



ALnox™

Analgesia
during painful
interventions
in children.



ALnox™

ANALGESIA DURING PAINFUL INTERVENTIONS

Certain diagnostic or therapeutic interventions are particularly painful and stressful for children, such as lumbar puncture, venepuncture, myelography etc. Young patients often describe these interventions as the worst and most unbearable aspects of their treatment. Caregivers are obliged to ensure the prevention and relief of pain related to these acts. The choice of analgesia must take into account the benefits and risks of each method in a given context. The choice is not always easy for those interventions that are painful but relatively short lasting. **ALnox™** is an equimolar mix of nitrous oxide and oxygen that is considered an ideal agent for these situations. **ALnox™** is analgesic but also sedative and anxiolytic. It is of quick onset, rapid elimination and has few undesirable side effects⁽¹⁾. A 50% nitrous oxide/ 50% oxygen mix has been used outside of operating theatres in many countries since the 1960's. Its use in paediatrics started in the early 90's.

HISTORY

Nitrous oxide was first manufactured in 1772 by Priestley, and Davy noted its analgesic effects as early as 1800. This analgesia was confirmed by Colton and Wells in 1844 who administered the gas during dental treatment. In 1868, Andrews mixed nitrous oxide with oxygen allowing it to be administered for longer periods of time. Klikovich was the first to report its use for pain relief in child birth (1881) and then for myocardial infarction⁽¹⁾. Nitrous oxide has been widely used in general anaesthesia since the end of the nineteenth century. It is no longer used as a single agent in this context but is still often used in addition to other drugs⁽²⁾. Nitrous oxide is also widely used in dentistry. Current use of nitrous oxide, aside from its use in general anaesthesia, dates from the early 1960's. In 1961, a premix of nitrous oxide and oxygen supplied in a single bottle became available. This formulation allowed protocols for the autoadministration of the gas to be developed using a demand valve. It was initially used in childbirth⁽³⁾. Since then, many studies have reported the use of nitrous oxide and oxygen in a wide variety of clinical situations.

PHYSICAL AND PHARMACOLOGICAL PROPERTIES

Nitrous oxide is a colourless, and virtually odourless, gas. The mixture of nitrous oxide and oxygen is stable at temperatures above -9°C and at 139 bar. At temperatures lower than this, the nitrous oxide becomes liquid and falls to the bottom of the cylinder. This effect can be reversed if the cylinder is subsequently warmed to 13°C or above before use and briskly inverted three times. In practice, for security reasons, the cylinders should be stored at a temperature of at least 0°C . The use of nitrous oxide in oxygen at a concentration of 50% does not imply the same protocols as those for anaesthesia as this concentration is insufficient to induce general anaesthesia. Nitrous oxide is over 36 times more soluble in the blood than nitrogen and does not bind to haemoglobin. The gas is not metabolised by the body and is eliminated unchanged from the lungs. The effects of nitrous oxide outside of the central nervous system are few⁽⁴⁾. Nitrous oxide diffuses rapidly across the cellular membrane. An analgesic effect may be detected within 20 seconds following inhalation and reaches its maximum at between 3 and 5 minutes. Cortical function is depressed and all types of sensation are altered. Thus, the senses of taste, smell, temperature, pressure and pain are reduced. There is also an effect of general relaxation, anxiolysis, amnesia and euphoria.

Subcortical functions are little altered. The cough and laryngeal reflexes are not noticeably affected⁽⁴⁾. Roberts and Wignall showed that children sedated with nitrous oxide for dental care kept their laryngeal reflexes intact and did not inhale 10ml of a radio-opaque solution applied to the tongue during administration⁽⁶⁾.

METHOD OF ACTION

The mechanism for the analgesic action of nitrous oxide is not fully understood but recent studies have made some progress. It has been shown that nitrous oxide inhibits NMDA receptors, which play an important role in the transmission of nociceptive signals and in hypersensitisation to pain⁽⁷⁾. It has also been shown that nitrous oxide has a stimulating effect on dopaminergic neurones, causing secretion of dopamine and/or noradrenaline. This could explain certain of the effects of nitrous oxide. When taken together, the results of the studies to date suggest the hypothesis that nitrous oxide causes the liberation of endogenous opioids in the periaqueductal grey matter. These opioids would then stimulate the noradrenergic neuronal pathways, thus blocking the transmission of nociceptive signals by liberation of noradrenaline, which acts upon the alpha 2 receptors of the dorsal horn of the spinal cord⁽⁸⁾. It should be noted that noradrenergic inhibitor neurones are not fully functional at birth. Studies in the rat have shown that nitrous oxide has no analgesic effect if the descending pathway is not mature. These

findings might question the use of nitrous oxide in newborn babies or young infants. Extrapolation to humans is, however, extremely delicate, and clinical experience demonstrates a positive effect of nitrous oxide when administered to even premature babies⁽⁹⁾.

