



Limited analgesic efficacy of nitrous oxide for painful procedures in children

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Accepted 10 February 2008

ABSTRACT

Study objective: Nitrous oxide (N₂O) is an attractive agent for procedural analgesia and sedation of children in the emergency department (ED). Despite increasing use, efficacy data for painful procedures are limited. This study aimed to determine pain scores during ED procedural sedation with N₂O in the ED setting.

Methods: Prospective observational study of N₂O use as a sole agent for procedural analgesia at a tertiary children's hospital ED. Pain scores were obtained from patients and parents using visual analogue or faces scales, as appropriate. Parent and staff satisfaction with sedation and analgesia were assessed.

Results: 124 children aged 1–17 years (mean 8.1) underwent procedural analgesia with N₂O for 131 procedures. Most procedures were orthopaedic (44%) or laceration repair (30%). In 51% of patients (95% CI 42% to 60 to 23%) pain scores remained unchanged and in 34% (95% CI 26% to 43%) pain scores increased. Overall, 34% (95% CI 26% to 43%) patients had intraprocedural scores of 50 mm or greater and 21% (95% CI 14% to 29%) had pain scores of 70 mm or greater. Some procedures such as fracture reduction had a larger proportion of patients with high pain scores or 50 mm or greater (45%) and 70 mm or greater (29%). Staff rated both sedation and analgesia as "adequate" in 92%. Parents contacted in follow-up were satisfied or very satisfied with procedures in 96% and sedations in 93%.

Conclusion: Data indicate that parents and staff are generally satisfied with N₂O for procedural use in the ED. The efficacy of N₂O as a sole agent in very painful procedures is limited.

The use of nitrous oxide (N₂O) for paediatric procedural sedation has been reported from many countries.^{1–6} Most research has used 50% N₂O and there have been concerns regarding the variability of the analgesia and sedation provided.^{1–7} It has been suggested that N₂O should not be used for procedures causing more than a low level of pain.⁸ Randomised controlled trials of the use of N₂O for painful procedures in the paediatric emergency department (ED) have been reported since 1998,² and in recent years the use of 70% N₂O has become accepted and more widespread, with its use expanded to other settings.^{9–10} However, the efficacy of N₂O for painful procedures has yet to be completely defined.

The primary objective of our study was to characterise the efficacy of N₂O for procedural sedation and analgesia (PSA) in a paediatric ED.

MATERIALS AND METHODS

Design and setting

We conducted a prospective observational study in the ED of a large, urban children's hospital with an annual ED census of 60 000 patients. All children presenting to the ED from August 2003 to March 2004 who received N₂O for PSA were eligible for enrolment. The only formal exclusion criteria was the use of additional sedative agents. This study was approved by the hospital human research ethics committee.

When a child required PSA with N₂O, the examining doctor informed one of the researchers or trained research assistants who obtained informed verbal consent and made arrangements for a follow-up phone call. N₂O administration was available via demand valve fixed 50% N₂O/50% oxygen, marketed as Entonox and via a continuous-flow system using the Quantiflex MDM machine, which delivers 0–70% N₂O and includes a scavenging system to decrease environmental contamination.

A case report form was developed to record data before, during, and after PSA with N₂O. This included age, past medical problems, American Society of Anaesthesiologists (ASA) class, procedure, drugs used in addition to N₂O, highest concentration of N₂O used and deepest level of sedation attained. Pain scoring by patient and parent was recorded 5 minutes before the procedure and immediately after its completion.

Data

Patients were classified according to ASA physical status classification (class 1, normal healthy patient; class 2, patient with mild systemic disease with no functional limitation; class 3, patient with severe systemic disease with definite functional limitation; 4, patient with severe systemic disease that is a constant threat to life; 5, moribund patient who is not expected to survive without the operation).

