European Archives of Paediatric Dentistry (2021) 22:409–415
https://doi.org/10.1007/s40368-020-00569-z

ORIGINAL SCIENTIFIC ARTICLE

Child behaviour during dental care under nitrous oxide sedation: a cohort study using two different gas distribution systems

T. Vanhee[1] · F. Lachiri[2] · E. Van Den Steen[2] · P. Bottenberg[2] · A. Vanden Abbeele[1]

Received: 6 May 2020 / Accepted: 21 September 2020 / Published online: 16 October 2020

Abstract
Purpose Conscious sedation by inhalation of a mixture of nitrous oxide and oxygen (CS) is a technique used in dental care for anxious, handicapped or uncooperative patients. The very special objective of this cohort study is to compare the behaviour of young patients during dental care under CS in two hospitals using different gas distribution systems.
Methods Young patients were divided into four categories: young child (YC), phobic anxiety (PA), mental disorder (MD), occasional indication (OI). Differences in behaviour scale at various time points according to the sedation system used were established and compared using Mann–Whitney tests.
Results This study showed that there is no difference in behaviour during dental care in YC after sedation. In PA, a significant difference in behaviour is only observed during local anaesthesia ($p = 0.024$).
Conclusion No significant differences detected in children's behaviour under conscious sedation using different gas administration systems. The delicate stage of local anaesthesia in PA patients can be facilitated with repeated sessions of dental care under conscious sedation.

Keywords Conscious sedation · Nitrous oxide · Paediatric dentistry · Behaviour · Gas distribution system

Introduction

Conscious sedation by inhalation of a mixture of nitrous oxide and oxygen (CS) is an effective means for the management of uncooperative children requiring dental care in paediatric dentistry services in hospitals (Bryan 2002). The majority of CS dental care is successful in anxious children (> 90% of cases) (Foley 2005; Hennequin et al. 2012). This medical tool increases the cooperation of young patients by reducing anxiety during dental care (Burnweit et al. 2004; Galeotti et al. 2016). Inhaled after a period of induction, the nitrous oxide mixed with pure oxygen, allows to decrease the painful perception during dental care (Hammond and Full 1984). Two gas distribution systems are used for CS in paediatric dental care: the mixing system with a bottle of N_2O and a bottle of O_2 and the system using a fixed equimolar mixture of N_2O and O_2 (EMONO) readily available in a single tank from the supplier. The mixing system is widely used for dental care around the world except in some countries like France while the EMONO system, widely used in general medical practice is more widespread in the French paediatric dental practice. Both systems have advantages: the mixer system allows to manage the concentration of N_2O (capped at 50%) and maintains pure O_2 available to speed up recovery. Drawbacks are a higher level of sophistication and costs as it depends on an electronic system for mixing. Furthermore, pure N_2O is present at the operatory. In the EMONO system, the mixing is already done, the dentist has no risk of N_2O overdose except in case of gas demixing, it can be operated independent of a power supply and at lower cost. Whatever the system used, this does not affect the oxygen saturation of haemoglobin (Primosch e al. 1999). The effect of nitrous oxide administration can be measured by the success or failure rate of the treatment or using behavioural observation with instruments like of Venham scale (Collado

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s40368-020-00569-z) contains supplementary material, which is available to authorised users.

✉ T. Vanhee
Tania.Vanhee@ulb.be

1 Department of Operative and Paediatric Dentistry, Université Libre de Bruxelles, Brussels, Belgium

2 Oral Health Research Group, Vrije Universiteit Brussel, Route de Lennik, CP 622 808, 1070 Brussels, Belgium

et al. 2006). Indeed, one of the first interests of CS in the context of paediatric dental care is to improve the cooperation of patients to be able to take care of them serenely and safely. Behaviour is therefore an essential element in the estimation of the success of care under CS. Despite extensive literature on dental care under CS in paediatric dentistry, no study has compared the behaviour of young patients during CS dental care based on the gas distribution system used. Often we just find studies on one of the two systems but it has never been possible to compare the two on the same city. Indeed, a system is more often developed in one region than in another. For example, in France, the premixed system with a naso-oral mask is the most used, while in the Netherlands, it is the system with the two separate gases and a nasal mask. It is therefore difficult for the same observer to compare the behaviour of patients over the same period and in the same region. Our situation in Brussels, through the diversity of our linguistic communities, meant that, in the French-speaking university hospitals, the practitioners were trained in France and learned to use the EMONO system while in the Dutch-speaking university hospitals, the practitioners were trained in the Netherlands and have expertise in using the two-cylinder system. This study is therefore exceptional. The very special objective of this study is to compare the behaviour of children in care for dental care under CS according to the gas distribution system used.

