

To Assess the Sedative Effects with Midazolam on Arterial Oxygen Saturation during Spinal Anaesthesia in Infraumbilical Surgery

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Abstract

Background: For managing and completing the surgical process, there are different types of drugs and approaches are used. The use of anaesthesia is one of the major things that considered for managing the surgical process without pain. The spinal anaesthesia is commonly used by the care professionals for maintaining the surgical process carefully and better recovery of the patients. Nowadays local anaesthetics along with spinal anaesthesia are broadly applied especially for ambulatory surgery. Sedation has been used for improving the acceptance of the patient for regional anaesthesia and help to improve the wellbeing of the patient during the surgery. There are different types of anaesthesia used but midazolam is one of the common anaesthesia that used by the medical experts since 1978.

Aim: To assess the sedative effects with midazolam on arterial oxygen saturation during spinal anaesthesia in infraumbilical surgery

Method: The study is being conducted using the randomized controlled clinical study between January 2020 and January 2022 at Bhima Bhoi Medical college and Hospital Balangir Odisha focusing on the patients at operation theatre and post operative room. To complete the study, 100 ASA grade 1 and 2 patients both male and female between the age of 20 to 50 years involved. These patients had lower abdominal surgery that completed in ninety minutes.

Results: The outcome of the study shows that there were five types of operations performed. Commonest operation was inguinal herniorrhaphy (29%), next being vaginal hysterectomy (27%). Least number of patients came from orthopaedics department (10%). Two means of midazolam of group A & B ($2.71-2.75=0.04$) is not greater than the SE of 2 means i.e. 2×0.093 . There is no statistically significant difference between the initial doses of Midazolam between two groups. But the total doses of Midazolam are statistically different, i.e. the second group needed more Midazolam than the first group. The actual difference between two means of doses of Bupivacaine ($2.94-2.96=0.02$) is not greater than twice the value of SE between the means is not statistically significant difference in doses of Bupivacaine between two groups.

Conclusion: Respiratory rate remained unchanged, the fall of SpO₂ in group B patients could be attributed to the diminution of tidal volume and so hypoventilation was found to be the major cause of fall of SpO₂ in this group of patients. The lower limit for alarm should be set at 85% because severe hypoxaemia defined as a saturation of oxygen at 85% or less.

Keywords: anaesthesia, surgical, midazolam.

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Introduction

For managing and completing the surgical process, there are different types of drugs and approaches are used. The use of anaesthesia is one of the major things that considered for managing the surgical process without pain[1]. The medical experts are using different forms of anaesthesia according to condition of the patient and analysing the effects of post-surgery[2]. The spinal anaesthesia is commonly used by the care professionals for maintaining the surgical process carefully and better recovery of the patients. Nowadays local anaesthetics along with spinal anaesthesia are broadly applied especially for ambulatory surgery[3]. Many patients have poor tolerance for long periods of immobility or the noises associated with procedures. So sedatives play a major role to have amnestic effects[4].

Sedation has been used for improving the acceptance of the patient for regional anaesthesia and help to improve the wellbeing of the patient during the surgery. There are different types of anaesthesia used but midazolam is one of the common anaesthesia that used by the medical experts since 1978[5]. This helping to block the spinal nerves in the subarachnoid space and extensively used by the surgeons in now a days[6]. The major advantages of this type of anaesthesia involve the good analgesia with profound muscular relaxation, blunts stress response to surgery, minimal respiratory effects, minimal intra-operative blood loss, cost-effective[7]. It lowers the incidence of postoperative thromboembolic events. Moreover, it provides superior analgesia in early postoperative period with

minimal risk of postoperative cognitive dysfunction Midazolam is a relatively water-soluble benzodiazepine[8]. It is a short-acting drug used commonly as sedative and anaesthetic induction agent. It has anxiolytic, hypnotic, anticonvulsant and anterograde amnestic property[9].

Midazolam is preferable to diazepam due to some reasons that involve effective and greater degree of anterograde amnesia than diazepam, lasting for 20-30 min. Rapid onset of action, more intense effect than diazepam in equivalent doses and rapidly cleared from plasma than diazepam[10]. Respiratory depression may be greater with midazolam which may be 5-9 times more than with diazepam. It is dose related, onset in 3 min, duration on an average for 15 minutes[11]. Moreover, midazolam is a useful intravenous adjuvant to local or regional anaesthesia for a variety of therapeutic and diagnostic procedures. Titrated intravenously to produce sleep, or more commonly, dysarthria, midazolam produces mild sedation and amnesia in patients for diagnostic and therapeutic procedures[12].

