



## Nitrous Oxide Sedation 10 Years Retrospective Review in a Pediatric Dental Clinic in Cluj Napoca, Romania

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### Abstract

**Aim:** To evaluate the 10 years outcomes of Nitrous Oxide Sedation (NOS) and to verify the referral reasons, indications, the safety and the effectiveness of this behaviour management method (BMT) when it is administered by a trained pediatric dentist and/or accompanied by an anesthesiologist in a pediatric private clinic in Cluj Napoca/Romania.

**Methods:** This was a retrospective review of prospectively-collected data (March 2008 - March 2018) of the case notes of patients aged between 3 - 12 years old attending for Nitrous Oxide Sedation in a pediatric private dental clinic. A quantitative approach to explore the use of NOS was used. The research items were categorized into 7 categories: NOS referrals, Nr. referrals for NOS with previous unsuccessful NOS, NOS sessions performed, age distribution, successful NOS, undesirable effects of NOS, NOS for local analgesia reason as prophylactic sedation.

**Result:** From 6218 NOS referrals, 4022 cases were solved without NOS but by non-pharmacological methods, 1089 (17,5%) patients had previous unsuccessful NOS experience, 1892 cases were selected and performed by NOS, 4400 NOS sessions were performed, 3084 sessions (70%) were successful, 369 underwent procedural analgesia with NOS as prophylactic sedation for dental procedures, and 938 for anxiolysis and analgesia.

**Conclusion:** NOS is a brilliant pharmacological BMT method for prophylactic sedation if the indications and the NOS guidelines are respected. NOS is not a panacea for all kind of anxieties or pediatric dental procedures. The BMT methods must be performed as the first choice before referral for NOS and - as any pharmacological BMT methods- NOS must be accompanied by a psychological one.

**Keywords:** Nitrous Oxide Sedation; Prophylactic Sedation; Sedation Referrals; Conscious Sedation Indications; NOS Outcomes; Pediatric Patients

### Introduction

Dental treatment and alleviation of dental pain is a basic human right that exist regardless of age. Anxiety and pain management during dental treatment are important factors in delivering safe and effective dental care. All children and their parents should expect nowadays painless, high quality dental care. Till the "gold time" of dental decay as a complete preventable illness, we have to educate and keep the patient capable of and willing to utilize and to cope with the current operative dental services. The pain

control during local anaesthesia delivery (LA) is too -a major issue in Paediatric Dentistry especially when used for preschool children [1]. The lack of appropriate analgesia can have long-term consequences in children, including fear, behavioral changes, care avoidance, and sleeplessness. Various non-pharmacological and pharmacological techniques are recommended by the European and American Academy of Pediatric Dentistry to enable the dental practitioner to perform quality oral health care for the pediatric patients [2].

The gold standard of pain and anxiety control is general anesthesia, but the higher risks, costs and personnel/resources commitment required must be balanced with the advantages of patient comfort, particularly for short, minor procedures. Moreover, this process requires a hospital operating theater, bears substantial cost on the Romanian health care system, and can act as a barrier to care because of limited access of pediatric patients in the operating room setting. However, Romania's entry into the European Union in 2007 brought along the fundamental freedom of travel and the possibility for Romanian specialists to freely practice their activity in other countries. This event led to the migration of many anaesthesiologists towards economically more developed countries. It seems that 30% of Romanian anaesthesiologists have left their jobs between 2008 and 2012 [3]. Consequently, even for patients with the financial means and desire to receive general anesthesia or intravenous deep sedation in a private clinic, it is becoming more difficult for them to receive these services due to physician shortages and lack of qualified anesthesia nursing personnel in Romania.

With the shift away from anesthesiologist or general anesthesia in the hospital operating room - parents were quicker to embrace an alternative pharmacologic technique managed by a dentist able to administer nitrous oxide in the dental office.

Its modern use outside the operation theater, started in 1961 when Tunstall introduced a stable mixture of nitrous-oxide and oxygen in equal proportions in a single cylinder for the relief of pain during labor. Soon, the analgesic use of this gas mixture spread over other settings, such as ambulances, hospital wards and during physiotherapy. Both the anxiolytic and the analgesic properties of the equimolecular mixture of oxygen and nitrous oxide (EMONO) have also been very useful in the dental office [4].