Methods

The observations were made in two cohorts of patients from paediatric dentistry department of two hospitals in the Brussels (Belgium) region, Saint-Pierre University Hospital Cesar de Paepe site (CdP) and Tandheelkundige kliniek (VUB). Inclusion criteria: every patient aged 2 to 18 admitted for dental consultation under conscious sedation between 10/11/2017 and 23/02/2018. The exclusion criteria correspond to the usual precautions required for dental care under conscious sedation.

This study was reviewed and ethical permission was granted by the Local Hospital Ethics Committee of the Saint-Pierre University Hospital in Brussels (approval number O.M. 007) under the reference B076201734522.

Used at CdP, a fixed gas administration system (FIX) is used (ANTAFIL®, SOL SpA, Monza, Italy) consisting of a cylinder containing mixture of 50% O_2 and 50% N_2O at a pressure of 185 bar at 15 °C. The flow rate is adjusted using a mechanical valve system to an average of 6 l/min.

The gas is administered to the patient by a latex-free naso-oral mask (QuadraLite™, Intersurgical, France) with a one-used antibacterial filter (Clear-Guard™, Intersurgical, France) connected to the administration circuit (Mapleson D deluxe bain breathing system, Intersurgical, France) (Picture 1 in ESM). After at least 3 min of induction, the mask is placed on the nose, allowing access to the oral cavity for dental care.

The second sedation system, used at VUB, is Parker's MATRX MDM® system (MIX). This system is used with two GCE Medical bottles, one containing 100% O_2 at a pressure of 200 bar at 15 °C and the other containing 100% N_2O at a pressure of 100 bar at 15 °C. Each cylinder of gas is connected to the flowmeter. The gas is administered via a corrugated pipe from the flowmeter to the nasal mask (Picture 2 in ESM).

This system is accompanied by a gauge, located on the flow meter, to adjust the percentage of oxygen and nitrous oxide that is administered to the patient. The flow rate is adjusted according to the respiratory rate of the patient.

6 l/min is recommended by the EAPD guidelines. On the FIX system, the flow can be adapted and we follow the inflation of the reservoir bag so that it is neither too tight, if not enough. It must be just flexible enough and allow visualisation of the respiratory rate by inflating and slightly deflating the reservoir bag.

For the MIX system, the maximum flow rate is set by the company but it is adapted at the start of the consultation before the titration by observing the inflation of the reservoir bag.

Patients were divided into four categories: young child (YC), phobic anxiety (PA), mental deficiency (MD), occasional indication (OI) (Collado et al. 2006).

YC are patients less than 5 years old, without mental development problems; PA are patients from the age of 5, without mental development problems, showing signs of anxiety or phobia during previous conventional dental care; MD are patients from the age of 5, with a mental disability or a cognitive or behavioural disorder; OI are patients who could be treated conventionally but in which the dentist judged that they might benefit from CS for an intervention that could be more invasive such as an extraction after trauma or requested by the orthodontist.

For this study, behaviour was assessed using the modified Venham Behavioural Scale (Picture 3 in ESM) (Hennequin et al. 2012), a hetero-assessment scale that measures the behaviour of young patients during conscious sedation dental care based on well-defined criteria (Moura et al. 2016). It is a descriptive scale of behaviour that can be used to record the behaviour of patients throughout the session according to a score ranging from 0 to 5 (Veerkamp et al. 1993). A training session was conducted using the visualisation of ten videos of young children with different behaviours during dental care.

The behaviour score was noted at five time points: at the first contact with the patient, in the treatment room or in the waiting room (T0); when applying the mask on the face/nose (T1); at the end of the induction, at least 3 min after the application of the mask (T2); when performing local anaesthesia (T3) and eventually during the intervention (T4).

All observations were performed by a single, trained observer who did not participate in the clinical procedures. A form completed during the sessions included the patient's information: age, sex, medical history, session number, patient category, intervention performed and behavioural score.

