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Ambulatory Surgery

Selective spinal anaesthesia in ambulatory surgery

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Abstract

Background and objectives: selective spinal anaesthesia (SSA) is preferable in day hospital surgery. The present investigation aims to confirm the usefulness and safety of this technique. Methods: 250 patients (ASA I–II, mean age 42 ± 3 years) scheduled for day-hospital surgery were enrolled in our study. The puncture was performed with the patients in a lateral position, the ill side down; for proctological surgery the puncture was performed in a sitting position. A 27G Whitacre needle was always used and 1% hyperbaric bupivacaine was administered in 30 s or more, preceded by a single dose of fentanyl (20 μg) injected very slowly. The position was maintained for 10 min. Hemodynamic parameters (SBP, DBP, HR) and pulsoximetry were recorded before anaesthesia (T_0), 5 min after subarachnoid injection (T_1) and then every 15 min (T_n) up to the completion of the surgical procedure. In the last 100 patients enrolled in our study haemodynamic data (CI, EF, SVRI, MAP,HR) were recorded by using a non invasive bioimpedenzometric method, before anaesthesia (T_a), after 15 min (T_b), 60 min (T_c) and 240 min (T_d). The postoperative course was evaluated from the end of surgery on, with regard to analgesic consumption and residual analgesic degree. The incidence of adverse effects was evaluated. Results: the level and degree of anaesthesia was excellent in 183 and good in 67 patients. SBP, DBP, HR and pulsoximetry showed an excellent stability during the study. Haemodynamic stability was confirmed by data obtained with bioimpedenzometry that showed significant variations in CI ($P < 0.001$), SVN ($P < 0.0001$) at T_b and T_c as to basal five values. Postoperative analgesia was excellent and the incidence of side effects very low. Conclusions: we believe that the method is suitable for day-hospital surgery because it is easy to execute and provides an excellent degree of surgical anaesthesia, cardiovascular stability, postoperative analgesia and patient safety. © 1997 Elsevier Science Ireland Ltd.

Keywords: Superselective spinal anaesthesia; Ambulatory anaesthesia; Circulatory effects

1. Introduction

'Day-hospital' surgery is often favoured due to several advantages concerning the rationalization of medical service costs, limitation of surgery patients overheads, reduction in waiting lists, greater availability of staff and beds for major surgical pathologies, social and psychological benefits for the patient and a reduction for patients in temporary disability and their absence from home and work [1]. The greater resort to this kind of surgery compels the anaesthetist to use techniques and drugs that join together high safety, shortage of side effects and fairly short times of recovery [2,3]. The aim of the present study was to evaluate the usefulness and safety, in ambulatory surgery, of tby selective spinal anaesthesia (SSA) carried out with 1% hyperbaric bupivacaine. In addition we considered the postoperative course with regard to side effects, pain symptomatology and the use of analgesic.

2. Materials and methods

The study protocol was approved by the Institutional Ethics Committee, and informed consent was given by patients.

250 patients (ASA I–II, mean age 42 ± 3 years, mean weight 69 ± 1.6 kg, mean height 164 ± 7.3 cm) scheduled for 'day-hospital' surgery were enrolled in our study. All the patients included in our protocol were

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Table 1
Puncture level and anaesthetic dose in each kind of surgery

Surgery	No. of patients	Time (min)	Puncture level	Bupivacaine dose (mg)
Saphenectomy	78	84.2 ± 18	L_4-L_5/L_3-L_4	6
Hernioplasty	69	58.4 ± 16	L_2-L3/L_3-L_4	8
Varicocelectomy	43	31.6 ± 10	L_2-L_3	6
Proctological surgery	60	32.1 ± 7	L_4-L_5	6

studied between January and June 1995. Anaesthesia was carried out in the lateral position, the ill side down, performing the puncture at the interspace as appropriate to surgery. Only for proctological surgery, the puncture was performed with the patient in sitting position. A 27 G Whitacre needle was always used. One percent hyperbaric bupivacaine was administered in 30 s or more, preceded by a single dose of fentenyl (20 μg) injected very slowly (Table 1).

After injection, the lateral position was maintained for about 10 min until the anaesthesia level was stabilized. The patients undergoing proctological surgery were positioned for 10 min seated with lifted and bent legs.

Fluid therapy was carried out in all the patients only during surgery by infusing saline solution at the rate of 5 ml/kg per h. After surgery all the patients were allowed to drink.

Hemodynamic parameters (SBP, DBP, HR) and pulsoximetry were recorded before anaesthesia (T_o), 5 min after subarachnoid injection (T_1) and then every 15 min (T_n) up to the completion of the surgical procedure. These data were statistically analyzed by one-way ANOVA.

Metameric level of anaesthesia and motor block were evaluated 10 min after the injection by means of pinprick test and Bromage score respectively. The resumption times of motility and ambulation were also assessed from subarachnoid injection on.

The postoperative course was evaluated from the end of the surgery on, with regard to analgesic consumption, during the first 12 h, and residual analgesic degree, by means of a visual analogue scale (VAS) every 20 min during the first 3 h.

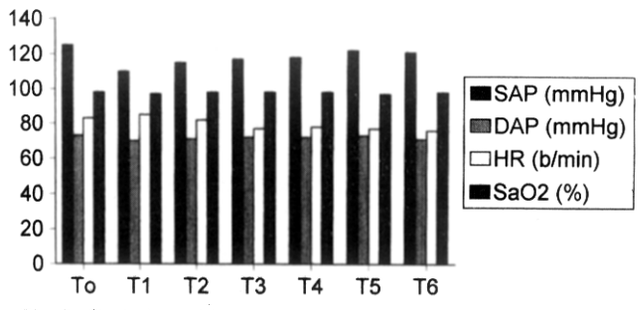

Fig. 1. Variation of haemodynamic and respiratory parameters

Statistical mean and S.D. of these data were computed.

Finally, the incidence of adverse effects (urinary retention, headache, nausea, pruritus, backache) was evaluated.

Hemodynamic evaluation was carried out in the last 100 patients enrolled in our study using a non-invasive bioimpedenzometric method (BoMed NCCOM3-R7). This method allowed us to survey the values of cardiac index (CI), ejection fraction (EF), peripheral vascular resistances (SVRI), mean arterial pressure (MAP) and heart rate (HR), before anaesthesia (T_a), after 15 min (T_b), 60 min (T_c) and 240 min (Td). Statistical analysis was performed by one-way ANOVA.

3. Results

The mean time required for surgery was 51.5 ± 25.0 min. Subarachnoid injection was easy to perform in 208 patients and more or less difficult, but always possible in the remaining patients. The level and degree of anaesthesia was excellent in 183 cases and good in 67. No additional systemic administration was ever necessary.

All patients began eating again 2 h after surgery and were discharged within 8 h, except five patients in whom two incidents of headache and three of urinary retention were noticed. Nausea was observed in 10 patients and was treated with ondansetron 4 mg i.v.

Pruritus was noticed in 15 patients. No other side effects were observed. Pulsoximetry and hemodynanmic data (SBP, DBP, HR) evaluation, carried out in all patients, showed an excellent stability of blood pressure and pulsoximetry at the considered times. A negligible

Table 2
Bioimpedenzometric haemodynamic data

	T_A	T_B	T_C	T_D
MAP (mm Hg)	90.3	91.9	90.7	90.5
HR (b/min)	77.2	74.8	71	75.3
CI (l/min per m^2)	4.13	3.48**	3.52**	4.11
SVRI (Fl Ohm/m^2)	1745	2152*	2137*	1757
FE	65.1	64.3	64.3	65.1

* $P<0.001$, ** $P<0.0001$.

Table 3
Anaesthesia level and anaesthetic block regression in the different kind of surgery

Surgery	No. of patients	Anaesthesia level	Block regression (min)
Hernioplasty	31	$T_{10}-L_3$	155 ± 30
	38	$T_{11}-L_4$	
Varicocelectomy	43	$T_{10}-L_3$	148 ± 34
Saphenectomy	47	$T_{12}-S_5$	160 ± 25
	31	L_1-S_5	
Proctological surgery	60	L_4-S_5	152 ± 32

not significant decrease in HR (10% vs. T_o) during the 1st h after the anaesthesia (Fig. 1) was observed.

Hemodynamic stability was confirmed by data obtained with bioimpedenzometry that showed significant variations in CI ($P < 0.001$), SVRI ($P < 0.0001$) at T_b and T_c as to basal values. At T_d all values went back to preoperative levels (Table 2).

Data relevant to anaesthesia level and motor block, in the different kind of surgery, are summarised in Table 3 and Table 4.

Mean recovery times of motility and ambulation were 97.4 ± 31 min respectively. Table 5 and Table 6 show data relevant to the postoperative course collected also by telephone) that concern residual analgesia (VAS score) during the first 3 h (Table 5) and the number of patients that requested additional analgesic (ketoralac 30 mg. i.m.) during the first 4, 8 and 12 h after surgery (Table 6).

4. Discussion

Elements of paramount importance for anaesthesia in 'day-hospital' surgery are:

1. Achievement of an early and efficient postoperative mobilization, made possible by excellent hemodynamic stability and prolonged postoperative analgesia.
2. Lack of consequences such as prolonged effect and side effects of anaesthesia.
3. Possibility of an early food intake.
4. Immediate communication with relatives.

Table 4
Motor block in the different kind of surgery

Surgery	No. of patients	Motor block (%)
Hernioplasty	24	100
	35	66
	10	33
Varicocelectomy	39	66
	4	33
Safenectomy	71	100
	7	66
Proctological surgery	9	33
	51	0

Although easy and quick to perform, spinal anaesthesia has not been used until a few years ago, because of frequent hypotensive crises, and prolonged motor block and post-dural puncture headache [4–6].

SSA anaesthetized only a restricted part of the body and required a reduced dosage of drugs, producing a less severe sympathetic block which is always hemodynamically well compensated. The excellent pressure stability noted in all patients agrees with these observations [7].

Subsequent hemodynamical study confirms this data and points out that it is achieved through excellent reciprocal compensation of the considered parameters.

Anaesthesia level was always reached during the 10 min of the 'fixed' decubitus and was always adequate to the operation. Motor block was never excessively widespread and always homolateral to the surgery side. A sella anaesthesia, in most cases followed by absence of motor block, was noticed in proctological surgery.

The short return to motility and ambulation are an important datum for ambulatory surgery, as well as the low incidence of side effects [2,3].

Above all, an insignificant incidence of headache was observed; the use of a traumatic needle allowed us to get through aura separating the fibres without dissecting them [8–10].

In our opinion, the high degree of postoperative analgesia due probably to the fentanyl addition made early ambulation possible.

All of these factors contributed to the rapid discharge of the patients in perfect condition. Most of them were able to begin working again soon after their release.

5. Conclusions

All the patients interviewed were satisfied with anaesthetic technique with regard to both the preoperative and the postoperative period.

Objectively we found the method to be suitable for day hospital surgery because it is easy to execute and provides an excellent degree of surgical anaesthesia, postoperative analgesia and patient safety.

Particularly favourable is the remarkable shortness of time required before the patient can feed and walk normally.

Table 5
Residual analgesia (VAS) during the postoperative first 3 h

	0	20 min	40 min	60 min	80 min	100 min	120 min	140 min	160 min	180 min
VAS (mean ± S.D.)	—	—	—	1.2 ± 0.2	1.5 ± 0.3	1.9 ± 0.2	2.2 ± 0.3	2.8 ± 0.4	3.1 ± 0.3	3.4 ± 0.2

Table 6
Number of patients that requested additional analgesic

	4 h	8 h	12 h
No. of patients treated with Ketorolac 30 mg i.m.	11	11+23	11+23+31

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Tramadol via oral administration and superselective spinal anaesthesia in 'one-day surgery'

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Abstract

The analgesic efficacy and tolerance of tramadol, particularly via oral administration, were evaluated in 180 patients (age range 18–69 years), undergoing ambulatory surgery and superselective spinal anaesthesia. The patients were divided into three groups (A, B and C). 40 drops of tramadol were administered to the subjects of group A 30 min before surgery; the same dose was administered to the patients of group B after surgery; no supplementary analgesia was administered to the group C. Intraoperatively, the respiratory and cardiovascular parameters were monitored in each group. Intraoperatively and postoperatively the degree of analgesia was evaluated by using a visual analogue score (VAS) and a four step verbal scale (FSVS). The results showed a significantly superior and prolonged analgesic effect in the groups treated with tramadol, particularly if it was administered before surgery. Furthermore an excellent profile of drug tolerance with no significant side effects, especially respiratory depression, were observed. © 1997 Elsevier Science Ireland Ltd.

1. Introduction

The well known additive analgesia, obtained from the combination of local anaesthetics with opioids, is often used to alleviate intra- and postoperative pain via epidural or intrathecal instillation but its effectiveness should not be overly exploited in ambulatory surgery.

The use of local anaesthetics in superselective spinal anaesthesia is suitable to 'one day surgery' but the simultaneous use of opioids may result in dangerous disadvantages,including, especially, respiratory depression.

This study was designed to assess the analgesic efficacy, safety and duration of action of tramadol, a new synthetic opioid, which, considering its potency, has comparatively few of the disadvantages associated with other opiates.

Its antinociceptive potency and profile may derive from its combined opioid binding activity and inhibition of monoamine uptake. The antinociceptive activity of tramadol is mediated by a double mechanism:

1. It is a weak agonist for all types of opioid receptors with higher selectivity for $^{\mu}$-receptors.
2. It causes inhibition of neuronal noradrenaline uptake and serotonin release; these are transmitters in descending inhibitory pathways which enhance analgesia.

As reported in literature, it is suggested that the analgesic activity and clinical attributes of tramadol are a consequence of non-opioid as well as opioid mechanisms [1]. Each component independently contributes to the overall analgesic activity and thus, in concert, results in a significant reduction in the side-effects profile typically associated with opioids. So the analgesic efficacy and potency of tramadol have not been associated with clinically significant side-effects such as respiratory or cardiovascular depression, constipation, sedation urinary retention [2,3].

2. Patient and methods

One hundred and eighty patients (108 males and 72 females, age range 18–69 years, ASA I–II) were included in this randomized double blind study. The

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Table 1
Patients' decubitus, puncture level and dose of anesthetic in every kind of surgery

	Decubitus	Puncture level	Dose of hyperbaric bupivacaine
Hernioplasty	Lateral position	T12-L1/L1-L2	8 mg (0.8 ml)
Varicocelectomy	Lateral position	T12-L1	8 mg (0.8 ml)
Saphenectomy	Lateral position	L2-L3	6 mg (0.6 ml)
Proctological surgery	Seated	L4-L5	6 mg (0.6 ml)

surgical procedures performed were hernioplasty (58), saphenectomy (42), varicocelectomy (33), proctological surgery (47). Their duration was not more than 100 min. Criteria for selection of cases were:

1. Absence of any cardiac, respiratory, renal or other pathologies that may affect the parameters for clinical evaluation of cardiorespiratory performance.
2. Absence of mental illness.
3. The patients must not be on psychotropic drugs likely to influence the sensation of pain.

The patients were divided into three treatment groups. Group A was made up of patients treated with tramadol (40 drops = 100 mg) 30 min before surgery, and with placebo at the end of the operation; Group B included patients that received the same analgesic in the same dose at the end of surgical suture, and placebo 30 min before surgery; Group C was composed of patients treated only with placebo.

The surgery was carried out by superselective spinal anaesthesia with pencil point needle (Whitacre 25–27 G). The dose of local anaesthetic and patient's decubitus were different and related to the surgery type (Table 1).

Intraoperatively, heart rate, ECG and SaO_2 were monitored continuously and non-invasive blood pressure was noted every 10 min. Pain relief was measured by using a four step verbal scale (0 = no pain; 1 = slight pain; 2 = moderate pain; 3 = severe pain) every 15 min. The respiratory (SaO_2) and cardiovascular parameters (SAP, DAP, HR) were recorded every 10 min for statistical analysis.

SaO_2 was monitored post-operatively (at 30 min, 60 min, 3 h, 6 h, 12 h) and analgesia was scored using a visual analogue scale and four step verbal scale. Side-effects were evaluated intra-and postoperatively.

Statistical analysis was performed using Student's t-test and analysis of variance for one factor for parametric data. The χ^2-test and comparison of percentages were used for qualitative data.

3. Results

All three groups were homogeneous with regard to age, weight, sex, ASA, type and duration of surgery (Table 2). Intraoperative blood pressure and heart rate showed a little decrease in comparison with their baseline values in each group, but it was not statistically significant [Figs. 1–3]; SaO_2 was stable (97–99%) and pain relief was excellent in all three groups (FSVS = 0/1)[Fig. 4]. No side-effects were observed. Postoperatively, during the first 2 h after surgery, pain relief was very good (VAS < 3; FSVS = 0/1) and it was comparable in the three groups. Nevertheless a statistically significant increase of VAS and FSVS values was observed from the 3rd h on in the Group C and from the 6th h on in the Group B. VAS and FSVS values were firmly stable at low levels in the Group A. 20% of patients of group C required further analgesia at the 3rd h and 18% of patients of group B required it at the 6th h. They received ketorolac 30 mg i.m.

As regards the side-effects, there were two cases of vomiting in the patients of Group A, and one case of nausea and one case of drowsiness in the patients of Group B, but no negative effects on respiratory or cardiovascular parameters were observed at therapeutic doses.

4. Discussion

Our studies showed that tramadol is very effective, well tolerated and a safe analgesic in the relief of postoperative pain. Particularly, the combination of tramadol with superselective spinal anaesthesia appeared interesting to us in ambulatory surgery. The additive analgesia, obtained from the combination of local anaesthetics with opioids, is often used to relieve intra-and postoperative pain. This synergic action is due to their different mechanism. The local anaesthetics inhibit the conduction of the stimulus in the nerve by

Table 2
Patients' data and kind of surgery in three groups

	Group A	Group B	Group C
Number of patients	61	58	61
Age (years)	Range 18–69		
Sex (m/f)	35/25	35/23	37/23
Body weight (kg)	69 ± 11	68 ± 9	70 ± 10.5
ASA (I/II)	41/20	39/19	41/20
Duration (min)	55 ± 29	60 ± 28	58 ± 31

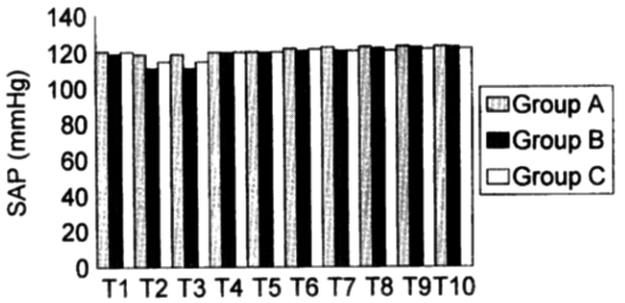

Fig. 1. Variations of SAP in three groups at different times.

Fig. 2. Variations of DAP in three groups at different times.

means of blocking the channels of sodium. Opioids reduce the release of the neurotransmitters at the axonal ending of the pain receptors at presynaptic level, and induce hyperpolarization of the membrane of the posterior spinal cord neurons at postsynaptic level.

Nevertheless, the potent analgesic drugs in common use (pethidine, pentazocine) are known to match their analgesic properties with some degree of respiratory or circulatory depression, adverse effects which limits their use in ambulatory surgery. On the contrary, tramadol, particularly when administered orally, as with drops, proved capable of providing significant pain relief in a short time, a long duration of analgesia and optimal compliance, because there were no clinically significant adverse effects, such as respiratory depression, which could interfere with the ambulatory patient's outcome [4]. Furthermore, the analgesic effect was better and was obtained using lower doses of the drug when tramadol was administered before the surgical trauma, probably because the abnormal postoperative neuron sensitivity induced by the surgical tissue damage was prevented.

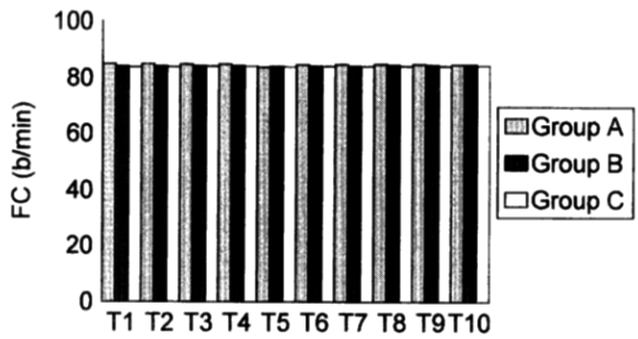

Fig. 3. Variations of FC in three groups at different times.

Fig. 4. Variations of SaO_2 in three groups at different times.

5. Conclusion

This study confirms that tramadol is a very effective, potent and well tolerated analgesic for postoperative pain, especially in cases where cardiocirculatory and respiratory depression are undesirable.

The absence of hypnotic effects further increases its value since patients are able to cooperate in promoting a quick and safe outcome.

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Ambulatory Surgery

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 $T1$, $T2$, $T3$, $T4$ and $T5$, 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 resedation.

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

Table 4
Scales for valutation 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 diffcult 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 ± standard deviation; HR, heart rate; SAP, systolic blood pressure; SpO_2, 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 ($t_{\beta 1/2} = 1.7–4$ 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 anaesthetic and improved intraoperative conditions and outcome for the patient.

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Ambulatory Surgery

Tension-free hernioplasty: stop and go ambulatory technique

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Abstract

The appearance of the mesh prosthesis on the market determined radical changes in the treatment of groin hernia. There had been no substantial variations for over a century since the invention of Bassini's technique in 1877. The 'tension-free' hernioplasty makes the operation easy; it allows the use of local anesthesia and it lowers remarkably the chance of recurrence and complications. In this work the authors, with experience in herniorrhaphy according to Trabucco, illustrate the technique they use to perform the operation in an office-based surgical suite. Moreover, they explain how they eliminate the risk of recurrence that immediate mobilization of the patient and consequent movement of the prosthesis or creation of seroma may cause. In order to avoid these risks, the authors fix the polypropylene prosthesis with human fibrin spray glue. The patients are selected according to their psycho-social characteristics and the operating risk according to the classification of the American Society of Anesthesiology (ASA). They are informed in detail of the method, are treated in an ambulatory fashion, being hospitalized for 2 h on average, are sent home with an analgesic prescription for 24 h and a phone number to use in case of complications. The authors started this method in January 1996 and have treated six patients so far, aged between 23 and 69. The results, although limited and preliminary, have demonstrated the feasibility of the technique, the very good compliance of the patients, the lack of both immediate and belated complications, and the validity of the method regardless of age.

A reassuring fact that has been noticed by examining the forms for pain evaluation is the remarkable reduction of pain after the operation compared with patients treated with the traditional Trabucco technique. This fact may be due both to the better preparation of the patients and to the lower mechanical stimulus from the plug covered with fibrin glue. © 1997 Elsevier Science Ireland Ltd.

Keywords: Anesthesia; Groin hernia; Hernioplasty; Mesh prosthesis

1. Introduction

Groin hernias represent one of the most common pathologies in general surgery. Their frequency has been increasing with the rise in life expectancy. After over a century since the first herniorrhaphy was performed by Bassini, many surgical techniques have tried to reduce the number of recurrences, which range from 10 to 25% [1,2], the duration of stay in hospital and the convalescence time after the operation. In the 1950s, herniorrhaphy underwent radical changes due to the appearance of the mesh prosthesis. This prosthesis was used by Rives and Stoppa first and, later, by Liechtenstein, Trabucco and Gilbert, who initiated the 'tension-free' philosophy, the concept of '1-day surgery' and an increasing use of local anesthesia. These authors' techniques have had great success because of their effectiveness, the simplicity of execution and the scarcity of complications, together with a recurrence rate below 1% [3–5].

In our division of General Surgery we adopted the tension-free Trabucco technique in August 1991, liking its conceptual effectiveness and its simplicity, completely neglecting Bassini's technique that we had formerly used in almost all cases. To date, 489 operations have been performed using Trabucco's technique (455 males, 35 females; 461 elective and 28 as emergencies). The average age of the patients was 57.9 years (range: 6–92 years) (Table 1).