Aim and objectives**Aim**

To assess the sedative effects with midazolam on arterial oxygen saturation during spinal anaesthesia in infraumbilical surgery

Objectives:

- To assess the effect of oxygen supplementation in midazolam induced sedation during spinal anaesthesia in infraumbilical surgery.

- To study the incidence of episodes of oxygen desaturation during spinal anaesthesia in infraumbilical surgery.
- To study the role of non-invasive pulse oximeter for monitoring the vitals of patient after giving spinal anaesthesia and sedation with midazolam.

Method and material

The study is being conducted using the randomized controlled clinical study between January 2020 and January 2022 at Bhima Bhoi Medical college and Hospital Balangir Odisha focusing on the patients at operation theatre and post operative room. To complete the study, 100 ASA grade 1 and 2 patients both male and female between the age of 20 to 50 years involved. These patients had lower abdominal surgery that completed in ninety minutes.

In this study randomization was achieved by simple randomization method. Simple randomization is defined as randomization based on a single sequence of random assignments. Here complete randomness of the assignment of a subject to a particular group is achieved. In this study a dice containing numbers from one to six was used to assign the subjects to group. The participants after obtaining consent were asked to throw dice. If the dice showed an odd number i.e. 1,3,5 then subject were assigned to Group A and when dice showed even numbers i.e. 2,4,6 then subjects were assigned to Group B. Subjects in both group received spinal anaesthesia and then they were sedated with intravenous initial dose 0.05mg/kg of midazolam and then 1mg as required. The subjects in group A received oxygen throughout the surgery whereas subjects in group B received oxygen only when saturation fell below 85%. Subjects received supplemental oxygen via Magill's circuit and face mask at the flow rate of 5 liter/min.

Inclusion criteria:

- Adult patients aged twenty to fifty years scheduled for elective lower abdominal surgery requiring less than ninety minutes duration.
- Consenting adult patients of ASA physical status 1 and 2
- All consenting patients selected for spinal anaesthesia

Exclusion criteria:

- Any contraindication for spinal anaesthesia
- Patient who underwent procedures which may require transfusion of blood / blood product
- Obese patients i.e. BMI > 30 kg / m²
- Patients with severe cardiovascular, pulmonary, renal, metabolic
- Diseases and neurological diseases (ASA Physical status III and IV)
- Patients with hyperpyrexia and recent infection
- Patients with allergy to any study drug
- Patients on antiplatelet treatment or with bleeding diathesis or coagulopathy
- Patient with haemodynamic instability, severe hypovolemic state
- Patients with local infection over back or sepsis
- Patients with spinal deformity
- Patients showing undue anxiety and restlessness
- Pregnant patients

Subjects were informed about the study and information brochure was provided to them. Study related all questions were answered. Then consent form was signed by subjects or their relatives if they were not able to do so. For operation subjects underwent all essential preliminary anaesthetic check-up and then on the day of operation. Subjects were given spinal anaesthesia first and after achieving spinal anaesthesia block, they were sedated with intravenous midazolam. There were not any additional benefits provided to patients for

enrolling in the study. Also, no additional charges were levied to the subject for enrolling in this study.

Results:

Table 1: Patient characteristics according to age, sex and body weight (n1=50, n2=50).

		Group A with O2	Group B without O2	P Value	Significance
SEX	Female	20(40)	19(38)	0.838	Not Significant
	Male	30(60)	31(62)		
AGE (yrs)	Mean ± Std. Deviation	54.96 ± 8.05	54.56 ± 7.7	0.839	Not Significant
Weight (Kg)	Mean ± Std. Deviation	43.54 ± 4.24	44.06 ± 4.09	0.515	Not Significant

The table shows that patients recruited for the study were similar in age range, sex and body weight.

Table 2: Distribution of surgical procedures performed in the two groups (n1=50, n2=50)

Name of surgery	Group A with O2	Group B without O2	Total	P Value	Significance
1. Inguinal herniorrhaphy	14(28)	15(30)	29(29)	0.995	Not Significant
2. Vaginal hysterectomy	14(28)	13(26)	27(27)		
3. Patellectomy	6(12)	6(12)	12(12)		
4. Open reduction & internal Fixation of # both bone leg	5(10)	6(12)	11(11)		
5. Perianal fistulectomy	11(22)	10(20)	21(21)		
Total	50	50	100		

It shows that in the study groups there were five types of operations performed. Commonest operation was inguinal herniorrhaphy (29%), next being vaginal hysterectomy (27%). Least number of patients came from orthopaedics department (10%).