To date- nitrous oxide sedation (NOS) has a long history of safe use in dentistry and offers the clinician predictable clinical outcomes. The agent provides almost pain, motion, and anxiety-free surgery, requires no fasting, intravenous line or post-procedure monitoring and may be administered by non-anesthesiologists. It is considered a preferred technique for the pharmacological management of anxiety in pediatric dental patients in the dental office [4,5] and the second most accepted BMT by parents in the United States. In Germany there is a renewed interest in dentist-administered nitrous oxide sedation as an alternative to deep sedation or general anesthesia conducted by an anesthesiologist. In 2010, nitrous oxide sedation was officially approved and regulated by the Kuwaiti Dental Board [5].

There are two models for NOS use and administration: the EMONO model (the equimolecular mixture of oxygen and nitrous-oxide promoted especially in France (authorized for French private practices in December 2009) and the patient based nitrous-oxide sedation model -PBNOS model used in the USA/Switzerland using the adjustable mixture of nitrous oxide and oxygen. Nevertheless, EMONO has not been accepted in all countries of the world. It is primarily used in the United Kingdom, Australia, and South Africa. In the United States, nitrous oxide is used as PBNOS method [6]. Nitrous-oxide sedation according to the patient's need is considered « patient based ». The gas is titrated to the necessary level in order to achieve wellbeing and sufficient analgesia. The titration model is regarded as the current standard of care when administering nitrous oxide for sedation. Because of individual biovariability, patients will require different levels of nitrous oxide on different days and for different procedures [7].

In Romania the studies and implementation of behaviour managements techniques BMT and NOS as a BMT in paediatric dentistry started in 2008 by Statov [8,9] following an Erasmus Education Program in France by "Victor Segalen" University. The pioneer for using this new medical service in Romania is a private paediatric clinic. During the first 5 years (2008 - 2013) it was implemented the French model (EMONO with rapid induction and all ways attended by an anesthesiologist) and the last other 5 years (2013 - 2018) alternatively the both models-the EMONO model for preschoolers and the PBNOS for older children and adolescents. Nitrous oxide was available marketed as Entonox via Linde Gas Budapest and later via Linde Gas Romania for EMONO model. N<sub>2</sub>O administration was made by demand valve fixed 50% N<sub>2</sub>O/50% oxygen. For PBNOS model the administration was made by a continuous-flow system using the Quantiflex MDM machine which delivers 0 - 70% N<sub>2</sub>O for PBNOS from 2 cylinders, 1 of pure nitrous oxide and the other of pure oxygen and including a scavenging system to decrease environmental contamination.

Analysis completed by Hulland., *et al.* [10] revealed that on the basis of a 10-year retrospective study, the utilization of nitrous oxide-oxygen sedation as a single agent provides effective and safe conscious sedation for pediatric patients.

To date no study has explored such use in Romania.

**Methods**

**Study design**

**Data Collection**

The study sample was identified from clinical dental records of paediatric patients who received dental treatment in this private dental clinic during 10 years: March 2008 till March 2018. Patients aged between 3 and 12 years old were selected. The clinical records were extracted, recorded and reviewed by the main author. The children with recognized contraindications to nitrous oxide were NOS excluded: patients with nasal obstruction, Eustachian tube compromised or recent ocular or cranial surgery. The most important contraindication it was patient refusal. All the notes were done by the main author NVG. 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; The source of patients referrals in Happydent Clinic was represented by the general dental practitioners from the city Cluj Napoca/

Transylvania or from all the country. Traffic census of the clinic is 1 000 patients/month fitting seamlessly into a busy paediatric surgical practice.

**Results**

The results from this systematic review are presented under the two following headings:

1. (See table 1): The methods (psychological or pharmacological) used for case referrals with following 7 subheadings: Nr. referrals for NOS, Nr. referrals for NOS with previous unsuccessful NOS experience. Nr. referrals accepted and performed by NOS, Nr. referrals solved by non-pharmacological BMT, Nr. referrals solved by analgo-sedation, Nr. referrals solved by GA, Nr. abandon.
2. (See table 2): The NOS results in details are represented as in table 2.

