

A comparison of sedation techniques in plastic surgery of the face: midazolam versus midazolam plus tramadol

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1. Introduction

An increase in the number of plastic surgery operations executed in day-hospital requires surgeons and the anaesthetists to find suitable therapeutic protocols. It is known that today, a remarkable percentage of ambulatory services are performed under locoregional anaesthesia associated with sedation techniques which must be complication free and well tolerated [1].

Insuring only essential analgesic effect is fundamental in reducing the anxiety of the subject in order to acquire adequate collaboration during surgery as well as the quick recovery of neurocompartmental functions.

Sedative drugs such as propofol or thioental have been used extensively as adjuvants in locoregional anaesthesia. Recently, benzodiazepines and, in particular, diazepam and midazolam have been used also [2].

In the literature, a large amount of data appears on the use of combinations of benzodiazepines and narcotics given either as a premedication or intraoperatively [3]. One of the most commonly used combinations is midazolam with fentanyl at low dosage to avoid the risk of respiratory depression, blunting of airway reflexes and the appearance of other side effects such as nausea and vomiting [4,5].

Today a new opioid analgesic, tramadol, is available. Besides having the potency and rapid action of an opioid, it produces no significant effect on respiratory dynamics, on the cardiovascular system and no constipation, nausea or vomiting [6-8].

In this study, we have investigated the efficacy of combined tramadol and midazolam in plastic surgery of the face in a day-hospital.

2. Materials and methods

The study includes two groups of patients (A and B) undergoing plastic surgery of the face under local anaesthesia in a day-hospital (Tables 1 and 2).

The premedication included trazodone (50 mg) and atropine (0.01 mg/kg) intramuscularly (i.m) and all patients were monitored with continuous ECG, automated blood pressure and pulse oxymetry. The haemodynamic values were recorded at times *T*1, *T*2, *T*3, *T*4 and *T*5, recording the heart rate (HR), the blood pressure and the pulse oxymetry (Table 3). Local anaesthesia was given using mepivacaine 2% with epinephrine at a concentration of 1:100 000.

Group A received midazolam at a dose of 0.1 mg/kg intravenously just prior to local anaesthetic injections and group B received the same dose of midazolam and tramadol at 2 mg/kg with 8 mg ondansetron.

Patient response was graded immediately by the surgeon using four scales (Table 4). All the patients were discharged from hospital only after vital functions were checked and found normal. Statistical analysis was conducted using Student's *t*-test, χ^2 analysis by constructing the tables 2×2 and analysis of variance (ANOVA) when necessary.

Table 1
Type of procedure

	Group A		Group B	
	N	%	N	%
Blefaroplasty	5	33.3	6	40.0
Skin tumour	6	40.0	8	53.3
Liposuction	3	20.0	1	6.7
Scar revision	1	6.7	—	—

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Table 2
Patient characteristics

	Group A		Group B		P
	\bar{X}	S.D.	\bar{X}	S.D.	
No. of patients	15		15		
Age (years)	43.8	9.205	44.4	11.531	NS
Sex					
Male	5 (33.3%)		4 (26.7%)		NS
Female	10 (66.7%)		11 (73.3%)		
Weight (kg)	63.1	8.101	62.1	10.477	NS
Time of procedure (min)	49.0	12.564	47.8	13.610	NS
Midazolam					
Initial dose (mg)	6.4	0.783	6.3	1.065	NS
Additional dose (mg)	3.4	1.630	0.6	0.828	0.001

NS, not significant.

3. Results

The study groups were comparable in terms of age, weight, sex, duration of procedure and initial amount of midazolam given.

There was a significant difference between groups in the additional dose of midazolam, which was higher for group A than group B (3.4 ± 1.630 vs. 0.6 ± 0.828 ; $P < 0.05$). The haemodynamic values recorded at $T1$ and $T2$ were similar for both groups. There was a decrease in HR and arterial blood pressure at $T3$ and $T4$ for group B. The mean oxygen saturation during both procedures at $T1$ and $T2$ was 98%, while with tramadol–midazolam sedation, the oxygen saturation was still lower than the preoperative value (Table 5). There were no significant perioperative complications in either group even though three patients with midazolam–tramadol sedation experienced slight nausea and vomiting.

Scores for both groups are indicated in Table 6. A significant majority of patients of group A did not receive adequate sedation (33.6%), compared with 13.3% of group B.

