A COMPARISON OF SEVOFLURANE WITH MIDAZOLAM TO PROVIDE SEDATION TO PATIENTS FOR SURGERY UNDER LOCOREGIONAL ANAESTHESIA

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ABSTRACT

Objectives: To compare the quality, speed of recovery, and side effects of sevoflurane sedation compared with intravenous midazolam.

Study Design: Quasi experimental, double-blind, comparative study.

Place and Duration of study: Operation theatre complex, Combined Military Hospital Rawalpindi from 1st June 2006 to 31st Dec 2006.

Patients and Methods: Total of sixty patients, American Society of Anaesthesiology I-III aged 18-70 years undergoing surgery under locoregional anaesthesia were divided into two equal groups by convenient sampling.

Group A: (n=30) received Sevoflurane sedation.

Group B: (n=30) received Midazolam sedation.

The patients were sedated gradually during the procedure and maintained at Observer's assessment of alertness and sedation (OAAS) score of 3. At recovery the OAAS score was measured at 5, 10 and 30 minutes after stopping the drug administration. Subjective assessment of quality of recovery was measured by visual analog scale (VAS) determined at baseline and 5, 10, and 30 min of recovery.

Results: On observer's assessment of alertness and sedation score no significant difference was observed between the two groups in the first 10 min after drug discontinuation but after 30 min all patients in group A and 26 out of 30 patients in group B had returned to an OAAS of 5 (p= 0.039). Subjective recovery as assessed by VAS scores showed that patients were more awake, had higher energy level, were less confused and better coordinated in group A sedation at 10 and 30 min post-procedure as compared to midazolam group B.

Conclusion: Sevoflurane for sedation produced faster recovery as compared to intravenous midazolam measured by OAAS score and subjective assessment on VAS scale. However, sevoflurane is complicated by a high incidence of intra-operative excitement.

Keywords: Sevoflurane, midazolam, conscious sedation, recovery

INTRODUCTION

Sedation for surgical procedures performed under locoregional anaesthesia has usually been achieved with a variety of intravenous medications, such as benzodiazepines, barbiturates, and propofol [1]. Midazolam, a benzodiazepine, is widely used for conscious sedation because it produces dose related sedation as well as amnesia and anxiolysis.[2] Nitrous oxide, has been used for conscious sedation in obstetrics, dental, and ambulatory surgery. Except for limited use for analgesia during labour and delivery, volatile anaesthetics have seldom been used because of airway irritation and pungency.

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Sevoflurane, a fluorinated methyl isopropyl ether, has been used frequently for inhalational induction of anaesthesia because of non pungency and low incidence of respiratory irritability. Sevoflurane provides a smooth induction with decreased incidence of cough, breath holding, laryngospasm, and bronchospasm as compared to halothane and particularly to desflurane [3]. Sevoflurane is useful for short procedures and facilitates quick recovery. Sevoflurane exhibits a low blood gas partition coefficient, which is associated with both a rapid induction of anaesthesia and quick emergence. Because of nonpungency, rapid induction,and quick elimination, Sevoflurane may qualify to provide sedation [4].

To compare the quality, speed of recovery, and side effects of sevoflurane sedation compared with intravenous midazolam.

PATIENTS AND METHODS

A total of 60 patients for surgery under locoregional anaesthesia divided into two groups; A (n=30) and B (n=30) were included.

Inclusion Criteria:

- Age 20-70 years
- Scheduled for elective surgery of upper limbs or lower half of the body; anticipated duration 0.5-2 hour
- Willing for loco-regional anaesthesia with sedation.
- ASA I-III

Exclusion Criteria:

- Pregnant patients
- History of taking opioids or sedatives within last 24 hour.
- Patients at increased risk of aspiration like full stomach and obese patients.
- Having contraindications to locoregional anesthesia like patient's refusal, non cooperative patient, bleeding diathesis and local infection.
- High risk patients (ASA IV and V).

