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Nitrous oxide analgesic effect on children receiving restorative treatment on primary molars

ABSTRACT

Aim *Pain experienced during dental treatment increases the risk of developing dental anxiety in children who will became anxious adults, avoiding dental care. It is therefore essential to provide pain-free dental treatment. The strongest fears are often associated with injections: being able to successfully complete painless restorative treatment without the need for local anesthesia injection is therefore an important goal. Nitrous oxide administration by means of Langa's Relative Analgesia (RA) technique has been demonstrated to have both sedative and bland analgesic properties: the mechanism by which N_2O exerts its analgesic effects is now understood. The purpose of this study was to test the analgesic effectiveness of Nitrous Oxide used in the RA technique as the only analgesic agent for restorative treatment of primary molars presenting caries lesions without pulp involvement.*

Methods *Ninety patients aged between 3.2 and 9.4 years, 38 males and 52 females, ASA I and II, were included in the study. One hundred and thirty-four restorations were completed on primary molars with caries lesions without pulp involvement (1/3 to 2/3 into dentin): 72 restorations were completed on 48 patients under RA in the Study Group and 62 restorations were performed on 42 patients under RA and local anaesthesia (LA) in the Control Group. At the end of each session, the perception of pain experienced during treatment was rated by each patient using the Wong-Baker FACES® Pain Rating Scale.*

Results *No statistical difference on self-reported pain perception was seen in the Study Group (treatment under RA) and in the Control Group (treatment under RA plus LA administration). The results also showed no significant difference in pain sensation between males and females; age as well as gender did not affect the results between groups.*

Conclusions *Nitrous oxide as used in the Langa's RA technique is effective in providing a sufficient analgesic outcome during restorations of primary molars when there is no pulp involvement, with no need for LA supplement.*

Keywords *Children, Local anesthesia, Nitrous oxide, Primary molars, Pain, Relative Analgesia, Restorations.*

Introduction

Pain, which is subjective, is recognised as an unpleasant sensory and emotional experience associated with actual or potential damage [Kühnisch et al., 2017]. Dental treatment may represent a stressful situation with a variety of potentially unpleasant stimuli that might be related to pain. Dental procedures and local anaesthesia (LA) administration in particular, are often a source of anxiety in children, which in turn increase pain reactivity [Nuvvula et al., 2015]. It is therefore very important to use specific interventions to manage anxiety and prevent pain during dental care. Patients' fears may be acquired through vicarious experiences, such as parents' fears or impact of dental care on others. Nevertheless, direct personal experience is the most common source of dental fear: the perception of pain during dental treatment has been proven by research to be a major risk factor for dental anxiety [Versloot et al., 2009; Alvesalo et al., 1993]. A painful procedure, as well as the expectation of pain, increases the risk of development of dental anxiety [Krikken et al., 2008; Klingberg et al., 2007]. On the other hand, it has been found that anxiety is a state of mind that affects pain perception, i.e. pain may be experienced as worse when there is anticipated anxiety [Versloot et al., 2008] and children often show their distress about the dental setting with an aversive behaviour. This sometimes leads to management problems [Lourenco-Matharu et al., 2016] and anxiety may result in unsatisfactory outcome or failure of performing dental procedures [Cianetti, Paglia et al., 2017]. Therefore, it is essential to prevent and reduce the risk of pain whenever possible [Klingberg et al., 2017]. When local anaesthesia is properly administered, it is effective for pain-control in treating children and has very low adverse or side effects. There are different painful procedures that represent relative indications for LA administration, e.g. caries

excavation and/or restorative procedures. The choice of local anaesthetic agent depends on each patient's age and medical status, behaviour, anxiety, cooperation, planned treatment, operator's preferences and includes the use of alternatives methods in case of failure. However, the administration of local anaesthetic agents may cause pain due to the injection in the corresponding tissue of the oral cavity; such pain on administration in conjunction with dental treatment should be avoided and minimised. If LA is not provided an additional provision of sedation or general anaesthesia should be considered [Kühnisch et al., 2017].