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In 18 cases the operation was bilateral and in 24 cases we found different kinds of hernia together. In 51 cases the operation was performed under general anesthesia, in 25 cases with epidural anesthesia, in 192 cases with spinal anesthesia and in 221 cases under local anesthesia. The average stay in hospital of the patients after the operation was 1.7 days for those operated under local anesthesia, slightly lower than for the patients operated under spinal anesthesia (2.1 days), but definitely better than the ones who underwent epidural anesthesia (5.7 days) or general anesthesia (7.8 days) (Table 2).

Follow-up has been done on all the patients, with check-ups after 1 month, 6 months and then yearly, with a 70% compliance, and only one recurrence was noted. Another case, which was initially classified as a recurrence, was identified as a crural hernia at the time of the operation. Satisfied with the results, we thought of lowering the stay in hospital to zero days, performing the operation on an ambulatory basis in order to optimize the results both from the economic and organizational points of view for the hospital and from the psychophysical point of view for the patient.

In order to do so we have prepared a technique, called 'stop and go', which, after a careful selection of the patients, allows us to perform herniorrhaphy on an ambulatory basis, allowing the patient to stay in the hospital for an average of only 2 h.

2. Materials and methods

In January 1996 we started selecting patients with groin hernia, in order to submit them to the stop and go operation. The selection is done according to the ASA class of risk, enrolling the ASA 1 and ASA 2 patients and hospitalizing the others. Another important factor is the social and psychological condition of the patient, who is informed in detail and has to accept the method. Exclusion criteria are obesity, a multirecurrent or huge hernia, allergy to local anesthetic, distance from the hospital (> 90 min) and poor or no family support (Table 3).

We have enrolled six patients so far, aged between 23 and 69 years. After having undergone clinical and hematochemical examinations and after having being evaluated by the anesthetist, the patient, on the day of the operation, arrives in the hospital where he is prepared for the operation in a room next to the operating room. He walks to the operating room, lies down and, while informed of what is happening, undergoes the operation.

Local anesthesia is carried out in different stages with direct infiltration of the ilioinguinal, iliohypograstric, genitofemoral nerves with 10 ml of 2% carbocaine (mepivacaine), 10 ml of 0.5% marcaine (bupivacaine), tamponing with 5 ml H_2CO_3 and diluted with 75 ml NaCl. On average, we use 60% of the anesthetic solution. In no case has it been necessary to use general anesthesia.

According to Trabucco's technique, a 4–6-cm incision is made and we expose the external oblique aponeurosis, which is opened to the level of the external inguinal ring. After having prepared the inguinal canal and the spermatic cord, we isolate the hernia sac, taking particular care at the internal ring. We never open the sac, except in cases of strangulated hernia. It is reduced and checked to ensure that it is sufficiently free. By making the patient cough or strain, we check that it comes out easily.

We then set a polypropylene circular plug of 5 cm diameter at the internal ring level. At this stage, the coughing does not result in the hernia sac coming out. We double the fascia trasversalis with a continuous suture that goes from the pubic tubercle to the inguinal internal ring, in order to level it. We then fashion the polypropylene plug so that the lower limit goes over the pubic tubercle by about 1 cm. We set the plug on the fascia trasversalis, paying attention not to form wrin-

Table 1
Cases of hernioplasty according to Trabucco

Operations by appointment	461 (94.3%)
Emergency operations	28 (5.7%)
Males	455 (93.1%)
Females	34 (6.9%)
Average age (years)	57.9
Total no. of operations	489
Recurrences	1 (0.2%)

Table 2
Stay in hospital and kind of anesthesia

Kind of anesthesia	No. of operations	Average stay
General	51 (10.4%)	7.8 days
Epidural	25 (5.1%)	5.7 days
Spinal	192 (39.3%)	2.1 days
Local	221 (45.2%)	1.7 days
Stop and go	6	2 h

Table 3
Stop and go hernioplasty: selection criteria for patients

	Yes	No
Psychosocial conditions	Favorable	Unfavorable
Anesthesia risk	ASA I–II	ASA III–V
Obesity	<30%	>30%
Recurrent hernia	1st Recurrence	Multirecurrent
Distance from hospital	<90 min	>90 min
Family support	Present	Absent

kles or empty spaces below it, which may cause seroma, without any stitches because the pressure from the tissues themselves and the rapid fibroplastic response will fix the plug in position.

Fibroblastogenesis induced by the plug starts after 5 or 6 h. In order to avoid dislocation of the prosthesis that may be caused by the immediate mobilization of the patient, we apply in the stop and go method the human fibrin glue (2 ml tissucol spray), in order to uniformly fix the plug before fibroblastogenesis starts or at least before it develops sufficiently. Tissucol spray (2 ml) is applied on the whole of the surface of the plug so that it is fixed and also perfectly flat.

We conclude the operation by suturing the fascia and positioning the spermatic cord in a subcutaneous site. The cutis is sutured with a vicryl rapid intradermic suture that does not require removal. Once the operation is over, the patient is asked to get up and, together with members of personnel, the patient walks to his room where he dresses and goes home.

Patients are requested not to drive for 24 h, but they can resume normal activities on average on the 2nd day and manual working or sport activities from the 2nd week.

A phone number they can call for advice is given to the patient. The use of postoperative analgesics and possible postoperative complications (hemorrhages, subcutaneous hematomas, edema and/or ecchymosis of the scrotum or penis) are explained both to the patient and his relatives in order to reduce possible fear in the postoperative period.

3. Results

The initial results are very encouraging. In all the patients who have undergone a stop and go hernioplasty, we have found complete acceptance of the method. In no case has it been necessary to subject the patient to general anesthesia during the operation. The average time for the operation has been 35 min. The average stay in the hospital has been 2 h. The possibility of reaching the operating room on foot and, above all, the possibility of going back to the patient's room on foot has raised enthusiasm in the patients, no matter what their age was. No patient has needed check-ups apart from routine ones. We have had complications neither in the short nor in the long term.

In the first two cases, we had planned a clinical checkup after 24 and 72 h, and then, just like the usual follow-up, on the 7th day, after 1 month, after 6 months and then yearly for 3 years. From the third case onwards, we have decided to plan the usual check-up scheme also for the stop and go hernioplasty, unless differently required by the patient. At the 7th day check-up, we have asked the patient to fill in an operation and postoperative pain evaluation form, with grades ranging from 1 to 10. With all the patients, the initial pain evaluation was around 3–4, regarding the cutis infiltration, then the pain goes down to 1 or 2 during the operation. As for postoperative pain, we have had 1 for the first day and nothing for the following days.

The almost complete absence of pain is very different between the patients treated with the stop and go method and the ones treated with the traditional technique, for whom the pain level stays around 3–4 until the 5th day and then 1–2 until the 6th or 7th day.

This has an objective verification in the analgesic treatment required by the patients. We prescribe analgesic for 24 h, and then according to needs. The patients submitted to a stop and go procedure have not used further analgesic but the patients treated with Trabucco's classical technique have used analgesic, on average, until the 4th or 5th day.

4. Discussion

The arrival of prosthesis hernioplasty has created a real revolution in the treatment of hernias. The repair of the wall defect, at the basis of the hernia, using a mesh plug rather than using the anatomical structure of the wall, has made it possible to drastically lower the rate of recurrence, to make both short- and long-term complications almost disappear, to reduce postoperative pain and to drastically reduce the stay in hospital to a few hours.

This is due to the fact that by not using the nearby anatomical structures and by not fixing the plug onto them, the ailment due to the traction on the anatomical structures themselves disappears, and hence the postoperative pain decreases. The physiopathological basis of the plastics is based on the ability of the plug to stimulate a strong fibroblastogenesis that strengthens the weak point that caused the hernia.

In Trabucco's technique we see that the plug, set on the internal inguinal ring, is sufficient to block the hernia neck. The plug, once set on the back of the wall of the inguinal canal, makes the plastics doubly safe.

When, after a positive experience with this technique, we considered the possibility of undertaking an ambulatory treatment, our only concern was the possible dislocation of the plug because of the immediate mobilization of the patient. In fact, we know that the fibroblastogenesis begins about 5 or 6 h after the operation. This could cause an increase in terms of recurrence, both because of seroma and because of an incomplete fibrosis of the wall defect because of the dislocation of the plug.

We were driven to optimize hernia treatment both in terms of costs and in terms of the welfare of the patient

who, in an ambulatory setting, is able to have his operation without giving up the comfort of his own house. On the other hand, we feared an increase in complications and recurrences. We believed we could allay our fears by fixing the polypropylene plug with human fibrin spray glue. In this way, the plug is perfectly leveled and fixed on the back wall of the inguinal canal, at the same time eliminating the danger of seroma below the plug which, by giving rise to spaces, can cause recurrences.

The other datum that comes out in this still short experience of ours is the remarkable reduction of pain with the stop and go method. This fact, in our opinion, can be explained by two considerations. Firstly, it could be due to a better psychological approach with the patient, who is constantly informed of everything that concerns him, with a resulting decrease of the anxiogenic component of pain. Secondly, considering that the anxiogenic component is at a maximum during the operation and then should spontaneously decrease in the postoperative period, the remarkable reduction of pain could be caused by the absence of mechanical stimuli by the plug on the nerve-endings, since the plug is covered with fibrin.

This information must be verified with greater numbers than what we have so far, but it is definitely a stimulus to continue further with this experience.

5. Conclusion

Our experience with the ambulatory technique is still of too short duration to be able to draw a definite conclusion, but at first sight we can state that this kind of hernioplasty is simple to perform and gives excellent results, without complications or recurrences until the check-up after 1 month. The patients themselves like this method both for the low pain and for the possibility of performing the operation under local anesthesia, and also because it allows them to go back home and quickly resume normal activities. The results we have so far have also proved that this technique is handy and does not depend on the surgeon. In our division, all the surgical operators have performed it, obtaining the same results. We can thus conclude that the hernioplasty according to Trabucco, using human fibrin glue to immediately fix the plug, makes it possible to perform the operation in an office-based surgical suite, makes it possible to keep the costs at a low level with a more rational use of hospital beds and allows the patient to have his problem solved without giving up the comfort of staying in his own home.

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New opioids in 1-day surgery

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Abstract

The development of 1-day surgery has determined the need to adopt anaesthetic techniques that allow a quick discharge. While this is possible with loco-regional techniques, general anaesthesia has a longer recovery period because of the pharmacological profile of currently available drugs. Over the last few years, pharmaceutical research has been developing new drugs that guarantee a rapid elimination and a predictable offset to be employed in day surgery. Among these drugs, remifentanil is a new opioid which seems promising in regard to these characteristics. In this review we present pharmacokinetic and pharmacodynamic characteristics of remifentanil and the possible clinical implications that result from its use in 1-day surgery. © 1997 Elsevier Science Ireland Ltd.

Keywords: Anesthesia; Opioid; Remifentanil; Surgery

1. Introduction

New demands regarding the management of the surgical patient arise from the need to reduce the postoperative period and recovery as much as possible and the attempt to treat 'routine' patients with 1-day surgery when possible.

As regards intravenous analgesics used intraoperatively, no drug responds adequately to these new demands. In fact, the only intravenous drugs that provide an efficacious intraoperative analgesia are synthetic opioids. Opioids employed today, however, are characterised by pharmacokinetic properties which make their use unpredictable. Their relatively long duration of action (the opioid with the shortest duration of action is alfentanil: $t_{1/2\beta} = 90$ min) potentially delays the patient's recovery time and their redistribution from the tissues to the blood could cause late adverse effects.

In the last few years, new anaesthetic agents with a shorter duration of action have been studied and commercialised. Examples include muscle relaxants (mivacurium and rocuronium), a hypnotic agent (propofol) and new halogenated agents (desflurane and sevoflurane).

As for the opioids, it is only recently that a new compound that could respond to the recent demands in anaesthesia has been developed. This compound, like its precursors fentanyl, sulfentanil and alfentanil, belongs to the anilidopeperidine class with a difference in the chemical structure: an ester linkage which has the property to undergo hydrolysis by non-specific blood and tissue esterases. Among these opioids called esterase-metabolised opioids (EMO), remifentanil is the first to be commercialised and is actually in phase III study both in Europe and in the United States.

The aim of this paper is to analyse the real advantages of this new drug intraoperatively as well as postoperatively with particular attention being paid to the pharmacokinetic and pharmacodynamic properties described in the literature to date.

2. Pharmacology

Remifentanil is a hydrochloride salt of 3-[methoxycarbonyl-4-[(1-oxopropyl)phenylamino]-1-piperidine] propanoic acid methyl ester. Its chemical structure is similar to that of fentanyl, alfentanil and sulfentanil,

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since they all belong to the same 4-anilidopiperidine structural class.

Remifentanil has been synthesised by the substitution of the aryl groups of the 4-anilidopiperidine structure with a lipophilic group (methyl ester). This new structure maintains the characteristics of the aryl group binding, but the enzymatic breakdown by esterases forms a polar group which has a lower affinity to the sites of action of the drug [1].

Since remifentanil is a very unstable compound, it is available as a lyophilised powder which contains free bases and glycine with the addition of hydrochloric acid or sodium hydroxide to reach a pH of 3.0. It is soluble in water ($pK_a = 7.07$) and can be prepared for injection with water or 5% dextrose solution [2].

The most important and singular pharmacokinetic characteristics of remifentanil concerns its metabolism. In fact, this drug is metabolised primarily by non-specific blood and tissue esterases. A total of 90% of the drug is de-esterified, forming a carboxylic acid, GI-90291 [2], which is eliminated with the urine without further changes [3]. A smaller part is converted to GI-94219 by an *N*-dealkylation [2]. Thus, unlike other opioids, only a minor part of remifentanil undergoes hepatic metabolism.

This is confirmed in the literature by elevated clearance values which are 3–4 times above the hepatic blood flow rate (Table 1).

The clearance of remifentanil (34.7–71.4 ml/kg per min) is higher than that of other fentanyl derivates since the clearance of fentanyl is 10–20 ml/kg per min, of sulfentanil 10–15 ml/kg per min and of alfentanil 4.2–9.0 ml/kg per min.

It seems that a fast elimination rather than the redistribution is responsible for the loss of the therapeutic effect of remifentanil [2].

As regards the distribution volumes (V_{ss}) analysed to date, they appear to be comparable to those of alfentanil. In a study in 1993, Egan et al. reported for remifentanil a V_{ss} of 31 ± 7.4 l [4] and in another randomised, crossover and comparative study between remifentanil and alfentanil, the V_{ss} for two opioids was found to be 22.4 and 38.2 l, respectively [5]. The V_{ss} of fentanyl and sulfentanil, however, are higher (280 and 173.9 l, respectively) because of their higher liposolubility.

Table 1
Remifentanil and alfentanil clearances [3–6]

References	Remifentanil	Alfentanil
Egan et al., 1993 [4]	40.0 ml/kg per min (168 l/h)	—
Westmoreland et al., 1993 [6]	58.6–71.4 ml/kg per min (246–300 l/h)	—
Glass et al., 1993 [3]	41.2 ml/kg per min (173 l/h)	9.0 ml/kg per min (37.8 l/h)
Egan et al., 1994 [5]	34.7 ml/kg per min (146 l/h)	4.2 ml/kg per min (17.6 l/h)

The half-life of distribution for remifentanil ($t_{1/2a}$) is 0.9 min, which is lower than that of fentanyl (15–20 min) and alfentanil (4–17 min). The half-life of elimination ($t_{1/2\beta}$) of remifentanil is 9.1 min [4,5], which is definitively lower that those of the other opioids: 120–240 min for fentanyl, 120–180 min for sulfentanil and 60–120 min for alfentanil.

Nothing has been published concerning the protein linkage of remifentanil, but Egan et al. [5] suppose that the drug binds to a high extent to plasma proteins, as do other opioids.

Egan et al. [4,5] and Westmoreland et al. [6] state that remifentanil has a linear pharmacokinetic which can be confirmed by the evidence that the total clearance and the V_{ss} are independent from the dose after bolus injection of 5–30 mg/kg as well as after 20 min of an infusion of 1–8 mg/kg per min of the drug.

As mentioned before, the main metabolite of remifentanil, GI-90291, is eliminated without further alterations by the kidneys. Consequently, renal impairment significantly prolongs the half-time of elimination. However, no specific clinical problems resulted in these cases, since GI-90921 is, in fact, a mu-agonist with an affinity for the mu-receptors, but this affinity is only 1/300 to 1/1000 that of remifentanil.

It seems from different published studies that remifentanil could be used without particular restrictions in patients with renal or hepatic impairment [7–10]. Moreover, no alterations in the pharmacokinetic parameters with regard to gender, age, weight and height have been documented so far [2,6].

Finally, a defect in pseudocholinesterase appears not to influence the pharmacokinetics of remifentanil. In vitro tests demonstrated that remifentanil is not a valid substrate for the butirilcholinesterase (pseudocholinesterase) [2]. In vivo, this drug does not seem to interact with succinilcholine, which is also metabolised by the pseudocholinesterase.

Many authors use a particular concept to compare the pharmacokinetics of the different opioids: the 'context-sensitive half-time' [3,4,6]. It is defined as the time needed to reduce the drug concentration by 50% after the interruption of a continuous infusion aimed at maintaining a constant plasma concentration (the context is the duration of infusion). The context-sensitive half-time is useful for drugs that, like opioids, present a complex three compartment pharmacokinetic profile and for which the half-time of elimination does not reflect the global degradation curve of the drugs.

Hughes et al. [11] stated that the context-sensitive half-time allows a more significant graphic representation of some pharmacokinetic parameters.

The context-sensitive half-time of remifentanil is very short (3–5 min) and does not increase with an increase of the infusion rate [3–6,12] Other opioids show a context-sensitive half-time which directly depends on the duration of administration and is found to be noticeably longer than that of remifentanil [2].

Kapila et al. [12] suggested that the time needed to reduce the concentration of remifentanil at their action sites of 80% is about 5 min. This corresponds approximately to the time needed to make the patient able to leave the operation theatre.

Like other 4-anilidopiperidine opioids, remifentanil interacts as a mu-receptor agonist [12]. Naloxone acts as an antagonist [13], whereas antagonists selective for other subtype receptors have no effects.

The alterations on the EEG caused by remifentanil are those of other opioids, namely, an increased amplitude and a decreased frequency of the EEG waves [14]. The potency of remifentanil is slightly inferior to that of fentanyl [15] and, as different authors suggest, 16–50 times greater than that of alfentanil [3,16,17].

The main metabolite, GI-90291, has a markedly weaker action. Cunningham et al. [18] estimate the potency to be 1/300 to 1/1000 that of remifentanil. Nevertheless, other studies are needed to establish whether or not this metabolite prolongs the duration of action of remifentanil in patients with renal impairment.

The speed of onset of the therapeutic effect of remifentanil is very fast, similar to that of alfentanil. Egan et al. [16] states that the $t_{1/2ke0}$ of remifentanil is 1.41 min and that of alfentanil 1.13 min; $t_{1/2ke0}$ is defined as the delay between the achievement of a peak blood concentration and the pharmacodynamic peak effect of a drug.

Side effects of remifentanil are comparable to those of the fentanyl-family opioids. In particular, respiratory depression appears early—as with alfentanil—but has a much shorter duration [3].

Cardiovascular effects of remifentanil are similar to those of other fentanyl derivates and are caused by a increased vagal nerve activity mediated by the CNS and not due to histamine release [2].

Remifentanil also determines nausea, vomiting and muscular rigidity [3,4].

3. Therapeutic considerations

An intraoperative intravenous opioid should have the following characteristics:

1. rapid onset of action
2. rapid and foreseeable response to dosage variations
3. intraoperative haemodynamic stability
4. absence of accumulation and consequently no effects at distance even after a prolonged administration
5. no adjustment of the dosages is necessary in patients with renal or hepatic impairment, or for other variables such as gender, age, weight and height
6. reduction of hypnotic agents and other sedatives
7. rapid resolution of the effects and early recovery from anaesthesia
8. cost reduction.

Based on the pharmacokinetic and pharmacodynamic data previously described, it seems that remifentanil meets these demands. In fact, its esterase metabolism renders the action of remifentanil foreseeable and its use easy, since no accumulation phenomena have been observed and recovery from anaesthesia is rapid. The short action of the drug may allow a continuous adaption of the dosage to the intraoperative pain intensity, which varies significantly in different surgery periods. This would result in a better balance of anaesthesia with a more specific and adequate opioid use.

There seem to be no limitations of use in patients affected by renal or hepatic impairment, or in elderly patients. Moreover, it seems to improve haemodynamic stability due to a better tolerability during the different phases and to a dosage reduction of other hypnotics (propofol [19], tiopentale [16] and isoflurane [20]) and the need for anaesthesia, and not because of a reduced cardiovascular depressant effect compared with other opioids. The reduction of hypnotics may not only have clinical advantages but also economic effects. In fact, a polypharmacological treatment to maintain an adequate anaesthesia stage is not always the most economic one since expensive drugs such as propofol and last-generation halogenates must often be associated. In addition, delivery systems and sophisticated monitoring are required.

The real economic advantages of remifentanil may not depend on a more limited anaesthetic drug consumption but on a reduction of induction, recovery and discharge times in anaesthesia. In fact, the rapid recovery from anaesthesia and the absence of a drug redistribution from the tissues to the blood reduce the risks of delayed effects and allow a rapid discharge of the patients from the operating theatre. This improves the management of the operating rooms and reduces the need for recovery rooms which are, however, rare in Italian hospitals.

The characteristics of remifentanil could make it useful in 1-day surgery and in invasive and painful diagnostic procedures that require adequate analgesia and a rapid recovery of consciousness. Remifentanil may thus be a first-choice drug for these procedures and render them safer. Physicians would thus be stimulated to employ 1-day surgery and diagnostic methods with a consequent reduction of hospital recoveries and correlated costs.

Table 2
Recommended starting infusion rates and dose ranges for remifentanil

Indication	Remifentanil bolus infusion (μg/kg)	Remifentanil continuous infusion (μg/kg per min)	
		Starting rate	Range
Induction of anaesthesia in ventilated patients	1	0.5–1	—
Maintenance of anaesthesia			
Nitrous oxide (66%)	—	0.4	0.1–2
Isoflurone (starting dose 0.5 MAC)	0.5–1	0.25	0.05–2
Propofol (starting dose 100 μg/kg per min)	—	0.25	0.05–2
Parenteral analgesia in immediate postoperative period	Not recommended	0.1	0.025–0.2
Anaesthesia in spontaneous ventilation	Not recommended	0.04	0.025–0.1

Remifentanil, like other fentanyl derivates, has some negative aspects. As with other opioids, respiratory depression, nausea, vomiting, bradycardia, hypotension and muscular rigidity are common. However, the most important problem associated with remifentanil, especially for those who have little experience with this drug, is the rapid loss of the analgesic effect after the interruption of drug administration.

This effect is inconvenient if it happens during anaesthesia but it may also be annoying shortly after recovery. In this period the patient perceives pain with maximum intensity. It is therefore advisable to administer the drug in a continuous manner, preferably with a continuous infusion device (pump), throughout the whole duration of the surgery until the closure of the skin, with the dosages proposed in Table 2. Once the patient has recovered from anaesthesia, adequate analgesic therapy should be set up as soon as possible.

Today nothing can be said about the utility of remifentanil for postoperative pain since clinical experience is lacking.

Continuous intravenous infusion during the postoperative period in hospitalised patients has given positive analgesic results, so far without side effects or dangerous inconveniences for the patient.

Remifentanil has not yet been proposed for the treatment of chronic pain but it may be interesting to evaluate its use in boluses for breakthrough pain.

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New muscle relaxants for anesthesia during 1-day surgery

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Abstract

In the last few years, the growth of 1-day surgery and the introduction of new techniques have increased the need for general anesthesia with endotracheal intubation and mechanical ventilation. The end point of 1-day anesthesia is early patient discharge home. Therefore, new muscle relaxant agents have been propounded to anesthetists to achieve this. In this paper, we analyze pharmacological and clinical characteristics of available newer muscle relaxants and evaluate their possible use in 1-day surgery.
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Keywords: Anesthesia; Muscle relaxant; Neuromuscular block; Surgery

1. Introduction

In the last few years, 1-day surgery has progressively gained importance. In fact, 60% of the patients in the US scheduled for surgery are at present treated in an outpatient setting [1].

