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Continuous intravenous versus bolus parenteral midazolam: a safe technique for conscious sedation in plastic surgery

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SUMMARY. Conscious intravenous sedation is a safe alternative method to general anaesthesia. We have used a technique of continuously titrated, as opposed to incremental boluses of, intravenous or intramuscular midazolam for conscious sedation, with tumescent adrenaline-lignocaine solution for local anaesthesia, routinely in 421 plastic surgical procedures between 1997 and 2000. All patients were American Society of Anesthesiologists (ASA) class I or II. Conscious sedation was administered through our protocol of continuously titrated doses of midazolam in dextrose saline. The operative field was injected subcutaneously with varying volumes of diluted lignocaine and adrenaline, depending on the anatomical region. Preoperative sedation was administered 1 h before the procedure in the form of an intramuscular injection of pethidine and promethazine (Phenergan). Intraoperatively, a subset of patients received up to four divided diluted doses of pethidine. A preoperative 4 h starvation period pronounced the effect of the sedative. No intraoperative conversions to general anaesthesia were needed, and no sedation complications occurred. No unplanned re-admissions secondary to nausea, prolonged drowsiness or pain were required. All patients who were treated using this technique had an uneventful postoperative course. Hospital stay was substantially shorter than following general anaesthesia, which provided a significant reduction in medical-care expenses and a faster return to work. In conclusion, conscious sedation administered by titrated intravenous midazolam is a well-tolerated, safe, consistent, predictable and effective anaesthetic choice for a variety of plastic surgical procedures, many of which would commonly be performed under general anaesthesia. © 2003 Published by Elsevier Science Ltd on behalf of The British Association of Plastic Surgeons

Keywords: continuous intravenous midazolam, benzodiazepine titration, lignocaine and adrenaline tumescence, plastic surgery without general anaesthesia.

Developing countries, such as Jamaica, are now seeing an increased demand for aesthetic plastic surgery. This may, in part, be due to the impact of the print and electronic media. In the past, requests for cosmetic surgery came from a small percentage of those with high socioeconomic status. The most significant increase in demand in the last decade, however, has been in the middle and lower socioeconomic groups. The factors that have traditionally limited access to cosmetic surgery by those in the middle and lower socioeconomic groups include: (i) fear of general anaesthesia (although this is not exclusive to patients in these groups); (ii) the overall cost of surgical management; and (iii) a lack of health insurance coverage for most cosmetic surgical procedures.

There has been a trend toward cost-effective ambulatory surgery, with an increasing number of plastic- and cosmetic-surgery operations being performed under local or regional anaesthesia.[1–3] Parenteral conscious sedation using benzodiazepines has been widely used in ambulatory plastic surgery because of its effectiveness, flexibility and relatively low cost.[1–5] However, continuous titrated intravenous sedation is a novel technique that may overcome some of the safety concerns surrounding the administration of intravenous or intramuscular incremental boluses of benzodiazepines.[1,2] Conscious sedation combined with tumescent local anaesthesia has helped patients to overcome their fear of anaesthesia and has significantly reduced the costs of anaesthetic procedures for our patients.

The intravenous sedative of choice in all our procedures is the short-acting imidazobenzodiazepine, midazolam. Like other benzodiazepines, midazolam is an anxiolytic sedative, hypnogenic muscle relaxant, anticonvulsant and effective tranquilliser. These properties are based on its interaction with receptors in the central nervous system, causing an elevated inhibitory effect of gamma-aminobutyric acid (GABA). The advantages of midazolam over other agents are that it is water-soluble and has a highly desirable pharmacokinetic profile with a relatively short half-life, a lack of active metabolites, a very rapid onset of action, a sleep-inducing action of pronounced intensity and a powerful antegrade amnesic effect of short duration. It is pain-free during intravenous injection, does not give postoperative phlebitis and has no hangover effects.[1–3]

We have used this approach with consistent, effective and predictable outcomes in a wide range of procedures, including facial rejuvenation (blepharoplasty and facelifts), breast operations (augmentation, mastopexy, reduction, post-mastectomy reconstruction), abdominoplasty, combined breast and abdomen operations, liposuction and other general plastic surgical operations.