A positive experience for a child in the dental environment is a primary objective of the paediatric dentist and to achieve this various behaviour guidance techniques are used. Behaviour guidance of young patients is vital to ensure safe and effective treatment while nurturing a positive dental attitude. Basic behaviour techniques include tell-show-do, voice control, non verbal communication, positive reinforcement, parental presence/absence, distraction and nitrous oxide/oxygen inhalation [AAPD 2017, Guideline on behaviour guidance]. While each technique has its merits, the use of nitrous oxide-oxygen inhalation sedation for the provision of paediatric dental treatment has shown to be a safe and effective alternative to general anaesthesia [Walley et al., 2015]. Nitrous oxide has a an excellent safety profile with few reported cases of adverse events (less than 1%), nausea and vomiting being the most frequent [AAPD 2017, Use of Nitrous Oxide]. It is a proven safe agent for use in many healthcare settings, from dental offices to emergency departments, specifically in the management of pain and providing conscious sedation.

Characteristics of an ideal sedation and analgesia agent would include the following.

- Providing good sedation and analgesia.
- Quick onset of action and rapid recovery upon discontinuation.
- Preservation of the cardiovascular and respiratory status of the patient.
- Amnesic feature.
- No allergic reactions.
- Irrelevant side effects .
- Non-traumatic administration: no intravenous access.

Nitrous oxide has almost all the mentioned properties, making it an ideal agent for procedural conscious sedation and analgesia: when inhaled it has been demonstrated to have both anaesthetic and analgesic properties [Malamed, 2010]. Around the 1800s the Cornish chemist Humphry Davy discovered the N_2O analgesic properties, describing nitrous oxide as "capable of destroying physical pain" [Davy, 1800].

N_2O-O_2 inhalation sedation aims at analgesia by raising the pain threshold of children during dental treatment with almost negligible adverse events and fast post-operative recovery.

Effectiveness of N_2O-O_2 inhalation sedation in raising the pain threshold and producing anxiolysis in paediatric dental patients makes it the preferred pharmacological behaviour management technique [Samir et al., 2015]. N_2O is a small and simple inorganic chemical molecule that has been used in clinical dentistry since the 19th century [Clark et al., 2015] and it is frequently used in modern dentistry as inhalation sedatation for paediatric dental procedures. It is a colorless gas that is stable at room temperature and ambient pressure which, in subanaesthetic concentrations, produces only analgesic and anxiolytic effects without unconsciousness [Damia et al., 2017]. In 1943 the analgesic effect of N_2O was judged to be comparable to that of opioid analgesic drugs: 30% of N_2O was deemed to be equieffective as 10-15 mg of morphine [Chapman et al., 1943]. In the middle 1970s it was first reported that N_2O-induced antinociception in mice and rats were sensitive to blockade by narcotic antagonist naloxone [Berkowitz et al., 1976]; N_2O-induced analgesia in human subjects was also antagonised by naloxone [Chapman et al., 1979; Gillman et al., 1980]. Studies have established an important role for opioid receptors in the periadequeductal gray area of the midbrain in pain modulation [Fujinaga et al., 2002]. There are multiple opioid receptors that are capable of mediating pain relief, and the specific subtypes of opioid receptors that mediate the antinociceptive effects of N_2O appear to depend on various factors, including the species, the regions of the brain, and the experimental noxious stimulus. N_2O induces release of endogenous opioid peptides that activate opioid receptors on GABA-ergic pontine nuclei. The stimulation of opioid receptors by N_2O-released opioid peptides inhibits the inhibitory GABA-ergic pathway, thus causing disinhibition of the descending noradrenergic pathway. The pathway activates descending noradrenergic system in the spinal cord that inhibits, or indirectly inhibits through a GABA interneuron, nociceptive processing at the level of the primary and second-order neurons which transmit sensory signals up the ascending nociceptive pathway [Emmanouil et al., 2007]. N_2O produces "relative analgesia", a term defined by Harry Langa [1968] as a chemically-induced altered psychological state which decreases or even eliminates the fear and pain of dental experience. For the Relative Analgesia (RA) technique, low concentrations of N_2O mixed with high concentrations of O_2 are administered to produce mild sedation and analgesia. The patient remains conscious and cooperative with protective reflexes fully maintained, also experiencing a pleasant, floating sensation [Samir et al., 2015].