To measure the level of sedation, a sedation scale with seven levels of sedation ranging from 6 to 0 (table 1) developed at the Children's Hospital of Wisconsin was used.¹¹ Decreasing sedation scores have been shown to be associated with an increasing rate of adverse events.¹¹ Depth of sedation was assessed on an ongoing basis during the procedure; the deepest level of sedation achieved was recorded on the case report form.

Adverse events were defined a priori as serious or mild. Serious adverse events included patient oxygen desaturation below 95%, apnoea, stridor, airway misalignment requiring repositioning, laryngospasm, bronchospasm, cardiovascular

Table 1 Children's Hospital of Wisconsin sedation scale¹¹

Sedation score	Patient's level of response
6	Anxious, agitated or in pain
5	Spontaneously awake without stimulus (talking)
4	Drowsy, eyes open or closed, but easily arouses to consciousness with verbal stimulus
3	Arouses to consciousness with moderate tactile or loud verbal stimulus
2	Arouses slowly to consciousness with sustained painful stimulus
1	Arouses, but not to consciousness, with painful stimulus
0	Unresponsive to painful stimulus

instability, pulmonary aspiration, unplanned hospital admission, endotracheal intubation, permanent neurological injury or death. Inadequate sedation was not regarded as an adverse event.

The primary outcome measure was pain as scored by children 5 years of age and over and by parents for children under 5 years of age. A visual analogue scale (VAS) was used for the self-reporting of pain in children 7 years of age and older and for parental scoring of children under 5 years of age. Children 5–7 years of age used the Faces Pain Scale—Revised (FPS-R).

The VAS scale is a 100-mm horizontal black line that has extreme values of “no pain” and “very much pain”.¹² The VAS has been validated for use in adults and in children.^{13 14}

The FPS-R scale is validated for children between 5 and 12 years of age. It consists of six faces representing various levels of discomfort or sadness, with the endpoints labelled “no pain” and “very much pain”.^{15–17} The values of the FPS-R scale were converted into a 0–100 mm scale.

Secondary outcome measures were parent and staff satisfaction with PSA and successful completion of the procedure or not. Satisfaction was measured on a five-point Likert scale of “very satisfied”, “satisfied”, “neither satisfied nor dissatisfied”, “dissatisfied”, to “very dissatisfied”.

Patients were telephoned by one of the researchers within 72 h to examine parent satisfaction with the procedure itself and the analgesia and sedation.

Analysis

All data were entered into an Access software database (Windows version 2003). Median values are reported with interquartile ranges (IQR) and proportions are presented with 95% CI when appropriate. We used χ^2 tests for dichotomous variables, t tests for parametric variables and Mann–Whitney U tests for non-parametric variables. For all tests, values of p less than 0.05 were considered statistically significant. Statistical calculations were performed using STATA software (version 10.0).

RESULTS

A total of 220 patients who received N₂O for PSA were enrolled during the 8-month data collection period. The study group consisted of 124 patients for whom pain scores before and during the procedure were available and after the exclusion of nine patients who had received intravenous morphine (n = 9) within 2 h before the procedure (table 2).

The 124 patients underwent 131 procedures during 124 episodes of PSA. The 124 primary procedures, as shown in table 2, were mostly orthopaedic procedures (44%) and laceration repairs (30%). Of the nine patients who underwent more than one procedure, eight also had an intravenous line

Table 2 Characteristics of ED patients receiving N₂O for PSA (n = 124)

	n (%)
Age, years	
Mean, range	8.1 (1.3–17.9)
Median, IQR	8.3 (4.9–11.0)
Sex	
Male	80 (64.5)
ASA status [§]	
1 and 2	118 (95.9)
3	5 (4.1)
Percentage of N ₂ O*	
70	100 (80.6)
60	6 (4.8)
50	18 (14.5)
Adjunctive agents [†]	
N ₂ O alone	109 (87.9)
Codeine	15 (12.1)
Primary procedures	
Laceration repair	37 (29.8)
Fracture reduction	31 (25)
Intravenous line insertion	15 (12.1)
Plaster/backslab	15 (12.1)
Relocation joint	8 (6.4)
Removal of foreign body	7 (5.6)
Removal of plaster, suture	3 (2.4)
Abscess drainage	3 (2.4)
Wound debridement	1 (0.8)
Joint aspiration	1 (0.8)
Other	3 (2.4)
Sedation depth [‡] [§]	
0	1 (0.8)
2	1 (0.8)
3	6 (4.9)
4	52 (42.3)
5	58 (47.1)
6	5 (4.1)
Adverse events	
None	103 (83.1)
Vomiting	7 (5.6)
Dizziness	5 (4.0)
Nausea	4 (3.2)
Agitation/hallucination	2 (1.6)
Other	3 (2.4)