Methods and results

We have used titrated midazolam as an intravenous sedative and adrenaline-lignocaine solution as a local anaesthetic routinely in 421 patients undergoing plastic surgery between 1997 and 2000. There were 83 males with an age range of between 12 and 65 years, and 338 females with an age range of between 18 and 80 years (Table 1, Fig. 1). All patients were admitted for 1 day; however, an overnight stay was optional.

Patient selection

Patients were drawn from male and female (non-pregnant) outpatients who had been scheduled for routine plastic, reconstructive and elective cosmetic surgery operations. Patients were interviewed at length, a detailed medical history was taken and a clinical examination was performed, with special emphasis on the cardiorespiratory system. Patients were all American Society of Anesthesiologists (ASA) physical status I or II. Those with a previous history of an allergic reaction to local-anaesthetic agents or benzodiazepines and those with cardiorespiratory disease were excluded. Older patients were included if they were healthy and had no evidence of cardiorespiratory disease.

The procedure and the method of sedation and local anaesthesia were explained to all patients. Patients were given a choice between general and intravenous-conscious anaesthesia and told of the advantages and disadvantages of each method. Written consent was obtained from every patient. Patients were advised to attend on the day of the operation, having starved for 4 h preoperatively.

Table 1 List of the types and numbers of cases performed under conscious anaesthesia

Procedure	Number of cases
total cosmetic-surgery cases	336
suction lipolysis	146
facelifts and blepharoplasty	50
rhinoplasty	25
breast reduction and mastopexy	30
suction lipolysis and subcutaneous mastectomy for gynaecomastia	30
breast augmentation	35
abdominal lipectomy	20
total general plastic-surgery cases (including wound excision and grafting, scar revision, hidradenitis excision and grafting, axillary breast excision, groin and fasciocutaneous flaps, large submuscular lipoma excision, and breast reconstruction using tissue expanders)	85

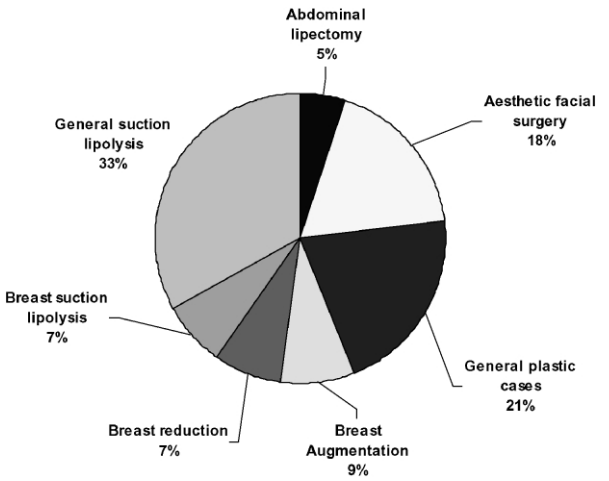

Figure 1—Percentages of the different types of procedures performed under conscious anaesthesia.

Procedures were carried out in both public and private hospital operating theatres with appropriate monitoring facilities, emergency equipment and anaesthetic back up. As most patients were discharged the same day, adequate care and support at home was considered essential, and a friend or relative had to accompany all patients home. We recommended that patients should not drive or operate machinery for at least 24 h after surgery. Routine laboratory testing was not performed in all cases; however, because of our patient population, a sickle-cell test and, in certain cases, relevant blood tests, ECGs and chest X-rays were performed.

Premedication

Premedication was administered to all patients 1 h preoperatively. Patients received varying doses of intramuscular pethidine and promethazine (Phenergan) according to age and body weight.