A treatment session was considered a success if sedation and care could be achieved and a failure when sedation or treatment could not be performed.

Statistical analysis

The statistical analysis makes it possible to determine the differences in behavioural Venham scores between the two populations during dental care after sedation at T2 and T3.

The null hypothesis is that there is no difference between the means of the behavioural scores of the two groups at T2 and T3. Behavioural scores are qualitative variables and we used the Mann–Whitney non-parametric *U* test for 2 independent samples for the statistical analyse or this variable. Concerning the session number variable, the distribution does not follow a normal distribution, the medians of the two groups are compared with the Mann–Whitney non-parametric *U* test for 2 independent samples.

The statistic analysis is performed using IBM SPSS v. 25.0 (SPSS Inc., Armonk, NY.)

Results

One observer attended 100 sessions of dental care under CS with 91 different patients. 44 patients at VUB with the MIX system (MIX) and 47 patients at CdP with the FIX system (FIX), were treated by 6 operators, 3 at each site. In case a patient received several CS sessions, the last session was selected for the study.

The total population observed had more female (55%) than male (45%) patients and the average age observed is 6.77 years.

PA patients represent 62% of the population, followed by YC 27%. There were 8 MD patients and only 2 OI cases.

The success rate of acts performed was 95%, there was no significant difference between the two sites ($p = 0.701$, Chi^2 test).

Among the cohort, five failures were noted, two in the MD group, one in the PA group and two in YC group. These children were not cooperative and had to be referred to general anaesthesia. The median number of sessions was one for the MIX and two for the FIX cohort. The number of sessions was higher for the YC and PA group undergoing the FIX protocol, 2 ($p = 0.026$) for YC and 3 ($p < 0.001$) for PA, Mann–Whitney test.

The different independent variables are grouped in Table 1. In this table, we find the description of the cohorts in terms of age, gender, indication as well as the success of sedation and dental procedures performed during sedation.

The distribution of Venham scores in the YC group, the results are very comparable: at T2 and T3, there is no significant difference in behaviour between the two groups ($p = 0.740$ at T2 and $p = 0.936$ at T3) (Fig. 1a).

For the PA group, the situation is different: more than half of FIX PA had a score of 0 (21 patients) compared to MIX PA (11 patients). Then, there is a significant difference in behaviour between the two groups at T2 ($p = 0.026$). For the other scores, the number of PA presenting the scores 1, 2, 3 and 4 is more or less similar for the two groups.

Indeed, at T3, The Mann–Whitney non-parametric *U* test indicates that there is no significant difference in behaviour between the two groups ($p = 0.223$) (Fig. 1b).

Discussion

This study could demonstrate that no significant differences could be detected in children's behaviour under conscious sedation using different gas administration systems. Slight behavioural differences could be observed due to possible operator or cohort effects.

The strong points are: comparison between two gas administration systems with an identical measuring instrument used by the same observer.

Points of possible criticisms are: possible underpowered by the number of subjects, confounding effects such as cohort and operator. This confounding effects are reduced by video training for using the hetero-rating behaviour scale.

All patients treated with conscious sedation have an initial consultation at the hospital to present them with the equipment, including the sedation mask. However, for many patients, and especially new patients, sedation is a new experience. Faced with this novelty, some patients show opposing reactions that hamper their cooperation despite a preparatory consultation. These patients will then require steps to restore confidence and, if this is not enough and the dental situation deteriorates with pain and infections, it will be necessary to proceed to a step of dental care under general anaesthesia.

The analysis of the number of sessions for the two categories of patients showed a significant difference for YC and highly significant for PA. Repetition of sedation care allows uncooperative patients to better cope with long-term dental care (Collado et al. 2006).