Nr. Total referrals for NOS	Nr. referrals for NOS with previous unsuccessful NOS	Nr. Referrals accepted and performed by NOS	Nr. referrals solved by non-pharmacological methods (BMT)	Nr. referrals solved by analgo-sedation	Nr. referrals solved by GA	Nr. abandon
6218 (100%)	1089 (17,5%)	1892 (30,4%)	4022 (64,68%)	202 (3,24%)	60 (0,97%)	42 (0,6%)

**Table 1**

Age of patient (years)	3 - 4	4 - 5	5 - 6	7 - 12	Total
Number of patients selected for NOS	288 (15.22%)	644 (34.04%)	560 (29.59%)	400 (21.15%)	1892
Successful NOS sessions	180 (5.83%)	1167 (37.84%)	1314 (42.60%)	423 (13.71%)	3084
NOS side-effects	3 (7.6%)	12 (30.76%)	18 (46.15%)	6 (15.38%)	39
NOS for profi-lactic sedation	0	192 (14.69%)	135 (10.33%)	42 (3.2%)	1307

**Table 2:** NOS Results.

1892 (30,4%) children of 6218 referrals were evaluated and selected for treatments under NOS. 1089 (17,5%) were children with at least one unsuccessful NOS experience. ASA status was I in 1854 cases (98%) and II for 38 cases (2%). Nr. referrals accepted and performed by NOS were 1892 (30,4%). Nr. referrals solved by non-pharmacological methods (BMT) were 4022 (64,68%). 4405 NOS sessions were performed. 262 children referred for NOS- and patients with intellectual disability and the completely non-cooperative children or with extensive dental decay were candidates for other sedation methods: analgosedation and general anesthesia in the hospital practice by courtesy of the medical team of Oro-Maxilo-Facial Clinic II Cluj Napoca. Of the 4405 NOS sessions 70% (3084) were successful in terms of both sedation and treatment. No serious adverse events were recorded. Minor adverse events were noted for 39 cases (0,1% of the sessions- behavioural, vagal, and digestive disorders). The most successful age group for NOS was 5 - 7 years 1314 (42.60%). The most side effects too: the group 5 - 7 years nr. 18 (46.15%).

## Discussion

Raducanu, *et al.* [11] in 2009 reported dental fear and anxiety to be up to 21% among a Romanian child population. It means a strong evidence for the professional pain and anxiety management (psychological and/or pharmacological) need in paediatric dentistry in this country. The ideal way to manage the dental anxiety is to prevent the dental diseases. In the absence of it - prevention of pain and anxiety is available via BMT psychological approaches. 4022 children (64,68%) referred for NOS significantly exhibit lower anxiety and higher cooperation in the second visit compared to the first visit-dedicated to familiarization- so the need for NOS was significantly reduced. Minim-invasive and pain free operative care in combination with a planning tailored to the needs and developmental stage of each individual child is an preventive option too. But there is neglected the prophylactic sedation and the fact that even the most cooperative subjects for operative dentistry may have become anxious and sensitized to the injection leading to higher reporting of pain at distress at the next visit [12]. This is the ethical reason (see table 2) that of 3084 NOS sessions 1307 sessions were performed for prophylactic sedation for children in need for local anesthesia (LA).

Patient selection and preparation for NOS is important for successful treatment as well as an imaginative induction so the patient can benefit a maximum from the sedation experience. Nitrous oxide inhalation sedation ( $N_2O/O_2$ ) is commonly employed to improve cooperation for pediatric dental procedures. The clinical efficacy of nitrous oxide is sufficient and predictable in most cases. However, there are children for whom nitrous oxide fails to provide adequate levels of sedation [13]. Severely phobic individuals will not benefit by  $N_2O/O_2$  administration. Deep sedation and general anesthesia will most likely be the procedure of choice for them. Some patients with claustrophobic tendencies may feel uncomfortable with the mask (nasal hood). But often these patients relax sufficiently during  $N_2O/O_2$  sedation. If the patients is unwilling or does not give consent the practitioner must not force the continuance of the procedure because this place the practitioner in legal jeopardy. While  $N_2O/O_2$  is effective for many children, inconsistency in efficacy may result in an aborted, traumatic, or even harmful dental experience for the child. In turn, early traumatic dental visits can contribute to life-long dental fear and avoidance. Moreover, the most resistant patients for psychological BMT or NOS are the anxious children with previous traumatic dental experience or failure of NOS. The dentist's ability to accurately predict a child's capacity and willingness to cooperate during a procedure becomes a major determin-

ing factor in the decision to use psychological BMT methods or NOS to facilitate a positive dental experience. However  $N_2O/O_2$  sedation is enhanced with the spoken words. Soothing, calm, humorous, encouraging words and actions of the operator facilitate the relaxing effect of the drug. Investigators believe the psychological preparation before  $N_2O/O_2$  administration has a significant impact on its effect [14].