The anxiolytic effects of nitrous oxide have been studied using animal models and are probably a result of the action of nitric oxide (NO). It is obvious that the overall analgesic effect is due to a combination of the specifically antinociceptive properties of the gas and its anxiolytic effect, as anxiety is known to increase pain perception.



CLINICAL RESEARCH

The level of analgesia obtained with a 50% nitrous oxide/ 50% oxygen mix varies according to the intervention performed and the patient. The first studies involving children were published in the 1980's. In 1983, Griffin et al. reported results of a 9 year retrospective study concerning around 3000 children who had received nitrous oxide at a concentration of 50 to 66% for minor surgery, such as sutures, fracture reduction, excision of verrucas or naevi. The authors reported that the majority of children presented reduced levels of pain and anxiety. Unfortunately, the study was not easy to interpret as, despite a large number of subjects, it was undertaken retrospectively and no precise criteria for the evaluation of pain were used⁽¹⁰⁾. Since this publication, many more articles have reported the use of nitrous oxide in many different clinical contexts.

Suturing

The first study concerning the suturing of wounds in child outpatients was reported by Garmis et al. in 1989⁽¹²⁾. 34 children requiring suturing were recruited and randomly selected to receive 30% nitrous oxide in 70% oxygen, or pure oxygen, associated in each case with local infiltration of lidocaine. Pain was assessed using the behavioural CHEOPS scale, and was found to be lower in the nitrous oxide group. This difference was only statistically significant for those children over 8 years of age. The concentration of nitrous oxide was low, however, and the subgroups stratified by age consisted of small numbers of children.

Luhmann et al. reported a prospective randomised clinical trial that demonstrated that nitrous oxide in oxygen was more effective than midazolam for reducing anxiety in 2 to 6 year old children requiring cutaneous sutures⁽¹³⁾. In 1998, Burton et al. published the results of a prospective, randomised, double blind study that confirmed the effectiveness of an equimolar mix of nitrous oxide and oxygen for the reduction of pain and anxiety in 2 to 7 year old children during wound closure⁽¹⁴⁾.



Lumbar puncture, myelograph

An open, prospective, but non-randomised French study was reported by Dollfus et al. that included 200 children given nitrous oxide in oxygen for lumbar puncture and myelography in association with local anaesthesia using Emla[®] or lidocaine. Pain was scored as absent or mild for 78% of the lumbar punctures and 73% of the myelographs ⁽¹⁵⁾.



Vene puncture

Henderson et al. reported the analgesic effects of nitrous oxide in oxygen for venepuncture⁽¹⁶⁾. Another prospective randomised clinical trial demonstrated the complementary analgesic effects of nitrous oxide in oxygen and Emla[®], with the combined effect being greater than that with one or other of the drugs⁽¹⁷⁾. Vetter demonstrated better analgesia with 70% nitrous oxide in oxygen compared to Emla[®] for venepuncture prior to general anaesthesia in 6 to 12 year old children⁽¹⁸⁾.



Fracture reduction

A mixture of nitrous oxide/oxygen has also been used in Emergency Departments for analgesia during fracture reduction, although with less success than in other clinical situations. Wattenmaker et al. reported an open prospective study consisting of 22 children undergoing fracture reduction, for the most part of the lower arm. Nineteen of the children reported mild to moderate pain⁽¹⁸⁾. Another study concerning the analgesic effect of nitrous oxide in oxygen during reduction of fractures was undertaken by Hennrikus et al. Forty six percent of children in this study reported severe pain⁽²⁰⁾. This investigation demonstrates the limits of the gas for this orthopaedic act.

An previous study reported that nitrous oxide in oxygen had an analgesic effect comparable to that of an intramuscular injection of meperidine and promethazine for the reduction of closed fractures in children⁽²¹⁾. Intramuscular injection is no longer acceptable for administration of analgesia, however.

Bronchial fibroscopy

A prospective randomised trial demonstrated the effectiveness of nitrous oxide in oxygen, in combination with oral premedication and local anaesthesia, for the reduction of pain and anxiety in children requiring bronchial fibroscopy⁽²²⁾.

Percutaneous renal biopsy

Piétrement et al. undertook a prospective but uncontrolled study on 107 children requiring renal biopsy, all but two of whom were over three years of age. An analgesic protocol using 50% nitrous oxide in oxygen was effective for 86.5% of children⁽²³⁾.

Intra-articular injection

The effectiveness of nitrous oxide in oxygen for intra-articular injection of corticosteroids for the treatment of chronic juvenile idiopathic arthritis in 55 children over seven years of age was reported by Cleary et al.⁽²⁴⁾.