In a subsequent study, patients could be grouped according to the number of sessions already performed. Then, PA

Table 1 Synopsis of the cohorts by socio-demographic variables, gas distribution system and type of intervention (*FIX* fixed gas administration system, *MIX* mixing system with a bottle of N_2O and a bottle of O_2, *YC* young child, *PA* phobic anxiety patient, *MD* mental deficiency, *OI* occasional indication)

		FIX	MIX	Total	*p* value	Statistics
Patients	*n*	47	44	91		
Gender						
M	*n*	26	15	41	0.046	Chi^2
F	*n*	21	29	50		
Age						
Mean		6.57	6.98	6.77	0.566	Student *t* test
SD		3.25	3.42	3.32		
Max		2	2	2		
Min		19	17	19		
Indication						
YC	*n*	12	13	25	0.540	Chi^2 YC/PA
	%	25.5	29.5	27.5		
PA	*n*	31	25	56		
	%	66	56.8	61.5		
MD	*n*	3	5	8		
	%	6.4	11.4	8.8		
OI	*n*	1	1	2		
	%	2.1	2.3	2.2		
Session number						
Mean		3.15	1.45	2.33		
SD		1.88	0.63	1.65		
Max		1	1	1		
Min		8	3	8		
Median		3	1	2	< 0.001	Mann–Whitney
Intervention						
Operative care	*n*	31	24	55		
	%	66	54.5	60.4		
Extraction	*n*	10	11	21		
	%	21.3	25	23.1		
Prophylaxis	*n*	3	7	10		
	%	6.4	15.9	11		
Failure	*n*	3	2	5		
	%	6.4	4.5	5.5		
Success	*n*	44	42	86	0.701	Chi^2 failure/success
	%	93.6	95.5	94.5		

patients would be observed during the first session under CS and during a second or third session.

Local anaesthesia is a special step in dental care because it causes an unpleasant sensation when the needle penetrates the mucosa, during the injection even if it is carried out with all the required precautions, including in particular an infiltration slow and controlled, and also at the time of the sensation of numbness of the tissues surrounding the injection area. This sensation can worry the patient and it is therefore essential to reassure him by effective verbal communication throughout the procedure. Indeed, local anaesthesia is the most feared moment in dental care, even if the cause of anxious or phobic behaviour of the young child at the dentist is multifactorial (Poulton et al. 2001; Locker et al. 2001).

The fear of the dentist is often associated with a negative experience, recalling the pain, during previous care. (Risløv Staugaard et al. 2017).

After observing children treated with both the two sedation systems, no differences in child behaviour attributable to a difference in gas administration method could be observed. The systems can be judged to be equivalent in clinical efficacy. The practitioner or hospital can then make a choice based on advantages and disadvantages found for each one of them.

Using the fixed gas administration system (FIX), the advantage of the naso-oral mask is to involve the young child. By applying the tell-show-do technique for confidence-building, the patient participates with the

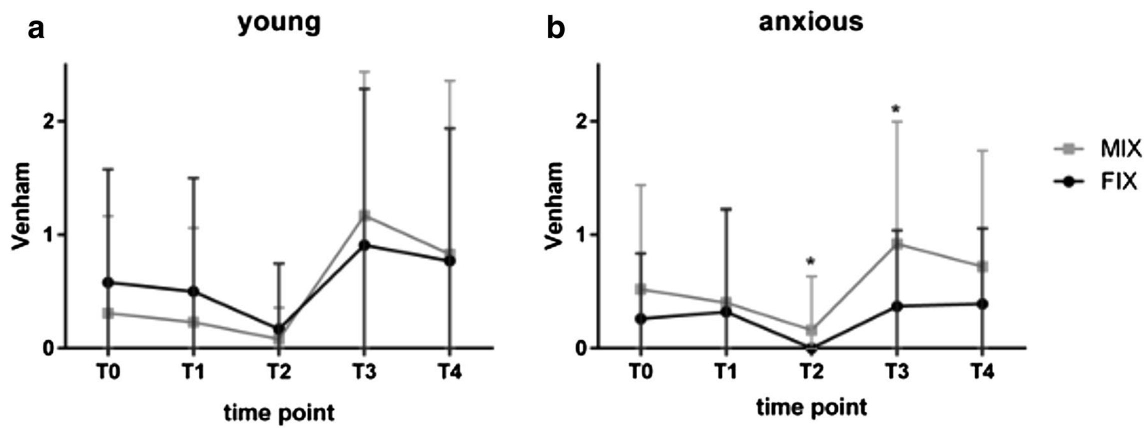

Fig. 1 Modified score Venham means for the MIX and FIX groups (a. YC patients, b. PA patients) (Timepoints (T) are given as follows: T0 = first contact with the patient, T1 = when applying the mask on the face / nose, T2 = end of the induction, T3 = local anesthesia, T4 = during intervention)

practitioner in placing the mask on the mouth and nose. The mask being on the nose and the mouth: bilateral communication is possible between the practitioner and the young patient. The child can speak in the naso-oral mask while with the nasal mask only, if the child speaks, all the gas used for sedation escapes and the gas can no longer have its effect. The practitioner can communicate with the child and thus distract him from his environment (Armfield and Heaton 2013). The flow rate and the concentration being constant, the practitioner can concentrate easily on the care, taking into account the fact that the inhalation can be stopped at any time if necessary.

