previous severe reaction to contrast medium)[3] *and* a low-osmolar medium was reasonably available.

In regard to both the issue of wrongfulness and negligence our courts will undoubtedly be influenced by what is considered 'common practice' and 'accepted practice' within a medical specialty,[12] and that may be co-determined by socio-economic considerations.

On the issue of informed consent, there is no indication that our courts will abandon their standpoint that the quantum of information to be supplied by the doctor to the patient is that which a reasonable doctor will give,[13] in favour of the current American judicial view that the standard is that of what the reasonable patient will require.[14] The English courts have also opted for the former, more 'conservative' view.[15] According to our law a patient must be informed of probable side-effects of a medical procedure[16] but need not be apprised of highly uncommon or very unusual side-effects.[13]

It would appear, therefore, that from a strictly legal point of view a radiologist need not inform the patient of the availability of a low-osmolar substance with its slightly lower risk of adverse side-effects. On the other hand, where a low-osmolar substance is in fact available in a particular practice and is economically within the means of the patient, it would certainly be reasonable for the doctor to apprise the patient of the position, and either to suggest the use of the safer substance or to leave the choice to the patient. But where, in a public hospital, the low-osmolar substance is not economically available for general use, there would obviously be no reason for the radiologist to canvass the issue at all when consulting with the patient.

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Blood oxygen saturation levels during conscious sedation with midazolam

A report of 16 cases

J. A. ROELOFSE, P. VAN DER BIJL, J. J. DE V. JOUBERT, H. S. BREYTENBACH

Summary

In a double-blind randomized study on 16 healthy individuals, two groups of subjects (8 in each group) received either midazolam (Dormicum; Roche) 0,1 mg/kg or placebo intravenously for conscious sedation during oral surgical procedures. Oxygen saturation of the blood was measured at different stages. Ten minutes after administration of the drug, the percentage oxygen saturation was significantly lower ($P < 0,05$) in the midazolam group than in the placebo group.

S Afr Med J 1986; 70: 801-802.

Departments of Anaesthesia, Oral Medicine and Periodontics, and Maxillofacial and Oral Surgery, University of Stellenbosch, and Tygerberg Hospital, Parowvallei, CP

J. A. ROELOFSE, M.MED., PH.D. (MED.)
P. VAN DER BIJL, B.SC. HONS, B.CH.D., PH.D.
J. J. DE V. JOUBERT, B.CH.D., PH.D. (ODONT.)
H. S. BREYTENBACH, M.SC., M.CH.D., PH.D. (ODONT.)

In spite of the remarkable efficacy of local anaesthetics and advances in techniques which make oral surgical procedures acceptable and often painless, the fear of pain and discomfort is a common problem among dental patients. For certain apprehensive patients whose fears cannot be adequately allayed, general anaesthesia may be used, but because of the potential hazards associated with this procedure it is not always considered to be a feasible alternative.

Intravenous administration of sedatives and narcotic agents, a practice referred to as conscious sedation, has been successfully used in conjunction with local anaesthesia for relief of anxiety, sedation, reduction of spontaneous movements, and amnesia. In contrast with general anaesthesia, verbal communication with the patient is possible throughout the procedure.

The results of conscious sedation studies[1] for cardiac catheterization, urological procedures, bronchoscopy and gastroscopy have shown that intravenous midazolam (Dormicum; Roche), a 1,4-benzodiazepine, also has the useful sedative and amnesic effects found with other benzodiazepines. Since several studies[2-4] have reported anaesthetic-associated deaths occurring in the dental chair, probably as a result of hypoxia, it was decided to investigate the effect of midazolam on blood oxygen saturation levels in patients receiving this drug for minor oral surgical procedures.

TABLE I. MEANS, RANGES AND *P* VALUES OF BLOOD OXYGEN SATURATION LEVELS

	Midazolam ($N = 8$)		Placebo ($N = 8$)		
Stage	Mean (%)	Range (%)	Mean (%)	Range (%)	*P* value
Pre-drug	**99,750**	**100,00 - 99,00**	**98,875**	**100,00 - 97,00**	**0,0796**
10 min post-drug	**96,125**	**99,00 - 92,00**	**99,250**	**100,00 - 98,00**	**0,0038**
Post-block	**97,125**	**99,00 - 94,00**	**98,000**	**100,00 - 97,00**	**0,2945**
15 min	**97,875**	**100,00 - 95,00**	**97,125**	**100,00 - 94,00**	**0,4479**
30 min	**97,375**	**99,00 - 95,00**	**96,625**	**100,00 - 95,00**	**0,1426**
45 min	**97,500**	**99,00 - 95,00**	**97,571**	**100,00 - 95,00**	**0,8581**