Technique:

Patients were divided into two groups; Group A: (n=30) received Sevoflurane sedation and Group B: (n=30) received Midazolam sedation. Patients in both groups were given locoregional anaesthesia i.e.,spinal, epidural, caudal or peripheral nerve blocks using 1-2% lignocaine or 0.5% bupivacaine. A 1:1 randomization ratio of sevoflurane sedation to midazolam sedation was chosen by flipping of a coin. A nasal mask was applied before administration of the study drug and 100% oxygen was given to the patient through Mapleson A breathing circuit. Sevoflurane concentration was increased slowly via TEC 5 sevoflurane vapourizer to a maximum of 1.0 MAC + 0.2-0.6% (vaporizer setting). Midazolam was titrated slowly to the desired effect. Depending upon the age of the patient a maximum dose of 0.1mg/kg was given. An observer who was not blinded to the identity of the study drug performed clinical assessment of depth of sedation. Sedation level was assessed every minute using the OAAS scale and titrated to an OAAS score of 3 (table-1). Maintenance level was defined as three consecutive OAAS scores of 3; subsequent assessments were made every 5 min. Postoperative milestones included the time of finishing the procedure (last suture or procedure equivalent),time of study drug stopped, time of arrival to designated recovery area, time to first OAAS score of 5 as the patient met the discharge criteria. Discharge eligibility criteria included awake, alert, and oriented patient equivalent to baseline, without vomiting and having room air oxygen saturation > 94% or at baseline.

Evaluation of Recovery:

The speed of awakening and return of preoperative baseline cognitive functions were assessed by OAAS score. An observer who was blinded to the identity of the study drug obtained baseline test scores preoperatively and repeated these tests at the end of the procedure in the operating room and several times in the recovery room according to the protocol defined. To ensure

the blinding of the observer in the operating room, all drug syringes were concealed and a nose clip was worn to avert any scent of sevoflurane. The OAAS score was measured every minute during the first five minutes during recovery and then at 10 min and at 30 min.

Subjective self assessment of quality of recovery was measured by visual analog scale (VAS) determined at baseline and 5, 10, and 30 min of recovery. Attributes that were assessed and scored from 0-100 included, level of alertness/sedation (0-100; almost asleep to wide awake), energy level (low energy to full of energy), clear headedness-confusion (confused to clear headed), coordination – clumsiness (extremely clumsy to well coordinated).

DATA ANALYSIS

The data was recorded in SPSS version 10.0. Return to preoperative OAAS levels, recall tests and patient subjective assessment by VAS were compared using student t-test. Side effects frequencies were compared using Chi square test. P value less than 0.05 was considered significant.

RESULTS

In group A there were 18 males (60%) and 12 females (40%) and in group B were 20 males (66%) and 10 females (33%). There were no significant differences in patient characteristics i.e. age (p=0.129), and weight (p=0.650) between the two groups.

Objective Recovery:

Return to an OAAS score of 5 after the discontinuation of study drug was determined. No significant difference was observed between the two groups in the first 10 min after drug discontinuation. However after 30 min all patients in group A and 26 out of 30 patients in group B had returned to an OAAS of 5 (p= 0.039) (table-2).

Subjective Recovery:

Subjective recovery as assessed by VAS scores showed that patients were more awake, had higher energy level,were less confused and better coordinated in group A sedation at 10 and 30 min post-procedure as compared to midazolam group B (table-3).

Side Effects:

The frequency of excitation and disinhibition was significantly higher in group A i.e. (23.7%) as compared to group B which had only 3.4% (p=0.023). However no significant difference was observed in the frequency of coughing, laryngospasm, apnoea and other complications between the two groups (table-4).

DISCUSSION

Regional or local anaesthesia offers many advantages over general anaesthesia like better analgesia, less blood loss,low incidence of thromboembolism and cost effectiveness. However, apprehension and anxiety during surgical procedures have reduced its popularity. Light to moderate sedation accompanying regional anaesthesia may allow the procedure to be more acceptable for the patient and the surgeon [6]. The ideal agent for conscious sedation should provide intra-operative amnesia and anxiolysis such that the patient is comfortable and cooperative [7]. In our study sevoflurane produced dose-related sedation. Recovery to base line cognitive functions was faster with sevoflurane and patients felt more awake (p=0.034), oriented (p=0.004), less confused (p=0.001) with higher energy level (p=0.032) as measured by VAS scores as compared to patients who received midazolam for sedation. However exetement-disinhibition (p=0.023) with sevoflurane sedation was significant and may limit the usefulness of this technique.

Our results are in accordance with Ibrahim et al [1] who compared the sedation with sevoflurane and midazolam and showed faster recovery of cognitive functions in sevoflurane group as measured by Digit Symbol Substitution Test (DSST) and memory scores compared with midazolam. However, in contrast to our study, they found no significant difference in the level of energy, confusion, excitement and clumsiness after

Table-1: Observer's assessment of alertness/sedation (OAAS).