Perioperative monitoring

All patients were monitored with continuous ECG, automated non-invasive intermittent blood-pressure measurements and pulse oximetry. The vital-signs data collected

Table 2 Intraoperative and postoperative vital-sign measurements

Vital sign	Intraoperative value	Postoperative value
pulse range (bpm)	64–88	72–89
SPO_2 range (% oxygen saturation)	96–99	96–99
systolic blood pressure <90 (*n*)	0	5
systolic blood pressure >150 (*n*)	0	0
nausea (*n*)	0	0
emesis (*n*)	0	0

during the intraoperative and postoperative periods are listed in Table 2. The antidotes flumazenil (a benzodiazepine antagonist) and naloxone (Narcan; an opioid antagonist) were kept in the operating theatre. A certified and registered trained nurse was with the patient at all times and took the relevant vital measurements whilst monitoring the patient's respiratory status and level of sedation. The nurse determined baseline measurements of heart rate and blood pressure for every patient. Thereafter, haemodynamic measurements using a Dinamap monitor and recorder were performed at regular 5 min intervals. Respiratory rate and pattern were also recorded every 5 min. Throughout the procedure, the nurse continuously appraised the patient's level of sedation by evaluating the vital observations and recorded measurements, and kept the surgeon fully informed of any changes and of the subtotalled doses of all administered medications.

Perioperative sedation

The requirement for intravenous sedation was 10 mg midazolam (the recommended maximum dose for midazolam is 0.15–0.35 mg kg^{-1}), which was infused into a 500 ml bag of 5% dextrose water. The infusion was then administered via a 20 G peripheral catheter. The surgeon administered all medication. The drip rate was adjusted to give a smooth slow infusion until the patient showed a clinical response. The initial signs of sedation were commonly slurring of speech and drowsiness. An adequate level of conscious sedation invariably followed these early signs. The end point of conscious sedation was considered to be drowsiness with the patient still reasonably responsive to verbal commands. After the initial infusion of 100 ml of diluted midazolam, sedation had reached an adequate level for the surgeon to begin the injection of tumescent local anaesthesia in most cases. Without exception, once the patient had reached an adequate level of anaesthesia, the rate of infusion could be slowed considerably, at which point surgery could be commenced.

The sensitivity of patients to midazolam varied significantly. The infusion rate was thus varied according to patient sensitivity in order to achieve an adequate level of sedation. Sedation of most patients required the use of midazolam only, and this could facilitate up to 4 h of conscious anaesthesia (Table 3). The drip rate was, therefore, guided by evaluation of the patient's cardiorespiratory status and other parameters, such as the age of the patient and the length of the procedure. Induction and maintenance of sedation was best achieved when the patient had starved for at least 4 h preoperatively. Towards the end of the procedure, the drip rate was tapered off and then stopped.

Patients were discharged the same day, except in cases of planned or unexpectedly long procedures, when overnight observation became necessary, or where patient circumstances dictated an overnight stay owing to a lack of available care and support at home. None of our patients experienced any respiratory distress or apnoea. No intraoperative conversions to general anaesthesia were needed, and no anaesthetic complications occurred. No unintended re-admissions secondary to nausea, prolonged drowsiness, pain or other medical reasons were required. All patients who underwent this technique had an improved postoperative course. Hospital stay was substantially shorter than the average stay following general anaesthesia, providing a significant reduction in medical-care expenses, with a hastened return to work.

Table 3 Procedure duration, sedative doses and outcome

Duration of procedure (min)	Number of cases	Midazolam dose (ml of titrated fluid)	Recovery time (min)	Number of unintended overnight admissions
30–60	25	250–300	30–40	0
60–120	195	300–500	60–90	3
120–180	146	500	90–240	7
180–240	55	500	120–240	0

Perioperative tumescent local anaesthesia

The requirements for tumescent local anaesthesia varied according to the operation being performed and the patient's age and body weight. The exact amount of tumescent anaesthetic fluid depended on the procedure being performed. For most cases, except suction lipolysis, we used a 0.25% lignocaine with 1:500 000 adrenaline solution. This was made by mixing 1 ml of 1:1000 adrenaline in 500 ml of normal saline. This solution was used to dilute 2% lignocaine to 0.25%. This solution was mainly used for local anaesthesia by perioperative injection at the anatomical site being operated on; although, in liposuction, it was used for both anaesthesia and tumescence. In suction lipolysis, we used 0.1% lignocaine (the maximum dose for lignocaine is 7 ml kg^{-1} body weight) and 1:1 000 000 adrenaline.