The aim of 1-day surgery is to achieve a good therapeutic result and an early patient discharge from hospital. This makes it necessary to adapt '1-day anesthesia' which includes adequate patient selection and anesthesia that provides a rapid recovery of patient autonomy. The introduction of new surgical techniques (laparoscopic surgery, for instance) extends the indications for 1-day surgery and increases the need for general anesthesia with endotracheal intubation. Therefore, muscle relaxants are of major importance in the clinical practice of 1-day anesthesia, since they permit tracheal intubation and mechanical ventilation and facilitate the surgical procedures [2].

Muscle relaxants act on the neuromuscular junction and can be classified into two groups: agonists or depolarizing muscle relaxants and competitive or non-depolarizing muscle relaxants.

Depolarizing muscle relaxants bind to the receptor and mimic the action of acetylcholine, a neuromuscular mediator. Since these drugs are not inactivated by acetylcholinesterase, they bind to the receptor for a longer time than acetylcholine. The consequence is a prolonged depolarization of the end plate and a neuromuscular block through a mechanism of desensibilization [3,4].

Non-depolarizing muscle relaxants have a competitive action with acetylcholine at the receptor site. After binding to the postsynaptic receptor, they block the ion channel and the ion flow through it. Therefore, the membrane is not depolarized and the muscle becomes flaccid [3–5]. They are classified in benzylisoquinolinium compounds, quaternary amines and aminosteroid compounds [3].

In the last 4 years, four new non-depolarizing muscle relaxants (pipecuronium, rocuronium, doxacurium and mivacurium) have been commercially available. They have been synthesized in an attempt to find the drug with the ideal pharmacokinetic and pharmacodynamic profile for specific surgical needs. Moreover, other muscle relaxants such as cisatracurium, a stereoisomer of atracurium, have been clinically tested.

In this paper, we analyze the pharmacological characteristics of these new muscle relaxants for anesthesia and their possible use for anesthesia during 1-day surgery.

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1.1. Pipecuronium

Pipecuronium is a long-acting muscle relaxant which provides an ideal condition for tracheal intubation approximately 150–300 s after the administration of a dose of 0.05–0.07 mg/kg [4,6]. The time of recovery from neuromuscular block varies significantly in the different studies, which is also due to the diverse parameters considered. At a dose of 0.07 mg/kg, the recovery of 25% of the response to the first twitch of train of four (T_1 25%) is 95 min, while the recovery of T_1 75% is 136 min [6]. At a lower dose (0.05 mg/kg) the recovery of 90% of the response to the first twitch of the train of four (T_1 90%) is 90 min [4]. Pipecuronium is an aminosteroid with an elevated renal excretion (38%) and a reduced hepatic elimination (2%) [7]. In patients with renal impairment, the prolonged half-life of elimination (275 vs. 127 min in healthy patients) and the reduced clearance (1.5 vs. 2.5 ml/kg per min) make this drug unsuitable [8]. Pipecuronium, like other aminosteroids, is deacetylated in the liver, and its clearance may thus be prolonged in patients with hepatic impairment. Even though the percentage of drug excreted in bile in 24 h is low, its elimination may be reduced by an extrahepatic biliary obstruction [3].

1.2. Doxacurium

Doxacurium is a benzylisoquinolinium compound with a very slow onset of action: the onset time is 6 min at a dose of 0.05 mg/kg [9] and 10–14 min at a dose of 0.025 mg/kg [4]. The duration of action is long. The recovery of T_1 75% is 116 min at the dose of 0.05 mg/kg, while the recovery of T_1 90% is 80–100 min at the dose of 0.025 mg/kg [4,9]. Plasma hydrolysis is not significant since this drug is excreted unchanged through the kidney at percentages ranging from 25 to 90% [2,10,11]. Renal impairment reduces its clearance and prolongs the half-time of elimination [10], increasing the pharmacodynamic effects [12]. The contemporary use of volatile anesthetic agents reduces the required dose of doxacurium by 20–40% if compared with the administration of N_2O and fentanyl [13]. It releases little histamine and has no cardiovascular effects [4].

1.3. Rocuronium

Rocuronium is a monoquaternary aminosteroid compound with a rapid onset time and an intermediate duration of action [14–18]. The onset time of the neuromuscular blockade after the administration of a bolus of 0.6 mg/kg is about 60–70 s with a duration of action measured by T_1 25% and T_1 75% of 43 and 66 min, respectively [17,18]. This drug does not seem to induce significant variations in histamine release and guarantees, therefore, a good hemodynamic stability [4,19]. Some authors, however, suppose an important vagolytic effect [18]. The potency of rocuronium is a seventh of that of vecuronium [4] and approximately 30–33% of the drug is excreted through the kidney [20,21]. The pharmacodynamic effects of the drug are similar in patients with renal impairment and in healthy subjects even if an increased distribution volume of the compound and a prolonged half-time of elimination have been observed in patients with renal impairment [22]. Other authors hypothesize that the administration of rocuronium in these patients prolongs the clinical effects [21]. This drug has been used at a dose of 6 mg in 50 patients as a pretreatment 60 s before induction of anesthesia with succinylcholine (1.5 mg/kg). In these patients, fasciculation due to depolarization was reduced to 8% and the incidence of myalgia within the 4th postoperative day decreased to 20–28.6%, making it significantly more efficacious than vecuronium [23].

1.4. Cisatracurium

Cisatracurium is a non-depolarizing benzylisoquinolinium muscle relaxant of intermediate duration of action. It is a purified stereoisomer of atracurium 3 times more potent but with a slower onset of action [24–28]. Its elimination occurs spontaneously in an organ-dependent manner by non-enzymatic hydrolysis (Hofmann elimination: degradation rate depends on the patient's pH and temperature producing laudanosine and a monoquaternary acrylated metabolite which undergoes hydrolysis by a non-specific plasma esterase). However, hydrolysis of cisatracurium by plasma esterases is not the most important pathway for the elimination of the drug [29,30] and this drug can, therefore, be used in patients with renal and/or hepatic impairment [31]. A lower histamine release than with atracurium has been described [32].

1.5. Mivacurium

Mivacurium is the only non-depolarizing muscle relaxant with a short duration of action. This drug is a bis-benzylisoquinolinium diester which is rapidly hydrolyzed by plasma cholinesterases at a percentage of about 88% compared with succinylcholine [33] and is degraded to only partially active metabolites [34,35]. At equipotent doses, the onset time of mivacurium is comparable to that of atracurium [11,33]. The onset time is not always predictable since it is influenced by some factors difficult to evaluate, such as muscular perfusion and circulation [36]. The induction bolus (0.20–0.25 mg/kg) provides good conditions for endotracheal intubation (abolition of 95–100% of T_1) within a time period ranging from 90 to 150 s from the administration [4]. Other authors report that the mean onset time

of mivacurium is longer (229 s) [37]. The duration of action is 6–8 min if measured with the recovery index (time for recovery of T_1 from 25 to 75%) and 25 min if measured with the recovery of T_1 90% [4]. The functional recovery from neuromuscular blockade is 2–3 times faster with mivacurium than with atracurium [11,33]. These data are confirmed by other authors who demonstrated that the clinical duration and the recovery from neuromuscular blockade assessed by means of the recovery index are significantly shorter with mivacurium (13 and 6 min, respectively) than with rocuronium (28 and 11 min, respectively), administered in a single dose during a general balanced anesthesia [37]. In order to maintain an adequate neuromuscular block, mivacurium can also be administered by continuous infusion since its short plasma half-life does not determine accumulation at doses of 6–7 μg/kg per min. The association of volatile anesthetic agents (halothane and isoflurane) and children increases the potency of the curare, reducing the dose requirements of infusion by 32 and 70% from the initial infusion rate after 30 and 80 min, respectively [38]. The short duration of action of mivacurium does not usually make the use of antagonists necessary [39]. Many authors report a functional inhibition of plasma cholinesterases due to the administration of anticholinesterase drugs such as neostigmine. Therefore, in cases requiring the use of an antagonist, edrophonium should be administered, because it does not interfere with the plasma cholinesterase activity and it provides a much faster recovery from neuromuscular block than neostigmine [39,40]. Others disagree with the use of edrophonium and suggest the use of neostigmine–pyridostigmine [41–43]. In patients with renal or hepatic impairment, plasma cholinesterase activity is reduced [44] and the distribution volume increased. Consequently, the duration of the block in these patients is increased by 30–50%. The recovery from neuromuscular blockade is shorter in small children (< 10 min), and prolonged in the elderly, in renal- or hepatic-impaired patients and in heterozygotes for plasma cholinesterase. Known or probable homozygosis (about 1:2500 to 1:3000 patients) is a contra-indication for the use of this drug since variably prolonged blocks (> 3 h) may appear [45].

2. Therapeutic considerations

Before the introduction of the non-depolarizing muscle relaxants with intermediate duration of action, succinylcholine was the most used neuromuscular blocker in 1-day surgery [2], due particularly to its short onset and offset time. On the one hand, succinylcholine has unquestionable advantages but, on the other hand, its clinical use over the years has evidenced many problems. Its parasympathetic mimetic activity may be responsible for sinus bradycardias (especially in children) and for episodes of bradyasystolic arrest described after a repeated dose in adults [2,4]. Besides, the incidence of myalgia after the administration of this drug varies from 0.2 to 89%, with a higher frequency in females and after minor surgery in outpatients, where the analgesic consumption is reduced. These muscular pains may be of severe intensity and last up to 4 days. Many authors suppose a correlation between muscle pain and muscle damage caused by a desynchronized contraction (fasciculation) which appears in the first phase of pharmacological muscle paralysis [2–4,24,46–50]. There are also many reports which describe the occurrence of hyperkalemia after administration of succinylcholine, especially significant in the presence of some pathologies such as burns, trauma, neuromuscular diseases, head injury, abdominal infections and renal impairment where a marked release of potassium could cause cardiac arrest [2,3,51,52]. Succinylcholine seems also to be responsible for increased intragastric, intra-ocular and intracranial pressures [2–4,53–55]. Finally, this drug is one of the main trigger substances of malignant hyperthermia, a rare but potentially fatal muscular disorder [56].

The non-depolarizing muscle relaxants currently used in 1-day surgery (vecuronium and atracurium) have specific advantages over succinylcholine in terms of adverse effects, but they also have a slower onset of action and a longer duration of action.

Among the new muscle relaxants, pipecuronium and doxacurium do not appeal to anesthetists practising '1-day anesthesia'. In fact, these drugs are long acting [57] and do not allow a rapid recovery and an early discharge of patients.

Rocuronium and cisatracurium, which are intermediate-acting muscle relaxants, seem to be more interesting in the clinical setting of 1-day anesthesia. Rocuronium has the most rapid onset of action compared with the other non-depolarizing agents, providing good intubating conditions within 60 s [23]. It seems to guarantee a good hemodynamic stability [4,19] and its onset of action, which is almost as rapid as that of succinylcholine, may be useful in patients with residual gastric contents [4]. Besides, rocuronium pretreatment is particularly effective in reducing fasciculation and myalgia due to succinylcholine and, in this respect, rocuronium is superior to vecuronium [23]. Cisatracurium may be considered the compound of choice for patients with renal or hepatic failure [31], and produces lower histamine release than atracurium [32].

There is no doubt that the muscle relaxant of major interest for use in 1-day surgery is represented by mivacurium, because of its short offset time. The onset of action is similar to that of atracurium and vecuronium, but recovery from the blockade is much more rapid [4]. Mivacurium appears to be the drug of choice

when a rapid and spontaneous recovery from neuromuscular blockade is indicated [37]. Besides, as reported by some authors [58,59], avoiding the administration of antagonists (neostigmine/atropine, neostigmine/glycopyrrolate) decreases the incidence of postoperative nausea and vomiting, adverse effects that limit an early patient discharge. Transient significant histamine plasma levels with consequent cutaneous flushes and transient hemodynamic changes after a rapid administration (5 s) of boluses of mivacurium have been reported by some authors [19,60], but no statistically significant alterations of the hemodynamic values (heart rate and arterial pressure) were reported after slower infusion of boluses (15 s) either in young or in elderly patients [60].

In conclusion, all old and new non-depolarizing intermediate or short-acting muscle relaxants may be considered for intermediate or long lasting 1-day surgical procedures, but mivacurium chloride represents today the first choice for short procedures, due to its pharmacokinetic and pharmacodynamic characteristics.

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Ambulatory Surgery

Proposal for a diagnostic–therapeutic protocol in the handling of the day surgery patient (based on our experience in 1995)

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1. Introduction

The administrative evolution which has been going on in our country for the last few years has made it necessary to face economic–health problems that had not previously been considered in Italy. The prospect is that health funding will not be replenished as needed, but financed on the basis of new parameters dictated by the Ministry of Health and the regional administration. Therefore, since the end of 1994, we have instituted diagnostic–therapeutic protocols so as to optimize health spending at least for those groups of diseases treatable within a 24-hour period without medico-legal sequelae. This has been made possible as a consequence of the evolution of newer anesthetic and micro-invasive surgical techniques.

2. Materials and methods

We have examined hernia, vein, hemorrhoid, breast and endoscopic surgery, together with other such pathologies, treated in the period from January 1 to December 31, 1995 in the Institute of Clinical Surgery and Surgical Specialties of the University of Siena.

The diagnostic–therapeutic protocol has been applied in 155 cases of lower limb varicose vein ligature and stripping, 139 hernioplasties with prothesis application, 37 hemorrhoidectomies, 13 minor breast operations (mammary biopsies and quadrantectomies), and 21 colonoscopic polypectomies which required a day hospital treatment regime for control of possible bleeding complications.

The diagnostic protocol has been taken on in a pre-hospitalization regime by first having the patients undergo a group of hematological examinations, developed in agreement with the anesthetists, chest X-ray, ECG, and an anesthetic visit prior to operation (Table 1).

Once this phase has been completed, which takes about a single morning, the operation date is set within 3–10 days. This variability was a consequence of the availability of the operating tables and of the characteristics of the major operations, since we do not yet have, as we hope to do in the near future, an operating table exclusively for this type of surgery.

Patients were discharged on the same day of operation after an accurate check of their vital parameters, consciousness levels, movement control and sphincter control. All patients were given a medical support number for any problem which might arise until their next hospital visit.

Utilizing disease related groups (DRGs), we calculated the gross income of the treatment of these pathologies, both in a day surgery (DS) regime and in a normal average 8-day hospital regime.

For venous pathology, if we, as in the past years, were to have gone through an ordinary admission, our clinic would have gained £539 555 000, while utilizing the DS method we gained £404 705 000. For hernia surgery, we changed from £368 350 000 to £276 332 000; for hemorrhoid pathology from £104 895 000 to £78 662 000; for breast surgery from £36 400 000 to £27 391 000; for colonic polypectomy from £56 700 000 to £10 626 000.

From our clinic's budget, we have subsequently been able to calculate the average cost of a hospital bed stay per day considering all the specific points for these types of pathologies, averaging £540 000. If we multiply this last number for the days of average stay for our section, which in this last year has come to be 8 days, we obtain the expense of £4 320 000.

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From this last result we can deduce that for lower limb varicose vein stripping, utilizing a normal hospital bed stay we would have lost £130 045 000, while utilizing the DS regime we gained £321 005 000; for hernia pathology we would have lost £232 130 000, while in the DS regimen we have gained £201 272 000; for hemorrhoid pathology in ordinary admittance we would have lost £54 945 000, while in the DS regimen we have gained £58 682 000; for breast pathology in ordinary admittance we would have lost £19 760 000, while in the DS regimen we have gained £20 371 000. Finally, with endoscopic colon polypectomy, paradoxically, both in a DRG regime and in a DS regime we would have lost £34 020 000 and £714 000, respectively. If, for this type of pathology, we had utilized a short-DRG regimen, this being 2 nights of in-hospital stay, we would have gained £34 860 000.

Table 1
Standard examinations: protocol 1

(1) Hematological exams:
- Hemogram + leukocyte count
- Azotemia, creatininemia
- Electrolytes
- Glycemia
- Biluribin
- Transaminases
- γ-GT
- Alkaline phosphatase
- PT, aPTT
- Blood group

(2) Complete urine examinations
(3) Parenchyma chest film
(4) ECG

Therapeutic protocol A

(1) Pathologies to operate on:

Pre-op.	Antibiotic prophylaxis 07:00 with a monodosage antibiotic (3rd generation cephalosporine)
Post-op.	
Day 0	Normal saline 500 ml + Vit. K 1 amp. + Vit. C 1 amp. + anti-H_2 1 amp. (x3) Diclofenac 1 amp. i.m. if needed (maximum 3 amp./day) Ca–heparine 0.2 × 2 subcut. **For DS patients, dismissal the same evening**
Day 1	Normal saline 500 ml + Vit. K 1 amp. + Vit. K 1 amp. + anti-H_2 1 amp. (×2) Monodosage antibiotic Ca–heparine 0.2 × 2 subcut. Diclofenac 1 amp. i.m. if needed 1st Diet
Day 2	Monodosage antibiotic Ca–heparine 0.2 × 2 subcut. Diclofenac 1 amp. i.m. if needed 2nd Diet Patient can start to walk **Dismissal for short-DRG patients**

(2) Pathologies not to operate on:
As with protocol sub-1, excluding i.v. therapy
Free diet

Economic balance of final costs up to Dec. 31st, 1995

Reagent materials	2 400 000
Photo materials and diagnostic papers	3 400 000
Pharmaceutical and dialysis materials	245 600 000
Medicines	556 000 000
Pharmaceuticals bought directly	3 000 000
Economal products (pens, paper, staples etc)	38 400 000
Sanitary economal products	41 600 000
Maintenance	67 000 000
Telephone	30 800 000
Heating	141 600 000
Electricity	65 000 000
Town gas and water	38 200 000
Cleaning costs	32 800 000
Goods with absorbable costs	18 000 000
Diagnostics	1 053 800 000
Operating rooms	2 186 600 000
Alimentaries	395 000 000
Laundry	142 600 000
Sterilization	56 400 000
Sanitary physics	4 200 000
ER	260 400 000
Radiology	513 600 000
Dependant personnel	2 232 400 000
University-appointed personnel	478 200 000
Administrative services	465 000 000
Sanitary services	124 200 000
Various expenses	177 200 000
Total	9 373 400 000
Daily expenses/pat.	540 000

3. Conclusions

With the new health financial regulations we have found the need to coordinate our productivity with the new DRGs. Thus, we regularized our clinic's internal organization, so as to standardize our work and to reduce to a minimum time losses and improper admittances, and reconcile the least possible hospital stay time with the same safety standards. From our analysis, the optimal hospital stay is a DS regime which allows for a 75% DRG tariff reduction pay from the regional administration. This result being quite advantageous for diseases such as inguinal hernia, varicoceles, lower limb varicose veins, hemorrhoids and benign breast pathologies for their low post-operative risk and a high

DRG in the DS regime. However, for endoscopic polypectomies, the best treatment is a short-term DRG (2-night hospital stay). The net gain of £600 606 000 will be utilized to try to balance the net negative DRG of other hospital stays.

It is important to highlight that this proposal is preliminary, because from January 1996 we are studying the possibility to apply diagnostic–therapeutic protocols to other pathology groups to treat both in a DS regime and in a short DRG regime. The latter means an ordinary admittance that allows a patient to remain in the hospital for at least 2 nights and whose cost is thus limited to £1 080 000.

Due to the rapid evolution of computerized systems and the importance of a better rationale in diagnostic–therapeutic stays, over the last 3 months we have been conducting a test run on the computerization of our clinic for its clinical–administrative–educational handling, utilizing the same protocols stated above. A computerized clinical journal is already under way and all administrative data that we have or will possess in the near future will be computerized.

We also hope that the Tuscany Regional Administration will undergo a critical review of the DRG table based on the data we collected in our clinic for the region itself in the month of May last.

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Ambulatory Surgery

Mivacron in ear nose and throat pediatric day-surgery: a comparison vs. atracurium

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1. Introduction

Tonsillectomy and adenoidectomy are considered minor surgery and can be performed under local anesthetic. But these operations, when performed under local anesthesia in children can provoke psychological shock, because of the sight of the operating room and the medical staff. We operate under general anesthesia when the patient is a child, thus avoiding psychological trauma as well as the coercive immobilization manoeuvres necessary to safely manage the patient [1].

For these reasons the authors have studied and compared two non-depolarizing muscle relaxant drugs: the new drug mivacurium chloride (MIVACRON) and the classic atracurium besilate (TRACRIUM) in ear, nose and throat Pediatric Day Hospital Surgery. The most interesting features of these two drugs in a Day Hospital setting is their rapid onset time and their equally rapid recovery time [2]. Our aim was to evaluate the two drugs and to decide which was more suitable for use in Pediatric Day Hospital Surgery.

2. Methods

50 pediatrics patients, 36 male and 14 female, aged from 4 to 12 years old, with mean weight of 33 ± 16 kg, that underwent tonsillectomy and/or adenoidectomy have been studied. The 50 patients were randomly assigned in two groups: G.A. (group atracurium) and G.M. (Group mivacurium) of 25 units each. Surgery mean time was 25 ± 5 min. The anaesthetic technique used was common in both groups: premedication with atropine 0.01 mg/kg and diazepam 0.15 mg/kg effectuated with thiopental (TPS) 4–5 mg/kg per i.v. way followed, per maintenance, from isoflourane 1% in $0_2 + N_20$ at 1:2 proportion. Neuromuscular blockade (NMB) was obtained, in G.A., with atracurium 0.5 mg/kg followed eventually by 0.05 mg/kg boli. In G.M. mivacurium chloride (MIVACRON) was utilized 0.2 mg/kg, in NaCl 0.9% at 1:1 proportion, infused in 30–40 s immediately before TPS and followed by 0.1 mg/kg boli per maintenance. The E.C.E.; H.R.; M.A.P.; T.O.F. 95 and 25–75% were monitored. Intubation, in the preoperative period, by Mallampati test and in induction of NMB by Cormack score and Wilson modified scale were evaluated. Two muscle relaxant drugs were administered during the maintenance period. The characteristics of intubation were evaluated by the anaesthetist using a four step score (excellent, very good, tolerable and difficult). The eventual phenomena of histamine release and side effects were recorded in both groups.

Female	14
Male	36
Age	4-12 years
Mean weight	33 ± 16 Kg

3. Results

All children showed Mallampati test of status I–II; in 43 patients (86%) the Cormack score was grade I and in 7 patients (14%) grade II. For all patients the Wilson modified scale was of A grade. In both groups, that were homogeneous, abduction of the vocal cords was very good/excellent for all patients and occurred in max 120 s with easy subsequent intubation. The vital parameters did not show variations due to muscle relaxant drugs and remained normal in all patients. The total consumption of MIVACRON, in maintenance period, was 2 boli in 7 patients (28%) and 3 boli in 11

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(44%), whereas in 7 younger patients (28%) the induction bolus alone was sufficient, since they were adapted to a mechanical ventilator and showed no activity because of the isoflourane NMB effect. In G.M., recovery occurred in a mean of 12 min from the last dose of the drug, whereas in G.A. mean recovery time was 45 min max from last dose. No further doses of the drug were necessary in G.A. because the inductive dose and the isoflourane were enough to maintain the N.M.B. effect. It should be emphasized that flushing due to histamine releasing occured in 21 patients in G.A. (84%) whereas in no patients in G.M. no flushing occured. After a maximum of 6 h from the end of surgery patients achieved complete psycho-aptitudinal recovery and were released.Total consumption of muscle relaxant drugs in boli after induction dose:

Mivacron	Atracurium
17 Pts (28%)	10 Pts (100%)
27 Pts (28%)	20 Pts (100%)
311 Pts (44%)	30 Pts (100%)

4. Conclusion

From the data obtained we can assert that, in O.R.L. Pediatric Day Surgery, the MIVACRON represents a significant pharmacological improvement. It allows us to effect general anaesthesia without the long postoperative period of surveillance which was necessary when other muscle relaxant drugs were utilized. Compared to atracurium, we prefer to utilize MIVACRON because it is more wieldy and especially, because it creates no phenomena of histamine release. Moreover, it should be emphasized, that likewise with atracurium, it is not necessary to utilize neostigmine to antagonize NMB. In conclusion, at present, MIVACRON represents the ideal choice for the NMB in O.R.L. Pediatric Day-Surgery.

