

# Sedation with 50% nitrous oxide/oxygen for outpatient dental treatment in individuals with intellectual disability

Denise Faulks\* BDS MSc;

Martine Hennequin DCD PhD, Service d'Odontologie, Centre Hospitalier Universitaire de Clermont-Ferrand, Clermont-Ferrand;

Sylvie Albecker-Grappe DCD PhD, Fondation Sonnenhof, Bischwiller;

Marie-Cécile Manière DCD, Faculté de Chirurgie Dentaire, Centre Hospitalier Universitaire de Strasbourg, Strasbourg;

Corinne Tardieu DCD PhD, Faculté d'Odontologie, Hôpital de La Timone, Marseille;

Annie Berthet DCD, Faculté de Chirurgie Dentaire, Centre Hospitalier Universitaire de Reims, Reims;

Maryse Wolikow DCD PhD, Faculté de Chirurgie Dentaire, Paris V, Centre Hospitalier Universitaire d'Ivry, Ivry;

Dominique Droz DCD, Faculté de Chirurgie Dentaire, Centre Hospitalier Universitaire de Nancy, Nancy;

Serge Koscielny PhD, Institut Gustave Roussy, Paris;

Peter Onody PhD, Medical Department, Air Liquide Santé International, Paris, France.

\*Correspondence to first author at EA 38 47, GEDIDO, Université d'Auvergne, Faculté de Chirurgie Dentaire, 11 Boulevard Charles de Gaulle, 63000 Clermont-Ferrand, France.

E-mail: denise.faulks@u-clermont1.fr

Persons with intellectual disability have difficulty in cooperating with outpatient care, and many are referred for general anaesthesia. Intellectual disability has traditionally been a contraindication for conscious sedation. We evaluated the behavioural impact, effectiveness, and tolerance of sedation in this population using a fixed 50% nitrous oxide/oxygen mixture as a single agent. We used dental treatment as a model of outpatient care; 349 patients (192 males, 157 females; mean age 22y [SD 14]; range 3–81y) were recruited over a 12-month period at seven centres. Sedation was deemed successful if planned dental treatment was completed. Behaviour was scored with the modified Venham scale. Out of 605 sessions, 91.4% were successful. No serious adverse effects occurred. Minor adverse events (such as nausea) occurred in 10.1% of sessions. We conclude that the use of safe and effective conscious sedation may reduce the indications for general anaesthesia.

The provision of outpatient care for the population with intellectual disability is recognized as being difficult, and many patients are regularly referred for routine care under general anaesthesia because of lack of cooperation in the surgery or as a result of medical complications. Access to general anaesthesia may be difficult or inappropriate in many situations, and thus outpatient examination and treatment remain neglected aspects of care for persons with intellectual disability. Conscious sedation may provide an alternative management method, but these techniques have traditionally been contraindicated for persons with intellectual disability or a psychiatric disorder for fear of aggravating existing behavioural or medical problems, or because of perceived lack of cooperation.<sup>1–5</sup> The effects of inhalation sedation using nitrous oxide in oxygen (N<sub>2</sub>O/O<sub>2</sub>) are mild, of rapid onset, reversible, short-lasting, and of little systemic impact compared with other sedative drugs.<sup>6</sup> Indeed, the American Society of Anesthesiologists Task Force on sedation and analgesia by non-anaesthetists considers that inhalation of less than 50% N<sub>2</sub>O entails minimal risks and, thus, excluded this mode of anxiolysis from their practice guidelines.<sup>7</sup> In consequence, a 50% N<sub>2</sub>O/O<sub>2</sub> premix may be considered as the first level in the sedation process, and should be tested in the same conditions as any other drug.<sup>8</sup> Anecdotal evidence demonstrates that an increasing number of centres are now successfully using inhalation sedation in the population with intellectual disability and it has been recommended by the Royal College of Surgeons of England for this group.<sup>9</sup> It is a technique that, therefore, merits further evaluation in relation to the special care population.

The aim of this prospective study was to evaluate the effectiveness, tolerability, and behavioural impact of sedation for invasive outpatient care under local anaesthesia in persons with intellectual disability using inhalation of a fixed 50% N<sub>2</sub>O/O<sub>2</sub> mixture as a single agent. The objectives were to assess the possibility of providing treatment under sedation, to assess the incidence of adverse effects, and to assess change in behaviour during sedation by the use of a behavioural scale.