The purpose of this study was to assess the effectiveness of nitrous oxide used in low concentrations (≤ 50%) with the Relative Analgesia technique, as the solo analgesic agent in children receiving Class I and Class II restorations for caries lesions without pulp involvement on primary molars.

Methods

The present study was conducted as a prospective randomised control study. Data were collected for children who were treated receiving Class I and Class II restorations on primary molars in two private practice dental offices. The study was conducted in accordance with the World Medical Association Declaration of Helsinki [WMA, 2013]; parental informed consent was obtained for every child.

Inclusion criteria

- Healthy patients: ASA I and II.
- Aged between 3 and 10.
- Delivery of treatment requiring the Langa's RA technique, due to emotional disposition, mild anxiety, gag reflex, behaviour concerns.
- No previous Relative Analgesia experience.
- Presenting interproximal and/or occlusal caries lesion with no pulp involvement, in need of Class I or/and Class II restorations on any primary molar, on either side of maxilla or mandible.

The included depth of the lesion was diagnosed from pre-operative radiographs as follows:

- C1: caries lesion in the enamel for less than one third into dentin.
- C2: caries lesion in the enamel for less than two thirds into dentin.

Exclusion criteria

- Medically and mentally compromised children.
- Children aged ≥ 10 years.
- Children < 3 years of age.
- Children with previous conscious sedation experience.
- Children with a history of significant behaviour management issues.
- Children presenting Class IV or V caries.
- Children presenting caries on any deciduous tooth other than molars.
- Children presenting possible pulp involvement in caries lesions (more than 2/3 into dentin).

Ninety-five patients aged between 3.2 and 9.4 years, 53 females and 42 males, met the inclusion criteria. Only 90 children were eligible participants: 52 females and 38 males with the mean age of 6.2 years. Treatment was delivered using N_2O-O_2 sedation with or without local anaesthesia: 72 restorations (20 Class I and 52 Class II) were completed on 48 children under nitrous oxide-oxygen Relative Analgesia only (Study Group) and 62 restorations (19 Class I and 43 Class II) were performed on 42 children under nitrous oxide-oxygen RA and local anaesthesia (Control Group). Children were randomly assigned into either the study or control group.

Prior of each restoration depth of the lesion was measured; concentration of nitrous oxide and use of local anaesthesia, as well as appointment length were recorded. To provide fillings with appropriate longevity and required mechanical properties, nanohybrid composite was always used as restorative material of carious primary molars.

RA technique was performed on all patients, using the sedation machine equipment (Matrix and TecnoGaz). The technique uses subanaesthetic concentrations of nitrous oxide delivered with high percentage of oxygen from dedicated machinery via a nasal mask [Galeotti et al., 2016]; the duration of RA was controlled and the patient could quickly return to normal activities. To induce sedation 40% N_2O and 60% O_2 concentrations were used for all patients (Study group and Control group) until adequate conscious sedation was achieved. During the procedure the patient was asked to breathe through the nose in order to maintain the desired level of sedation, while verbal contact with the patient was always preserved; all patients were responsive to simple orders and verbal commands. Further increases in nitrous oxide concentration were provided according to patient's need to reach a limit percentage of 50% O_2 and 50% N_2O, as recommended by AAPD guidelines [AAPD 2017, Use of Nitrous Oxide] to reduce side effect occurrence. If necessary, the concentration of N_2O was decreased to 35%. A flow rate of 3 to 6 L/min was administered based on patient's respiratory capacity.