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ELSEVIER

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Ambulatory Surgery

Use of local and local-regional anaesthesia plus sedation during aesthetic plastic surgery procedures in ambulatory and day surgery

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Abstract

In the field of aesthetic plastic surgery the use of local anaesthesia and sedation is continuously increasing due to patient demand and due to its safety. It is also more comfortable for the surgeon to have a cooperative patient. The costs are reduced and the surgery appears to be less traumatic. The local anaesthesia and sedation are to be balanced based on the type of surgery and on the patient's characteristics. A total of 120 patients received intravenous sedation of midazolam and ketamine immediately prior to local anaesthetic injection and successively every 20/30 min intraoperatively. Different mixtures of local anaesthetic at volumes 'believed' beyond limits have been used without any trouble at all. There were no perioperative or postoperative complications. Patients and surgeon related a high degree of satisfaction with this approach. © 1997 Elsevier Science Ireland Ltd.

Keywords: Anaesthesia; Sedation; Surgery

1. Introduction

The use of local anaesthesia and sedation is increasingly growing in aesthetic plastic surgery. Patients and their relatives, who are worried about possible complications and side effects connected to general anaesthesia, are requesting local anaesthesia. It also makes it possible carry out the majority of interventions in day hospital with consequent minor surgical trauma and minor costs.

When the local anaesthesia and sedation are well dosed and therefore well combined, it is possible to submit the patient to a long lasting operation where numerous areas are involved.

Between 1994 and 1995, 120 patients 19–55 years old, mostly females, underwent surgical intervention using local anaesthesia and sedation. Fifteen percent of these were combined surgeries (Table 1). Postoperative recovery time was between 1 and 6 h. Only 5% of the patients asked to spend the night in the hospital.

There are two important aspects to consider when using this methodology:

(A) The type of local anaesthetic to be used, its mixture (Table 2), its appropriate local concentration and the maximum volume that can be administered to the patient without the risk of overdosage toxicity.

(B) The use of drugs which administered intravenously, lead quickly to sedation, analgesia and amnesia and which can, at the same time, be eliminated shortly or which if necessary, can be easily opposed by antagonists at the end of surgery.

Finally, in the immediate postoperative phase, the choice of an efficacious analgesic is very important as it must reduce pain to the minimum while allowing the patient to return home.

2. Materials and methods

The choice of the anaesthetic to be used depends upon the type of intervention [1,2]. In the case of lipoaspiration we use lidocaine which, for its features, better meets the needs of this procedure. It has in fact

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a faster action compared to other local anaesthetics, a higher diffusion capacity and a higher plasma level, potentially dangerous, compared to other local anaesthetics (from 3–7 μg/ml) [3]. During this type of surgery, when more than one area is to be treated (prevision of aspirated fat over 2.0 ml) (Fig. 1), we can use up to 90 ml of lidocaine at 2% in a percentage generally between 0.1 and 0.2% with adrenaline 1:500 000 injecting and aspirating first on one side, then the other. With this system, even if using a high volume of drug, the anaesthetic eventually absorbed is very diluted, maintaining a low plasma level of lidocaine.

As it has been widely clinically proven by many authors [4–7] during lipoaspiration the plasma level of anaesthetic remains low, due to the limited vascularization of the adipose tissue. This is even more reduced by the addition of adrenaline and by the lipoaspiration itself which eliminates part of the injected mixture. In five patients we measured the lidocaine level 1 h from the beginning of the surgery and 1 h after it and we ascertained that the level was always under the potentially dangerous limit.

In fact, the use of adrenaline permits a lower absorption of the anaesthetic resulting in the reduction of plasma level, reduced emetic loss and a longer lasting effect of the anaesthesia. Furthermore by mixing the anaesthetic with Ringer lactate and sodium bicarbonate we obtained an increase in pH, raising the quantity of non-ionized anaesthetic and thus also its tissue diffusion, concentration in nerve fibres and, consequently, the onset of the block, preventing the full perception of the stimulation of the pain [8,9].

In the case of breast reduction we also use bupivacaine 0.1% being a more powerful and longer lasting anaesthetic. We usually employ more than one mixture of anaesthetic with different concentrations.

Concentrations used were higher for the areas to be incised (lidocaine 0.5%) and for the areas close to nerve endings (bupivacaine 0.1% + lidocaine 0,5%) and were at a lower concentration (lidocaine 0.1–0.2%) for the areas of undermining which have less algogenous receptors [10,11].

In five patients submitted to breast reduction we have recorded the lidocaine serum level that appeared to remain under the dangerous limit. Also, with combined surgery, we use different anaesthetic mixtures in order to exploit their single features.

Table 1
Combined procedures performed: 15% of patients

Cosmetic breast + liposuction	8
Cosmetic face + liposuction	3
Rhinoplasty + liposuction	3
Cosmetic breast + rhinoplasty	2
Miniabdominoplasty + liposuction	2

Table 2
Volume of local anaesthetics abitually used

Liposuction	(prevision of aspirated fat over 2.0 liter) up to 90 ml of lidocaine 2% adrenaline 1–500.000
Breast reduction or abdomen	50 ml lidocaine 2%, 10 ml bupivacaine 0.1%, mepivacaine 2%, adrenaline 1–250.000
Breast implant	50 ml lidocaine 2%, adrenaline 1–200.000
Cosmetic face	50 ml lidocaine 2%, 10 ml mepivacaine 2%, adrenaline 1–250.000

The area to be operated first is injected with lidocaine while the second area to be treated is injected with mepivacaine as it is slower at onset but has a longer lasting action. Then we start surgery on the first area.

This technique is appropriate when the predicted duration of the first operation is less than 30/40 min. Furthermore we suggest that, when possible, the patient spreads a thick layer of anaesthetic cream (EMLA) (Astra-Simes SpA, Milano) on the involved areas at least 1 h prior to surgery in order to reduce the pain when the anaesthetic is injected [12].

To obtain amnesia, sedation, reduce anxiety and decrease the incidence of possible convulsions caused by local anaesthetics, we use a mixture of midazolam and chloridrated ketamine [13–19].

Patients receive intravenous premedication with atropine 0.5 mg and fentanil 0.05–0.1 mg, 15 min before surgery. Just prior to local anaesthetic injection, in order to reduce or even eliminate its painful stimulus, patients receive a quick intravenous dose of midazolam 0.3–0.5 mg/kg and, ketamine 0.4–0.5 mg/kg depending on their age, weight and the surgery they will undergo. Successively, every 20–30 min the patients receive, an additional intravenous infusion which is 1/4 of the initial solution to maintain adequate analgesia and sedation. In some cases to improve the analgesic effect, there is an additional use of fentanil between 0.05 and 0.1 mg.

All surgery was performed with patients monitored throughout the procedure with automated blood pressure, continuous ECG, and pulse oximetry. An antibiotic prophylaxis is always given for 24–48 h. Also 20 mg of nefopam are generally injected during the immediate postoperative phase as analgesic. It is used because it operates well on the pain without interfering with coagulation and has limited side effects.

3. Results

There were no perioperative or postoperative complications, no nausea or vomiting and no incidence of nightmares. On the other hand patients frequently reported a pleasant illusion of bright colours. One patient reported the illusion of playing a video-game. A very

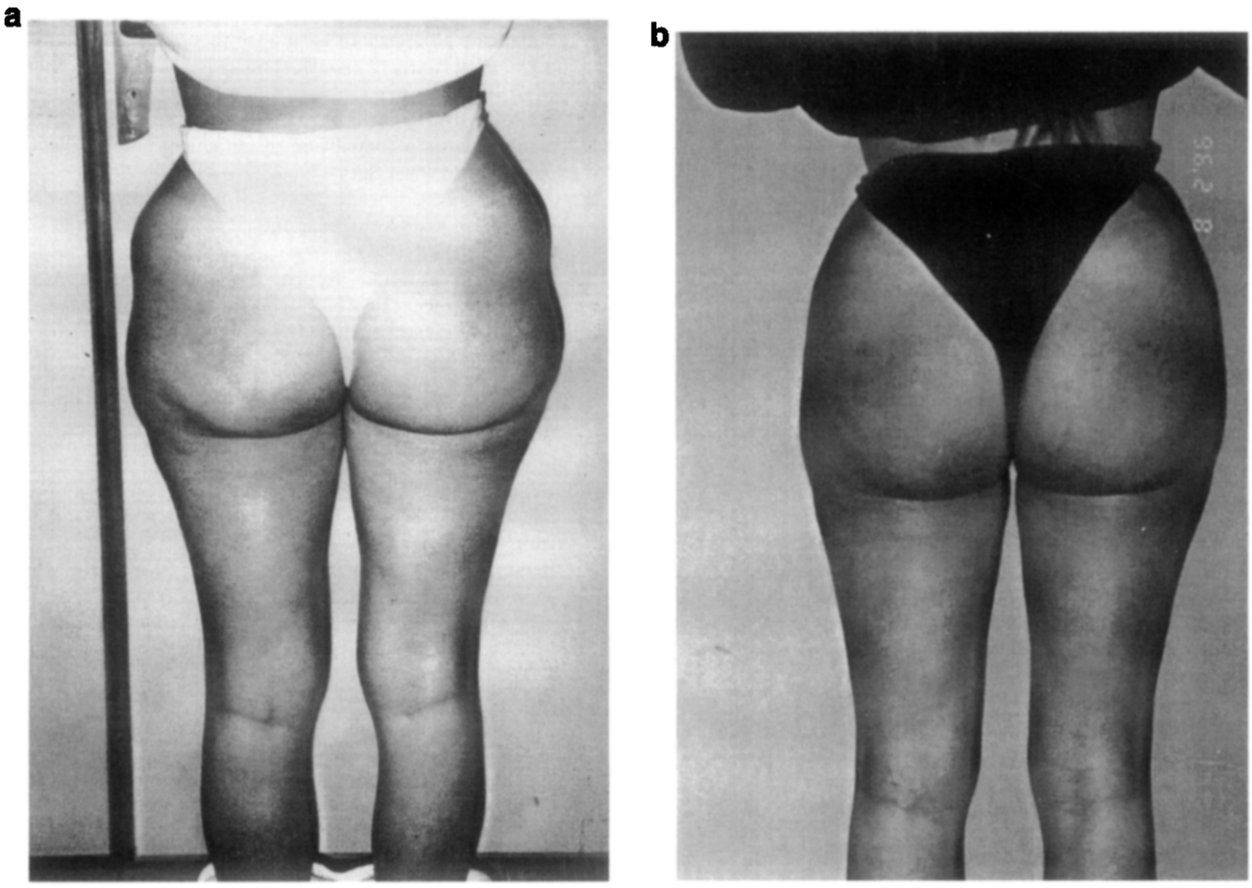

Fig. 1. (a) Preoperative and (b) postoperative views. Liposuction of flanks, trocanteric, knees and inner thigh areas (2.2 ml of fat aspirated).

low percentage of patients, generally the more anxious, reported a moderate recall of pain perception during anaesthetic injection and sometimes during surgery.

All patients said they were satisfied with this technique.

4. Conclusion

Midazolam is an effective anxiolitic, sedative and amnesic agent which acts rapidly, with a fast metabolic clearance. Ketamine is an efficacious analgesic, even at low doses, which produces deep analgesia of short length without causing respiratory depression or loss of protective pharyngeal and laryngeal reflexes. It has a fast onset and offset action. Furthermore ketamine with midazolam produces a more effective sedation. The use of fentanil as analgesic during premedication enhances the effect of ketamine and maintains a prolonged state of analgesia.

Table 3
Mixtures of local anesthetic

Lidocaine	0.1–0.5%
Mepivacaine	0.1–0.5%
Bupivacaine	0.1%
Adrenaline	1–100.000/1–500.000
Lactated ringer	Sodium bicarbonate

Percentages of local anaesthetics generally used. The higher percentages are used for the areas to be incised and/or close to nerve endings.

The opportunity of safely using different local anaesthetics at variable dosages (Table 2) and percentages (Table 3), as necessary, together with an efficacious sedation allows the surgeon to attempt a wider range of interventions. Furthermore, we believe that it is time to begin to re-evaluate the volume of local anaesthetic that it is possible to use safely during surgical interventions.

The advantages are many: the opportunity for ambulatory and day hospital surgery with reduced costs; less worries and anxiety for patients; more cooperation with the surgeon during surgery and last but not least the absence of the possible problems connected to general anaesthesia.

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Ambulatory Surgery

Mivacurium chloride for anesthesia in day surgery

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Abstract

Anesthetic techniques for day surgery must foresee a prompt recovery of alertness, ambulation and alimentation. The aim of our study is to evaluate mivacurium chloride in outpatient general anesthesia. Twenty patients, aged 18–55 years, American Society of Anesthesiologists (ASA) class I–II, undergoing surgical procedures were studied. Mivacurium (0.2 mg/kg) was administered to provide neuromuscular relaxation and endotracheal intubation was performed. Additional doses of 0.1 mg/kg mivacurium were given to maintain neuromuscular block, monitored by Relaxograph (Datex). In all patients, mivacurium provided satisfactory conditions for tracheal intubation after a mean time of 120 ± 15 s. Spontaneous recovery after the last dose of mivacurium was obtained in a mean time of 15 min. No side-effects or significant hemodynamic changes were recorded. The incidence of histamine-related side-effects was low. Mivacurium produces spontaneous recovery of neuromuscular block in a short time and shows some ideal properties for anesthesia in day surgery. © 1997 Elsevier Science Ireland Ltd.

Keywords: Anesthesia; Day surgery; Mivacurium

1. Introduction

Anesthetic management for day surgery requires prompt postoperative presence of alertness, ambulation, alimentation and good analgesia; the challenges of outpatient general anesthesia are to provide a rapid recovery to enable the patients to go home on the same day of the surgical procedure. The ideal properties of a neuromuscular blocking agent for short surgical procedures applied to day surgery or ambulatory day-care patients are as follows:

- it should have a short onset time;
- it should be a non-depolarizing acetylcholine antagonist to avoid some side-effects of depolarizing agents as vagotonic effect and postoperative myalgia;
- it should be non-cumulative and not sequestered in tissues with spontaneous breakdown, independently of organ function and metabolism;
- the agent should not cause histamine release with adverse effect on the cardiovascular system or other organs.

Mivacurium is a new benzylisoquinolinium choline-like diester neuromuscular blocking agent that shows some of these properties. The aim of our study was to evaluate if mivacurium could be a suitable agent for short procedures in day surgery [1,2].

2. Method

Twenty patients, all of them American Society of Anesthesiologists (ASA) physical status I or II, aged from 18 to 55 years, were studied.Eight patients were male and 12 were female.

Patients were excluded from the study if they had a history of: malignant hyperthermia; unusual sensitivity to neuromuscular blocking agents; alcohol or drug abuse; psychiatric, neuromuscular or cardiac diseases; impaired renal or liver function; asthma; exposure to amynoglycoside, antibiotics, lidocaine within 48 h of the study; exposure to antihistamines or antidepressant drugs within 1 week of the study.

All patients were scheduled for elective outpatient procedures with a duration of less than 1 h requiring tracheal intubation. Premedication included atropine

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Table 1
Modified scheme of Lund and Stovner for conditions of tracheal intubations

Grade	Characteristics
Excellent response	Good relaxation, vocal chords open, no response to IOT
Satisfactory	Good relaxation, vocal chords open, minimal coughing on IOT
Fair	Vocal chords moving, marked coughing, IOT requiring firm pressure
Poor	Poor jaw relaxation, vocal chords closed

(0.01 mg/kg) and fentanyl (1.5 mcg/kg i.v.); the induction of general anesthesia was realized with propofol (2 mg/kg) and the maintenance with additional fentanyl as clinically indicated and N_2O/O_2 (50%/50%).

Neuromuscular block for endotracheal intubation was obtained with mivacurium chloride (0.2 mg/kg) injected over 30 s. Supplementary doses of 0.1 mg/kg were administered to maintain neuromuscular block.

ECG was recorded continuously on a monitor with a four-channel recorder. Non-invasive blood pressure was monitored by Dinamap with 5-min intervals. End tidal CO_2 was monitored by infrared absorption monitor and SpO_2 by pulseoximetry.

To monitor the neuromuscular block, we used the Relaxograph Datex nerve stimulator delivering supramaximal impulses of 0.2 ms in a train of four (TOF) pattern (2 Hz) at intervals of 20 s; the ulnar nerve was stimulated at the wrist, using surface electrodes [4,5].

The spontaneous recovery to *T*95% and the *T*25–75% index were recorded. The intubating conditions were graded using a modified scheme of Lund and Stovner (Table 1).

3. Results

The 20 patients studied had pseudocholinesterase activity and dibucaine number in the normal range; the mean duration of surgical procedures was 30 ± 15 min. In all cases, a bolus of mivacurium (0.2 mg/kg) was administered and endoctracheal intubation was performed after a mean time of 120 ± 15 s. The intubating conditions were judged excellent in three patients and satisfactory in the other 17.

The incidence of histamine-related side-effects was low. In three patients, we observed flushing of the face, neck and upper chest which in one case was accompanied by transient hypotension (−9%), promptly corrected with crystalloid infusion.

During anesthesia, heart rate (HR) and mean arterial pressure (MAP) did not change significantly from baseline values at 1.5 and 5 min after mivacurium (0.2 mg/kg) injected over a period of 30 s. No cardiac arrhythmias were noted in any patient.

Table 2
Results

Onset time	120 ± 15 s
*T*25%–*T*75% index	6 ± 1.2 min
*T*95%	25 ± 3 min

The mean 25–75% recovery index (RI) was 6 ± 1.2 min. The time for spontaneous recovery to 95% twitch height after the last dose of mivacurium occurs in 25 ± 3 min (Table 2) [3–5]. In no cases did neuromuscular block require reversal with neostigmine. All patients were able to be discharged within 6–8 h after the end of surgical procedures.

4. Discussion and conclusions

In our study, mivacurium proves to be suitable and to have the adaptable characteristics for use in day surgery. This drug has a short onset time with satisfactory conditions for tracheal intubation after about 2 min. Moreover its use in ambulatory surgery is safe with regard to its elimination by plasma cholinesterase, although the duration of action of mivacurium may be significantly prolonged in the case of plasma cholinesterase deficiency. No cumulative effects were noted [3]. Reversal is seldom necessary, avoiding the use of neostigmine that can cause nausea or vomiting. In our experience, the incidence of histamine-related side-effects was minimal, with only transient changes of cardiovascular parameters. Our data with the use of mivacurium as a bolus confirm that this non-depolarizing muscle relaxant could be safe and useful in day surgery.

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Ambulatory Surgery

New frontiers in bariatric surgery laparoscopic adjustable silicone gastric banding (LASGB)

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Abstract

LASGB is a minimally invasive procedure indicated for the treatment of morbid obesity. Since January 1996, six patients have successfully undergone the laparoscopic procedure. Preoperative BMI was 42 ± 3.1; range 39–46. Mean operative time was 260 ± 110, range was 160–360. Mean hospital stay was 3 ± 1 days. © 1997 Elsevier Science Ireland Ltd.

1. Introduction

The role of surgery in the treatment of morbid obesity has been controversial. Recently the NIH Consensus Development Conference on gastrointestinal surgery for severe obesity has considered as potential candidates those with a body mass index (BMI) > 40, or BMI between 35 and 40 with high risk comorbid conditions [1]. Bariatric surgery is based on two fundamental concepts: malabsorbtion and gastric restriction. The most popular gastric restrictive procedure is the Mason vertical banded gastroplasty [2]. Kuzmak in 1986 introduced the silicone inflatable gastric banding [3]. Belachew and Cadiere, independently, showed the feasibility of the laparoscopic approach using the gastric banding [4,5]. This study reports the initial experience with LASGB performed in University of Naples opening the way in southern Italy to minimally invasive surgery for morbid obesity.

2. Patients and methods

From January 1996 to May, 27 patients with BMI > 35 were referred to the minimally invasive bariatric surgery outpatient clinic of 'Federico II' University in Naples. The NIH criteria were required for patients to enter the protocol of preoperative investigations. Contraindication to LASGB are reported in Table 1. Clinical and laboratory preoperative investigations are summarized in Table 2. The operation is performed under general anesthesia with patients in the lithotomy and anti-Trendelenburg (30–45°) position. The arrangement of the surgical team and video-instrumentations, and trocars sites are reported respectively in Fig. 1 and Fig. 2. Closed $C0_2$ (12–14 mmHg) pneumoperitoneum is generally performed. The first step is measurement of the proximal gastric pouch using the INAMED calibrating tube balloon inflated to 20 ml. The surgical access through the hepatogastric ligament

Table 1
LASGB: contraindications

Gastrointestinal pathologies
Peptic disease
inflammatory diseases (i.e. Crohn)
Portal hypertension
Congenital diseases (i.e. Atresias, Stenosis)
Hyatal hernia (> 5–6 cm)
Previous Surgery on upper abdomen
Psychiatric disorders
Infections
Age < 16 years

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Table 2
Protocol of preoperative investigations for candidates to LASGB

Blood tests
routine
Epatitis markers
Thyroid hormones
Serum cortisol and gastrin
Clinical consultation of
Cardiology
Psychiatry
Endocrinology
Dietology
Pneumology
Anesthesiology
Orthopedy
Gastroenterology
Radiological examination of
Chest Head
Sella turcica
Gastrointestinal tract
Sonography of
Heart
Thyroid
Liver and biliary tract
Pancreas
Pelvic organs
Others
ECG
Spirometry
Endoscopy (helicobacter pilory)
Doppler lower limbs

Fig. 2. LASB. Trocar sites. T1 = video camera; T2 = operator; T3 = operator (lap-band insertion); T4 = stomach retractor and T5 = liver retractor.

is obtained opening the avascular space between the Latarjet nerve and the lesser gastric curvature 3 cm below the cardias. The phrenogastric ligament is opened on the greater curve. A retrogastric tunnel is created by blunt dissection from the lesser to greater curve. The band (INAMED Srl) is introduced into the peritoneum through a 33 mm port (Ethicon-Endosurgery) which replaces the left subcostal trocar. Routine gastro-stenometric control is performed before and after band closure. Three or four gastric seromuscular stitches from the proximal to the distal compartment prevent the band dislocation. The injection reservoir is connected to the inflatable silicone tube outside the abdomen and the entire system is fixed by nonabsorbable suture.

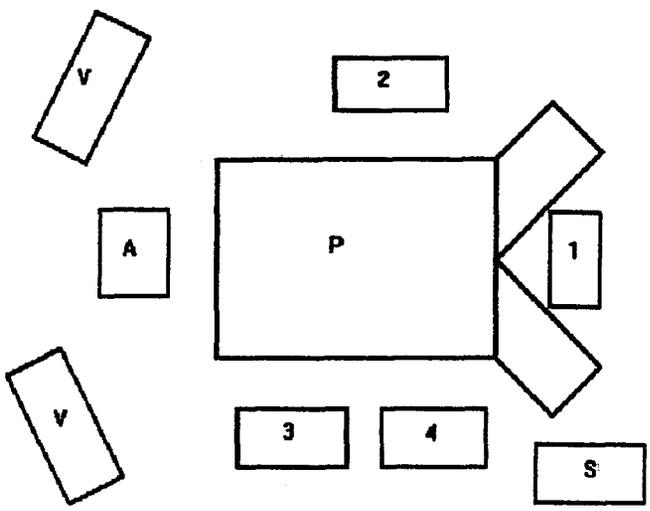

Fig. 1. LASGB. Arrangement of the surgical team and video instruments. P = patient in lithotomic position; 1 = surgeon; 2 = cameraman; 3 = assistant; 4 = instrument nurse; V = video and A = anesthetist.

3. Results

Six female patients underwent an uneventful videolaparoscopic procedure (Mean age 38.6 ± 9.9; range 27–50. Mean BMI 42 ± 3.1; range 39–46). In one case associated laparoscopic cholecystectomy was performed. Mean operative time was 260 ± 110 min, range 160–360. Postoperative complications observed were an erosive gastritis of the proximal pouch ($n = 1$) and lung atelectasia ($n = 1$), both resolved conservatively. Mean hospital stay was 3 ± 1 days with full rehabilitation at discharge. Results in terms of weight loss expressed by BMI preoperatively and at follow-up per single patient are reported in Fig. 3.

