**ORIGINAL ARTICLE**

Conscious sedation in Spinal Anaesthesia : A comparative study of Propofol versus Midazolam

**Authors:**

1. Dr. Asjad Sharif, MCPS Anaesthesia, FCPS Anaesthesia, Consultant Anaesthetist, CMH RWP. (Responsible for correspondence about the manuscript)

Email: asjadsharif@gmail.com

 Mob: 0300 5773317

2. Dr. Syed Ehtesham Haider Naqvi, Anaesthesia Registrar, CMH RWP.

 Email: syedehteshamhaidernaqvi@yahoo.com

 Mob: 03345518813

3. Dr. Amanat Khan, FCPS Anaesthesia, Consultant Anaesthetist, CMH RWP.

 Mob: 03005053751

**ABSTRACT**

**Background**:

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

**Study design:** Observational analytical study.

**Setting and Duration**: The study was conducted at Departments of Anaesthesia and Intensive Care, Combined Military Hospital, Rawalpindi from November 2014 to July 2015.

**Methodology:** The study was carried out in 60 patients undergoing various elective surgical procedures under spinal anaesthesia. The patients were divided into three groups of 20 patients each. 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 and was treated as a control group. The patients were interviewed through a structured questionnaire at the time of pre anaesthetic assessment 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. 10 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 anaesthesia in alleviating preoperative anxiety and apprehension. Midazolam proved to be a better agent than Propofol for the purpose.

**Key words:** Conscious sedation, Spinal anaesthesia, Propofol, Midazolam.

**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 possible1. Consciousness is defined as a state of awareness of surroundings and alertness to events2. 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 diagnostic3,4, surgical and therapeutic procedures. Its use in spinal anaesthesia is becoming increasingly popular5. The goals6 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. It provides calming effect and minimizes stress. Despite the established record7 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 pharmalogical agents by several common routes8,9. But in this study intravenous route is adopted and Propofol is compared with Midazolam10,11.

**MATERIAL AND METHODS**

It was an observational analytical study in which effects of conscious sedation in spinal anaesthesia 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 ASA – I and ASA – II. Both male and female cases (male – 42 and female – 18) were randomly selected. The cases who were administered spinal anaesthesia were restricted to lower abdominal, orthopaedic and perineal elective surgical procedures (Table – I )

 **Table – I Variety of Surgical procedures**

|  |  |  |
| --- | --- | --- |
| **Serial No** |  **Indications**  | **No. of Patients** |
| **1** | Hernia / Hydrocele | 15 |
| **2** | Orthopaedic Surgery | 07 |
| **3** | Apppendicectomy | 10 |
| **4** | Ovarian Tumours and Mass | 03 |
| **5** | Tubal ligation | 05 |
| **6** | Vaginal hysterectomy | 05 |
| **7** | Perineal Surgery | 15 |
| **Total** |  | 60 |

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 of 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 anaesthesia 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 anaesthesia was administered in lying position with 25 gauge spinal needle using 2 ml of 0.75% hyperbaric Bupivacaine in each case. Non invasive blood pressure, O2 saturation and ECG 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 preanaesthetic 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, incidence of vomiting were excluded from the study.

 **Data analysis**

Descriptive statistics was 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. 10 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 (Table II, III and IV).

 **Table II – Patients given conscious sedation with Propofol (n=20)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **A** | Were you comfortable being asleep during procedure? |  **Very much** |  **Slightly** |  **No** |
| **No.** | **%age** | **No.** | **%age** | **No.** | **%age** |
| 10 | 50 | 06 | 30 | 04 | 20 |
| **B** | 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 – Patients given conscious sedation with Midazolam (n=20)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **A** | Were you comfortable being asleep during procedure? |  **Very much** |  **Slightly** |  **No** |
| **No.** | **%age** | **No.** | **%age** | **No.** | **%age** |
| 15 | 75 | 03 | 15 | 02 | 10 |
| **B** | 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 – Patients not given any conscious sedation (n=20)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **A** | Were you uncomfortable and apprehensive during procedure being wide awake all the time? |  **Very much** |  **Slightly** |  **No** |
| **No.** | **%age** | **No.** | **%age** | **No.** | **%age** |
| 10 | 50 | 02 | 10 | 08 | 40 |
| **B** | Do you wish that it would have been better if you were asleep during the procedure? | 10 | 50 | 02 | 10 | 08 | 40 |

**DISCUSSION**

During surgery under spinal anaesthesia5 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. The results of the study prove Midazolam to be better sedation and amnesic drug having 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. It also required controlled circumstances as compared to Midazolam. A study conducted by Wappler F12 also confirms the leading position of Midazolam in conscious sedation, anaesthesia and intensive care. Similar results were achieved in another study carried out by Patterson13 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. In another study it was shown that Midazolam was better at providing amnesia than Propofol at the same level of sedation14. 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 in some studies15. According to the study by Rodrigo16 the advantages of Propofol over Midazolam were the ease with which the degree of sedation could be altered and quick recovery. Its disadvantages were pain on injection, increased talkativeness, the extra equipment needed and the cost. These results are also in agreement with our study. A study by deAdres and Bolinches R17 again concluded that continuous infusion of Propofol and Midazolam for sedation in regional anaesthesia were equivalent with respect to efficacy and safety. According to another study both drugs were equally effective sedative agents18.

 While going through the above mentioned studies it is evident that result 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 requirements19 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 anaesthesia in calm and quite patients 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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