Providers: 2 appropriately trained paediatric dentists with over than 15 years of experience, with the aid of dental nurses. All personnel involved had current training in paediatric basic life support. Treatment was carried out successfully in all patients, indicating that the operators were proficient at providing RA technique, with no adverse effects seen with nitrous oxide administration or linked to anaesthetic injection. A light meal was suggested to be consumed within the 2 hours prior to the RA session, as per AAPD guidelines [AAPD 2017, Use of Nitrous Oxide]. When LA injection was performed (Control group), RA was administered by either one of the two operators.

Control Group: topical 5% lidocaine gel was applied on the area of injection 2 minutes prior to administration of LA; 2% mepivacaine solution with 1:100,000 epinephrine or 4% articaine with 1:200,000 adrenaline was used as local anaesthetic, slowly injected in the span of 50-60 s.

Duration of session ranged from 20 to 55 minutes; the mean length of appointment was 40.2 minutes. Upon completion of treatment, 100% oxygen flow was provided to all patients for 4-5 minutes.

The Visual Analogue Scale "the Wong-Baker FACES® Pain Rating Scale" (Fig. 1) was used by the operators to estimate the level of pain experienced by each child during treatment delivery by asking the child to choose the face that best described his/her own pain perception while receiving treatment. The reliability of the above scale has been mentioned in previous studies [Wong et al., 1988; Simi et al., 2015].

Statistics

Statistical analysis and graphs were generated using R software with "stats" and "ggplot2" libraries respectively. Data normality was prior tested in order to verify if parametric or non-parametric approach was required for this study.

		Control	Study	p-value
N		42	48	
Age (mean (sd))		6.42 (1.33)	5.94 (1.35)	0.097
Gender (%)	F	25 (59.5)	27 (56.2)	0.920
	M	17 (40.5)	21 (43.8)	
Vas (mean (sd))		1.81 (0.92)	1.58 (0.68)	0.184

TABLE 1 Evaluation values of pain perception measured with the Wong-Baker FACES® Pain Rating Scale, in the Control group and in the Study group

FIG. 1 Italian version of the visual analogue "Wong-Baker FACES® Pain Rating Scale" used to ask children to rank their pain level (Whaley & Wong).

Results

Ninety-five children were assessed for eligibility in the study. Five children were excluded from the study as they did not report their pain perception through the choice of the face on the VAS Scale (the Wong-Baker FACES® Pain Rating Scale) which best described their pain level.

General records of 90 children (eligible participants) aged between 3.2 and 9.4 years, with the mean age of 6.2 years (SD± 1,35) were evaluated. Of a total of 90 children the majority were females (57.8%). The Study Group included 27 females (56,2%) and 21 males (43,8%); the Control Group consisted of 25 females (59,5%) and 17 males (40,5%) as reported in Table 1.

One hundred and thirty four restorations on primary molars were completed, divided in 95 Class II and 39 Class I. The treated teeth were:

- 41 maxillary first primary molars and 28 second primary molars;
- 34 mandibular first primary molars and 31 second primary molars.

At the end of each session, the perception of pain was evaluated using the VAS scale "the Wong-Baker FACES® Pain Rating Scale" [Wong-Baker FACES Foundation, 2018]. The patient showed his/her pain level experienced during treatment by pointing at one of the six faces between the two endpoints immediately post-operatively. Faces reflect the progressive severity of perceived pain from left to right (Fig. 1), from No pain (face 1), Mild pain (face 2), Discomforting-Moderate pain (face 3), Distressing pain (face 4), Horrible pain (face 5), to the Worst Possible Pain (face 6).

The results are as follows (Table 2).

Study Group

- No pain (first face): 24, 15 males and 9 females.
- Mild (second face): 18, 8 males and 10 females.
- Discomforting (third face): 5, 4 males and 1 female.

Control Group

- No Pain (first face): 19, 7 males and 12 females.
- Mild (second face): 14, 6 males and 8 females.
- Discomforting (third face): 9, 3 males and 6 females.
- Horrible (fifth face): 1 female.

Data normality was tested using the Shapiro-Wilk test. Since data were not normally distributed (p= <0.05) (table 3; Fig.2), a non-parametric approach was used; differences between groups were tested by Kruskal–Wallis test (χ^2= 2.375494; p-value= 0.1232526).