Failures in obtaining cooperation and NOS with treatment success could be caused by [8,9]:

- Lack of fragmented treatment for children with attention and cooperation deficits.
- Unadequated children management method with interference from parents.
- Ineffective communication and language use.
- Ignoring or failure in recognising the anxiety.
- Useless explanations.
- Incorrect evaluation of child compliance.
- Failure in anticipation of pain management measures.
- Choosing aversive measures before pharmacological ones.
- Applying pharmacological measures after the installment of fear or pain.
- Failure in applying pain management conditions.
- Expected results are not obtainable always after the first appointment for NOS.

**Referrals:** Some practitioners doesn't want the most difficult patients in their practice. Currently, child patients are referred to sedation services for their dental treatment based on the opinion of their dentist. This means that the decision of referral is subjective. The IOSN is a tool - as its name indicates - to be used to assess the need for sedation. The IOSN can be used as a referral tool to help clinicians to make a decision about referring adult patients to have sedation for their dental treatment, and also as a health needs assessment tool for commissioners. This tool investigates the need for sedation by ranking a combination of information on patient anxiety, medical history and the complexity of the clinical treatment. p-IOSN may be a useful tool that can be utilized to predict child patients who would benefit from sedation for their dental treatment. However, the p-IOSN is still in the investigational stages and further research is required prior to its use on clinical grounds [15].

**Monitoring:** We found many studies where EMONO was used without a medical presence, which probably reflects the ease of its use. However, in this study all children sedated with EMONO were observed by one attending anesthesiologist. It should be underlined that although EMONO use is safe, patients should always be clinically monitored by a dedicated staff member. The practitioner is responsible for the possible complications associated with the intended level of sedation and those associated with the next deeper level therefore because moderate sedation may occur or be intended considerations for obstructed airway and pre-procedure fasting guidelines are addressed [14]. Pre-procedure fasting guidelines are recommended in the ASA practice guidelines. Normally a light meal is appropriate if eaten 1 hour before the procedure but because moderate sedation could be achieved intentionally or unintentionally it is recommended that a light meal with no fried or fatty foods be consumed at least 6 hours before sedation procedure and no liquids be consumed before 2 hours. Fasting rules are questionable and vary slightly between the European countries, prior to conscious sedation it is recommended, that the child shall be fasted according to the following rules [16]:

- No clear liquids 2 - 3 hours before NOS.
- No solid foods or non-clear liquids 4 hours before NOS.

Clear liquids are non-fruity juice, water, tea, and coffee. All milk products (non-clear liquids) are considered as solid foods. Children under school age shall drink sugar containing clear liquid up to 2 hours before treatment in order to avoid low blood sugar. For the emergency patient, where proper fasting has not been assured, the increased risk of sedation must be weighted against the benefits of the treatment, and the lightest effective sedation should be used. If possible, such patients may benefit from delaying the procedure.

Guidelines are used to inform clinical practice and improve the quality of health care. Poorly developed guidelines may emphasize the incorrect intervention. The EAPD guidelines in sedation for paediatric dentistry "had to be based on lower levels of evidence, such as guidelines developed by other professional organisations, as well as clinical experience" [16]. However the last document regarding NOS is CED -Resolution on the use of nitrous oxide inhalation sedation in dentistry from 2012 (quoted by 5) but it is a political document - aimed at supporting the benefits, the safety and the usefulness of the use of N<sub>2</sub>O in the dental office - and not a clinical guideline. The document has not been updated since 2012.

All the advantages of the NOS emphasized in many studies and countries [17] have favored a great market success in Romania that has eclipsed and surpassed the university medical education and/or continues in the field. The campaigns for the promotion and sale of inhaled inhalation equipment and/or unscheduled educational programs have resulted in inaccurate applications, omissions, failures, failures and professional frustrations that question both the value of the technique and the professional ethics. The overconfidence in NOS method without both BMT and NOS knowledge background leads that the NOS method being misused, overused or underused.

## Conclusion

This study offers an insight of the current management of pediatric patients in Romania and gives strong supporting evidence for the safety and effectiveness of inhalation sedation using 50% N<sub>2</sub>O/O<sub>2</sub> EMONO or PB-NOS in a pediatric dental practice for healthy patients. The NOS technique is not difficult; correct case selection, pre-procedure psychological preparation and titrating the drug while observing and monitoring the patient response by a dedicated sedation staff is the key to success. But some questionable issues are under the sign of an emergency pressure for European and national authorities to update the actual clinical guidelines and regulations covering nitrous oxide inhalation sedation in Europe and in Romania.

## Conflict of Interest

The authors declare no conflict of interest.

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## Ethical Standards

All procedures performed in this study were in accordance with the ethical standards of institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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