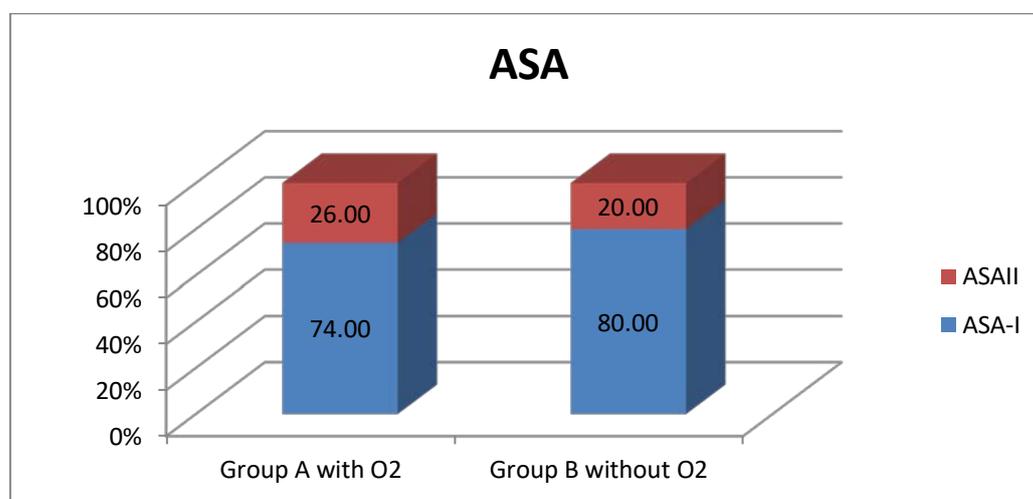


Figure 1: ASA distribution

Table 3: Distribution duration of surgery in the two different groups (n1=50, n2=50)

		Group A with O ₂	Group B without O ₂	P Value	Significance
Duration of surgery (Minutes)	Mean \pm Std. Deviation	82.7 \pm 5.83	83.64 \pm 5.02	0.402	Not Significant

The table shows that there is practically no difference in the duration of surgery in the two groups.

Table 4: Distribution of doses of Midazolam (in mg) in two groups (n1=50, n2=50)

		Group A with O ₂	Group B without O ₂	P Value	Significance
Initial Dose of Midazolam (Mg.)	Mean \pm Std. Deviation	2.75 \pm 0.41	2.71 \pm 0.4	0.612	Not Significant
Total Dose of Midazolam (Mg.)	Mean \pm Std. Deviation	4.35 \pm 0.69	4.37 \pm 0.61	0.964	Not Significant

From the above table it is evident that two means of midazolam of group A & B (2.71-2.75=0.04) is not greater than the SE of 2 means i.e. 2×0.093 . There is no statistically significant difference between the initial doses of Midazolam between two groups. But the total doses of Midazolam are statistically different, i.e. the second group needed more Midazolam than the first group.

Table 5: Distribution of doses of Bupivacaine (in ml) in two groups of study population (n1=50, n2=50)

		Group A with O ₂	Group B without O ₂	P Value	Significance
Doses of Bupivacaine (in ml)	Mean \pm Std. Deviation	2.94 \pm 0.16	2.96 \pm 0.14	0.507	Not Significant

From the above table it is evident that the actual difference between two means of doses of Bupivacaine (2.94-2.96=0.02) is not greater than twice the value of SE between the means is not statistically significant difference in doses of Bupivacaine between two groups.

Table 6: Distribution of saturation of O₂ in two groups recorded every 5th min of induction (n1=50, n2=50)

SAO ₂ Time in minutes	GROUP		P Value	Significance
	Group A with O ₂	Group B without O ₂		
	Mean \pm Std. Deviation	Mean \pm Std. Deviation		
0	99.94 \pm 0.24	99.2 \pm 0.61	<0.001	Significant
5	99.9 \pm 0.36	97.96 \pm 0.75	<0.001	Significant
10	99.92 \pm 0.27	96.84 \pm 1.08	<0.001	Significant
15	99.9 \pm 0.3	95.72 \pm 1.58	<0.001	Significant

20	99.88 ± 0.33	93.36 ± 2.34	<0.001	Significant
25	99.86 ± 0.35	91.4 ± 3.64	<0.001	Significant
30	99.86 ± 0.35	90.72 ± 3.91	<0.001	Significant
35	99.94 ± 0.24	90.44 ± 4.23	<0.001	Significant
40	99.88 ± 0.33	91.92 ± 4.38	<0.001	Significant
45	99.86 ± 0.4	93.66 ± 4.54	<0.001	Significant
50	99.9 ± 0.3	95.98 ± 2.87	<0.001	Significant
55	99.94 ± 0.24	97.06 ± 2.55	<0.001	Significant
60	100 ± 0	97.82 ± 2.26	<0.001	Significant
65	100 ± 0	98.66 ± 1.45	<0.001	Significant
70	100 ± 0	99.08 ± 1.19	<0.001	Significant
75	100 ± 0	99.44 ± 1.11	<0.001	Significant
80	99.96 ± 0.2	99.5 ± 0.93	<0.001	Significant
85	99.94 ± 0.24	99.58 ± 0.84	0.003	Significant
90	99.92 ± 0.27	99.66 ± 0.56	0.005	Significant