No statistical differences were observed between Control Group and Study Group in terms of VAS absolute value: there was no significant difference in children's pain perception between the two groups in relation to VAS choice on the Wong-Baker FACES® Pain Rating Scale (Fig.3, Fig.4).

The within comparison showed that there was no statistically significant difference in VAS values between males and females, in the Study Group (p=0.562) and in the Control Group (p=0.699), as shown in Table 4.

The inter-group comparison indicated that there was

Intergroup comparison	FACE 1	FACE 2	FACE 3	FACE 4	FACE 5	FACE 6
Study Group	15 males	8 males	4 males	None	None	None
	9 females	10 females	1 female			
Control Group	7 males	6 males	3 males	None	1 female	None
	12 females	8 females	6 females			

TABLE 2 Results of the perception of pain experienced during treatment, expressed post-operatively by patients using the Vas Scale "Wong-Baker FACES® Pain Rating Scale".

	W	P-value
Vas	0.9676788	0.02432592

TABLE 3 Normality data tested with Shapiro-Wilk test.

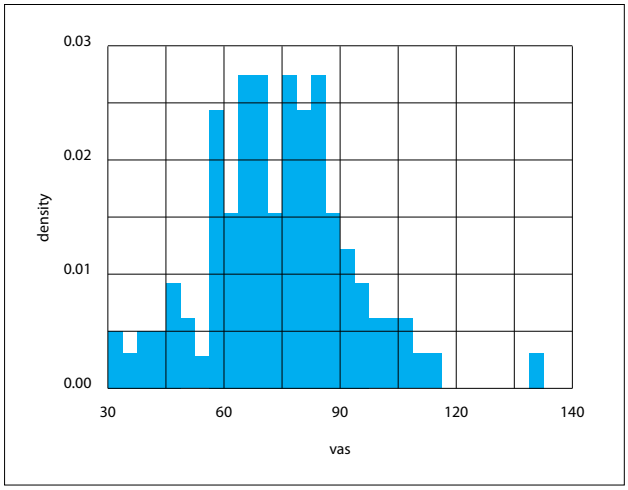

FIG. 2 Graph showing sample distribution.

no statistical difference between the 2 groups: the values reported by the children did not show a statistically significant difference (p=0.123).

With the limitation of categorical data, a negative correlation between age and VAS values was observed indistinctly between groups (R^2= -0.414, p<0.001) (Fig. 5).

Discussion

Nitrous oxide is a gas inhalation agent that has a long history of administration in procedures requiring analgesia and sedation, and it is usually appreciated by young patients [Arcari et al., 2008]. For many years since its discovery N_2O has been used by clinicians without a clear knowledge of its mechanism of action. Only in the last 40–50 years there has been significant research elucidating the mechanisms of the analgesic, antianxiety and anaesthetic effects of N_2O [Emmanuouil et al., 2007]. In the paediatric emergency department, nitrous oxide is currently employed to manage pain during several procedures: fracture reduction, laceration repair, venipuncture [Huang et al., 2016]. It was indeed found that children undergoing even minor procedures, as foreign body removal, intravenous catheter placement and drainage of abscess, experience a substantial decrease in pain and anxiety when receiving N_2O and standard care versus standard care alone [Duchicela et al., 2017]. N_2O is frequently employed in the treatment of the paediatric population during dental procedures: it is a drug widely used to reduce anxiety in children but to a lesser degree,