4. Discussion

An ideal adjunct to local or regional anaesthesia should provide anxiolysis, sedation, amnesia and analgesia for any painful aspect of the procedure, including performance of the anaesthetic injections.

Table 3
Haemodynamic value recording (time)

$T1$: Basal value
$T2$: After premedication
$T3$: Prior to local anaesthetic injection
$T4$: 5 min after injection of local anaesthetic
$T5$: End procedure

The benzodiazepines are highly effective drugs for producing amnesia and sedation and relieving anxiety, but the goal of analgesia has led most workers to incorporate a narcotic analgesic into their technique.

Our goal was to use the pharmacological cocktail strategy to find the combination which could provide adequate analgesia with a reduced dose in order to shorten recovery time and to reduce the depressive and other side effects (cardiovascular, respiratory effects, etc.). In our opinion, the combination of midazolam plus tramadol produces the defined desired end points.

Intravenous injection of midazolam produced significantly faster peak serum levels and its metabolic clearance is roughly 10 times higher than that of diazepam. When compared with diazepam, it is reported to be an effective anxiolytic, sedative and amnesic agent [9,10]. Therefore, postoperative residual sedation should be far lower than when using midazolam, as is presumably the risk of re-sedation.

Midazolam produces high peak brain tissue level in a few minutes because it has a rapid redistribution phase

Table 4
Scales for valuation of patient

(a) Patient response to infiltration of the local anaesthetic:
0 = No reaction
1 = Facial grimace only and/or unintelligible verbalization
2 = Distinct verbalization of pain perception and/or movements of extremities
3 = Sustained and significant resistance
(b) Patient sedation score:
0 = Drowsy or asleep but easily arousable by verbal stimulus
1 = Asleep and difficult to arouse by verbal stimulus (oversedated)
2 = Awake and anxious or disturbed (inadequately sedated)
(c) Patient verbalization score:
0 = none; 1 = mild; 2 = moderate; 3 = severe
(d) Patient movement during surgery:
0 = none; 1 = mild; 2 = moderate; 3 = severe

Table 5
Perioperative haemodynamic values

Group A										
	T1		T2		T3		T4		T5	
HR	74.3	12.418	90.6	11.782	67.0	7.309	69.8	10.472	71.2	11.883
SAP	137.0	15.901	134.3	14.499	131.4	13.611	133.2	12.736	132.6	12.638
SpO ₂	98.1	1.162	97.5	1.060	96.3	2.003	96.9	1.351	97.6	1.755
Group B										
HR	73.8	11.326	91.3	10.284	61.9*	6.348	61.7*	5.583	64.2*	6.854
SAP	138.0	13.896	135.0	12.962	129.8	13.123	130.6	12.365	131.6	13.479
SpO ₂	98.4	1.089	97.6	1.451	94.2*	1.401	94.6*	1.312	95.2*	1.793

All numbers are reported as mean \pm standard deviation; HR, heart rate; SAP, systolic blood pressure; SpO₂, oxygen saturation; T1, T2, T3, T4, T5, see text.

* Significant difference between study groups ($P < 0.05$).

Table 6
Results of score

	Score			
	0	1	2	3
Reaction to injection				
Group A	20.0	20.0	40.0	20.0
Group B	53.3*	40.0*	6.7*	—
Degree of sedation				
Group A	33.3	33.3	33.3	—
Group B	66.7*	20.0	13.3	—
Vocalization				
Group A	53.4	13.3	20.0	13.3
Group B	53.3	33.4*	13.3	—
Movement				
Group A	33.3	26.7	33.3	6.7
Group B	33.3	53.3*	6.7*	6.7

All numbers are presented as percentages of each score.

* Significant difference between study groups ($P < 0.05$).

($t_{a1/2} = 6-15$ min), followed by a slower metabolic clearance ($t_{\beta1/2} = 1.7-4$ h). Tramadol is a centrally acting analgesic with higher efficacy than the analogue codeine, and it preserves both respiratory and laryngeal reflexes [11]. A recent study has shown that tramadol possesses selectivity for μ -receptors and monoaminergic re-uptake inhibition [12].

The mean total of midazolam dose was significantly lower in the tramadol group than in the midazolam-only group to maintain adequate sedation.

In conclusion, the use of midazolam alone was highly successful in short procedures with local anaesthesia, although the combination with one dose of tramadol reduced both the pain of the injection of local anaes-

thetic and improved intraoperative conditions and outcome for the patient.

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