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Research Article

Patients' satisfaction with sedoanalgesia versus subarachnoid analgesia in endourology

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KEYWORDS

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Abstract *Objective:* In this study the effectiveness and safety of sedoanalgesia technique compared to spinal anesthesia in endourology procedure as well as patients' satisfaction was assessed. *Patients and methods:* A prospective randomized study was performed in 80 adult patients, ASA I, II, and III who underwent various endoscopic procedures randomly allocated into two groups 40 patients each: Sedoanalgesia group, received local anesthesia (2% lignocaine gel), i.v. midazolam incremental doses 0.015 mg/kg on demand, and i.v. fentanyl 2 μg/kg, and 0.5 μg/kg on demand interaoperative, and Spinal anesthesia group received 2.5 ml heavy bupivacaine 0.5% to achieve around T10 level. We recorded vital parameters, and the number of cases with hemodynamic, respiratory complications, nausea and vomiting, and conversion to general anesthesia (failure). Postoperatively the intensity of pain (VAS 0-100 mm), time to first analgesic request (VAS $\geqslant$30), patient satisfaction (complete, partial or not satisfied) and time to readiness for discharge were assessed. *Results:* There was no significant difference in intra, postoperative hemodynamic changes and complications between groups but hypotension was more frequent in Spinal group. Immediate

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postoperative, there was no significant difference in pain score between groups, but 1 and 2 h postoperatively there were higher pain scores in Sedoanalgesia group. Time to first analgesic request and readiness for discharge were significantly less in Sedoanalgesia group, but the difference was not significant as regard satisfaction scores.

Conclusion: Sedoanalgesia is an effective, safe and simple alternative to Spinal anesthesia for endourology, with good patients' satisfaction and less time to discharge.

1. Introduction

As day case ambulatory surgery is becoming popular it affords shorter hospital stay and lesser morbidity, specialized skills are needed both for anesthesia and surgery to meet the needs of these patients [1].

Sedoanalgesia is a state which allows patients to tolerate painful procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal commands and/ or tactile stimulation [2]. Intravenous sedoanalgesia has been described as a safe and cost effective alternative to general or regional anesthesia [3]. It can reduce the necessity of nursing staff, anesthetists as well as anesthetic equipments, it is also less time consuming [4]. Sedoanalgesia is suitable for day-case procedures in urology [2], it has facilitated the performance of number of minimally invasive urological procedures [3]. Not many reports were encountered in support of this method, but some strongly advocate this practice [3,5–10].

The term sedoanalgesia gives equal meaning to its true components; sedation and analgesia either with or without local aneshesia. In endourology, benzodiazepines are the most popular drugs used, of benzodiazepines midazolam either i.m. 30 min before (5–10 mg) [3,9] or i.v. titration (1–5 mg) [1,2,4] was used in many studies.

Short acting narcotics are the most effectively used drugs in sedoanalgesia because they can be given in small incremental doses and titrated to the desired effect, fentanyl 0.5–1 μg/kg incremental doses and if patient developed discomfort, additional doses of 25 μg [4].

This study compared midazolam and fentanyl sedoanalgesia with intrathecal bupivacaine in endourology procedures.

2. Patients and methods

This prospective study carried on in 80 adult patients of ASA physical status I–III and age range 18–64 years who underwent various endoscopic procedures of the upper and lower urinary tract. Patients were given adequate counseling regarding sedoanalgesia, spinal anesthesia, as well as the surgical procedure. Informed written consents from all patients were taken after approval of Anaesthesiology Department Ethics Committee.

Patients with expected invasive surgical manipulation, expected difficult airway, patients unable to cooperate, or any contraindication to intrathecal anesthesia were excluded from the study.

On patient arrival to operating theater ECG, blood pressure and oxygen saturation monitors were attached to the patient, and 16 G intravenous canula was inserted in dorsum of non dominant hand, ringer solution was infused at a rate of 7 ml/kg/h.