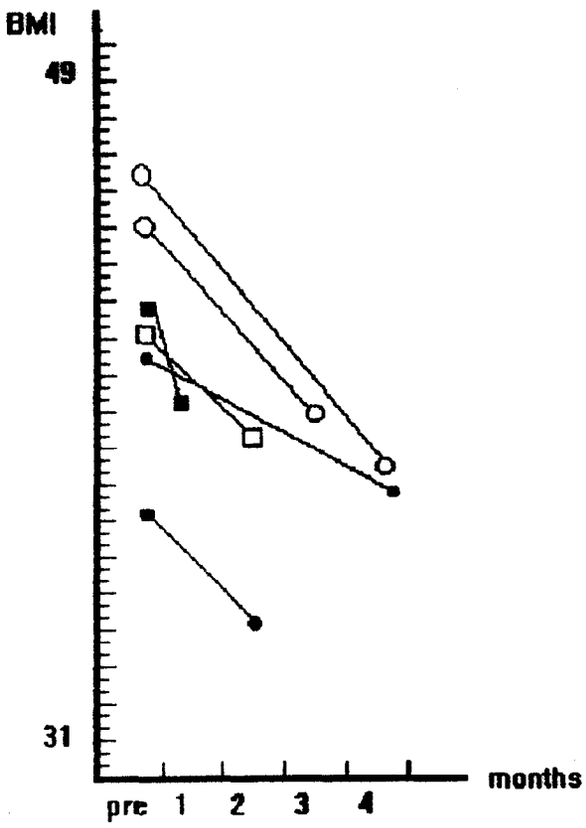

Fig. 3. LASGB. Weight loss of six patients.

4. Discussion

LASGB is an attractive procedure. The rationale of this operation is the dramatic reduction of the gastric volume to reduce food and caloric intake. This is obtained by a technique which is minimally invasive for the stomach and the abdominal wall. Since the proximal pouch is very small, the system is very powerful in controlling the diameter of the new pylorus, but it is also completely reversible. The results of gastric banding in terms of weight loss have been already proved by prospective randomized trials comparing this technique with Mason procedures. The percentage of weight loss in the relative period of time, in fact, has been similar for the two groups of patients operated with different laparotomy techniques [6]. The laparoscopic approach for adjustable silicone gastric banding has been recently introduced in clinical practice in a few centers. The techniques which are presently available need further refiniments and meticolous standardization. Early rehabilitation is an attractive goal for bariatric surgery which can be obtained through minimally invasive techniques and laparoscopy. Experience in advanced laparoscopy and laparoscopic general surgical procedure in obese patients is a basic requirement in performing LASGB [7]. Results of weight loss at long term follow-up of LASGB are awaited. With growing experience, LASGB could be considered a 'one day surgery' procedure in the near future.

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ELSEVIER

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Ambulatory Surgery

Guidelines for clinical use of local anaesthetics in minor ambulatory surgery with no anaesthetist's care

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1. Introduction

For doctors operating in public or private health structures, and sometimes in the patient's home, it is everyday practice to perform local anaesthesia by infiltration or troncular block when painful therapeutic manoeuvres are involved (suture of small wounds, dental care, episiotomy, removal of small surface growths, biopsies, etc.). In such practices there is generally no reservation about operating in the absence of a specialist in anaesthesiology and resuscitation.

Occasionally, however, instances are reported of serious complications or even deaths during surgery with local anaesthesia, and this is frequently the case in private ambulatory surgery. In these cases it is not always possible to document the lines of demarcation of professional responsibility (in terms of error of evaluation by the operator regarding the general conditions of the patient, or errors in the dosage of drugs or performance of techniques); but it is often possible to demonstrate, with hindsight, that the presence of a physician expert in anaesthesiology and resuscitation would reasonably have enabled such effects to be obviated.

It is worth noting that the literature contains no clear-cut and reliable indications regarding the margins of acceptability of the practice in question, nor any clear lines of demarcation to identify the situations in which it is possible to operate according to such criteria and those where further assessment is necessary or this type of intervention should not be performed. All the more so, since not all physicians carrying out local anaesthesia have had the opportunity, during their training, to examine thoroughly not only the pharmacology of local anaesthetics and the techniques of local anaesthesia, but also the essential manoeuvres of cardiopulmonary resuscitation, which may often be needed in cases of accidents.

It is important to recall that for local hospitals an Anaesthesia and Resuscitation Service is not obligatory, whereas it is so for regional and provincial hospitals. Hence, in the local hospitals, interventions with local or loco-regional anaesthesia may be performed without the assistance of the anaesthetist and a resuscitation service. Moreover, there is no regulation prescribing limits to the utilisation of these techniques for any graduate in medicine and surgery who is licensed to exercise the profession and duly enrolled on the professional register.

Within the hospital structures, and especially the larger ones, accidents from local anaesthetics are probably less frequent than elsewhere, and certainly of a less serious nature. In spite of this, anaesthetists are not infrequently called to the operating table for consultation, for treatment of vago-vagal syndromes, episodes of arrythmia, lipothymic crises or, more rarely, symptoms of genuine overdose, absolute or relative, of local anaesthetics.

It should anyway be emphasised that, even where local anaesthesia in the absence of an anaesthetist is warranted and dosages are correctly established, the employment of local anaesthetics, like any other medical act, is subject to a series of possible complications or side-effects.

In any case, the use of local anaesthetics is subsumed into the broader context of pharmacological therapy and hence, like it, must be subject to the general principles of drug therapy, according to which the interaction between patient and substance administered gives rise to a number of phenomena that can be defined, described and quantified with a reasonable margin of precision [6]. The aim of the Guidelines pro-

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posed herein is to optimise the possibility of defining, describing and quantifying these phenomena in advance for operators having to administer local anaesthetics to patients who require them, in the absence of specialists in anaesthetics and resuscitation. Also it would seem neither reasonable nor realistic to assume the presence of the specialist anaesthetist in all cases of surgery under local anaesthesia. Concerning the doctrine of quality, they stand as both a reference document and a device to enable conformity with procedures, having been drawn up with precise regard for the standard UNI EN ISO 9002 [13].

2. Origin and aim of the work [9–10]

The Guidelines that follow are the fruit of reflection by physicians belonging to the 'Working Group for One-day Surgery' of Modena Hospital, regarding the subject of common orientation on the use of local anaesthetics, to be applied in circumstances where the presence and collaboration of anaesthetists is not envisaged. In particular, it is felt necessary to provide guidelines that, while respecting the various requirements of the different surgical specialities, envisage—in line with criteria shared by all operators involved—the performance of local anaesthesia through all stages, from evaluation of the patient and identification of the possible risk factors, to the choice of the most appropriate anaesthetic, the patient's informed consent, the techniques of optimisation and enhancement of the drugs used, the clinical supervision during local anaesthesia and the surgical manoeuvre entailed, to the documentation of the activity performed, the management of failure and the treatment of possible complications.

Currently, the literature offers none of the data needed to define the real frequency of accidents from local anaesthetics in public or private structures, nor to distinguish between small accidents and serious ones. The principal difficulty in making even an approximate estimate stems from the fact that, hitherto, it has not been deemed necessary, systematically and in all cases, to adopt any specific procedure so that possible side-effects in the performance of local anaesthesia can be properly recorded and periodically analysed, with the aim, among other things, of ongoing technical improvement.

The present work has its origin in these reflections. It is in line with the themes and operating methodology belonging to a quality system, understood as a management philosophy aimed at defining the standards that characterise a particular performance or product, at establishing a precise path of the work performed, and at checking and correcting possible errors, evaluated as 'non-conformity'.

The field of operation of this first edition is restricted to superficial, non-invasive surgery, not requiring administration of sedative or analgesic drugs, performed on patients free of risk factors and belonging to ASA Classes I–IIa. The goals do not include here the definition of criteria according to which dedicated anaesthetic assistance should be held necessary during an operation carried out under local anaesthesia.

Lastly, these Guidelines were devised with the aim of contributing to the definition of operative standards by which minor surgery can be performed, in a purely ambulatory regime, in public or private structures, and, if necessary, outside the circuits and provision of assistance reserved for one-day surgery.

3. Guidelines for clinical use of local anaesthetics

3.1. General remarks (see UNI EN ISO 9002—4.3: Contract review) [1,2,5,12]

The safe use and correct choice of local anaesthetic requires that the operator performing the local anaesthesia has:

- a precise knowledge of the characteristics of these drugs, their possible toxic effects, the doses that can be used safely and the factors that may influence the expected plasma concentration following administration of a given amount of the drug;
- a precise knowledge of the patient and his/her clinical history, with special attention to such elements as may appear risk factors vis-à-vis the administration of local anaesthetics;
- The availability of equipment needed for clinical supervision of the patient and/or monitoring of vital functions, plus any equipment that may become necessary in case of complications or adverse reactions.

3.2. Criteria of choice for local anaesthesia (see UNI EN ISO 9002—4.3: Contract review) [4,5,7]

In every case, the decision to operate with local anaesthesia must take account of the following premises:

- the surgery must be feasible, with dosages of LA not exceeding the maximum permitted for the drug used, making allowance for appropriate adjustments with reference to age, body weight, site and times of administration and simultaneous use of vasoconstrictors;
- sufficient comfort for the patient must be guaranteed (absence of pain, duration of operation predictably limited to 40–60 min); prior to intervention, the patient must be informed as to the type of anaesthesia to be performed and the risks associated therewith;

- the criteria inherent in the technique of performance and safety must be followed (monitoring of vital functions, possibility of venous access and fluid replacement, of administration of vagolytic, cortisone, antihypertensive and minor sedative drugs; availability of equipment and drugs for cardiopulmonary resuscitation; availability of material for documentation and recording all stages of the operation performed);
- for troncular block, use of electrostimulators and thorough study and analysis of evoked muscular response is recommended.

3.3. Evaluation of the patient (see UNI EN ISO 9002—4.3: Contract review) [1–2]

Even where low doses of local anaesthetics are involved, pre-assessment of the patient is always essential, in order to identify the ASA class and the presence of possible pathologies, risk factors or contra-indications to use of local anaesthetics. The following are deemed to be risk factors:

- hypovolaemia and shock
- epilepsy
- assumption of MAOI drugs and tricyclic antidepressives
- hypertension
- coronary impairment
- serious arterial disease
- insulin-dependent diabetes
- porphyria
- previous allergic symptoms following LA administration.

It must also be specified that:

- epilepsy is a classic contra-indication for local anaesthetics [3]; with lidocaine, the contra-indication is relative, but it must be recalled that even minimum overdose may produce convulsions; in such cases, therefore, local anaesthesia will be performed only after venous access has been made available;
- hypertension and coronary impairment are risk factors mainly as regards the use of anaesthetic solutions containing adrenalin;
- since mepivacaine and bupivacaine may accentuate vasospasm in presence of serious arterial disease, in such cases the drug of choice is lidocaine without vasoconstrictor.

3.4. Choice of local anaesthetic and modality of administration (see UNI EN ISO 9002—4.9: Process control)

- Since the safest drug, from the point of view of allergy and intrinsic toxicity, is lidocaine, this must be deemed the first-choice drug [1,2].
- Thereafter, the choice falls on mepivacaine.
- Bupivacaine will be used only if effectively indicated in view of its long-lasting action and in cases where analgesia of the required duration cannot be obtained by addition of vasoconstrictors or alkalinising agents to less toxic substances, or in case of ascertained contra-indication to use of lidocaine and mepivacaine.
- In every case, bupivacaine will be used with continuous ECG monitoring, bearing in mind its potential cardiotoxicity and after ensuring that the patient presents no heart disease and is not taking calcium antagonists, beta-blockers [8] or benzodiazepines.
- Every injection or re-injection must be preceded by aspiration, in order to detect possible vascular ruptures.
- The aspiration must be moderate and not involve any change of position of the needle.
- The injection of local anaesthetic should not be rapid, especially in richly vascularised tissues.
- Whenever it becomes necessary to administer large amounts of LA and where this is not contra-indicated, it is preferable to employ the form associated with the vasoconstrictor [12].

3.5. Use of adjuvants (see UNI EN ISO 9002—4.9: Process control)

- Adrenalin is the most efficient of the vasoconstrictors; it can be used when no contra-indications are present [1,2].
- The recommended concentration in adults is 1/100 000; in children the preferred concentration is 1/200 000, and 1/400 000 in unweaned babies.
- Adrenalin-containing solution must not be used for blocks in regions where the arterial vascularisation is of terminal type (digital, penis and periorbital blocks).
- In order to halve the LA concentration, with the result (though there is not complete agreement on this point) of increasing its duration of action and reducing its time of latency, 10% sodium bicarbonate may be temporarily added, at volume equal to the LA [1].

3.6. Clinical supervision (see UNI EN ISO 9002—4.9: Process control) [4]

- During the operation, the patient's general condition must be supervised by a member of the team, who will be assigned this explicit task in advance.
- The patient must be supervised in order to identify possible reactions to the drugs used and physiological or behavioural alterations. By means of observation or monitoring of the variables indicated by the member of the team responsible, the supervision will regard the condition of the circulation (e.g. arterial

pressure, cardiac frequency and rhythm), oxygenation (e.g. skin colour, respiratory frequency, saturimetry) and mental state (e.g. through ongoing verbal contact).

- The person entrusted with this supervision must be sufficiently familiar with the working of any monitoring equipment that may be necessary and capable of interpreting the information collected.
- The documentation recorded on the local anaesthesia form must state exactly the type of assistance and intra-operative supervision performed.

3.7. Management of failure (see UNI EN ISO 9002—4.13: Control of nonconforming product)

If the type of anaesthesia performed should be insufficient to ensure analgesia, the situation may present problems for both patient and operator, so that not only is the necessary comfort for patient and operator not guaranteed, but even the safety of the patient and of the operation may be placed in jeopardy.

- In such cases, steps must be taken to respect the dignity of the person and the safety of the operation.
- The critical point is the operator's ability to discern whether further administrations of LA may or may not produce toxic reactions.
- In case of doubt or failure, or if it becomes necessary to administer sedatives and/or analgesics, the cooperation of an anaesthetist must be urgently requested.

3.8. Documentation of activity performed and back-up forms (see UNI EN ISO 9002—4.3.4: Records; 4.16: Control of quality records)

The performance of a small operation requiring a dose of LA of 100 mg or over (i.e. 20 ml of local anaesthetic at 0.5%, 10 ml at 1%, 5 ml at 2%) must be described on an appropriate form stating:

- summary of medical history and objective examination of the patient;
- type of drug used;
- dose administered in ml and concentration of the solution;
- site of injection;
- number of injections performed;
- times of administration;
- intra-operative assistance and monitoring effected and summary of significance of the data collected by means of said assistance and monitoring.

3.9. Discharge (see UNI EN ISO 9002—4.10.4: Final inspection and testing)

- Prior to discharge, it is indispensable for the patient to have regained a general condition compatible with leaving hospital and returning home.
- Following ambulatory surgery with local anaesthesia leading to transitory motor block of the muscles of a lower limb, it is essential to wait until the motor block has completely regressed [11].
- In every case, the patient must be completely informed on the duration and extension of a possible motor block, even partial and therefore expressed as a muscular weakness, that may remain after local anaesthesia.

3.10. Audit, corrective action and quality control (see UNI EN ISO 9002—4.17: Internal quality audit)

The use of local anaesthetics during ambulatory surgery without dedicated anaesthetic assistance should be consistent with the contents of these Guidelines.

At the start of each year, the surgical teams will check the availability of equipment and drugs for the treatment of LA complications in the places—other than the operating theatres—where they intend to perform minor surgery under local anaesthesia without the assistance of an anaesthetist, and will appoint one of their number to be responsible for the periodic maintenance and supply of said equipment.

In the presence of abnormal reactions or complications (anaphylactic reactions, overdose reactions, vago-vagal reactions, emotional reactions or other), a blood sample (5–10 ml in EDTA) will, if possible, be promptly obtained and sent to the pharmacological laboratory to determine plasma levels of local anaesthetic, after the patient has been informed. Complications (overdose reactions, vago-vagal reactions, emotional reactions, anaphylactic reactions, or other) arising during the use of local anaesthetics in conformity with these Guidelines will be described on the local anaesthesia form and notified in confidence to the Working Group.

At the start of each solar year, the descriptions of the said complications will be reviewed by all members of the team, with the aim, if necessary, of making revisions to these Guidelines.

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Ambulatory Surgery

One day surgery selection and preparation of pediatric patients

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1. Introduction

One day surgery (ODS) has been performed for many years in our pediatric surgical department. In 1975 we began to discharge children the day after surgery, but they were hospitalized one day before to perform preoperative routine laboratory tests and the anesthetic visit. From 1980 to 1984 the tests and the anesthetic visit were performed some days before scheduled surgery in the consulting room. Since 1984 laboratory tests have not been required routinely, but only when justified by clinical evidence of disease [1–3].

Therefore, there has been a very gradual introduction of this practice, which has since gained wide application, and further expansion may be expected.

Beside the benefits for children and their families, the increasing demand for minor surgery, and the costs of hospital stay have promoted the natural evolution from ODS to outpatient surgery. This practice is particularly suitable for children, who rarely suffer from systemic diseases and recover earlier after surgery. Furthermore, most surgical procedures in children are simple and require less complicated surgical techniques.

In our pediatric surgical department ODS has been applied since 1975, wheareas outpatient surgery (with discharge from the hospital within the same day of surgery) has been adopted more extensively only in the last year. Table 1 shows the procedures commonly performed on an outpatients basis at our department.

The anesthetic techniques are based on loco-regional anesthesia combined with sedation or on general intravenous anesthesia.

The accurate selection of the patients is a necessary condition to the successful outcome of surgery performed in an outpatient setting [4–7]. Other primary factors which we have to consider are the preparation of the parents and the choice of the anesthetic technique, in order to minimize complications which may prevent the discharge from the hospital.

Our operating room is in function from 8 a.m. to 8 p.m. and the morning is preferably devoted to major surgery, so very often procedures which would be potentially performed as outpatient surgery end late in the afternoon, compromising discharge. For this reason in our department of all the children who might benefit from an outpatient procedure, the discharge on the same day of surgery was possible only in 40% of the cases and on the following day in 60%. The most frequent causes of hospitalization were the time of surgery (late in afternoon) and the wish of parents for a longer hospital stay.

No children submitted to an ODS procedure have been readmitted because of postoperative complications.

2. Selection of patients

In order to assure the successful outcome of ODS it is important to have an organizational program to accurately select both patients and surgical procedures.

A complete history and physical examination of the child are the best preoperative screening, as many studies confirm [3,8]. On the basis of our experience, we can affirm that the clinical assessment is much more impor-

Table 1
Procedures in ambulatory surgery in 1995

Procedures	No. of patients
Inguinal herniorraphy	120
Hydrocelectomy	30
Orchidopexy	64
Circumcision	14
Colonscopy	5
Esophagoscopy	5
Surface surgery	91
Tracheo-bronchoscopy	4
Incision and drainage of abscess	7

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tant than routine laboratory tests, which are often only sterile data neither adding nor modifying anything to the patient's treatment [9,10].

Since 1984, laboratory tests, X-ray examination and ECG are not routinely required for healty pediatric patients scheduled for ODS in our hospital.

Investigations are requested only if the child's history and/or the physical examination reveal abnormalities that might benefit from further probing. This occurs in an extremely small number of cases (< 5%); therefore more than 95% of our children undergo minor surgery without any preoperative tests. We consider the anesthetic visit as very important for both the clinical assessment of the patient and for the psycho-emotional approach with the child and the family [11].

The visit is planned about a week before the scheduled surgery. On the anesthetic record the anesthetist writes the answer to a few specific questions which are addressed to the parents and which concern possible risk factors, such as previous and underlying diseases, predisposition to allergies and current pharmacological therapy. Then a careful physical examination is performed, in order to assess the child's health status, with particular attention to his/her chest, neurological system, muscle tone and anatomical shape of both the skull and the oral cavity in order to identify any difficulties with tracheal intubation. If the clinical examination does not reveal abnormalities no further tests are required and the child is considered suitable for ODS. Any child in good general health (ASA physical status 1 and 2) is considered suitable for ODS with the exception of children suffering from a respiratory infection. They are considered suitable for outpatient surgery only if they can undergo loco-regional anesthesia or general anesthesia without tracheal intubation. Children suffering from respiratory tract infections and requiring tracheal intubation, are hospitalized overnight, whereas children with fever or mucopurulent secretions have their surgical procedure delayed.

Children of ASA 3 class whose systemic disease is well controlled (diabetes, leukemia) particularly benefit from outpatient treatment. These children undergo frequent and repeated hospitalizations because of their underlying disease and thus an earlier discharge is more convenient both for psychological reasons and for their peculiar predisposition to infections.

As far as infants are concerned, we consider suitable for ODS those of ASA 1 and 2 classes, if older than three months for full-term infants, and older than six months for preterm infants.

The literature does not support outpatient surgery in younger infants, particularly if they are ex-premature infants, because they are more disposed to complications following surgery [12–15]. These infants are admitted to hospital overnight and we are awaiting the results of a study, still in progress in our department, on the incidence of postoperative complications in infants during the first months of life.

The parents of pediatric outpatients must warrant their reliability in the postoperative management of their children and must be able to understand and to apply the instructions.

The distance from hospital is not a reason for exclusion, since there is a high density of hospitals in our country.

The planned surgical procedure must induce only minimal physiologic derangement, it must not involve the abdomen, thorax or central nervous system and must not be prone to perioperative bleeding.

3. Preparation of children

The preparation of children and their families begins with the anesthetic visit in the consulting room.

The informed consensus of parents is essential. During the visit, parents are given verbal information about the admission and the surgical procedure and written instructions about fasting, premedication, anesthetic technique, postoperative awakening, control of pain and resumption of feeding. The informed consensus about the anesthetic technique is also important.

The approach to children older than four years is made easier by the projection of a videotape, where a child explains his experience with admission to hospital and surgery.

The parents of younger children are supported in their task by a story which explains to the child his future experience, using words suitable for his age and comprehension.

Admission to hospital is scheduled for 7.30 in the morning. If there is enough time before surgery, the child is allowed to drink clear liquids (up to 2 h before) or to take a light breakfast (up to 6 h before), and to spend his/her time in a play room provided with toys, drawing material and a video-recorder showing a wide choice of cartoons. The child is not restricted to bed during the waiting time.

In our practice the premedication is an integral part of the anesthetic procedure [16]. The time of administration is established by the anesthetist responsible for the operating room so that we have the maximal effect when the child arrives in the operating room. Nowadays the main purpose of the premedication is not the vagolytic effect but the child's emotional protection and amnesia.

In our department premedication is given to all children older than 10 months.

The premedication is different according to age (rectal fentanyl 5 μ/kg and droperidol 0.125 mg/kg up to 5 years and oral diazepam 0.4 mg/kg and droperidol to children older than 5 years) and is administered from

45 to 60 min before entry to the operating room. For less invasive procedures we administer rectal ketamine (10 mg/kg) which can be enough for the whole operation or can be supported by local anesthesia. EMLA cream (Astra) under an occlusive dressing is used to obtain painless venous access.

One of the parents accompanies the child into the operating room and remains there during the induction of anesthesia. The parental presence reduces the psychological trauma and the stress in children.

Whenever possible, we consider loco-regional anesthesia as a first-choice technique because it has the advantage of a prolonged postoperative analgesic effect. Most of our procedures are performed with loco-regional anesthesia and deep sedation. When necessary, a general intravenous anesthesia is carried out with neuroleptic analgesia, non depolarizing muscle relaxants and tracheal intubation.

At the end of surgery, the needle used for the venous access is withdrawn and the patient is brought to the room still asleep.

He/she will start drinking about 2 h later. After 3 h from surgery he/she is assessed by the anesthetist for discharge according to the Steward criteria. When maximal score is obtained the patient can be discharged. Otherwise he is reassessed 2 h later.

4. Results

Out of 1675 children who underwent surgery during 1995, 867 (52%) responded to the criteria established for ODS. 347 (40%) of them were discharged on the same day of surgery. 520 (60%) children required overnight hospital stay for the following reasons:

- 102 on parental request;
- 358 because the operative procedure started late in the day;
- 31 for persistent vomiting;
- 29 for postoperative fever.