Using the gas mixing device (MIX), the advantage of the nasal mask fixed and adapted to the patient is to reduce the gas leak. This gas leak can cause an adverse effect in healthcare professionals, frequently encountered during inhalation of N_2O, including headache (Field et al. 1993). The gauge on the flow meter allows to adapt the flow rate according to the child's breathing throughout the treatment. A button also makes it possible to adapt the N_2O concentration according to the observed heart rate. The practitioner can thus give the young child a concentration of less than 50% N_2O.

This system has a bottle of O_2, recovery is by inhalation of pure O_2 for 5 min. Using the fixed gas composition recovery is in ambient air or when needed a separate oxygen tank is available.

In the literature, both systems have been analysed for air pollution. Whether it is the premixed system or the two-cylinder system, air pollution remains below the recommended standards at European level (Hennequin and Onody 2004; Gilchrist et al. 2007).

However, when the child cries, this atmospheric concentration of N_2O increases. Preparing the patient in terms of behaviour is therefore a prerequisite for management under conscious sedation. Hennequin and Onody (2004) specified in their article that demand valves can help to further reduce this environmental concentration of N2O.

While in most parts of the world dentists use a two-bottle and nasal mask system, in France recent publications show that the use of the premixed system is still heavily used (Prud'homme, Dajean-Trutaud, et al. 2019a, b). Each technique has its advantages and disadvantages, but being able to compare two teams, each with expertise in one of these methods, makes our study an exceptional work.

This study was carried out before the Covid-19 pandemic and therefore did not require advanced reflection about aerosol generating procedures. Since March 2020, following the pandemic, great questions have been asked about the contamination of masks and circuits. For the premixed system (FIX), the mask is for individual use, or even one-time use, and its cost is less than the nasal mask. In addition, it has a filter system as found in the operating room. For the two-bottle system, there is a choice between disposable or sterilizable masks. As it does not have an antibacterial filter, it is necessary to sterilise the entire circuit. The investment is greater because it is necessary to provide one circuit per patient and to have an adequate sterilisation service, such as central hospital sterilisation.

The AAPD advises the systematic use of the pulse oximeter for conscious sedation but this advice comes during 2018 and our data collection carried out in 2017–2018 (AAPD 2018). Then, we based ourselves on the EAPD guidelines which specify that the use of pulse oximetry, although interesting, is not essential because it would cause additional stress to the child (Hallonsten et al. 2005). During our study, we wanted to observe the behaviour of children in a usual framework of care outside the study. While pulse oximetry is recorded for each patient at the VUB site, this is not the case at CdP where the EAPD guidelines were followed. We find this same notion in the Belgian national recommendations regarding the use of conscious sedation by inhalation of nitrous oxide (Avis 9299—protoxyde d'azote 2016).

In all cases, monitoring is performed by a dental assistant (MIX) or a paediatric nurse (FIX), both trained in the use of the sedation system and in monitoring the patient's respiratory functions (Coté and Wilson 2019).

In a subsequent study, the use of the heart rate function of the pulse oximeter is of great interest for a further assessment of patient stress (Appelhans and Luecken 2006).

Despite the differences between sites and practitioners in terms of training in conscious sedation (obtained in Dutch in The Netherlands for VUB practitioners and in French in France for CdP practitioners), very few significant differences were found in the statistical analysis. Further study could be done with the same practitioner using both sedation systems on the same population. This approach would be interesting to compare only the two systems but we would lose the diversity factor present in this study.

Conclusion

Considering the limitations of the present study the following conclusions can be made:

- No significant differences detected in children's behaviour under conscious sedation using different gas administration systems.
- The delicate stage of local anaesthesia facilitated with repeated sessions of dental care under CS.

Compliance with ethical standards

Conflict of interest All authors declare having no financial interest or conflict of interest.

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