Patients were randomly allocated by computer code into two groups (40 patients each): Sedoanalgesia group patient was sedated by intravenous midazolam given in small incremental doses of 0.015 mg/kg and titrated to keep the patient between score 1 and 2 using a modified Observer's Assessment of Alertness/Sedation (OAA/S) scale [11] (where 1: awake/alert, 2: arouses easily, 3: arouses with vigorous stimuli, 4: responsive to painful stimuli, 5: asleep/unrousable). The analgesic used was intravenous fentanyl bolus dose of 2 μg/kg and during the procedure if there is pain complaint, 0.5 μg/kg incremental doses were given. As any sedation inevitably runs the risk of hypoventilation or airway obstruction; airway support and management were prepared.

The patient was positioned, painted and draped. Five minutes following sedation and analgesia; In urethral procedures topical anesthesia was started by introduction of 10 ml of lignocaine gel 2% by a 14 guage intravenous catheter through the external opening of the urethra. For bladder procedures 10 ml of lignocaine gel 2% diluted with equal amount of saline was instilled into the bladder. For ureteric procedures, retrograde ureteric catheterization was performed and 10 ml of lignocaine 1% gel was instilled in the renal pelvis and ureters. The surgeon was responsible for topical anesthesia application.

Spinal group received subarachnoid 2.5 ml heavy bupivacaine 0.5% in sitting position, midline Approach, at L4–5 interspace, with 25 gauge pencil point spinal needle to achieve sensory block around T_{10} level.

Oxygen 4–6 liter/min was administered by nasal prongs to all patients.

In the two groups failure of the technique was defined as severe or intolerable pain needs conversion to general anesthesia, the number of patients with failed technique was recorded and excluded from subsequent data analysis.

In all patients pulse, blood pressure, oxygen saturation (SpO_2) and respiratory rate were monitored baseline and every 5 min intraoperatively then 15, 30 min and every 30 min postoperatively till discharge.

Intraoperative complications including hemodynamic (pulse, blood pressure and SpO_2), respiratory (airway patency and rate) changes, nausea and vomiting were recorded.

Hypertension was defined as increase in mean blood pressure > 20% of base line reading, hypotension was defined as decrease in mean blood pressure > 20% of base line reading, tachycardia was defined as heart rate more than 110 bpm, and bradycardia was defined as heart rate < 45 bpm.

Hypotension was treated with rapid administration of intravenous fluids (300-500 ml) and ephedrine boluses 0.1 mg/kg.

Moderate oxygen desaturation was defined as SpO_2 90–95% and severe oxygen desaturation was defined as SpO_2 < 90%, Airway/ventilation complications were defined as any maneuver or placement of an airway required to permit unobstructed breathing and/or adequate ventilation. Our plan

for management was by arousal of the patient, oral airway placement, and temporary mask ventilation.

Postoperative data were taken by another resident who has no idea about anesthetic technique. The intensity of postoperative pain was assessed at 0, 1, 2, and 4 h using (0–100 mm) Visual Analogue Scale (VAS) [12] and time to first analgesic request recorded when patient ask for analgesia or when VAS $\geqslant$ 30.

Patient overall satisfaction with the anesthetic management was assessed, and this was graded as complete satisfaction, partial, or not satisfied at all [13].

Time to readiness for discharge was recorded. Discharge criteria included an alert oriented patient with stable vital parameters (within 20% of preoperative baseline), no nausea and vomiting or minimal that treated with oral medication, no pain or minimal acceptable to patient (VAS < 30), no Surgical bleeding or minimal, and recovered from motor and autonomic effects (steady gait and no dizziness) in Spinal group.

2.1. Statistical analysis

SPSS version 16 programs were used to enter data and statistical analysis. Data were presented as mean ± SD, range, number and percent. Comparison between the two groups was performed using unpaired Student's *t*-tests for parametric data, and Mann-Whitney test for nonparametric ordinal data. For data collected as proportions Chi-squared test (χ^2) and Fisher exact test were performed. A *P*-value < 0.05 was considered statistically significant.

3. Results

No failure occurred in Spinal group, but in Sedoanalgesia group 1 patient (2.5%) complaint of intolerable pain, 5 min later became agitated, poorly cooperative and converted to general anesthesia with spontaneous ventilation via LMA till the end of the procedure and excluded from the study.

Table 1 Patients' characteristics and surgical data.