3.2% of ambulatory patients were cancelled after arrival in the hospital for medical reasons.

Among 347 children discharged within the same day, 167 (48%) were discharged after the first assessment 3 h after surgery and 180 (52%) were discharged during the following 3 h. No child discharged within the same day or on the next day reentered the hospital afterwards.

The doctor on duty was called on the phone 37 times because of minor problems, which were solved by instructions dictated on the phone. No major complications occurred in the involved children and minor complications were not related to the absence of routine laboratory tests.

5. Discussion

On the basis of our experience we can affirm that ODS represents clear progress because of the several advantages and the total absence of complications, if patient selection criteria are strictly followed by surgeons and anesthetists [17–19].

In order to apply ODS the availability of appropriate hospital facilities and of a skilled staff are essential. It is important to obtain the trust of both patients and parents by providing adequate information about the procedure and by maintaining the same level of safety as offered by traditional in-patient surgery.

Even though ODS implies minor surgery, nothing must be overlooked, from the selection of patients to the anesthetic-analgesic aspect, up to the discharge criteria. The choice of avoiding, when possible, any routine preoperative investigations has proven to be a safe practice with clear advantages: reduction of the social costs for health care and less trouble for children and their parents. Nevertheless, it requires more attention from the anesthetist, who evaluates the child only by way of history and clinical examination.

The importance we attribute to premedication is largely confirmed by the child's reaction on approaching the operating room and the venous cannulation.

The choice between loco-regional anesthesia and general anesthesia must be suitable for the child and for the type of procedure. Not only a quick recovery but also a complete analgesia must be assured, in order to avoid any psycho-physical stress. According to our experience, even children submitted to general anesthesia with neuroleptic analgesia and muscle relaxants recovered rapidly (within 4 h) so that it was possible to discharge all of them within the day.

Among the major advantages of ODS is a more efficient utilization of hospital beds, facilities and staff for those patients who need them because of severe diseases. At the same time, ODS limits long waiting lists without compromising the safety or the quality of care, offering at the same time a brief hospital stay, which is appreciated by the children and their families.

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Ambulatory Surgery

Day-surgery organization in Sardinia: reappraisal of 5 years of activity

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Abstract

The authors report their personal experience of ambulatory surgery (AS) in a series of patients operated on from 1991 to 1996. The series includes 1118 surgical operations performed as outpatient procedures with immediate discharge. The following types of anesthesia were used: local infiltration (84%), superselective spinal (11%), blended or general (5%). Hernias of the abdominal wall, varicose veins and anorectal diseases were the more frequent pathologies operated on. Results of surgery are satisfactory, reconfirming the advantages of AS such as the absence of complications due to anesthesia and hospital stay, the better relationship between patient and surgeon, and the prompt return to working activities. © 1997 Elsevier Science Ireland Ltd.

Keywords: Ambulatory surgery; Day hospital; Day surgery

1. Introduction

Up to now, day surgery in Italy has not been so widely used as in the majority of the other European countries [1–5]. This is due to the fact that its development has not been at all favored by the main organs of public health (Ministry of Health, regional councils). In spite of the attempts of the Ministry of Health to clarify the situation, day surgery not only is not encouraged but even has improper funding. In fact the current system of refunds to the hospital is based upon payments related to pathology (so called DRG). With this system, the same procedure performed in day surgery is paid 25% less than the corresponding inpatient procedure. In Sardinia, day surgery is reimbursed at the same rate as day hospital care. For example, for a groin hernia operation, the Ministry DRG system pays Lit. 4 211 000 in the case of inpatient procedures, whereas the amount is Lit. 3 158 000 in the case of day surgery. In Sardinia, the corresponding rates are Lit. 3 369 000 and Lit. 583 000, respectively! Hence, what actually is done in the field of day surgery is due solely to the enterprise of hospital surgeons or of private health care operators.

In the field of public healthcare, it is currently possible to carry out only models of hospital-controlled integrated units where a small number of beds are assigned to day surgery and the operating rooms are utilized according to scheduled days. On the contrary, the model of the autonomous unit (freestanding unit of the US experience) [6,7] is widely used in private healthcare.

2. Materials and methods

In January 1991 at the Department of Surgical Sciences and Organ Transplantations, II Division of General Surgery, University of Cagliari, Sardinia, Italy, an integrated day surgery unit became active. This organization has incurred no further economic charges since the work is done with personnel and structures already active: 2-day hospital beds and the operating room for one session a week are utilized.

The work is scheduled according to the following steps:

1. first clinical evaluation; booking; chart with instructions and explanations for the patient; preoperative laboratory examinations and the filling out of anamnestic questionnaire by the patient

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2. anesthetic evaluation and filling out of the clinical chart
3. surgical procedure with a short postoperative check up; controlled discharge
4. follow-up at 1 week.

One surgeon and two residents are in charge of this activity. With the above organization model, we have been able to perform 1118 surgical operations in 5 years for the following diseases: abdominal wall hernias and incisional hernias (40.8%); anorectal diseases (17.4%); varicose veins (17.8%); urologic diseases (6.3%); breast tumours (4%); neck neoplasias (4%); cutaneous and subcutaneous tumours (3.8%); and other operations, i.e. appendectomies, gastrostomies, jejunostomies, rectocele (5.9%). The diseases submitted to ambulatory treatment are listed in Table 1. The patients, whose age ranged from 3 to 92 years, were classified according to the American Society of Anesthesiologists (ASA) classification: 74% of them were in ASA 1, 22% in ASA 2 and 4% in ASA 3, respectively.

Local anesthesia was used in 84%, superselective spinal anesthesia in 11%, and general or blended anesthesia in 5%. Failure to discharge the patient occurred in three cases (0.26%). No hospital admission occurred in the days following surgery. Local infections occurred in seven cases (0.6%) and wound hematomas in 56 (5%).

Table 1
Diseases submitted to ambulatory treatment

Inguinal hernia
Femoral hernia
Umbilical hernia
Epigastric hernia
Incisional hernia
Varicose veins
Hemorrhoids
Anal fissure
Fistula in ano
Pilonidal disease
Condylomata acuminata
Phimosis
Penile tumours
Appendicitis
Urethral polyps
Hydrocele
Spermatic cord cyst
Epididymis cyst
Varicocele
Cryptorchidism
Tumors of the skin and subcutaneous tissue
Breast tumours
Gynecomastia
Thyroglossal cyst
Diseases of the lymph nodes
Tumors of the salivary glands

3. Discussion

Day surgery is a healthcare organization model widely used in western countries. Its particular aims are the improvement of health services and a decrease of economic charges [8–11].

Specific guidelines for the management of such activity do not exist at present and only two organizational models are currently feasible, i.e. (1) hospital-controlled autonomous units, able to employ structures not adequately utilized or unproductive, and (2) hospital-controlled integrated units, that is beds and equipment already part of a department or center.

The first solution seems an attractive one, but it requires such an agreement of politicians and administrators that its fulfilment is difficult to obtain. On the other hand, only the organizing work of a responsible medical doctor is required to obtain the equipment and the personnel for day surgery activity.

Appropriate forms proved quite useful in simplifying the diagnostic–therapeutic program, thus reducing the personnel work load.

In detail, we employ:

- a very exhaustive form with explanations and instructions at the moment of the first examination and booking;
- a medical history chart that the patient has to fill out, date and sign before his anesthetic examination;
- a discharge sheet with clear indications on the problems which may arise in the post-operative course, together with a questionnaire on satisfaction with the procedure and with possible suggestions, to be returned within 3 months.

We believe that adoption of such forms can be very useful together with informed consent to avoid legal problems.

Since day surgery should be no-risk surgery, it should be performed by surgeons with wide experience; in the same way, anesthesiologists should be experienced in those techniques which are of particular importance when dealing with outpatient surgical procedures (new anesthetic drugs, selective peripheral anesthesias, laryngeal masks, etc.).

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Ambulatory Surgery

Restoration of saphenous–femoral junction competence with Venocuff® in 1-day surgery

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Abstract

The treatment of sapheno-femoral junction (SFJ) reflux represents the first step in an effective therapeutic program for varicose veins disease. SFJ valvuloplasty restores valve function by reducing vein wall dilatation at the valve annulus. The Venocuff® system makes it possible to band SFJ easily and safely. We used it in 10 cases with no early or late operating complications. Satisfactory SFJ competence has been achieved with aesthetic and functional improvement. © 1997 Elsevier Science Ireland Ltd.

Keywords: Sapheno-femoral reflux; Valvuloplasty; Venocuff®

1. Introduction

About 80% of patients suffering from varices of the long saphenous vein present some degree of reflux at the sapheno-femoral junction (SFJ) which is well detected by doppler CW and duplex sonography [1]. Therefore, the treatment of this reflux represents the first step of every therapeutic program, either ablative (short or long stripping) or conservative (CHIVA), for this pathology [2]. Histological observations show that sapheno-femoral reflux in early varicose vein syndrome is due to a separation of valve cusps in a dilated sclerotic vein wall. SFJ external valvuloplasty restores valve function by reducing vein wall dilatation [3,4]. In order to perform it, we used the Venocuff® system. This is a Dacron-strengthened silicon cuff which is placed around the vein at the site of the valve, to reduce incompetence and to bring the valve cusps into apposition [5].

2. Patients and methods

Patients were selected through accurate anamnesis and clinical examination, routine laboratory assessment (including AT III and fibrinogenemia dosage), doppler CW and duplex sonography. Inclusion criteria were: primary and early venous insufficiency; sapheno-femoral reflux not below the thigh; age under 45 years old; initial stage of venous discomfort with early varices and absence of cutaneous dyschromia; sonographic evidence of normal valve cusps (pre- and/or intra-operative). Exclusion criteria were: clinical history of superficial and/or deep thrombophlebitis (endothelial damage and increased thrombotic risk); previous or recent sclerotherapy (endothelial damage and increased thrombotic risk); congenital valve absence, abnormal valvular cusps; wide enlargement of the long saphenous vein; SF ostium diameter over 11 mm; local and/or general contra-indications to surgery (particularly inguinal dermatitis). In our Department, from January 1995 to the present, 10 women with a median age of 28 years (range 19–42) have been operated on. All the patients were subjected to 'short-term' antibiotic prophylaxis (teicoplanine plus third-generation cephalosporine) and all the operations were performed under local anesthesia and as 1-day surgery cases. Through an inferior transverse inguinal approach (3 cm), the SFJ was dissected, as in a conventional saphenous ligation. All collateral veins of the terminal saphenous vein were tied and dissected. Terminal and subterminal valves were localized by inspection and

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intra-operative ultrasonography. Venocuff® was placed around the valvular site [4] (Fig. 1). Restoration of SFJ patency and competence were assessed qualitatively by following the 'milking technique'. We occluded the saphenous vein 3 cm proximally to Venocuff® using a vessel loop. The proximal segment was then emptied by 'milking' blood into the distal segment. If this maneuver is found to be possible and easy, patency is assessed. Every filling of the proximal segment, spontaneously and/or elicited by Valsalva, and/or compressive maneuvers, represents blood reflux through the valve. To confirm these clinical data, we performed an intra-operative duplex Doppler scanning, using the Valsalva and/or compressive maneuvers. These clinical and instrumental evaluations were useful in detecting residual reflux and saphenous vein patency, making it possible to perform correction by valvuloplasty or, eventually, conventional surgery. In the last two cases we used intra-operative angioscopy, through the largest tributary vein. This examination confirmed the presence of a complete apparatus of terminal and subterminal saphenic valves, making it possible to more accurately calibrate the valvuloplasty. Finally, an elastic bandage was used for 9 days, postoperatively followed by a compression stocking for 30 days according to the degree of deep venous insufficiency.

3. Results and conclusions

There were no early or late operating complications and return to normal work and life activity occurred 2–4 days after the operation without any antithrombotic prophylaxis. A mean follow-up of 5.8 months (range 1–15) was carried out by monthly clinical examination, CW doppler and duplex sonography (Fig. 2). We found no pathological signs with normal SFJ competence and patency. Eight patients declared a complete remission of symptomatology (nocturnal cramps, swelling and heavy legs) with satisfactory aesthetic and functional improvement. Two patients with a medium degree of deep venous insufficiency had persistent symptoms of heavy legs, with, however, a significant reduction compared with the preoperative situation. In conclusion, external SFJ valvuloplasty seems capable of restoring continence of the superficial venous system by treating one of the causes of chronic venous insufficiency—vein wall dilatation at the valve annulus. An adequate follow-up is necessary to assess long-term results. If this technique makes it possible to preserve and/or restore normal hemodynamics in the long saphenous vein (LSV), it will be a great medical goal. In fact, LSV is still the most successful graft available for arterial, cardiac and venous by-pass [6].

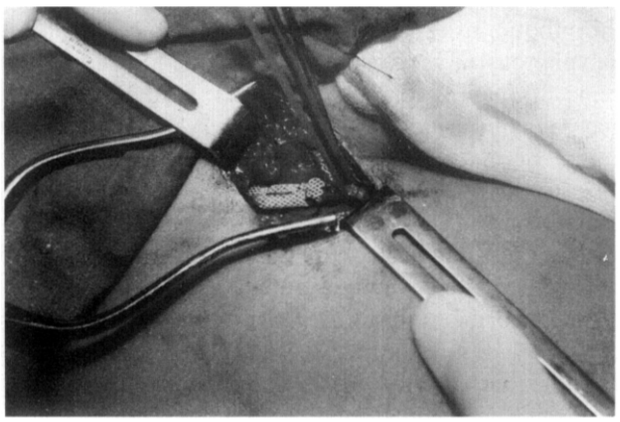

Fig. 1. Venocuff positioned around terminal sapheno-femoral vein in correspondence of the valvular site.

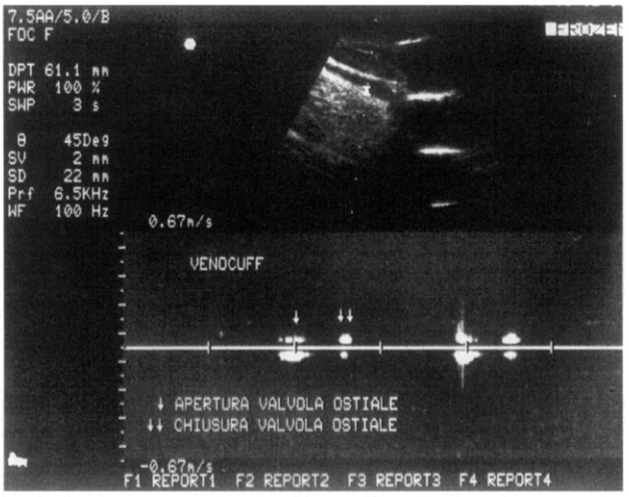

Fig. 2. Duplex sonography after Venocuff application: demonstration of the valvular lock (↓ opening and ↓↓ closure of valvular ostium).

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Ambulatory Surgery 4 (1997) 169–171

Ambulatory Surgery

Prevention of emesis in 1-day ophthalmic surgery: double-blind comparison of ondansetron, droperidol and placebo

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Abstract

In a randomized, double-blind study, we compared the prophylactic efficacy of ondansetron at a dose of 0.1 mg/kg (OND) vs. droperidol at a dose of 0.075 mg/kg (DBP) vs. placebo (PLA) in 120 patients undergoing pediatric 1-day ophthalmic surgery. Results showed an incidence of emesis in 10% of the OND group, in 37.5% of the DBP group and in 65% of the PLA group. Prophylactic administration of ondansetron represents the anti-emetic agent of choice in pediatric 1-day ophthalmic surgery.
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Keywords: 1-Day surgery; Ondansetron; Post-operative nausea and vomiting (PONV)

1. Introduction

Post-operative nausea and vomiting (PONV) is one of the most common complications of ophthalmic surgery. It results from stimulation of the extra-ocular muscles during general anesthesia, which triggers the oculo-gastric (also called oculo-emetic) reflex. This derives from stimulation of the chemoreceptor trigger zone in the area postrema through the labyrinth pathways or ciliary ganglion [2,9,11].

Immediate and delayed emetic post-operative manifestations, frequently difficult to treat, originate from these phenomena. A high percentage of PONV in this type of surgery is well known [1,4,12].

The aim of this study was to evaluate the incidence of emesis in ophthalmic 1-day surgery and the validity of anti-emetic agents for the prophylaxis of PONV.

2. Materials and methods

A total of 120 patients, aged 3–14 years, ASA score I, undergoing ambulatory ophthalmic surgical procedures (ophthalmic visit in narcosis 58 cases, lacrimal duct probing 14 cases, strabismus 31 cases, conjunctival and palpebral trauma 17 cases) were enrolled in the study, after written informed consent by their parents. Eighteen of the 120 patients included in the study had had previous episodes of post-anesthetic emesis. Ten patients were affected by conditions predisposing to vomiting (diabetes, chetoacidosis, gastro-enteric or endocrine disorders) and were excluded from the study. Demographic patient data are reported in Table 1.

General anesthesia, preceded by premedication with atropine sulphate at a dose of 0.02 mg/kg, was induced

Table 1
Patient characteristics and surgery data

	PLA	DBP	OND
Number	40	40	40
Sex (M/F)	18/20	21/19	20/22
Age (years)	10 ± 2	9 ± 3	9 ± 4
Weight (kg)	18 ± 1	17 ± 3	18 ± 2
Previous PONV	5	6	7
Duration (min)	19 ± 5	21 ± 4	20 ± 3
Type of surgery			
Visit in narcosis	20	19	19
Lacrimal duct probing	5	4	5
Strabismus	10	12	9
Trauma	5	7	5

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Table 2
Results

	Emesis				Total	No emesis
	0–2 h	2–4 h	4–6 h	6–24 h		
PLA	10	7	4	5	26 (65.0%)	14 (35.0%)
DBP	8	5	2	—	15 (37.5%)*	25 (62.5%)
OND	2	1	1	—	4 (10.0%)*	36 (90.0%)
PLA[a]	3	1	—	1	5 (19.2%)	0 (0.0%)
DBP[a]	2	2	—	1	5 (33.3%)	1 (16.6%)
OND[a]	1	—	1	—	2 (50.0%)	5 (71.4%)

[a] Patients with previous emesis.
* $P<0.05$ vs. other groups.

with thiopentone (3–4 mg/kg) and vecuronium bromide (0.08–0.1 mg/kg); orotracheal intubation was performed. Anesthesia was maintained with $N_2O + O_2$ (60:40), fentanyl 0.0002 mg/kg and isoflurane 0.5–1.5%. Repeated doses of vecuronium bromide (1 mg every 30–45 min) were administered.

Residual neuromuscular blockade was antagonized with neostigmine and atropine sulphate. When necessary, ketorolac tromethamine (0.4 mg/kg) was administered as analgesic in the immediate post-operative period. All patients were allowed to consume small quantities of liquids (100–150 ml) up to 3 h before induction of anesthesia. Double-blinded, randomized prophylaxis of post-operative vomiting compared ondansetron (0.1 mg/kg) (OND) both to droperidol (0.075 mg/kg) (DBP) and placebo isotonic saline solution (PLA).

All agents were administered immediately before induction. We did not consider nausea as a separate event, since in our experience it always precedes emetic episodes in ophthalmic surgery.

Patients were discharged from the ward 6 h after the end of surgery. Emesis was registered at the following intervals: 0–2; 4; 4–6 and 6–24 h after discharge.

The χ^2 test was applied to the data obtained and $P < 0.05$ was considered statistically significant.

3. Results

Demographic data (age, weight, duration of surgical proceedings, previous post-anesthetic episodes) regarding the three groups of patients studied demonstrated no statistically significant differences. Comparative results of the study are reported in Table 2, showing a 65% incidence of emesis in the PLA group, 37.5% in the DBP group and 10% in the OND group; in the last group, no cases of delayed emesis (6–24 h) were registered. In three cases of the PLA group and in one case of the DBP, admission to the ward for the night following surgery was necessary. Prevention of emesis with OND was successful in 71.4% (vs. 16.6% in the DBP group and 0% in the PLA group) of patients who had had previous episodes of PONV. As regards timing, a higher incidence of emesis was observed in the first post-operative period (0–2; 2–4 h), while a decrease occurred in the late period (6–24 h), especially in the DBP and OND group. Undesirable effects are reported in Table 3.

4. Discussion

Anti-emetic prophylaxis with OND reduced PONV episodes by 30% vs. placebo and droperidol, decreasing both frequency and incidence of emesis. A 65% incidence of emesis in the PLA group is in agreement with the international literature, relative to this type of surgery [3,5,10].

Ophthalmic surgery is associated with a high incidence of PONV. This can be explained by the following factors: type of surgery (traction on extra-ocular muscles in strabismus surgery); anesthetic agents employed (halogenated, opioids); anxiety and post-operative pain; and particularly important in children, time of fasting; intra-operative hydration grade; time-to-drink in the post-operative period [8]. Multifactorial pathogenesis of post-anesthetic emesis and its high incidence require its systemic prevention in pediatric ophthalmic surgery.

Table 3
Undesired side-effects

	PLA	DBP	OND
Itching	4	3	3
Muscular rigidity	2	9	—
Trigeminal pain	12	9	7
Dizziness	5	4	5
Drowsiness/sedation	3	8	3
Restlessness	2	2	1
Hypotension	—	1	—

Hirsch [7] describes a so-called 'loss of recovery time' in an ambulatory structure provoked by PONV, which can be directly correlated with an annual decrease of surgical procedures and is estimated, in economic terms, at approximately $519 000 a year. This, correlated to the low cost of OND (0.1 mg/kg prophylaxis costs $15) [6], confirms the validity of the drug in terms of cost–benefit.

Ondansetron is efficient in 90% of pre-treated cases and, in particular, in 71.4% of cases with a history of previous post-anesthetic emesis. These results demonstrate its significative validity vs. PLA and DBP. Results obtained in the DBP group demonstrate its minor efficacy vs. OND and a significantly higher incidence of side-effects, including muscular rigidity, which, in this study, did not prolong recovery time, but represents a potential danger in the case of early discharge.

In the group of pre-treated patients with OND, no case of delayed emesis, a potential cause of delayed release or re-admission to the hospital, was observed.

Prophylactic administration of OND at a dose of 0.1 mg/kg is highly effective in reducing the incidence of post-anesthetic emesis in ophthalmic pediatric 1-day surgery: DBP, at the dose tested, proved to be less effective and to be associated with a high incidence of side-effects. A reduction of costs and recovery time is also probable in patients pre-treated with OND.

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Ambulatory Surgery

Ambulatory treatment of varicocele

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Abstract

The authors describe their experience in the ambulatory treatment of varicocele. Forty-four patients were treated through an infrapubic approach and only one recurrence was observed. The authors conclude that ambulatory treatment of varicocele is safe, easy to perform and the patient can resume his daily activity within 48–72 h. © 1997 Elsevier Science Ireland Ltd.

Keywords: Infrapubic approach; Retroperitoneal ligation; Testicular vein; Testicular venography; Varicocele

1. Introduction

Varicocele is a reflux syndrome with varicose dilatation of the testicular veins. It occurs in 8–23% [1] of the adult male population and usually affects the left side. Patients suffer from scrotal discomfort and often show sub-fertility with changes in the sperm count. Treatment is always advisable since improvement in the sperm count, besides disappearance of discomfort, is usually obtained.

Surgery can easily be performed as a day surgery case under local anesthetic, allowing the patient to return to normal life within 48–72 h. We report our experience with 44 patients treated as outpatients at our institution.

2. Anatomy

The testicular veins drain the testis and the epididymis. The first tract of the veins is called the pampiniform plexus. This plexus forms a counter-current heat-exchange mechanism which lowers the blood temperature in the testicular artery. Just below the external inguinal ring, the plexus coalesces into three or four veins which traverse the inguinal canal before uniting into two spermatic veins running on either side of the artery. These veins contain valves. The left spermatic vein enters the left renal vein at a right angle whereas the right spermatic vein enters the inferior vena cava at an acute angle.

Several connections are described between the spermatic veins and:

1. the sapheno-femoral junction
2. the contralateral spermatic veins via suprapubic connections
3. the lumbar veins
4. the inferior vena cava
5. the perineal veins.

However, the pathophysiological classification of varicocele is based on reflux pathways [2]: type 1, reflux in the internal spermatic vein (high nutcracker); type 2, reflux in the external spermatic veins which enter the external iliac vein (low nutcracker);and type 3, reflux in both the above mentioned venous systems.