Responsiveness	Speech	Facial Expression	Eyes	Score
Responds readily to name	Normal	Normal	Clear, no ptosis	5
Lethargic response to name	Mild slowing	Mild elaxation	Glazed or mild ptosis	4
Responds to name only if called repeatedly	Slurring	Marked relaxation	Glazed or marked ptosis	3
Responds only after mild prodding	Not ecognizable			2
No response to prodding or shaking				1

OAAS is the lowest score in any of the four categories.

Table-2: OAAS score after cesation of study drug.

	Group A Sevoflurane	Group B Midazolam	P-Value
OAAS 5 min	4.13+0.43	4.07+0.45	0.561
OAAS 10 min	4.40+0.50	4.33+0.48	0.599
OAAS 30 min	5+0	4.87+0.35	0.04

** Results are expressed as mean ± SD*

Table-3: VAS scores for.

Alertness	Group A	Group B	P-Value
At 5 min	60 + 3.7	58.6 + 3.7	0.169
At 10 min	72.5+ 4.3	69.8 + 4.9	0.031
At 30 min	88 + 4.2	85.5 + 4.6	0.034
Energy Level			
At 5 min	64.3 + 6.3	62.6+ 4.1	0.081
At 10 min	75.3 + 5.2	71.6+ 3.03	0.002
At 30 min	92.3 + 4.5	90 + 3.7	0.032
Clearheadedness			
At 5 min	64 + 5.6	62.5 + 4.3	0.25
At 10 min	74.6+5.07	71.6 + 3.03	0.007
At 30 min	92.6+3.65	89.16+4.16	0.001
Coordination			
At 5 min	63.5+ 4.9	61.5 + 3.5	0.076
At 10 min	74.6 + 4.7	71.6 +3.03	0.005
At 30 min	92.6 + 3.1	89.6 + 4.5	0.004

** Results are expressed as mean + SD*

Table-4: Adverse effects.

	Group A Sevoflurane	Group B Midazolam	P-value
Excitement or disinhibition	07(23.7%)	01(3.4%)	0.023
Coughing	02(6.7%)	01(3.4%)	0.55
Laryngospasm	01(3.4%)	02(6.7%)	0.55
Breath Holding	0	01(3.4%)	0.31
Secretions	01(3.4%)	0	0.31
Shivering	01(3.4%)	01(3.4%)	1.00
Transient Apnea	0	01(3.4%)	0.31
Bradycardia (HR <60)	01(3.4%)	0	0.31
Tachycardia (HR>100)	0	01(3.4%)	0.31
Hypotension (20%↓MAP)	01(3.4%)	0	0.31
Dizziness	0	01(3.4%)	0.31
Hiccuping	01(3.4%)	0	0.31

the procedure with the two drugs and the incidence of disinhibition- exetement with sevoflurane was higher (35%) than that in our study (23.7%). It might be because Ibrahim et al used face mask that causes anxiety and claustrophobia [1], where as we used a nasal mask in our study which is more tolerable.. Wang et al [8] have also described their good experience with sevoflurane sedation via nasal mask for upper GI endoscopy.

Results of our study are comparable to the results of Lahoud et al [9] who compared sevofurane and nitrous oxide with nitrous oxide alone for inhalational conscious sedation in children having dental treatment and showed that by using the six point Venham scale 67% children given sevoflurane had a score of 1 (relaxed and fully cooperative) compared with 32% given nitrous oxide alone.

Jurgens reported a case of successful MRI of a lady under inhalational anesthesia with sevoflurane who was not responding to 20 mg of I/V diazepam [10].

A potential difficulty with inhalational sedation in contrast to IV sedation is that part of the anaesthetic gases inevitably escape into the ambient air. There is considerable epidemiologic evidence that trace concentrations of anaesthetics are associated with spontaneous abortions and infertility. [11] Therefore, the Eurpeon and United States health authorities recommend exposure limits for volatile anaesthetics [12].

CONCLUSION

On the basis of our experience we conclude that inhalational sedation with sevoflurane offers a useful, easily titratable and patient satisfying alternative to standard

I/V sedation with midazolam which produces quick and smooth recovery. It is safe if used with proper equipment like nasal mask and scavenging system especially in the hands of an experienced anaesthetist. However further studies are required to establish the superiority of sevoflurane sedation over I/V midazolam sedation.

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