*Highest nitrous oxide (N₂O) concentration administered.

†Adjunctive agents: codeine (alone or in combination with paracetamol) if given within 2 h before sedation.

‡Sedation depth (see Methods).

§ASA, American Society of Anesthesiologists; ED, emergency department; PSA, procedural sedation and analgesia.

§One missing.

placed and one had a plaster slab applied. Some patients received adjunctive codeine by mouth within 2 h before the procedure, as listed in table 2. All patients who underwent intravenous line insertion had topical anaesthesia (amethocaine 4%) applied before the procedure, although not all insertions occurred through anaesthetised skin. All laceration repairs were preceded by the application of topical wound anaesthesia (adrenaline–lignocaine–amethocaine gel) or infiltration of local anaesthesia with lignocaine. The level of deepest sedation was recorded in 123 patients (99%) (table 2); 94% of patients had scores equivalent to mild to moderate sedation (depth of sedation score 3 to 5). Two patients, both of whom had received N₂O 70%, had sedation scores equivalent to deep sedation (depth of sedation scores 0–2). None of the 124 patients in this study

Table 3 Pain scores during PSA with N₂O by primary procedure (n = 124*)

Procedures	Pain score during procedure*				
	n	0 (%)	1–49 (%)	50–69 (%)	≥70 (%)
Laceration repair	37	19 (51.3)	9 (24.3)	3 (8.1)	6 (16.2)
Fracture reduction	31	10 (32.6)	7 (22.6)	5 (16.1)	9 (29.0)
Intravenous line insertion	15	8 (53.3)	5 (33.3)	1 (6.7)	1 (6.7)
Application of plaster, backslab	15	7 (46.7)	3 (20)	2 (13.3)	3 (20)
Joint dislocation reduction	8	1 (12.5)	5 (62.5)	–	2 (25)
Foreign body removal	7	1 (14.3)	2 (28.5)	2 (28.5)	2 (28.5)
Removal of plaster/suture	3	1 (33.3)	1 (33.3)	1 (33.3)	–
Abscess drainage, incision	3	–	–	1 (33.3)	2 (66.7)
Wound debridement	1	–	–	–	1 (100)
Arthrocentesis	1	–	1 (100)	–	–
Other	3	1 (33.3)	1 (53.3)	1 (33.3)	–
Total	124	48 (38.7)	34 (27.4)	16 (12.9)	26 (21)

*Patient pain score if 5 years of age or older (n = 93) and parent pain score if less than 5 years of age (n = 31).
N₂O, nitrous oxide; PSA, procedural sedation and analgesia.

suffered a serious adverse event (one-sided 97.5% CI 0% to 2.9%). Twenty-one patients (16.9%, 95% CI 10.8% to 24.7%) experienced 21 mild and temporary adverse events in the ED (table 2).

