory sensations occur as afferent sensory supply to gut is not blocked. Vagal afferent is also not blocked and severe discomfort occurs while manipulating abdominal structures. Sedation besides relieving the above mentioned problems provides additional relief from anxiety and apprehension. Similarly listening to noises of cutting instruments is very disturbing for the patient and he is relieved of this agony by conscious sedation. Calm and quite atmosphere must prevail at all times in operation theatre. Communication and reassurance have been shown to decrease anxiety, stressful environmental factors like noise, proximity of other seriously ill or the unconscious patients. Our study shows that Midazolam has better sedative and amnesic effects, with no pain during administration, and better cardiovascular stability. Although Propofol sedation ends up in clear headed recovery, patient is up and about early, has got an antiemetic effect but the use of Propofol was quite taxing because top up doses were required at frequent intervals. One has to be very vigilant and alert regarding cardiovascular stability, respiratory depression due to lower therapeutic index.[12] It also required controlled circumstances as compared to Midazolam. A study conducted by Elvir Lazao OL[13] also confirms the leading position of Midazolam in conscious sedation, anesthesia and intensive care. Similar results were achieved in another study carried out by Bagchi D[14] and coworkers when Propofol sedation for outpatient gastrointestinal endoscopy was compared with Midazolam in 40 patients. It was concluded that although Propofol provided more rapid recovery as compared to Midazolam but also associated with pain on injection, a short amnesic span and reduced patient acceptance.[13] In another study it was shown that Midazolam was better at providing amnesia than Propofol at the same level of sedation.[15]

Propofol is associated with a more rapid onset of sedation and quick recovery than Midazolam. Midazolam, however is associated with a higher degree of amnesia, low incidence of venous complications and better patient acceptability than Propofol.[16] According to the study by Grendelmeier P the advantages of Propofol over Midazolam were the ease with which the degree of sedation could be altered and quick recovery.[17] Its disadvantages were pain on injection, increased talkativeness, the extra equipment needed and the cost. These results are also in agreement with our study.[17] A study by Lordan JT again concluded that continuous infusion of Propofol and Midazolam for sedation in regional anaesthesia were equivalent with respect to efficacy and safety.[18] According to another study both drugs were equally effective sedative agents.[19]

While going through the above mentioned studies it is evident that results of our study are in agreement with majority of the investigations but also differ from quite a few. The reason for these differences in results may partially be attributed to the dose and technique of administration. In addition, medication requirements[20] may be affected by various pharmacodynamic and pharmacogenetic differences among individuals. Clinically relevant factors including concomitant medication, age, ASA physical status and drug interaction can alter drug's pharmacokinetic properties and influence the outcome of results.

## CONCLUSION

Conscious sedation not only helped in smooth administration of spinal and with no degree of apprehension but also produced conducive circumstances for surgical procedure itself. Midazolam proved to be a better agent than Propofol for conscious sedation.

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**CONFLICT OF INTEREST**

Authors declared no conflict of interest

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## AUTHORS' CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under:

**AS:** Concept & study design, acquisition analysis and interpretation of data, drafting the manuscript, final approval of the version to be published

**SEHN:** Acquisition of data, drafting the manuscript, final approval of the version to be published

**AK:** Acquisition of data, drafting the manuscript, critical revision, final approval of the version to be published

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.