## Method

A longitudinal, prospective, multicentre trial was designed after a pilot study into the use of inhalation sedation in the population with special needs. Approval was obtained for this study from the local research ethics committee. Informed, written consent for participation in the trial was obtained from the legal guardian of each patient, and verbal consent was obtained from all patients wherever possible. A fixed concentration of 50% N<sub>2</sub>O/O<sub>2</sub> and a simplified, standardized technique of administration were chosen to reduce the number of confounding variables and to ensure reproducibility.<sup>8</sup>

## STUDY POPULATION

The population included all patients with intellectual disability presenting to seven investigator sites (five departments of paediatric dentistry, one unit of special care dentistry, and one dental unit in an institution for adults with disabilities) over a 1-year period. Patients were considered as having an intellectual disability if this had been diagnosed clinically or psychometrically, often associated with a neurological or psychiatric disorder (Table 1), or if they attended a dedicated special school, home, or work placement for persons with intellectual disability (formal IQ values were not available for all patients).

All patients were referred by a general dental practitioner, physician, or special care establishment because of a refusal to cooperate with dental treatment. Patients were excluded if they had received dental treatment without sedation in the month before the appointment, or if they accepted spontaneously treatment without sedation. Patients with a medical contraindication to the use of N<sub>2</sub>O were also excluded, notably persistence of any closed, air-filled cavity or risk thereof (e.g. pneumothorax, emphysema, pneumocephaly, cranial trauma, raised intracranial pressure), severe, incapacitating cardiovascular or respiratory disease, reduced consciousness of any origin, first term of pregnancy, or acute facial trauma, making application of a mask to the face difficult or painful.

#### MATERIAL

A premix of 50% N<sub>2</sub>O/O<sub>2</sub> at a pressure of 170 bars was used (Kalinox; Air Liquide Santé International, Paris, France). The N<sub>2</sub>O/O<sub>2</sub> mixture was administered via a nasal or a facial mask, chosen in relation to the age, the morphology, and the type of spontaneous respiration of the patient (nose- or mouth-breather). The gas was distributed via a pressure-reducing valve, a closed Bain system (a modified Mappleson-D system) with a double tube, reservoir bag, antibacterial filter, and a passive evacuation tube to the outside.

#### ADMINISTRATION TECHNIQUE AND BEHAVIOUR MANAGEMENT

Administration was undertaken by the dentist, who acted as operator, and an assistant. The aim of the inhalation sedation was explained to the patient, within the limits of their comprehension, and the expected sensations were described. For those patients unable to hold their own mask the operator applied the mask firmly to the mouth/nose to create a seal. For some patients, gentle constraint was necessary during induction (e.g. holding hands), but physical immobilization (papoose board or similar) was not used.

After an induction period of 3 minutes, the patient was solicited gently to open their mouth and dental treatment was started. The patient was monitored clinically for level of consciousness, colour of skin and mucosa, and respiratory rate and depth. Verbal contact and suggestion were maintained at all times, and conventional behaviour management techniques were continued to maintain the patient's confidence and cooperation.<sup>10</sup> Management techniques included positive reinforcement, reassurance, distraction, 'tell, show, do', voice control, relaxation and dissociation techniques, and transfer of

locus of control. When a facial mask was used, it was moved up and 'pinched' over the nose by the assistant for periods of 30 to 60 seconds to allow access to the mouth. Local anaesthesia with 4% articaine was performed if there was the least risk of pain during the procedure.<sup>11,12</sup> After completion of treatment, the patients were kept under observation for at least 10 minutes. On the rare occasions where nausea or vomiting was experienced by the patient, sedation was stopped momentarily but continued as soon as the patient became comfortable.

#### VARIABLES RECORDED

Patient characteristics were recorded (age, sex, and aetiology of disability). The duration of the sedation session was noted and previous experience of inhalation sedation was recorded (first time or regular attender). The use of local anaesthesia was also noted.