	Spinal (n = 40)	Sedoanalgesia (n = 39)
Age (years)	52.8 ± 12.7	50.7 ± 12.2
Weight (kg)	74.1 ± 10.6	70.7 ± 8.1
Sex		
Male	23	21
Female	17	18
ASA		
I	13	12
II	18	17
III	9	10
Site and type of surgery		
Ureter		
Stone	8	9
Stent Placement	7	11
Bladder		
Diagnostic	13	9
Biopsy	9	6
Stone	3	4
Time of surgery (min)	35 ± 13	37 ± 10

Data expressed as mean ± SD and number.
No significant differences between the two groups $P > 0.05$.

Table 2 Intraoperative adverse effects in both groups.

	Spinal (n = 40)	Sedoanalgesia (n = 39)
Hypertension	0 (0%)	2 (5.1%)
Hypotension	5 (12.5%)	0 (0%)
Tachycardia	0 (0%)	3 (7.7%)
Bradycardia	0 (0%)	0 (0%)
Moderate desaturation	0 (0%)	2 (5.1%)
Severe desaturation	0 (0%)	1 (2.6%)
Nausea	0 (0%)	2 (5.1%)
Vomiting	0 (0%)	1 (2.6%)

Data expressed as number (%).
No significant differences between the two groups $P > 0.05$.

Table 3 VAS score in both groups.

VAS	Spinal (n = 40)	Sedoanalgesia (n = 39)
0	1 ± 3	4 ± 9
1 h	4 ± 10	15 ± 16*
2 h	11 ± 14	21 ± 15**
4 h	39 ± 11	34 ± 10

Data expressed as mean ± SD.
* Significant compared to other group ($P < 0.005$).
** Significant compared to other group ($P = 0.023$).

Patients' characteristics and surgical data were comparable between groups (Table 1).

Midazolam mean dose dose in patients received Sedoanalgesia was 2.5 ± 1.1 mg with range (1–5 mg) and mode dose 2 mg. Mean dose/kg was 0.036 ± 0.016 mg/kg with range (0.014–0.07 mg/kg) and mode dose 0.027 mg/kg. *Fentanyl mean dose* was 181 ± 50 μg with range (120–320 μg) and mode dose 150 μg. Mean dose/kg was 2.6 ± 0.6 μg/kg with range (2–4 μg/kg) and mode dose 2 μg/kg.

There were no statistically significant differences in intraoperative adverse effects between groups (Table 2).

Immediate and 4 h postoperative there were no statistically significant differences in pain score between groups, but after 1 and 2 h postoperatively pain score was statistically significantly higher in Sedoanalgesia group compared to Spinal group (*P*-value < 0.005 and 0.023) (Table 3).

Time to first analgesic request and readiness for discharge were significantly shorter in Sedoanalgesia group patients compared to Spinal group (*P*-value < 0.005) (Table 4).

There was no statistically significant difference in satisfaction score between groups (Table 5).

4. Discussion

Urological procedures account for 10–20% of most anesthetic practices. Patients undergoing endourological procedures may be of any age, but most of them above fifty and many have coexisting medical illnesses [14].

Sedoanalgesia may drastically change the practice of urology. Safety, efficacy and cost effectiveness make sedoanalgesia a preferable alternative to general or spinal anesthesia for many urological procedures including ureteroscopic lithotripsy. Rittenberg et al. [15] were the first to report ureteroscopy under

Table 4 Time to first analgesic request and readiness for discharge.

In minutes	Spinal (n = 40)	Sedoanalgesia (n = 39)
Time to first analgesic request	101 ± 35	58 ± 20*
Time to readiness for discharge	263 ± 39	92 ± 18*

Data expressed as mean ± SD.
* Significant compared to other group ($P < 0.005$).

Table 5 Patients' satisfaction score.

Satisfaction	Spinal (n = 40)	Sedoanalgesia (n = 39)
full	35 (87.5%)	32 (82%)
partial	5 (12.5%)	6 (15.4%)
not	0 (0%)	1 (2.6%)

Data expressed as number (%).
No significant differences between the two groups $P > 0.05$.

local anesthesia. With the application of Sedoanalgesia for various urological procedures in 1020 cases by Birch et al. [5] patients treated as day care basis increased from 25% to 60% [4].