The use of additional pethidine intraoperatively

For procedures exceeding 2 h, titrated doses of pethidine were used in patients undergoing formal abdominal lipectomy with or without suction lipolysis, suction lipolysis inclusive of the abdominal wall or breast reduction. We diluted 50 mg of pethidine with 12 ml of normal saline and administered it in 3 ml aliquots as required throughout the procedure, taking into consideration the patient's age and their physical and medical status.

Discussion

Intravenous conscious sedation is currently being used extensively in ambulatory procedures. As more patients demand plastic and cosmetic surgical operations without general anaesthesia and become aware of the anaesthetic options available, it is of paramount importance that more surgeons become familiar with non-general-anaesthetic techniques such as intravenous conscious sedation.

In selected cases, we believe conscious sedation is preferable to general anaesthesia for the following

reasons: first, patients are not intubated and, therefore, complications of airway management do not arise; second, owing to its short duration of action, discharge was much faster and in most cases there was same-day discharge; third, avoidance of general anaesthesia may reduce the chance of developing a deep-vein thrombosis or a pulmonary embolism; fourth, there may be less postoperative pain, nausea and vomiting; fifth, as few drugs are used for anaesthesia, there are few drug-induced side-effects postoperatively; sixth, as a result of fast recovery and the absence of side-effects, there are no or few unintended re-admissions; and seventh, the whole procedure costs very little in comparison with general anaesthesia, as the costs of the anaesthetist and the anaesthetic machine and other equipment are obviated.[2,4]

Conscious sedation using midazolam was able to induce a state of anxiolysis, sedation and antegrade amnesia. The continuous-titration technique ensured a steady quiescent state, so that the tumescent local anaesthesia could be infiltrated comfortably and effectively. Midazolam is a rapid-acting water-soluble benzodiazepine. The advantages of using midazolam over other benzodiazepines include painless injection, a short duration of onset of action (midazolam has a fast redistribution phase with a $t_{\S\alpha}$ of 6–15 min, followed by a metabolic clearance of $t_{\S\beta}$ of 1.7–4 h), rapid sleep induction, ten-fold faster metabolic clearance than diazepam, leading to reduced postoperative residual sedation, a strong antegrade amnesic effect, absence of postoperative phlebitis, absence of adverse interactions with other medications used preoperatively, such as opiates and lignocaine, no hangover effect, more effective anxiolytic properties and safer yet stronger sedation.[3,5]

The only known absolute contraindications to the use of midazolam are hypersensitivity to benzodiazepines and acute narrow-angle glaucoma. Midazolam is also not recommended for use during pregnancy. However, precautions should be exercised in elderly people, chronically ill patients and children with cardiovascular instability. Known undesirable side effects include severe cardiorespiratory adverse events following a high dose or too-rapid intravenous administration in elderly patients or those with pre-existing cardiorespiratory systemic disorders. In the event of an overdose, careful observation and management of the cardiovascular and respiratory function is mandatory. Flumazenil is the recommended benzodiazepine antagonist and should be available in every operating theatre.

A narrow therapeutic-dose range for midazolam dictates a careful titration regimen with cardiorespiratory monitoring of the patient to prevent excessive sedation and respiratory apnoea.[1] We believe that administration of midazolam by dilution and continuous-drip titration is a step towards refinement of existing techniques to allow conscious sedation with maximum safety. Operations previously performed under general anaesthesia may now be alternatively performed under conscious sedation. The use of highly effective local anaesthesia delivered by subcutaneous infiltration of a dilute tumescent (high-volume) agent is a useful adjunct to procedures carried out under conscious sedation.[4] The importance of safety in this like any other anaesthetic technique cannot be overemphasised. Therefore, careful selection of patients, a clear understanding of the technique, use of sedative agents and antidotes, and continuous monitoring by a trained nurse with appropriate equipment are essential for ensuring maximum safety.

In conclusion, intravenous conscious sedation is a useful anaesthetic technique for patients considered suitable for ambulatory plastic surgery of relatively short duration in an appropriate setting. Important factors that will lead to a safe and successful outcome using this technique include careful patient selection, the presence of trained nurses, appropriate continuous monitoring, emergency equipment and back-up, and the administration of safe doses of continuously titrated midazolam. With adherence to these guidelines, the surgeon is able to offer the patient a safe, reliable and cost-effective technique as an alternative to general anaesthesia.

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