The primary endpoint was the behavioural impact of the sedation. Behaviour was scored by the dentist at time 0 (T0, namely when the mask is first applied to the face), at time 1 (T1, after the induction period and before the start of treatment), at time 2 (T2, during the first injection of local anaesthesia), and at time 3 (T3, during treatment). Behaviour was scored with the modified Venham scale,<sup>13,14</sup> which describes behaviour independently from the ability to provide treatment. Inter-investigator variability for the Venham scale was controlled before the study. Thirteen sequences of different dental care sessions, demonstrating different patient behaviours, were video recorded and scored three times by each investigator at 1-week intervals. The weighted kappa (overall and mean intra-observer) was 0.77, which corresponds to very good agreement between different ratings.

Additional endpoints were the capacity to perform the dental procedure and the tolerance of the drug. The success of the procedure was evaluated by recording the proportion of sessions in which planned dental treatment could be completed successfully under sedation. Failure was defined when sedation could not be administered (even if dental treatment was finally accepted after cessation of inhalation) or when neither sedation nor dental care could be undertaken. Tolerance of the drug during the treatment session was assessed by recording the proportion of sessions at which adverse events were observed.

#### DATA MANAGEMENT AND STATISTICAL ANALYSIS

Data sheets were individually checked and registered after

**Table I: Aetiology of intellectual disability and success of treatment related to aetiology**

Main diagnosis	% of patients (n=349)		% of sedation sessions (n=605)		% of successful sessions (n=553)	
	%	n	%	n	%	n
	Autistic behaviour or psychiatric disorder	27.8	97	29.1	176	87.5
Undiagnosed intellectual disability or psychomotor disorder	24.1	84	24.0	145	97.9	142
Congenital neurological disability <sup>a</sup>	17.5	61	16.5	100	87.0	87
Down syndrome	15.8	55	14.7	89	93.3	83
Rare syndrome or disease associated with intellectual disability	10.0	35	11.1	67	89.6	60
Acquired neurological disability <sup>b</sup>	4.0	14	4.0	24	95.8	23
Other	0.9	3	0.7	4	100	4

<sup>a</sup>Cerebral palsy, encephalopathy, multiple physical and intellectual disabilities, etc. <sup>b</sup>Multiple sclerosis, cancer, trauma, etc.

double capture. Data management was conducted in accordance with the process of good clinical practice. Groups of patients were defined according to type of disability. Inter-group comparisons were made for the success rate and the percentage of adverse events by using Fisher's exact test. The influence of the duration of the session on the rate of minor events was evaluated with the Wilcoxon sum-rank test, the variable being the type of minor event. The significance of the difference in Venham scores between the different steps (T0, T1, T2, and T3), was tested using the signed-rank test.

## Results

### DESCRIPTIVE RESULTS

In all, 349 patients were included in the study, for whom 605 treatment/sedation sessions were undertaken over the period of the study. The population consisted of 192 males and 157 females. Patients were aged between 3 and 81 years old (mean age 22y [SD 14]). Comparisons were made between patients aged 15 years or less (40.2%) and patients over the age of 15 years (59.8%). The principal aetiological factor for intellectual disability for each patient is given in Table I. The mean duration of inhalation was 22.6 minutes (SE 0.6; range 2–105). Over the study period the number of visits per patient ranged from 1 to 12.

### BEHAVIOURAL IMPACT

No difference was noted in the behaviour score at any time in relation to age and sex by using Wilcoxon's sum-rank test. Over half (52.1%) of the patients had a Venham score of 2 or more on application of the mask (T0; Table II), which corresponded to poor cooperation. As expected, comparison of differences between Venham scores at T0 (on placing the mask) and T1 (end of induction) showed that behaviour improved significantly during inhalation of the N<sub>2</sub>O/O<sub>2</sub> mixture (mean decrease in score 0.89 [SD 1.19];  $p < 0.001$ ). The difference in cooperation was slightly less favourable between T1 and T2 for the 272 patients undergoing injection of local anaesthetic (mean increase in score 0.25 [SD 0.84];  $p < 0.001$ ). Comparison of differences between Venham scores on placing the mask (T0) and during treatment (T3) showed that behaviour improved significantly during the session (T0 mean score 1.81 [SD 1.52]; T3 mean score 1.18 [SD 1.28];  $p < 0.001$ ). Sessions in which the patients had a Venham score of 0, 1, or 2 at T0 (68.8% of sessions) had a success rate of 95.2%. Sessions in which the patients had a Venham score at T0 of 3 or more (very poor cooperation) had a success rate of 83.1%.