Sedoanalgesia is a technique developed to provide safe and satisfactory operating conditions in a wide range of patients independent of age and overall level of fitness. It is eminently suitable for the elderly and medically unfit if there is adequate intra operative and postoperative monitoring [2].

The use of sedoanalgesia is especially applicable to institutions like ours, i.e., large teaching hospitals with a heavy work load, and long theater-waiting lists. There is an improvement in theater dynamics with little time wasted between cases. This results in greater time efficiency and greater work output per day leading to a reduction in the waiting list.

Secondly; Most of the patients will be alert and well oriented in a few hours and will discharged if their vital parameters are acceptable. This will help ease the burden on our already overcrowded wards. Malik et al. used sedoanalgesia for this purpose [1].

Thirdly sedoanalgesia can be used in patients with considerable risk from conventional anesthesia. This must especially be a consideration in urology which has a high percentage of patients who are elderly and medically unfit. These criteria are met with Rao et al. [2] for use sedoanalgesia in there institute.

However, there is reluctance to perform urological procedures under sedoanalgesia for fear of intraoperative pain, patient discomfort, nausea, vomiting, poor cooperation, unsatisfaction of the patient, or respiratory complications (airway obstruction or desaturation).

In our study we compared Sedoanalgesia with the Spinal anesthesia which is the commonest anesthetic technique for urological procedures in our hospital as regard to these aspects.

We used midazolam and fentanyl as drugs for sedoanalgesia which had already been reported safe and effective for endourological procedures. Benzodiazepines can safely provide sedation, anxiolysis and amnesia. In this respect midazolam has an advantage because of its short duration of action (1–3 h), profound antegrade amnesia combined with reduced sensory awareness. However, midazolam has no analgesic properties and pain relief is achieved by use of adequate local anesthesia and intravenous boluses fentanyl. Rao et al, also used these drugs [4].

With the spinal anesthesia there were frequent hypotension compared to sedoanalgesia patients, although it was easily managed it may be a major problem in patients with cardiovascular diseases or patients cannot tolerate fluid load.

Regarding the safety of Sedoanalgesia our patients developed only minor complications like tachycardia, change in blood pressure, change of oxygen saturation, nausea and vomiting but it still accepted technique. Rao et al. [4], Mcfarlane et al. [10], Qubbaj [3] and Birch et al. [5] also concluded its safety.

Poor cooperation, failure of the procedure and conversion to general anesthesia are considered mishaps but they were not common. In Rao, et al. [4] study, only 4.84% of patients opined this procedure was painful in middle ureteric stone procedure. In Malik et al. [1] study, no pain during all diagnostic cyctoscopies but during urethral dilatation pain occurred in 40% of patients, this means that selection of the patient is the most important factor; the condition that does not involve complex or time consuming procedures [16], a duration of 60–90 min is considered to be the time limit that requires regional or general anesthesia [17].

Rao et al. also documented that during the procedure, patients remain comfortable so long the scope is in the lumen. Any wrong maneuver causes pain to the patient who is not under complete anesthesia, thereby enabling the endoscopist to recorrect the procedure. Thus this advantage of sedoanalgesia prevented to cause any ureteral perforation [4].

Time to first analgesic request was less in patients who received Sedoanalgesia, and the intensity of pain was higher early postoperative. Although the Visual Analogue Scale for assessment of pain was rated below 30. In Rao et al. [4] study, Visual Analogue Scale in 80.65% of cases rated only 20. After receiving NSAIDs as first analgesia demand VAS was less because of its potentiation by remnants of serum narcotic (fentanyl). Also, readiness for discharge was faster in patients who received sedoanalgesia.

Over all satisfaction was accepted and equal in both groups. This was as in Mcfarlane et al. [10] study, 94% of patients was satisfied and near Rao et al. [4] study, 87.10% of patients the procedure was acceptable. Partially satisfied patients were due to intraoperative pain, nausea, and vomiting.

A reason for the high satisfaction rate may be that our patients were preselected by the surgeons for this procedure and were also well prepared for it by the surgeon and anesthesiologist.

5. Conclusion

Sedonalgesia is a safe and effective technique in endourology procedures with high rate of patients' satisfaction, and less

time to discharge. Appropriate patient selection, proper counseling and close monitoring are the key to success.

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