3. Materials and methods

From August 1987 to April 1996, 44 patients were treated as day cases for varicocele; 8.2% of all the ambulatory surgery performed (Table 1). One patient had bilateral disease and one was recurrent. The latter

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Table 1
Ambulatory surgery, July 1986–April 1996

	No.	%
Varicose veins	263	47.6
Pilonidal sinus	89	16.1
Varicocele	45	8.2
Carpal tunnel	34	6.2
Miscellaneous	121	21.9
Total	552	100

was related to previous high ligation performed elsewhere. The mean age was 24 years (range 13–61).

All the patients were studied preoperatively by means of one or more tests, such as Doppler, duplex-scan or color Doppler. All the patients had confirmed reflux in the spermatic vein and the pampiniform plexus. Almost half of the patients also had an impaired sperm count. The operation was performed on a day basis under local anesthesia (mepivacaine 1 and 2%, 5–10 ml.). The skin was incised at the external inguinal ring (infrapubic access) and the spermatic cord mobilized.

After the cremaster and the spermatic fascia were opened in the line of the cord and the structures identified and preserved, the dilated veins were individually ligated and divided. The skin was then sutured and dressed in the usual fashion and a firm scrotal support applied. The patient was put on antibiotics and discharged immediately.

Postoperative pain was slight or absent. The patients were seen on the 3rd, 7th and 30th postoperative days. Wound hematoma in one patient, which did not require exploration, was the only complication seen in this period. Follow-up showed only one recurrence. A 27-year-old patient, 18 months after surgery, had reflux in the pampiniform plexus related to a suprapubic vein fed by a contralateral varicocele.

4. Discussion

The treatment of varicocele in the past has shown a high recurrence rate. This was related to the poor preoperative diagnosis which was based only on clinical evaluation. In recent years, a noteworthy improvement in the diagnosis has been obtained by relating anatomy and pathophysiological pathways of reflux in the spermatic veins and the pampiniform plexus. The classification by Coolsaet [2] into three types seems to be the most suitable since it includes all the significant routes of reflux. The improvements relate to retrograde selective testicular venography, which is the gold standard amongst the diagnostic tools. Moreover, it allows non-surgical treatment of varicocele by means of coils [3], balloons and sclerosing drug insertion [4], which has given good results in experienced hands. A venogram should be performed in all patients, but it requires qualified structures, is invasive and sometimes has complications. Hence, when venography is not feasible, the treatment should aim to eliminate all the incompetent veins despite their routes and before their anastomoses.

The retroperitoneal ligation of the spermatic vein (Ivanissevich, Palomo, Laparoscopic ligature) [5–7] is always best done after venogram and is not suitable for the types 2 and 3 reflux; otherwise recurrence is frequent.

The inguinal or subinguinal approaches [3] to the testicular veins make the division of the dilated veins possible in the lowest part so that unusual routes of reflux are eliminated as well as the classified ones. Furthermore, these approaches can be undertaken on a day basis using local anesthesia and the patient can be discharged immediately, pain free. He can return to normal activities within 48–72 h.

Between the inguinal and subinguinal approach, we prefer the latter in the infrapubic site since, compared with the others, it is associated with a lower incidence of postoperative complications such as hematoma or hydrocele and is less painful.

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Ambulatory Surgery

Regional block anaesthesia in ambulatory surgical treatment of lower limb varicose veins

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Abstract

Ambulatory or Day Hospital surgery is economically advantageous but requires care in patient selection, choice of anaesthesia, drug administration and discharge criteria. Locoregional anaesthesia is particularly suitable in the treatment of lower limb varicose veins since complete reversal of the anaesthetic block in a few hours in non-hospitalized patients is possible. Our experience over 18 months involved 66 patients, aged 18–65 years, affected by venous insufficiency of the lower limbs belonging to ASA I and ASA II groups. We evaluated the patient's and surgeon's approval of the method and the need for systemic analgesia, perioperative sedation and/or further infiltration to complete the block. In the post-operative period we also evaluated mobilization, the need for analgesic therapy and the ability to discharge the patient. Troncular anaesthesia proved to be suitable for this kind of surgery, with a discomfort incidence of about 15% (patients who required sedation or analgesia). © 1997 Elsevier Science Ireland Ltd.

Keywords: Day surgery; Locoregional anaesthesia; Anaesthesia; Troncular block; Anaesthetic block

1. Introduction

Ambulatory or Day Hospital surgery is economically advantageous but requires care in patient selection, choice of anaesthesia, drug administration and discharge criteria.

Today, this kind of surgery is growing because it makes it possible to increase the number of patients operated upon without hindering the hospital departments. Furthermore, it is liked by patients who prefer to avoid hospitalization.

Locoregional anaesthesia is particularly suitable in the treatment of lower limb varicose veins since complete reversal of the anaesthetic block within a few hours in non-hospitalized patients is possible.

Several authors [1–4] have suggested different locoregional anaesthetic techniques for lower limb surgery. These include peridural anaesthesia, subarachnoid anaesthesia, superselective spinal anaesthesia, ischiatic and femoral block and Winnie's block (3 in 1).

Troncular anaesthesia is not used frequently in clinical training, although with a good anatomical knowledge and overall utilization of electrostimulation (ENS), good results in peripheral block [5], can be obtained.

We used this technique, generally carried out in orthopaedic surgery of the lower limbs, in saphenectomy. It proved to be effective with few complications.

The aim of our study was to evaluate lower limb troncular block in Day Surgery treatment of varicose veins.

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2. Materials and methods

Our experience over 18 months involved 66 patients, aged 18–65 years, affected by venous insufficiency of lower limbs belonging to ASA I and II groups. Patients were evaluated before the operation, and informed about the anaesthetic technique. We required the presence of someone to take care of them at home after the operation.

Locoregional anaesthesia, facilitated with the Electro Neuro Stimulator (Ecostim 900) affected a retrograde ischiatic nerve block, a Winnie block (3 in 1) at the level of the inguinal ligament and infiltration of the inguinal region [6].

The ENS generated DC electrical impulse through a metallic needle. The needle, which locates and stimulates the nerve, has an exposed tip but insulated sides to avoid accidental stimulation and thus reducing the risk of injecting the anaesthetic in the wrong sites.

The amplitude of the impulse made it possible to stimulate only nervous and not muscular tissue. With an amplitude of 0.5–1 mA nervous structures were stimulated at a distance of about 1–1.5 mm from the tip: rhythmical contraction of muscular masses innervated by the stimulated nerves [5] was observed.

Troncular block was carried out with a solution of local anaesthetics containing mepivacaine 2% and bupivacaine 0.25% with a 3:1 ratio. Infiltration was performed with mepivacaine 1% and bupivacaine 0.25% in equal parts.

The volumes of anaesthetic solution administered were 20 ml for the ischiatic nerve, 8–10 ml for the Winnie block and 15 ml for the inguinal region.

ECG, NIBP and SatO2 were monitored (Datex Cardiocap II). Moreover, we maintained dialogue with the patient to keep him calm and to evaluate the appearance of complications.

After the operation, observation was continued for about 8 h.

We evaluated the patient's and surgeon's approval of the method and the need for systemic analgesia, perioperative sedation and/or further infiltration to complete the block.

In the postoperative period we also evaluated mobilization of the limb, the need for analgesic therapy and the ability to discharge the patient.

3. Results

Troncular anaesthesia proved to be suitable for this kind of surgery, with a discomfort incidence of about 15% (patients who required sedation or analgesia).

The operation was performed in an average time of 42 min (range 18–72) without any complication (Fig. 1).

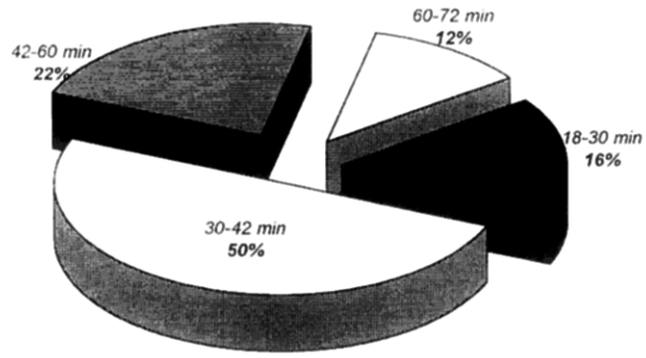

Fig. 1. Operation time.

Only 1 patient (1.5%) required perioperative systemic analgesia, whereas in 12 cases (18%) we preferred to administer propofol by infusion (3–6 mg/kg per h) to reduce the anxious state of the patient.

Anaesthetic block was supported by locoregional infiltration in 9 patients (13.6%), whereas in the remaining 57 cases (86.3%) (Fig. 2) it was adequate.

The dose of local anaesthetic was always lower than the recommended maximum.

Reversion of the monitorial block allowed the patient to walk within 4 h of the beginning of anaesthesia, while analgesia obtained with low concentration of bupivacaine adequately controlled postoperative pain.

In fact at the time of discharge in 58 patients (88%) reversion of block was not associated with pain, while in the remaining 8 (12%) administration of ketorolac 30 mg IM was necessary. Administration of ketorolac 10 mg per OS the night of the operation was recommended.

The method was considered very good by 57 patients (89%), good by 5 patients (7.5%) and poor by 2 patients (3%) (Fig. 3).

The surgeon's rating was very good in 55 cases (83%), good in 8 cases (12%) and poor in 3 cases.

Anaesthetists considered the results very good in 51 patients (77.2%), good in 12 patients (18%), and poor in the remaining three cases.

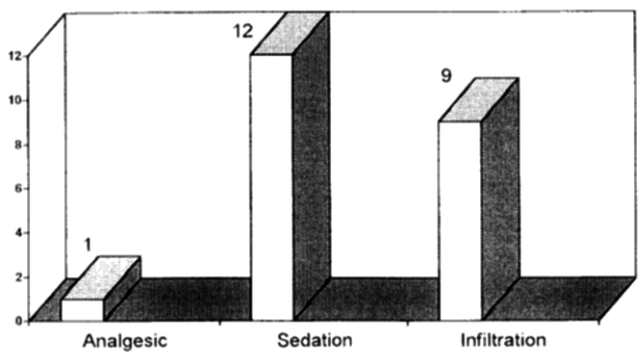

Fig. 2. Patients who needed analgesic, sedation or infiltration to complete the block.

Fig. 3. Methodic approval.

All patients were discharged the same day of their operation.

No complications were observed during the postoperative follow up.

4. Discussion

Several authors suggest different anaesthetic techniques than those used in this study for day surgery [1,2,4,7]. Some prefer variants of subarachnoid anaesthesia to reduce complications [1,2,8–10]. However, critical analysis of these results show that the incidence of complications was 5–10% [1–3] despite the precautions taken (selectivity, small caliber and atraumatic needle).

These complications (headache and back pain) are responsive to antiflogistic and fluid therapy and they are also resolved by bed-rest, but this is clearly against day surgery principles; admitting a patient after day surgery overloads surgical department activity.

Troncular block proved to be the anaesthetic technique of choice in Day Surgery treatment of varicose veins.

It provided adequate analgesia, with complete reversion of anaesthetic effects at the time of discharge; even in the case of the 12 patients who had an intraoperative sedation.

This kind of block, in comparison with central block, gives many advantages: lower instrumental and pharmacological invasiveness, absence of cardiocirculatory complications (hypotension and bradycardia), no involvement of sympathetic block (bladder globus), feasibility with associated infectious diseases, absence of headache and eventually a better acceptance by the patients since only one leg is blocked. Besides, the analgesic effect is more durable than in subarachnoid anaesthesia.

Nevertheless, we must stress that the anaesthetic block, even if facilitated by electroneurostimulation requires about 40 min of preparation time and an effort on the part of the surgical team similar to that required for hospitalized patients.

If we consider the cost, dose, time employed and ease of performance, other anaesthetic methods, particularly subarachnoid anaesthesia, are favourable, but troncular block makes it possible to discharge patients in a very short time thus facilitating day surgery procedures.

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Ambulatory Surgery 4 (1997) 179–180

Ambulatory Surgery

Ambulatory procedures and 'one-day surgery' in general surgery: analysis of 5-years experience

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Ambulatory surgery is assuming a role of increasing importance in the current health politics of cost containment. At present over 50% of all surgical procedures in the USA are performed on a day-hospital basis [1]. Easier bed availability, larger patient turn over, lower incidence of hospital infections, early post-operative mobilization and decrease in the number of absence days from work are connected to the reduction of costs. Patients with complex health problems can be candidates for this type of surgery. The fundamental pre-requisite for ambulatory surgery is the correct pre-operative evaluation of patients by means of laboratory tests, X-ray and EKG tests specific for the primary disease and an accurate anamnesis (ASA evaluation).

The most common surgical procedures are in the fields of gynaecology, orthopaedics, urology, ophthalmology and oral surgery. In general surgery, phlebology, inguinal and crural herniae, breast surgery and proctology represent the major fields of interest for ambulatory treatment and 'one-day surgery'.

In the last few years even minimally invasive procedures (laparoscopy and thoracoscopy) have been included among the techniques to be considered for such surgery [2]. According to the Swedish Planning Rationalization Institute (SPRI) 'one-day surgery' is described as 'surgery or other treatment of corresponding degree of difficulty which usually demands anaesthesia (local, regional, spinal, lumbar or general) and which includes a postoperative recovery period of 2–5 h before discharge' [3].

In any case, the surgeon must perform the operation skilfully and quickly to make sure that the patient recovers rapidly postoperatively. Elongated operating time due to a lack of familiarity with the surgical procedure on the part of the surgeon jeopardizes the potential results.

The patient's risk factors include age, cardiovascular and respiratory diseases, metabolic diseases, acute infections and debilitation.

Since complications occurring during the first 24–48 h differ from those which arise later on, we are used to subdividing the postoperative course into early and late phases.

More than 50% of early complications are due to haemorrhage. This is generally linked to technical faults by factors depending on the surgeon. Other early complications are vomiting, phlebitis, laryngospasm and drug reactions. Therefore, accurate postoperative and postanesthesiology monitoring is necessary. By adequate patient selection and accurate perioperative observation it should be possible to keep the incidence of major early complications below 1% and a mortality rate of 0% [4].

Complications which occur after 24–48 h are connected to improper treatment of the patient postoperatively and to the development of infections. The latter is more common in the presence of diabetes mellitus, in hepatic or renal disease, in patients taking corticosteroid drugs and in debilitated patients

Our study covers the period from January 1991 to December 1995. Three hundred and thirty-seven patients were treated on an ambulatory or 'one-day surgery' basis: 197 males (58.4%) and 140 females (41.6%). Seventy-six patients (22.6%) 44 males (57.9%) and 32 females (42.1%)) were aged 75 years or above with a range of 75–86 years. The remaining 261 patients (77.4%), with a range of 16–74 years, were 153 males (58.6%) and 108 females (41.4%). According to ASA classification 195 patients (57.8%) belonged to group I, 101 (30%) to group II and 41 (12.2%) to group III.

'Tension-free' hernioplasty was performed in 116 (34.4%) cases (30 of them bilateral), 41 patients (12.2%) underwent haemorrhoidectomy, 16 (4.7%) lateral

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sphincterotomy for anal fissure, 17 (5%) surgical treatment of abscesses and anal fistulas, 39 (11.6%) excision of benign breast lumps, 5 (1.5%) quadrantectomy with lymphadenectomy, 18 (5.3%) sapheno-femoral or sapheno-popliteal crossectomy (14 of them with stripping) with ambulatory phlebectomy according to Muller, 18 (5.3%) excision of pilonidal cyst, 12 (3.6%) port-a-cath positioning, 12 (3.6%) laparoscopic cholecystectomy, 9 (2.7%) surgical treatment for phimosis, 21 (6.2%) surgical treatment for varicocele and 13 (3.8%) surgical treatment for hydrocele.

General anaesthesia was used in 16.6% of the cases (56 patients); spinal anaesthesia in 13.1% (44 patients) and local anaesthesia in 70.3% of cases (237 patients). One hundred and eighty-eight (55.8%) patients were discharged within a few h postoperatively, the remaining 149 (44.2%) after a one-night stay. Up to the time of discharge no noteworthy complications were observed. However, fever occurred in 25 (7.4%) patients, pain was treated with common analgesics in 51 (15.1%) and 7 (2.1%) patients vomited. During domiciliary convalescence 11 complications (3.2%) were recorded, requiring a further day-stay in hospital for evaluation and treatment. These were 2 anal posthemorrhoidectomy abscesses, 2 persistent postquadrantectomy lymphorrheas, 5 posthernioplasty seromas and 2 cases of persistent pain in the superior abdominal quadrants after laparoscopic cholecystectomy.

It is certain that apart from economic aspects ambulatory surgery is quality treatment with good outcomes, Cohen and Dillon agreed in 1966 when they asserted that 'the patients' safety is not related to hospitalization or non-hospitalization: it is an attitude and when the selection of patients on the part of the surgeon is seriously performed, with an accurate anaesthetic technique there is no reason why we should expect a number of complications larger than those foreseeable during hospitalization' [5].

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Ambulatory Surgery

Randomized evaluation of ketorolac vs. fentanyl in elderly patients undergoing ambulatory surgery

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Abstract

Analgesic efficacy of a preemptive single dose preemptively of Ketorolac or Fentanyl in 102 elderly men undergoing general anaesthesia for multiple prostatic biopsies was assessed. Patients were randomly allocated to receive either (group A) Ketorolac 0.55 mg/kg intravenously (IV) 15 min before surgery or (group B) fentanyl 1, μg/kg IV 5 min before surgery. Anaesthesia was induced by means of propofol 15 mg/kg per h and maintained by means of propofol 7 mg/kg per h while patients were ventilated spontaneously using N_2O 70% in O2 via a to and fro system. Routine monitoring included mean arterial pressure (MAP), heart rate (HR), pulse oxygen saturation (SpO_2), respiratory rate (RR), end tidal CO_2 ($EtCO_2$). HR and MAP decreased during surgery with significantly lower values in the Fentanyl group. Fentanyl treated patients had higher ventilatory depression with frequent intraoperative apnoea. Group A needed supplemental doses of propofol to maintain adequate sedation. Sixty and 120 min postanaesthesia no differences were found for MAP, HR, RR, $EtCO_2$, pain and the tolerability of the procedure. The Ketorolac group had less adverse effects and could be discharged earlier © 1997 Elsevier Science Ireland Ltd.

Keywords: Elderly outpatients; Fentanyl; Ketorolac tromethamine; Prostatic biopsy; Day surgery; Pain; Drug cost

1. Introduction

For social and economic reasons outpatient procedures continue to increase in popularity. Elderly patients, more than others, can be involved in unexpected hospital admission for either surgical or anaesthetic sequelae [1–6].

In these patients the anaesthesiologist is required to provide safe analgesia, proper operating conditions and ensure rapid recovery with minimal postoperative sequelae assuring proper respect for discharge criteria. The potent and rapid acting opioid Fentanyl, despite many well known side effects, provides good intraoperative conditions and effective pain relief on emergence from general anaesthesia. [7,8].

Ketorolac tromethamine is a non-steroidal anti-inflammatory drug, available in parenteral as well as oral form, which has negligible effects on ventilatory control, hemodynamics and psychomotor control [9–12].

The aim of this study is to evaluate the impact of a minor analgesic like Ketorolac on intra and postoperative analgesia and discharge criteria compared to a major analgesic like Fentanyl, as part of a balanced anaesthesia with Propofol and N_2O in elderly patients undergoing prostatic ultrasound guided biopsies of the prostate.

2. Patients and methods

After obtaining institutional review board approval and written informed consent, 102 elderly men sched-

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Table 1
Demographic characteristics

	A ($n = 51$)	B ($n = 51$)	t-test
Age (years)	65.7 ± 6.6	63.7 ± 5.8	N.S
Weight (kg)	75.6 ± 9.5	78.3 ± 12.2	N.S
Height (cm)	171.7 ± 6.2	173.2 ± 5.9	N.S
BSA (m^2)	1.88 ± 0.14	1.92 ± 0.14	N.S

Mean values ± D.S. Group A = Ketorolac. Group B = Fentanyl.

uled for multiple prostatic biopsies (ultrasound guided) were enrolled in this study.

Patients, who were graded ASA physical status 1 or 2, with a median age of 64.7 ± 6.25, and satisfied the inclusion criteria, received IM atropine 0.01 mg/kg as premedication 30 min before coming to the operating room.

On arrival at the operating room, routine monitoring was applied, including ECG, non invasive automatic blood pressure cuff, pulse oximeter (SpO_2), end-tidal CO_2 ($EtCO_2$) and respiratory rate.

Patients were randomly allocated to two equal groups, to receive either Ketorolac 0.55 mg/kg (Group A, $n = 51$) or Fentanyl 1 μg/kg IV. (Group B, $n = 51$) respectively 15 and 5 min prior to the induction of anaesthesia, after placement of an IV catheter.

Anaesthesia was induced with Propofol 15 mg/kg per h and patients were allowed to breath spontaneously a mixture 70% nitrous oxide in oxygen via a to and fro system. The ultrasound examination was then performed using a transrectal biplanar-linear 7.5 MHz probe and a 14 ch, 20 cm long needle was inserted in the perineum. In the absence of signs of inadequate anaesthesia, Propofol was infused at 7 mg/kg per h.

Before induction (TO), 5, 10, 15 min after induction (T5, T10, T15) and 60, 120 min (T60, T120) after the end of Propofol infusion, mean arterial blood pressure (MAP), heart rate (HR), respiratory rate (RR), SpO_2 and end tidal CO_2 ($EtCO_2$) were recorded.

After discontinuation of Propofol and nitrous oxide we recorded when the patient spontaneously opened his eyes (time to eye opening), responded to simple verbal command to squeeze the investigator's hand (time to following commands), and gave their correct date of birth.

At 60 and 120 min after emergence we used a pain intensity score PIS (O = no pain, 1 = mild, 2 = moderate, 3 = severe) to assess pain and a visual analogue scale VAS (1 = poor, 2 = fair, 3 = good, 4 = very good, 5 = excellent) to assess the tollerability of the procedure. The requirements of incremental doses of anaesthetics and postoperative side effects were noted.

Six to eight prostatic biopsies were taken with the patients in the lithotomy position. Throughout the procedure 10 ml/kg normal saline was infused.

Surgical and ultrasonographic procedures were performed by the same physicians; even anaesthesia was administered by one anaesthetist who was aware of the analgesic agent used, but who took no part in the assessments. Monitoring data and recovery were recorded by a second anaesthesiologist unaware, in turn, of the anaesthetic technique used.

The amount of drugs administered intravenously was noted and cost analysis was performed.

3. Data and statistical analysis

3.1. Data transformation

All routine monitoring parameters at $T_n(T_5–T_{120})$, were computed as their per cent difference from TO, considered as baseline value, according to the formula: (TO − Tn):TO × 100.