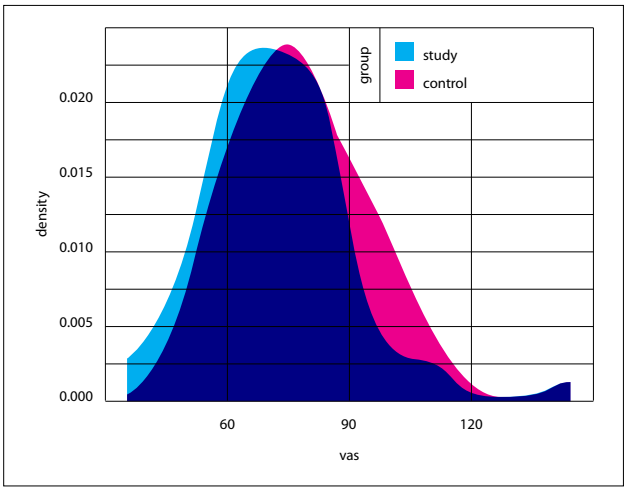

FIG. 3 No statistical differences were observed between Control group and Study group in terms of VAS absolute value.

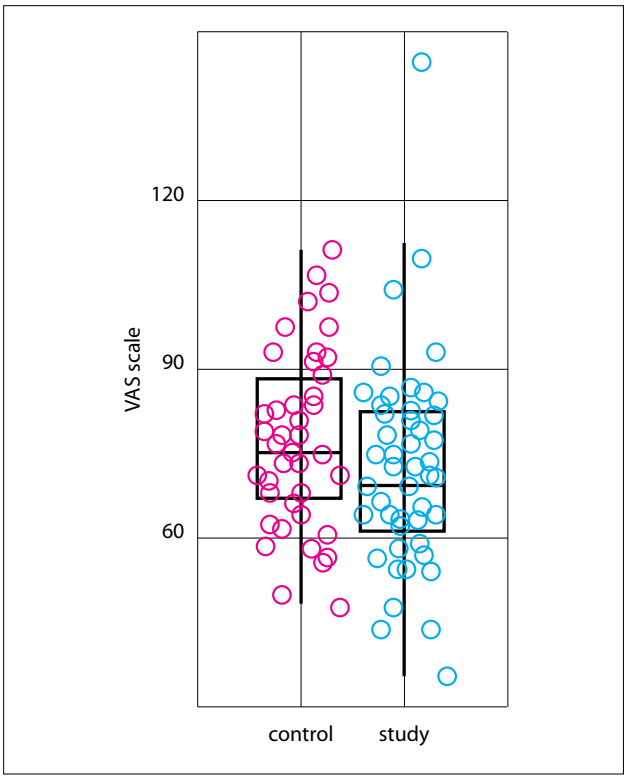

FIG. 4 No significant difference was found in children's pain perception between the two groups in relation to VAS choice on the Wong-Baker FACES® Pain Rating Scale.

	Male	Female	P-value
Study	1,24 (0,68)	1,63 (0,69)	0.562
Control	1,71 (0,77)	1,88 (1,01)	0,699

TABLE 4 Comparison of the difference in the Vas value between genders.