Pain scores during procedural sedation with N₂O

Preprocedurally, patients' pain scores ranged from 0 to 100 mm (median 32.5, IQR 10–70) and intraprocedural pain scores ranged from 0 to 100 mm (median 20, IQR 0–60). In 63 cases (50.8%, 95% CI 42% to 60%), the pain scores decreased during the procedure, compared with baseline. Fifty-five (44.3%, 95% CI 35.4% to 53.5%) of these cases experienced a decrease of 20 mm or more; in 89% of these cases the reduction was at least 50% of the preprocedural pain score. In 19 (15.3%, 95% CI 10% to 23%) cases pain scores remained unchanged during the procedure compared with baseline; nine of these had no pain before or during procedure. For 42 cases (33.8%, 95% CI 25.6% to 42.9%) the pain scores increased; 35 of whom experienced a pain increase of 20 mm or more (28.2%, 95% CI 20.5% to 37%). Overall, 42 (33.8%, 95% CI 25.6% to 43%) patients had intraprocedural scores of 50 mm or more and 26 (20.9%, 95% CI 14.1% to 29%) had pain scores of 70 mm or greater (table 3). Of those patients who required fracture manipulation (n = 31), 14 (45%) experienced increased pain during the procedure, eight of those experiencing a more than 20 mm increase compared with their preprocedural pain score.

An analysis of pain scores considering the procedures undertaken is provided in table 3. Of the procedures used at least 15 times, laceration repair and intravenous line insertion showed intraprocedural pain scores of 0 mm in approximately 50% of cases; fracture reduction showed 45% of patients with intraprocedural pain scores of 50 mm or more. Although infrequently undertaken procedures in this study, both abscess drainage and wound debridement had very high intraprocedural pain scores. We compared pre and intraprocedural pain scores

(dichotomised as <50 mm and ≥50 mm) according to the procedure performed, using those procedures performed 15 times or more (n = 98) (tables 3 and 4). Comparing across procedures, there was a significant difference in the preprocedural pain scores (p = 0.01); however, no significant difference was found between intraprocedural pain scores (p = 0.11).

The 42 patients (across all procedures) who experienced an intraprocedural pain score of 50 mm or more had a median preprocedural pain score of 48.5 mm (IQR 20–70), whereas the 82 patients with intraprocedural pain scores of 50 mm or less had a median preprocedural pain score of 28.5 mm (IQR 10–60, p = 0.04). Children under 5 years were more likely to have intraprocedural pain of 50 mm or more than older children (p = 0.049).

Staff and parent satisfaction

Ninety per cent of the 113 staff members who responded thought that both the analgesia and the sedation provided was adequate. Of the 42 patients who had pain scores of 50 mm or more during the procedure, 34 (80.9%) were thought to have received adequate analgesia from N₂O as stated by ED nurses. Three of 124 procedures (2.4%) had to be abandoned due to inadequate sedation or analgesia.

On follow-up, 119 (96.0%) parents could be reached, of whom 96% were satisfied or very satisfied with the procedure, 92% were satisfied with the sedation and 93% would be happy for their child to have PSA with N₂O again. When asked to question their children regarding their recollection of the procedure, 74 (62.1%) were able to recall it, 14 (11.8%) were unsure and 31 (26.0%) were unable to recall the procedure.

DISCUSSION

In the past decade N₂O has gained popularity for use in paediatric PSA. A number of studies have trialled it, often

Table 4 Pain scores before and during PSA with N₂O by frequent procedure (median and IQR)

Procedures (n)	Preprocedural pain score		Intraprocedural pain score	
	Median	IQR	Median	IQR
Laceration repair (37)	20	10–45	0	0–40
Fracture reduction (31)	35	20–70	30	0–70
Intravenous line insertion (15)	30	0–95	0	0–20
Application plaster/backslab (15)	70	20–100	10	0–60

IQR, interquartile range; N₂O, nitrous oxide; PSA, procedural sedation and analgesia.

against other techniques, for laceration repair, fracture reduction, dental procedures and vascular access.^{3–5 18–22} Most of this literature is with N₂O and oxygen mixtures in concentrations of up to 50% via demand valve or continuous flow. More recently, interest has been shown in higher concentrations of N₂O—up to 70%—given by continuous flow mixers.^{9 10 23} Studies have documented the ability to perform procedures safely using N₂O; however, its true efficacy as an analgesic has not been determined.^{10 23 24}

This study is the first to try and assess the efficacy of N₂O in all use in a paediatric ED. N₂O was used in a wide variety of procedures, with highly variable pre and intraprocedural pain scores. One third of patients had an increase in pain during the procedure, 83% of these having an increase of 20 mm or more. One third of patients reported intraprocedural pain greater than 50 mm, with 21% reporting pain of 70 mm or more. Procedures considered to be potentially very painful, such as fracture reduction and foreign body removal, had a larger proportion of patients with pain rated over 50 mm.