Subjects and methods

In this double-blind randomized study, 16 healthy individuals were divided into two groups and received either midazolam or saline, as placebo, intravenously. No premedication was given on the morning of surgery and the patients were treated as outpatients. All the procedures were carried out with patients in the supine position in a reclining dental chair. An indwelling 21-gauge butterfly needle was inserted into a vein on the dorsum of the hand. The intravenous dose of midazolam was given slowly over 15 seconds and limited to 0,1 mg/kg body weight since the objective was to obtain a sedated but still co-operative patient. Ten minutes after injection of the drug, the appropriate dental block was performed using a vasoconstrictor-free local anaesthetic. Verbal contact was maintained with patients throughout the procedure. Blood pressure, heart rate, respiratory rate, ECG and oxygen saturation values were recorded prior to injection and at various times throughout the study period. Systolic, diastolic and mean blood pressures were measured with a calibrated Critikon Dinamap adult/paediatric vital signs monitor. For information on the arterial oxygen saturation, a calibrated Ohmeda Biox III pulse oximeter was used, the sensor of which was placed on a finger. Oxygen saturation values were determined pre-operatively, 10 minutes after administration of the drug, 5 minutes after the local anaesthetic injection and every 15 minutes during the procedure (Fig. 1). Prilocaine 3% with octapressin was used in all cases for local anaesthesia.

Results

Table I shows the means, ranges and *P* values of blood oxygen saturation levels at various stages of the procedure for all subjects. Ten minutes after drug administration, the percentage oxygen saturation was significantly lower ($P < 0,05$) in the midazolam group than in the placebo group, as can also be seen in Fig. 1. This difference, however, had disappeared by the time further readings were taken.

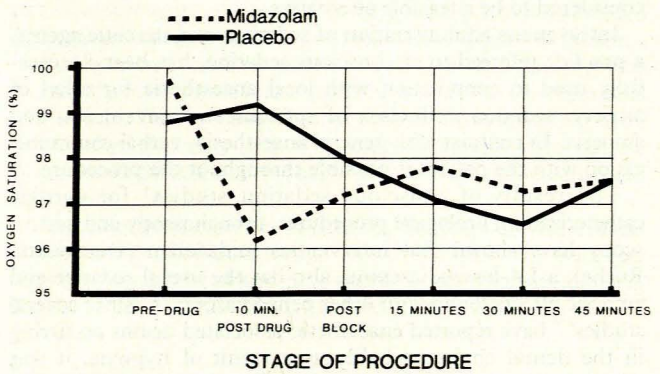

Fig. 1. Mean oxygen saturation levels at various stages of the procedure for patients receiving midazolam and placebo.

Discussion

Midazolam was introduced in 1976 for clinical trials in the USA. The drug exhibited properties common to other benzodiazepines, including anxiolytic, hypnotic, amnesic, muscle relaxant and anticonvulsant properties, but it also has several unique features. It is water-soluble at a pH below 4, highly fat-soluble at body pH, and possesses a short beta elimination phase of 1½ - 2 hours.[5] By virtue of its physiochemical properties and its rapid biotransformation, midazolam is an important addition to the existing drug armamentarium in certain areas of anaesthesia. It can be used as a premedicant, a sedative, and an induction agent, as well as a hypnotic.

Midazolam appears to be a safe and useful drug for the induction of anaesthesia in patients with normal or diseased cardiovascular systems because of its minimal haemodynamic effects and benzodiazepine properties.[6] Intravenous induction doses of midazolam can depress respiration, commonly causing temporary apnoea (lasting about 30 seconds) with an incidence in the adult population of patients of 18 - 78%.[7] High intravenous doses of either midazolam or diazepam cause the same degree of reduction in ventilation reaction and in carbon dioxide pressure. This is induced by the respiratory musculature, hence it can be concluded that these compounds exercise a direct but transient depressant effect on the respiratory centre, which can be intensified by simultaneous administration of opioid analgesics.[8]

While intravenously administered midazolam (0,1 mg/kg) appears to be a useful therapeutic adjunct to the management of anxious patients during difficult oral surgical procedures under local anaesthesia,[9] the present study shows that significant lowering of blood oxygen saturation levels may occur at these doses. Although this lowering was not severe and did not persist long enough to cause hypoxia, patients must be carefully observed and dosage regimens strictly adhered to when midazolam is used for conscious sedation procedures.

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