This difference was statistically significant ( $p < 0.001$ ).

The subgroup of patients with autistic behaviour had significantly poorer cooperation at the end of the induction period (T1; mean score 1.15 [SD 0.75]) than the rest of the study population (mean score 0.72 [SD 0.06];  $p < 0.001$ ). The behaviour score at T1 was not related to the incidence of adverse events.

### EFFECTIVENESS

The planned treatment could be performed under inhalation sedation for 91.4% of sessions ( $n = 553$ ). For 44.3% of these successful sessions, local anaesthesia was also administered. Success was not related to sex or age. The proportion of success in relation to diagnostic group is shown in Table I.

### TOLERANCE

No major adverse event was encountered. Minor adverse effect was encountered in 61 of the 605 sessions (10.1%; Table III). The duration of the sedation session was significantly longer for those patients who suffered from nausea or vomiting (mean duration 28.6min [SD 14.9]) than for those without digestive side effects (mean duration 22.1min [SD 13.7];  $p = 0.004$ ). No difference was found when controlling for sex or age.

## Discussion

This study demonstrates the effectiveness, tolerance, and positive behavioural impact of inhalation sedation by non-anaesthetists using a premix of 50% N<sub>2</sub>O/O<sub>2</sub> as a single agent in the outpatient treatment of persons with intellectual disability. The main limitation of the present study was the lack of a randomized control group, but a placebo group would not have been ethically acceptable in this context. Another criticism is related to the use of the modified Venham scale, which was originally designed to describe anxiety and behaviour during treatment in children.<sup>13,14</sup> It may, therefore, not be completely suitable for use in the adult population with intellectual disability. In addition, the behaviour ratings were scored by the operator-sedationist rather than by an independent observer.

All the patients included in this study had previously been unable to cooperate with dental treatment in the conventional setting, and many physically opposed treatment. Despite this high prevalence of behavioural problems, treatment under inhalation sedation was successful for most sessions (91.4%). Studies in other non-disabled dental patient groups have shown similar success rates for inhalation sedation with

**Table II: Percentage of Venham scores at all stages for all sessions ( $n = 605$ )**

Venham score	Summary of criteria	%			
		T0 ( $n = 605$ )	T1 ( $n = 605$ )	T2 ( $n = 272$ )	T3 ( $n = 583$ )
0	Relaxed, total cooperation	25.0	46.6	45.2	38.4
1	Uneasy, mild protest	23.0	32.1	32.7	29.2
2	Tense, moderate protest	20.8	10.6	12.9	18.0
3	Very reluctant, marked body movement	14.9	6.0	5.9	7.2
4	Very disturbed, gentle restraint necessary	10.4	3.1	1.8	4.6
5	Out of contact, total opposition, restraint	6.0	1.7	1.5	2.6

T0, at first application of the mask to the face; T1, at the end of the induction period (at least 3min after T0); T2, during local anaesthesia; T3, during dental treatment.

N<sub>2</sub>O/O<sub>2</sub>.<sup>12,15,16</sup> The present study focused on the sedative effects of the 50% N<sub>2</sub>O/O<sub>2</sub> mixture and did not evaluate the analgesic effects, which are more usually the primary measurement of success in medical studies.<sup>4,11,17</sup> The systematic injection of a local anaesthetic for any potentially painful procedure could, therefore, explain the high percentage of success in comparison with certain studies in medical or surgical fields.<sup>17</sup> The increase in the Venham score between T1 and T2 showed a slight behavioural reaction to the injection of local anaesthesia. It is unknown whether this reaction is related to the pain of injection, to psychogenic stress, or to the bitter taste of the anaesthetic solution. Cooperation was slightly better, however, during the injection than during actual dental treatment. Dental procedures induce a high level of anxiety as a result of a range of noxious stimuli including noise, vibration, smell and taste, and patients may feel unable to swallow or to breathe normally. This raised level of stress, combined with a decrease in available N<sub>2</sub>O as the mask is moved over the nose, could explain the increase in Venham score during actual treatment (T3).