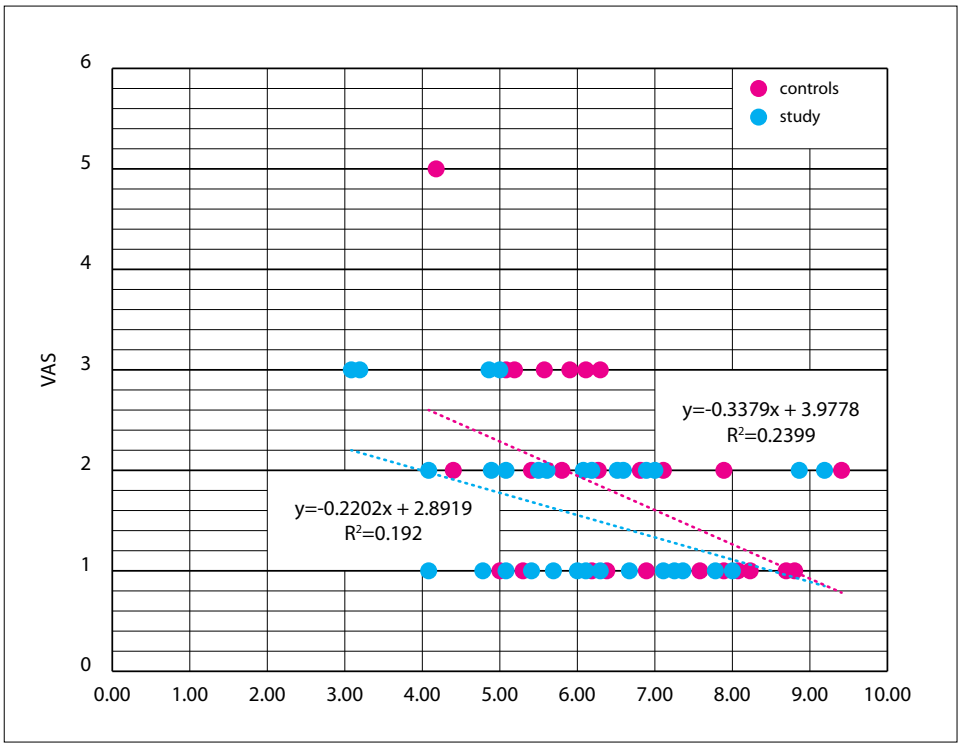

FIG. 5 Negative correlation between age and VAS values.

for its analgesic effects in the dental setting.

This seems to be the first study to evaluate nitrous oxide analgesic effect in the RA technique during restorative treatment of deciduous molars without pulp implication and, therefore, it is not possible to make a comparison with similar studies' findings.

The risk of developing a first carious lesion reaching the dentin in primary molars in otherwise caries-free children has been found to increase with age [Milsom et al., 2008] and data from the World Health Organization (WHO) indicate that dental caries, as included in gastrointestinal diseases, is still one of the most frequent health issues [Del Pinto et al., 2018]. The main conclusion of the present study is that restorative treatment (Class I and Class II restorations) of carious primary molars with no pulp involvement did not require local anaesthesia infiltration to achieve good pain control, due to the analgesic properties of nitrous oxide in the Relative Analgesia technique. RA is agreed to be safe and effective for young paediatric patients with low pain tolerance [Galeotti et al., 2016] and it is accepted that nitrous oxide in subanaesthetic doses produces analgesia, meaning a change in the patient's perception of pain [Malamed, 2010]. Indeed, a large number of subjects in the study group (50%) selected the first face of the Wong-Baker FACES® Pain Rating Scale to represent their pain level during treatment, thus indicating no pain. Moreover, all other patients ranked their pain as low (second face) or mild (third face). This can be attributed to the fact that one of the features of nitrous oxide in the RA technique is to raise the pain reaction threshold [AAPD 2017, Use of Nitrous Oxide] and children who have been sedated with N_2O often have little recollection of the painful aspects of the procedure [Pasaron et al., 2015]. The indications for use of nitrous oxide/oxygen inhalation analgesia-anxiolysis in the RA technique include patients for whom deep local anaesthesia cannot be obtained [Juntgen et al., 2013], confirming its ability to modify pain perception.

A recent retrospective cohort study found that the majority of children responds well to treatment when RA technique is used, and we concur that it is a viable treatment option instead of GA and for those children who do not accept dental treatment under LA [Madouh et al., 2018].

The results of the current study highlight that older children are more likely to experience less pain, as proven by their VAS choice. This could be explained by considering that, as they grow up, children usually learn effective methods to prevent and cope with pain [Anand et al., 2003]. However, untreated pain may have significant and lifelong physiological and psychological destructive consequences [Gaffney et al., 2003]. Expression of pain in children is known to be of great importance, as it enables heath care providers to consider children's pain manifestations and provide care. It is evident that each child and each adolescent has the right to pain-free diagnosis and treatment. All paediatric patients deserve painless high quality dental care, enhancing comfort [Galeotti et al., 2016]. There are striking individual differences in how everyone reacts to pain, which makes the assessment of pain an even greater challenge. When dealing with vulnerable populations such as toddlers and