The data and the graphs suggest that there is difference in the saturation profile of two groups of patient. Those with routine O₂ supplementation maintained adequate saturation throughout the period of observation. But the other group deteriorated after 30-35 min. reaching saturation around 90%. The condition improved after supplementation as and when required. If we consider the SD s of the values, it's seen that the group without routine O₂ supplementation was having a wider dispersion from the mean compared to the other group. So, it can be concluded that routine O₂ supplementation is helpful in maintaining adequate level of saturation; otherwise, some of the patients will be at risk of developing hypoxia after about half an hour of induction of anaesthesia.

Discussion

For patients undergoing surgery under central neuraxial anaesthesia, sedation is a valuable tool to provide utmost comfort to the patient. The aim of this study was to observe the effect of sedation with midazolam on arterial oxygen saturation during spinal anaesthesia in infraumbilical surgery. The objectives were to assess effect of oxygen supplementation in

midazolam induced sedation, study the incidence of episodes of oxygen desaturation and role of non-invasive pulse oximeter to monitor arterial oxygen saturation after sedation with midazolam, all during spinal anaesthesia.

In Group A (n=50) patients received supplemental oxygen via Magill's circuit and face mask at the flow rate of 5 liter/min routinely after achieving successful spinal anaesthesia, then patients sedated with midazolam 0.05mg/kg and supplemental dose of 1mg as required. Whereas in Group B (n=50) patients breathed room air after achieving successful spinal anaesthesia, then patients sedated with midazolam 0.05mg/kg and supplemental dose of 1mg was administered as required. The group B patients received supplemental oxygen via Magill's circuit and face mask at the flow rate of 5 liter/min, when arterial oxygen saturation came down below 85%. Moreover, the findings of the study suggested that in the groups there were five types of operations performed. Commonest operation was inguinal herniorrhaphy (29%), next being vaginal hysterectomy (27%). Least number of patients came from orthopaedics department (10%). According to the study of Tabuchi et al[13] compared

Midazolam (Group 'M', n = 15, 4 mg midazolam I.M.) with Hydroxyzine (Group 'H', n = 13, 50 mg hydroxyzine I.M.) in a randomized, double-blind study, there were greater following midazolam. The doses for intra-operative sedation of midazolam and pentazocine were the same in both groups. Mean doses of midazolam 2 mg and pentazocine 6 mg were required to produce sleep. Maintenance doses of Midazolam and pentazocine were 3.7 and 11.4 mg per hour respectively. No patients had recall of surgical procedure. Midazolam did not delay the postoperative re-sedation, which lasted about 2 hrs. The decrease in O saturation by pulse oximetry was significant in group M (4.5%) than group H (2.7%).

Apart from this from the study outcome, it is evident that two means of midazolam of group A & B ($2.71-2.75=0.04$) is not greater than the SE of 2 means i.e. 2×0.093 . There is no statistically significant difference between the initial doses of Midazolam between two groups. But the total doses of Midazolam are statistically different, i.e. the second group needed more Midazolam than the first group. But the other group deteriorated after 30-35 min. reaching saturation around 90%. The condition improved after supplementation as and when required. If we consider the SDs of the values, it's seen that the group without routine O₂ supplementation was having a wider dispersion from the mean compared to the other group. Munoz et al [14] found that 74% of patients who presented with drowsiness (due to benzodiazepine premedication) and anaesthetic level above T7 had desaturation compared to only 7% of those who were awake and had lower level ($P < 0.0005$). In this study as all the cases in both the groups, the extent of block was between T10 to T8, the effect of high spinal block on respiratory system and hence on arterial oxygen saturation has been avoided.

Conclusion

Respiratory rate remained unchanged, the fall of SpO₂ in group B patients could be attributed to the diminution of tidal volume and so hypoventilation was found to be the major cause of fall of SpO₂ in this group of patients. Group A patients also suffered from hypoventilation but administering supplemental oxygen overcame that hypoventilation and this supplemental oxygen prevented the fall of SpO₂ in patients of Group A.

Finally, ventilation perfusion mismatch might occur as a result of a combination of relative hypovolaemia, depression of cardiac output and reduction in functional residual capacity consequent upon the supine position. The lower limit for alarm should be set at 85% because severe hypoxaemia defined as a saturation of oxygen at 85% or less.

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