The experience of certain paediatric teams

Several paediatric teams have published their experience of the use of nitrous oxide in oxygen^(24,25). One French general paediatric service reported using the gas most often for lumbar puncture, dressing burns, venepuncture and wound closure⁽²⁵⁾. This open, non-randomised cohort study of 127 painful interventions reported that nitrous oxide in oxygen rendered pain absent or very mild for 83.4% of cases. Kanagasundaram et al. published a prospective cohort study consisting of 90 children who received 50 to 70% nitrous oxide for lumbar puncture, myelography or wound dressing⁽²⁶⁾. They found a marked decrease in scores of stress during the treatment compared to those taken before starting the act. The mixture was found to be more effective in children over 6 years of age compared to younger infants. Sixty-five percent of the children could not recall the intervention.

The amnesic effect of nitrous oxide is particularly important to avoid psychological trauma caused by painful interventions and may improve tolerance of repeated interventions in children with chronic disease. This effect of nitrous oxide in oxygen was reported by Miser et al. in a study of young cancer patients.

A large prospective multicentric French study consisting of 1019 children demonstrated that nitrous oxide in oxygen could be used in a wide range of painful interventions in children⁽²⁸⁾. The most frequently performed interventions in this investigation were lumbar puncture, bone marrow aspiration and suturing. Evaluation of pain was undertaken using a visual analogue scale going from 0 to 100. The median (interquartile) was 9 with a range of 0 to 30. Overall, the care personnel were satisfied or very satisfied with the technique in 88% of cases. Ninety-three percent of the 647 children able to reply to the question, indicated that they would like to receive the mixture again if they had to undergo another intervention.



INDICATIONS

Any short-lasting painful diagnostic or therapeutic intervention is a potential indication for the use of **ALnox™**. It is particularly indicated for: analgesia during emergency medical care, lumbar puncture, bone marrow puncture, venepuncture in phobic children or those without topical analgesia, superficial suturing in combination with local anaesthesia, reduction of simple fractures and dislocations, removal of drains or foreign bodies, wound dressing and care of burns of limited size, removal of trans-tympanic drains, percutaneous renal or liver biopsy, placement of urinary catheters and reduction of inguinal hernia, amongst others. Some centres also use the technique for bronchial fibroscopy and endoscopy of the upper digestive tract.

For children under the age of four years, **ALnox™** must be administered by a physician with experience of the technique. The gas must not be administered for periods longer than 60 minutes at a time and a daily treatment with **ALnox™** should not exceed two weeks in a row.



CONTRAINDICATIONS

ALnox™ is contraindicated in children with un-evaluated cranial trauma, altered consciousness, intracranial hypertension, gaseous emboli, emphysema, following a diving accident, with maxillofacial injury preventing the airtight placement of the mask on the face, undrained pneumothorax, or gastric or abdominal distension. Equilibration of the partial pressures of nitrous oxide between the blood and air filled spaces causes rapid expansion in these cavities. The gas should not be used at temperatures under -5°C .

UNDESIRABLE SIDE EFFECTS

Undesirable side effects are rare and rapidly reversible on discontinuation of inhalation. In 2001, Gall et al. reported on the adverse events experienced by children during 7511 treatment sessions under nitrous oxide in oxygen⁽³¹⁾. The average duration of administration was 11 min (SD +/- 6.6 min). Major adverse events were observed in 25 children (0.33%) and consisted of oxygen desaturation, airway obstruction, apnoea, bradycardia and loss of verbal contact. All of the above recovered spontaneously on discontinuation of the gas, and no children required assistance to maintain a clear airway. Undesirable events were noted more frequently in children under 12 months of age and when the gas was combined with midazolam and morphine. The addition of just one of these agents did not increase the percentage of adverse effects.

Other minor side effects may be noted. These include: paraesthesia (experienced as pins and needles or tingling), and paradoxical excitation (similar to that observed when other types of sedative are given). Nausea and vomiting may also be experienced but does not pose a problem as the laryngeal reflex remains intact. Personnel should be aware that excitation may also be a result of insufficient analgesia. Some children exhibit a panic reaction as they feel themselves lose control under the sedative effects of the gas. In the study undertaken by Kanagasundaram et al. vomiting was noted in 7.8% of cases, agitation in 4.4%, and dysphoria in 2% of cases⁽²⁶⁾. Luhman et al. reported vomiting in 6% of children receiving nitrous oxide in oxygen⁽¹³⁾.