Staff rated analgesia as adequate in the majority of procedures with N₂O overall. Notably, even in patients who reported pain scores equal to or greater than 50 mm, 81% of staff thought that analgesia was adequate. Parental satisfaction was also very high; most parents were happy to have the agent used again in their child.

Previous studies have suggested that for fracture reduction pain scores are variable, with up to 10% of children having no analgesic or sedative effect from N₂O. In general, pain scores show approximately 50% of patients having at least moderate pain.^{3 19} However, N₂O has been shown to be highly effective when accompanied by additional analgesic interventions for both fracture reduction^{4 25} and laceration repair.^{2 20} N₂O and adjunctive analgesia is reported to be as effective as both Bier's block¹⁹ and ketamine plus midazolam⁴ for fracture reduction.

Only three (2.4%) procedures in this study were abandoned due to inadequate PSA. This is in keeping with other N₂O studies,^{3 10} but higher than reported by Cravero *et al*,²⁶ who documented a 0.9% failure rate in 30 000 episodes of paediatric sedation/anaesthesia outside the operating room. It is better than the suggested 10% of children who have no analgesic effect from N₂O.³

It has been documented that a reasonable proportion of children, and approximately one third from our data, experience moderate to severe pain during procedures.¹ Perhaps it is time to consider N₂O as an adjunctive only in very painful procedures, and to explore ways to provide additional analgesia in concert. N₂O can be a useful analgesic and anxiolytic during the intravenous access needed to provide deeper sedation.²⁷ Recent literature would support the use of intranasal opioid as a preprocedural analgesic in the ED setting^{28 29} and perhaps we should now be looking at combining such analgesics with N₂O for non-parenteral PSA in painful procedures.

This observational study has several limitations. It would be ideal to assess efficacy in a randomised controlled trial. However, this would be difficult across heterogeneous procedures. Although this study includes all age ranges in which N₂O would be useful, self-report pain assessment tools are age-limited and continuous (VAS scale) and ordinal (FPS-R) scales are difficult to compare. In addition, self-report scales are problematical in children under 5 years of age and parent scores are limited proxies. Child and parent scores depended on their degree of understanding of the scales, despite the use of standardised instructions by the researchers before commencing N₂O PSA. A further limitation is the measurement of pain

scores only, without taking into account the level of distress children experienced. However, it is difficult for children, parents and staff to differentiate distress from pain. It may also be difficult for parents to judge satisfaction with the procedure or the sedation when their understanding and comparative experience with the ideal performance of PSA with N₂O is limited. Too few patients received N₂O 50% to compare its efficacy with N₂O 70%. We also did not record whether N₂O 50% was administered via continuous flow or fixed valve (Entonox). However, in our department Entonox is used very rarely due to the absence of a scavenging system and its age limitations. Finally, it must be recognised that a number of procedures under N₂O during the study period were missed or had incomplete documentation of scores, and were therefore omitted from final analysis. However, the age distribution and diagnoses of patients with incomplete scores who were excluded from analysis were similar to the study group.

CONCLUSIONS

Our data support the role of N₂O for PSA in the ED. Parents and ED staff are in general satisfied with the level of analgesia provided. However, we must also conclude that N₂O alone may not be the ideal drug in very painful procedures; further research into adjunctive analgesia is therefore warranted.

Funding: Grant support was received from the Victor Smorgon Charitable Fund, Melbourne, Victoria, Australia.

Competing interests: None.

Ethics approval: This study was approved by the hospital human research ethics committee.

Patient consent: Obtained.

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