Table 2
HR, MAP, RR, $EtCO_2$, SpO_2, during surgery

Times	Mean values (S.D)						Friedman test	
	Group A ($n = 51$)			Group B ($n = 51$)			A and B	T5-T10-T15
	T5	T10	T15	T5	T10	T15		
R	0.68 (10.9)	2.16 (12.31)	4.37 (12.11)	4.64 (12.22)	10.5 (15.3)	11.9 (14.2)	***	***
MAP	6.67 (9.8)	12.22 (11.31)	16.46 (10.53)	10.3 (8.9)	17.2 (9.13)	19.6 (9.9)	*	***
RR	−3.92 (25.6)	−10.83 (25.6)	−14.96 (24.58)	27.5 (41.3)	31.14 (47.1)	15.23 (39.32)	***	***
$EtCO_2$	−5.1 (13.5)	−3.53 (16.2)	−4.09 (16.03)	−7.5 (13.4)	−15.25 (18.3)	−16.95 (19.7)	***	N.S.
SPO_2	0.09 (1.8)	013 (1.7)	−0.31 (1.54)	0.45 (2.75)	1.25 (3.54)	0.84 (2.17)	N.S	N.S

T5, T10,T15, are recorded as their percent differences from T0, considered as baseline value according to the formula: (T0 − Tn): T0 × 100. Statistical analysis among times and between groups.Group A = Ketorolac. Group B = Fentanyl
* $P<0.05$
** $P<0.01$
*** $P<0.001$

Table 3
HR, MAP, RR, $EtCO_2$, SpO_2, during recovery

Times	Group A ($n = 51$)		Group B ($n = 51$)		Test	
	T60	T120	T60	T120	Gruppi	Tempi
$EtCO_2$	1.34 (7.94)	2.0 (8.17)	−0.6 (10.6)	−1.82 (10.4)	N.S[a]	N.S[a]
RR	−0.34 (17.3)	3.12 (19.7)	0.39 (31.3)	4.06 (23.89)	N.S[b]	N.S[b]
HR	9.19 (13.8)	10.83 (14.8)	10.63 (18.32)	12.03 (17.61)	N.S[a]	N.S[a]
MAP	8.99 (11.8)	8.8 (11.29)	8.95 (11.4)	7.78 (10.25)	N.S[a]	N.S[a]
SPO_2	−0.01 (1.27)	0.01 (1.25)	0.06 (1.56)	1.32 (8.27)	N.S[b]	N.S[b]

Mean Values (S.D) of T60 and T120 from discontinuation of N_2O and propofol.
Statistical analysis among times and between groups T60 and T120 are recorded as their diferences from To, considered as baseline value according to the formula $(T0 - Tn):T0 \times 100$.
Group A = Ketorolac. Group B = Fentanyl.
[a] Two-ways ANOVA
[b] Friedman test

3.2. Statistical analysis:

To verify the effects of the analgesics on per cent variations at T5, T10, T15, T60, T120 with respect to TO, the Friedman Test was used when it was impossible to show that the data were normally distributed, and two-ways ANOVA when it was possible [13,14].

The Mann–Whitney test was used to analyze differences in recovery, induction and total times between the two groups.

PIS data, expressed as frequency, in two groups at T60 and T120 were examined using the Fisher test.

In all cases a P error, less than 0.05 in rejecting H_0 hypothesis, was considered a statistically significant result thus defining a threshold at $P = 0.05$.

4. Results

Table 1 shows that there was no significant difference between the demographic characteristics of the two groups.

Table 2 and Table 3 show mean values and standard deviation (S.D.) of per cent differences at T5, T10, T15, T60, and T120 with respect to TO of HR, MAP, RR, $EtC0_2$, SpO_2. Both HR and MAP decrease in both groups at time 5, 10 and 15 with significantly lower values in the Fentanyl group; even the differences between time were significant while no difference was found at T60 and T120. There was no statistical difference in SpO_2 recorded in both groups. However, in the Fentanyl group frequent episodes of apnoea, followed by immediate assisted ventilation, could have influenced these data.

At T5, T10 and T15, RR increased in Group A, but decreased in Group B, with significant differences between both groups and times, while at T60 and T120 no differences were noted.

Table 4 shows that in Group A both induction and total anaesthesia times were significantly longer.

There were no differences between groups either for PIS or for VAS (Fig. 1, Fig. 2). Awakening time determined from discontinuation of Propofol and N2O, was considered the time when the patients could open their eyes, respond to verbal command and demonstrate orientation in time and space giving their correct date of birth. There were no differences between groups as to awakening time, but time to following commands proved to be near the threshold (Table 5).

Ketorolac, administered before surgery, had less intraoperative and postoperative side effects than Fentanyl (Table 6).

Analysis of intravenous anaesthesia drugs revealed a higher cost in the Ketorolac Group, but we did not take into account other anaesthesia-related direct and indirect costs, such as inhalatory drugs, staff time, equipment and supplies (Table 7).

Table 4
Induction time (T1), Surgery time (T2) and total anaesthesia time (T3)

	A ($n = 51$)	B ($n = 51$)	Mann Whitney test
T1 (min)	7 ± 2.6	6.08 ± 2.69	**
T2 (min)	10 ± 4.44	7.98 ± 3.85	*
T3 (min)	17 ± 4.27	14.06 ± 3.97	***

Mean Values ± S.D. and statistical analysis.
Group A = Ketorolac. Group B = Fentanyl.
* $P < 0.05$
** $P < 0.01$
*** $P < 0.001$

5. Discussion

In elderly patients anaesthetics have to provide intraoperative and postoperative analgesia, reduce metabolic

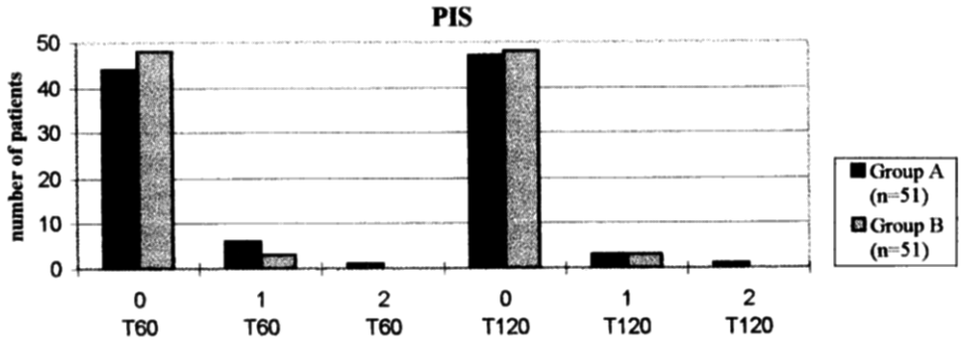

Fig. 1. Pain Intensive score (0–3) after 60 and 120 min. (T60–T120) from discontinuation of N_20 and Propofol. Score: 0 = no pain, 1 = mild, 2 = moderate, 3 = severe.

and autonomic responses to surgery, provide a rapid emergence from anaesthesia, low incidence of side effects and a short recovery time. Propofol, for its pharmacokinetics, compartment constants and clearance, seems to achieve this goal better than benzodiazepines and barbiturates [15–17].

The volume of central compartment and total body clearance is reduced more in the elderly than in adults and in children thereby reducing the dose required for induction and maintenance [4].

Dose and infusion rate influence the pharmacodynamic effects: a slow infusion, through a syringe pump, can be titrated to obtain satisfactory surgical conditions, minimizing adverse effects [3–6]. Nevertheless, hypotension, reduced cardiac output, ventilatory depression are more frequent when Propofol is associated with N_2O and/or to opioids [18].

Setting the induction rate at 15 mg/kg per h and the maintenance at 7 mg/kg per h, during surgery, a reduced MAP was more evident when Fentanyl was used, even though at low dose (1 μg/kg). MAP decreased less than 20% of the baseline value, partly due to the associated reduction in HR (Table 2). In fact clinical reports on Propofol describe slow heart rates despite a decrease in arterial pressure. Propofol causes resetting of the baroreflex without depressing its sensitivity, enabling a slower heart rate to be maintained despite any fall in blood pressure [19,20].

Diclofenac dosage (0.55 mg/kg IV) had to assure a plasma concentration appropriate for providing effective pain relief in a comparable group of patients undergoing suprapubic prostatectomy (Zatelli R. et al. unpublished data). We administered ketorolac 15 min before surgery in order to achieve plasma levels high enough to inhibit prostaglandine synthesis prior to tissue injury and to prevent central nociceptive sensation [9,21,22].

As Ketorolac has no cardiorespiratory depressant effect [11,12], the reduction in MAP and HR observed in the Ketorolac group could be related to Propofol, as well as the increase of $EtCO_2$ while spontaneous ventilation was maintained. On the other hand, Fentanyl treated patients had ventilatory depression, higher increase of $EtCO_2$, decreased RR up to frequent apnoea (Table 6).

Intraoperative requirements for supplemental Propofol and RR increase could suggest an occasionally inadequate analgesic effect produced by Ketorolac in this procedure (Table 2), while good PIS and VAS values and the significantly lower incidence of side effects indicated proper postoperative analgesia and comfort. Patients could be discharged 60 min after surgery (Table 6, Fig. 1 and Fig. 2).

Fentanyl enhanced Propofol's hypnotic action, providing a shorter induction and global time and a lower necessary dose of Propofol (Table 4). So the

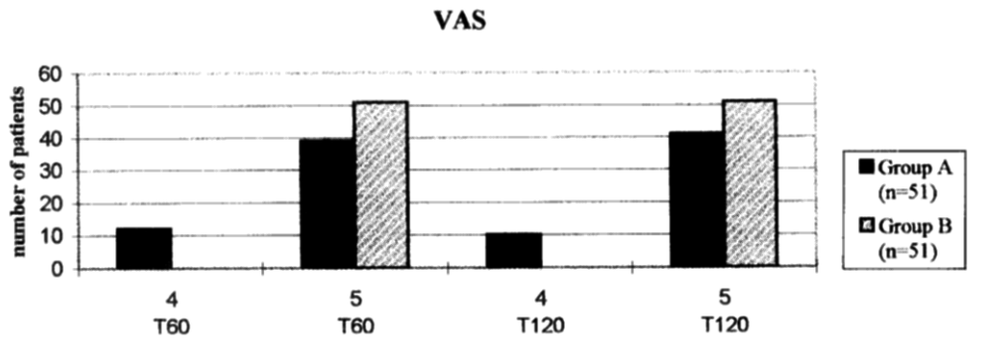

Fig. 2. Visual Analogic Scale (1–5) after 60 and 120 min. (T60–T120) from discontinuation of N_2O and Propofol. Score: 1 = poor, 2 = fair, 3 = good, 4 = very good, 5 = exellent.

Table 5
Time to emerge from anaesthesia determind from discontinuation of N_2O and propofol

	Mean values S.D.		
	A ($n = 51$)	B($n = 51$)	Mann-Whitney test
Time to eye opening (min)	4.25 ± 1.41	3.9 ± 1.97	N.S
First response to verbal command (min)	5.14 ± 1.48	4.49 ± 1.99	N.S
Oriented to time, place (min)	5.88 ± 1.7	5.55 ± 2.26	N.S

Mean values ± S.D. and statistical analyisis.
Group A = Ketorolac. Group B = Fentanyl

shorter time to follow commands ($P < 0.06$) may be related to the lower dose of Propofol used in the Fentanyl group (Table 5). Mild nausea had the same incidence in the two groups and could be related to the position, manual ventilation via a facial mask and to N_2O [23,24], drowsiness and headache were more frequent in the Fentanyl group (Table 6) and could possibly have been prevented in these elderly patients with the use of short acting optioids (sufentanyl or alfentanyl) [25–27].

The cost of IV drugs was significantly higher with Ketorolac, both because the drug itself is more expensive than Fentanyl, and because a larger amount of Propofol was required (Table 4, Table 7). In summary, Ketorolac given intravenously in Propofol anaesthesia, being associated with less intraoperative and postoperative side effects, may offer some advantages over opioids. Though involving a higher anaesthesia drug cost, it could save PACU nursing time and costs and assure a shorter time to discharge the patient [28–30]. More comprehensive studies on cost analysis are still necessary.

Table 6
Intraoperative and postoperative side effects

	A ($n = 51$)	B ($n = 51$)
Intraoper. apnoea	—	16 (31%)
Nausea	2 (3.9%)	1 (1.9%)
Somnolence	—	3 (5.9%)
Headache	—	1 (1.9%)
Total	2 (3.9%)	21 (40.7%)

Rate and % in group A = Ketorolac and group B = Fentanyl.

Table 7
Anaesthesia drugs costs

Group	Means	S.D.
A ($n = 51$)	£ 5035.5	557.6
B ($n = 51$)	£ 1522.3	410.1

T-test, $P < 0.001$. £ (Italian coin).
Group A = Ketorolac. Group B = Fentanyl.

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Ambulatory Surgery

The surgical therapy for the lower limb varices in day surgery

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Abstract

1775 varicose patients (1318 female, 457 male) with mean age 47.7 years have been operated in One Day Surgery in III Department of General Surgery and in the Phlebology Centre of the University of Siena between June 1 1985 and May 30 1996. 1274 (71.7%) patients underwent internal saphenectomy of which 947 (53.3%) through short stripping, 327 (18.4%) through long stripping, 106 (5.9%) external saphenectomy, 90 (5.1%) revision of the saphenous-femoral junction, 258 (14.5%) phlebectomies; 16 (0.9%) external valvuloplasty sec. Mancin, 31 (1.7%) other operations. All patients were discharged on the same day of operation. The obtained instrumental and clinical results show an improvement of haemodynamics, with 21% varicose residue for incontinence perforating veins on long stripping internal saphenectomy. In their experience in the surgical treatment of varicose veins, the authors affirm that the policy of One Day Surgery is not greatly affected by the surgical technique adopted but more so by the anaestesiological technique used and the clinical condition of the patients. © 1997 Elsevier Science Ireland Ltd.

Keywords: Varicose veins; Surgical treatment; One day surgery

1. Introduction

From the time that humans began holding themselves erect, varicose disease has been a pathological condition that afflicts man.

In Western Countries, Italy included, more than 20% of adults suffer from chronic venous insufficiency of the lower limbs' superficial circulation. This pathology, second only to influenzal syndrome as the cause for the loss of more than 1 working day [1].

The therapy for this disease is based on three main treatments: surgical treatment, sclerotherapy and elastic compression.

In the past, surgical treatment required hospital admission which sometimes lasted about one week with the patient confined to bed.

At present, the progressive reduction of the available economic resources, above all for medical services, and the consequent expense reduction for hospitals, have resulted in a further reduction of the beds available. That is why the operations are performed on a day surgery basis [6].

The surgical therapy for the limbs varices has been treated as an outpatient operation for over 10 years at the Interdepartmental Center for Research, and the Phlebolymphological Therapy and Rehabilitation Centre of the University of Siena which is directed by Professor Sergio Mancini. At present, after the introduction of the DRG (disease related groups) the disease is also treated in the Day Hospital.

2. Materials and methods

At the above mentioned centre from June 1985 to May 1996, 1775 patients suffering from chronic venous insufficiency of the lower limbs superficial circulation, have undergone surgical therapy. 1318 (74.3%) of them were female and 457 (25.7%) were male. Age ranged from 18 to 90 years; the average being 47.7 years.

The patients were treated only when the surgeon suggested surgical treatment to resolve their phlebological symptoms and after a careful selection of all those who asked for a medical examination at the center.

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During the pre-operative preparation, patients underwent hematochemical tests, ECG and, in the presence of respiratory insufficiency, a chest X-ray and an anaesthesiological evaluation.

Patients over seventy and those suffering from cardiopathy, bronchopneumopathy, nephropathy, metabolic disease, heavy obesity have recently been excluded from surgical treatment at the center and have been received in the operating theatre at the General Surgery III, where there is a better monitoring system and they can receive proper assistance. The day before the treatment, the patients usually undergo a further and more careful check up of their varicose pathology.

In addition to clinical examination, it includes a haemodynamic test of the lower limbs' venous circulation through a non-invasive instrumental diagnosis, such as the Doppler Examination and the HR Echography [2,4].

Since 1993 the Ecocolordoppler and since last February the Reflected Light Rheography through Angioflow have also been available.

At about 8 a.m. patients scheduled for treatment undergo a mapping of their varicose using a marking pen.

The anaesthesiological phase follows [3]. At present, the methodology suggests the trunk anaesthesia which permits the rapid recovery of the treated limb and the discharge of the patient. The anaesthesist sometimes chooses selective spinal anaesthesia or epidural on a technical basis or on the basis of the patient's clinical situation, which often includes large varicose veins which require extended operating time and selective spinal or epidural anaesthesia.

Local anaesthesia is frequently used when the surgeon has to treat both unilateral or bilateral multiple varices on the thigh and/or leg, according to Muller's technique.

At the beginning of our experience, general anaesthesia was also employed; nowadays, it is limited to those patients suffering from cardiopneumopathies or from a minor hepatic or renal insufficiency.

The surgical treatment starts with a small inguinal cut of about 3–4 cm, parallel to the inguinal ligament. Once the large saphenal vein is located, it is put on a tape, then the surgeon starts the crossectomy with collateral ligature and the section of the veins.

As soon as he gets to the femoral vein, he divides the saphena vein between two forceps and ligates the stump near the femoral vein. Then he puts a disposable plastic stripper in the saphena, following the caudal-skull direction. He then makes a distal cut usually on the upper third of the leg during short stripping and on the ankle during long stripping. When necessary, the surgeon avulses multiple varices through small cuts, according to Muller.

Finally he sutures the cutaneous cuts and puts steristrips on the small cuts. After treatment the limb is tightly wrapped with a stretchable bandage.

After about 2 h the treated patients are allowed to walk about and are usually discharged 4–6 h after the treatment. The post-operative check up are at 1, 7 and 30 days together with a final one after 6 months. It is suggested to each patient that he wears a leg support with a second compression ratio for about three months.

3. Results

The following data belong to a detailed analysis of 1775 surgical treatments at our Center of Phlebology since 1985:

947 (53.3%)	Internal saphenectomies through short stripping
327 (18.4%)	Internal saphenectomies through long stripping
258 (14.5%)	Mono and bilateral multiple varices of thighs and/or legs
106 (5.9%)	Superficial saphenectomies through short or long stripping
90 (5.1%)	Check up of the saphenous-femoral arch
18 (1.1%)	Treatments of venous ulcers
16 (0.9%)	Valvularplasties
8 (0.4%)	Felder's treatments
3 (0.2%)	Isolated crossectomies
2 (0.1%)	Check up of the saphenous-popliteus

As far as the kinds of anaesthesia is concerned, most treatments have been performed with local or regional anaesthesia. In the last three years trunk anaesthesia has been clearly prevalent:

858 (48.3%)	Trunk anaesthesia
339 (19.1%)	Epidural anaesthesia
235 (13.2%)	Spinal anaesthesia
221 (12.4%)	Local anaesthesia
122 (6.9%)	Total anaesthesia

Thanks to modern anaesthetic technology which allows immediate post-operative ambulation, about 98% of the 1775 patients were discharged the same day they underwent treatment.

This technology avoids the complications associated with general anaesthesia, such as water retention, nausea, vomiting, indisposition and vascular and bronchopulmonary complications.

No operative or post-operative mortality was recorded. 40 patients (2.2%) were detained at the hospital for a short period because of the onset of cephalea caused by the rachianaesthesia.

4. Conclusions

In the United States and all over Europe, Day Hospital Surgery has an important place, particularly because it decreases hospital expenses.

Varicose disease is a benign affliction and is generally treated using local or regional anaesthesia on an outpatient basis. Nonetheless, the habitual care taken in patient selection, reception and psychological preparation for treatment is essential. This must not be ignored becuase varicose vein surgery can be undertaken in a D.H. or on an outpatient basis [5,6].

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Ambulatory Surgery

Out-patient surgery of the varicose veins of the lower limbs: personal experience

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Abstract

We report our experience in the treatment of varicose veins of the lower limbs in the day surgery clinic of the 2nd Department of General Surgery of the University of Padova. From October 1990 to October 1996, 1522 cases of lower limb varicose veins were treated in our day-surgery clinic. Super-selective subarachnoid anesthesia was used in 94% of the cases. In all cases in which the incompetence of the saphenous trunk was demonstrated, crossectomy was associated with long or short stripping. There were no intra- or post-operative deaths and only limited morbidity. Post-operative hospitalization was required in four patients (three for headache and one for precordial pain). In conclusion, the out-patient treatment of varicose veins involves the same techniques as in-patient treatment. Therefore, the risks associated with surgery and anesthesia are very limited in a specialized center. © 1997 Elsevier Science Ireland Ltd.

Keywords: Anesthesia; Out-patient surgery; Varicose veins

1. Introduction

Day hospital treatment of lower limb varicose veins is already standard in the USA [1]. In Italy [2] it has come to be seen as a choice forced by the lack of hospital beds, long waiting lists for routine operations and the high costs of traditional surgery performed in an in-hospital regime.

Numerous studies concerning organizational, anesthesiological and surgical problems have been published and the guidelines for day surgery have already been established [3–5].

Day surgery experience is still limited in Italy and will have to be wider before it is possible to confirm the safety and effectiveness already demonstrated in other countries. Hence, we report our 6-year experience in the day surgery treatment of lower-limb varicose veins with particular emphasis on the analysis of data concerning minor and major complications after the application of surgical and anesthesiological techniques identical to those applied in traditional in-hospital surgery.

2. Materials and methods

From October 1990 to October 1996, day surgery treatment of lower limb varicose veins was performed in 1522 patients; 425 males (28%) and 1097 females (72%); the average age was 47 years (range 20–81).

Varicose disease was divided into the following groups through echo color Doppler examinations:

varices of the large saphena vein (1402; 92%)
varices of the small saphena vein (62; 4%)
varices of the perforating veins of the popliteal fossa (2) and of Hunter (2)
recurrent varices of the large saphena vein (54: 4%).

All operations were performed in a day surgery center independent of the hospital center and according to day surgery protocol.

The anesthesiological technique used most frequently was superselective subarachnoid anesthesia, performed in 1432 patients (94%), while a winnie block was per-

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formed in 15 patients (1%), local anesthesia alone in 47 patients (3%) and local anesthesia associated with propofol in 28 patients (2%).

The large saphena vein was treated with three types of surgical intervention:

radical crossectomy and long stripping (228; 16%)
radical crossectomy and short stripping (1072; 76%)
radical crossectomy alone (102; 7%).

Surgery of the small saphena vein included:

radical crossectomy and long stripping (4; 6%)
radical crossectomy and short stripping (54; 87%)
radical crossectomy alone (4; 6%).

Altogether, 232 long strippings (15%), 1126 short strippings (74%) and 106 crossectomies were performed. Moreover, 54 revisions of the sapheno-femoral crosses for recurring varices of the large saphena vein, two ligations of perforators of the popliteal fossa and two ligations of Hunter perforators were performed. A total of 61% of the patients underwent sclerotherapy of collateral varicose veins post-operatively. All patients were discharged with an adhesive stretch bandage which was removed after about 7 days.

Patients were checked on the 1st post-operative day and telephone contact was established so that patients could immediately report possible symptoms of complications related to the surgical wound or to the bandage.

3. Results

No deaths occurred intra- or post-operatively. Three patients who had undergone stripping of the large saphena requested post-operative hospitalization for headache caused by spinal anesthesia. One patient was admitted to the traditional hospital regime due to the appearance of intra-operative precordialgia but was released after only a 1-day stay.

The only anesthesiological complication was headache caused by subarachnoid anesthesia which occurred in five patients (0.3%), three of whom requested hospitalization. No complications related to overdose or allergic reaction to the anesthetic occurred in patients who received local anesthesia.

No infections of the wound, hemorrhaging of the inguinal or popliteal wound requiring reintervention, deep venous thrombosis, pulmonary embolism or other major surgical complications occurred.

Minor surgical complications were analyzed in a sample of 150 operated patients:

ecchimosis requiring no treatment (32 patients; 21%)
infiltration of the inguinal wound requiring no treatment (25 patients; 16%)
discomfort related to the elastic bandage in 70 patients (46%), requiring removal of bandage due to discomfort 19 patients (12%).

Two patients in this sample reported intolerable post-operative pain and 85 patients (57%) took analgesics during the post-operative period.

A total of 89% of the sample expressed a favorable opinion of the surgery and the post-operative phase, claiming to be highly satisfied. This was substantiated by the fact that the help-line received only six calls, none of which requested immediate medical assistance.

4. Conclusions

In our experience, treatment of varicose veins performed in day surgery is equivalent to traditional surgery performed in an in-hospital regime. In fact, the most frequent treatment was short stripping (74%) of the large saphena vein (92%) and superselective subarchnoid anesthesia was performed in 94% of the cases.

The procedure proved to be quite safe; no major surgical complications occurred [6]. The only significant complication to be reported was anesthesia-related, i.e. five cases of headache [7].

This low incidence of complications can be explained by the improvement in anesthesiological techniques, the accurate selection of patients who are suitable for day surgery, the specific experience of the staff and the organization of the clinic.

Patient tolerance and satisfaction were high. In fact, a large percentage of patients suffered relatively few symptoms and those reported were related to the bandage, which caused discomfort, mainly on the 5th or 6th post-operative day.

Day surgery of lower limb varicose veins has proved to be safe, effective, well accepted by patients and advantageous both from the economic point of view and from that of the availability of hospital beds. However, it requires a specific competence and knowledge of possible related problems that are not always strictly medical.

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