Adverse events were minor and relatively rare (10.1%) despite the medical complications presented by this patient group. The rate of adverse events was similar to that found for other techniques of N<sub>2</sub>O/O<sub>2</sub> sedation and other patient groups.<sup>12,15,16,18</sup> Nausea and vomiting are recognized complications of N<sub>2</sub>O/O<sub>2</sub> sedation, although they may also be anxiety-related manifestations of the sympathetic system. Five per cent of patients in the present study suffered from vomiting, which is comparable to, or slightly higher than, rates reported in the literature for other patient groups. In four studies of healthy but anxious children and of adults undergoing dental treatment, but using differing protocols of N<sub>2</sub>O/O<sub>2</sub> administration, the incidences of vomiting were 0.9, 1.2, 1.5, and 3.9%.<sup>5,12,15,16</sup> In three investigations into N<sub>2</sub>O/O<sub>2</sub> sedation for painful medical procedures, 3.7, 5.7, and 7.8% of patients experienced vomiting.<sup>10,11,18</sup> It is possible that a higher degree of medical and behavioural difficulties at baseline in the population with disability or in those undergoing medical procedures could explain this slightly higher rate (e.g. gastrointestinal problems or agitation). Incidence of vomiting has been reported to be related to the duration of sedation, and this was confirmed by the present study.<sup>12</sup> Vomiting is rarely serious, because the laryngeal reflex remains intact during inhalation sedation.<sup>19,20</sup>

In most cases, sedation and treatment can be recommenced immediately after vomiting. Fasting is not usually recommended before sedation with N<sub>2</sub>O/O<sub>2</sub>,<sup>21</sup> but further study into this factor is required.

Of the 605 treatment sessions, only 15 cases of increased agitation or euphoria were noted, despite these being recognized side effects of N<sub>2</sub>O/O<sub>2</sub> sedation.<sup>12,18</sup> Traditional fears of aggravating behavioural difficulties by the use of sedation for persons with intellectual or psychiatric disability are thus allayed. Headache, sweating, and pallor are also recognized complications of N<sub>2</sub>O/O<sub>2</sub> sedation and may be encountered in all patient groups.<sup>12,16</sup> The one patient who suffered a short epileptic seizure (about 1min in duration) had a known history of epilepsy and suffered no such episode at a subsequent sedation session within the study period. For the individual patients who suffered from epistaxis, hyperventilation, or fainting, it may be a matter of speculation that symptoms were more likely to have been related to anxiety than the result of the administration of the gas, because these are not recognized effects of N<sub>2</sub>O/O<sub>2</sub> sedation.

Comparing the different patient groups, those with autistic behaviour or a psychiatric disorder had significantly poorer cooperation after the induction of sedation than the study group as a whole. This group of patients is recognized as having particular difficulty in coping with dental and outpatient care.<sup>22</sup> In addition, intellectual disability is rarely associated with physical disability in this group, so opposition tended to be expressed physically rather than verbally or discreetly, giving high scores on the Venham scale. Although these findings imply that inhalation sedation is perhaps less effective for this group than for the population with intellectual disability as a whole, the success rate for patients with autistic behaviour or a psychiatric disorder was still very high (87.5%).

The fact that inhalation sedation has been shown to be safe and effective in the hands of trained non-anaesthetists<sup>10,12</sup> is important, because it may reduce the immobilization of anaesthetic resources for routine care in the population with intellectual disability. This has considerable public health implications in terms of reduction of unmet need, reduction of exposure to the risks of general anaesthesia, and in terms of the indirect and direct costs to the health system. It may also help to increase regular access to routine care, thus avoiding the repercussions of neglect on general health and quality of life in this population.<sup>1</sup> The use of a safe, simplified sedation technique, with a single agent, may be an argument for extending the indications of conscious sedation to other simple acts performed in the institutionalized setting by qualified care staff, such as phlebotomy or wound dressing.<sup>17</sup> It is essential, however, that anaesthetists be involved in the development, standardization, and teaching of such techniques and that mandatory qualifications be put in place around the world.<sup>7,23</sup>

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**Table III: Adverse events**

<i>Adverse event</i>	<i>Nr of sessions</i>	<i>% of total nr of sessions</i>
Nausea and vomiting	32	5.3
Nausea alone	7	1.2
Agitation	11	1.8
Euphoria	4	0.6
Sweating, pallor	2	0.3
Headache	1	0.2
Epileptic seizure	1	0.2
Epistaxis	1	0.2
Hyperventilation	1	0.2
Vasovagal attack	1	0.2
Total	61	10.1

The total number of sessions was 605.

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