PATIENT SECURITY

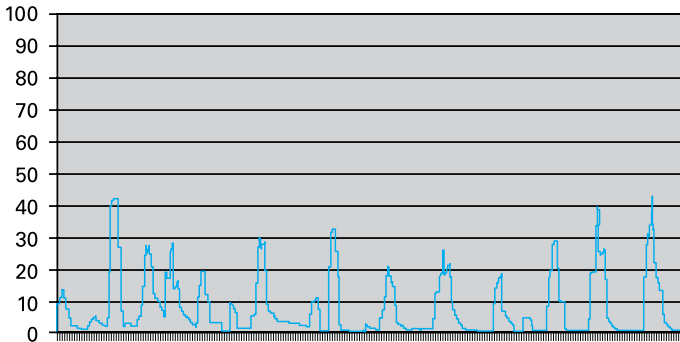
No serious accident has ever been reported concerning the use of nitrous oxide in oxygen, despite its wide spread use in many countries. No major adverse effect was reported by Griffin et al. in a study of 3000 children receiving between 50 and 70% nitrous oxide⁽¹¹⁾. Similarly, as noted in the section concerning undesirable side effects, Gall et al. reported no serious accident in a series of 7511 administrations of the gas mixture⁽³¹⁾.

PROFESSIONAL SECURITY

Repeated exposure to nitrous oxide over long periods of time has been reported to increase the risk of spontaneous abortion, hepatic disease and neurological disorders^(4, 32, 33). These effects were noted in operating theatres (before the introduction of closed circuit ventilation), and in poorly ventilated dental surgeries not using a system of evacuation. Nitrous oxide was used for several hours a day in the same room. Canadian legislation fixes the maximum average

level of exposure at 25 parts per million (ppm) of nitrous oxide over 8 working hours in locations where the gas is administered. This maximum level varies between 25 and 100 ppm, according to legislation in different countries. It is recommended that the gas be used in well-ventilated locations and a scavenging system should be used. Evacuation may be active, with a scavenging system, or consist simply of a tube leading to the outside (e.g. via a window).

Administration of *ALnox*TM with an on-demand valve and an evacuation system.



*Graph showing the variation in the maximum level of exposure of nitrous oxide over 16 days in a dental surgery with an average of 3.1 sedation sessions a day (range 1 to 6) of treatment under *ALnox*TM with an on demand valve system in dentistry. The average duration of administration of the gas was 21.4 min (range 8 to 37 min). For this period, the average maximum level of exposure was 22.1 ppm.*

METHODS OF ADMINISTRATION

A *Lnox*TM should be used only by or under the supervision of a licensed medical or dental practitioner experienced in the use and administration of this gas mixture and familiar with the dosage, the indications and effects of administration and the hazards, contraindications, side effects and precautions to be taken.



Administration

■ Time must be taken to explain to the child exactly what he/she will feel and how the procedure will be undertaken in order to obtain their total cooperation.

■ The reasons for the use of **ALnox™** must be explained to the child and their parents. This explanation should be reassuring and the analgesic benefit of the gas should be emphasized. The child needs to understand that he or she will not go to sleep, but will feel like he is in a type of dream.

■ The child should then be shown the mask and asked to place it over his/her face. If possible he or she may be given a choice of scented masks. The child should be allowed to manipulate, or even play with the mask before the system is connected. The administration of **ALnox™** must be accompanied by reassurance and distraction techniques in order to help the child to relax.

■ The system is then connected, the cylinder valve opened and the pressure checked.

■ The mask should never be applied to the face with the cylinder valve closed or empty. This error may be committed by inexperienced personnel, particularly if an on demand valve system is used. It is unlikely with the use of a reservoir bag, as the bag is seen not to fill.

■ One member of the care team must be dedicated to administer the gas and monitor the patient.

■ **ALnox™** should be inhaled for at least three minutes before the act is started. If the method is totally ineffective after five minutes of inhalation, a different method of analgesia should be chosen.

■ At the end of the act, the cylinder valve should be closed to avoid leakage.



Monitoring

Constant monitoring of the child during the procedure should be carried out by a member of the medical or paramedical staff, trained in the use of nitrous oxide in oxygen. Monitoring is clinical and aims to assess the state of consciousness of the child, and his or her respiration and colour. If contact is lost with the child, inhalation is interrupted. Personnel must be aware that vomiting may occur and be ready to rapidly place the child in the recovery position if necessary (lateral recumbent position).

CONCLUSION

Pain related to medical interventions may be experienced as the worst part of a hospital stay for a child. Caregivers should prevent and relieve such pain at every opportunity. **ALnox™** is an excellent solution for analgesia and anxiolysis during mildly or moderately painful interventions. It should not be used, however, for very painful acts, such as the reduction of a complicated fracture or drainage of an abscess. If the gas is not effective within five minutes, a different analgesic should be chosen. **ALnox™** is very easy to use and it is extremely safe when used as a single agent.



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