preschoolers who have limited verbal abilities, being aware of nonverbal communication of pain has been found to be of crucial importance [Versloot et al., 2009]. Younger children are at a distinct disadvantage because their vocabulary does not permit a detailed description of pain [Wong et al., 1988]; therefore, a reliable and valid pain scale should not rely on verbal descriptions of pain but find immediate correspondence through familiar images. The use of valid pain assessment methods to accurate assess pain in paediatric dentistry is indeed the key to adequate pain management, which in the end influences treatment success. Furthermore, the assessment of pain is at the base of all pain treatment; developing valid pain management measures is both a clinical and a research duty, especially for vulnerable populations [Versloot et al., 2009]. Hence, the Wong-Baker FACES® Pain Rating Scale has been selected for this study to rate each child's pain during procedures. A possible limitation is the assumption that children's choice of the face was correspondent to their perception of pain; however, we agree with a previous study which reported that there is no way of proving the experience of pain other than believing the person in pain [Wong et al., 1988]. The experience of pain is inherently private and not directly accessible to others; pain is both a concrete experience and an abstract concept, a highly dynamic and subjective experience, inclusive of complex thoughts and feelings as well as sensory events [Gaffney et al., 2003]. Observing the patients' facial expression and body language gives much information [Van Dijk et al., 2009], as there typically are expressive demonstrations, requiring judgment and skill on the part of observers. The operators found no difference in children's expression of pain during procedures between the two groups, as proven by the results. Children that participated in the current study did not have major behaviour concerns or severe anxiety, as this could have generated bias between real pain reaction and behavioural issues. Indeed, it is known that awareness of patient's characteristics such as personal history, previous experience, coping abilities and dental anxiety are important, as these factors greatly influence children's pain experience and expression [Versloot et al., 2009].

A recent systematic review reported a substantial agreement among previous studies in relation to gender differences, defining girls having higher dental fear than boys [Cianetti, Lombardo et al., 2017], as to confirm stronger internalising emotions as well as general anxiety and sadness that have been clearly demonstrated [Alvesalo et al., 1993]. The current study's findings suggest no significant difference between genders regarding pain upon completion of treatment under RA. This could be due to nitrous oxide properties of reducing the patient's awareness of the surroundings and reactions concerning painful stimuli. The same review has determined that the pooled prevalence of children's dental fear in Europe, Asia, Africa and North America varies between 10% and 20%, showing that the problem in the paediatric population is significant in different settings [Cianetti, Lombardo et al., 2017]. At least one child out of ten was found to have a level of dental fear that hindered his/her ability to tolerate dental treatment. As in most countries and cultures, also in Italy the most fearful aspects of the dental visit include receiving injections in the mouth [Paglia et al., 2017]. There is clear evidence that procedures involving needles are considered painful by children, the strongest fears being most often associated with injections [Versloot et al., 2009]. If young patients feel uncomfortable as something dreadful may happen to them in the dental environment, they are at risk for developing dental fear [Paglia, 2016]. Consequently, it has been recognised that techniques to eliminate or minimise the discomfort of common procedures such as injections are needed [Wong et al., 1998]. Inhalation sedation is known to be indicated in apprehensive patients with previous negative experiences of treatment and fear of the needle [Samir et al., 2015]. In this study no significant difference was observed between study group and control group in children's pain in relation to the VAS value, attesting that, under RA, there is no need for LA injection when restoring deciduous molars with no pulp involvement. This is of great importance also for other reasons: patient monitoring after administration of LA is required and parents, as well as patients, need to be informed about post-treatment risks, especially of self-induced labial-oral mucosa trauma. The only young girl in the Control Group who chose the 5th face in the Wong-Baker FACES® Pain Rating Scale, indicating horrible pain, seemed to be upset due to the unpleasant sensation of LA on the labial mucosa following treatment, which is a common issue when LA is administered. Hence, successfully deliver painless restorative treatment without the need for anaesthesia injection is desirable for both young patients and clinicians.

This study was subject to the following limitations:

- multiple operators; however, the choice of a reliable rating scale, as the Wong-Baker FACES® Pain Rating Scale to assess pain level improved the consistency and validity of the study's results.
- small sample size. Further research is needed to confirm our findings and compare data on the efficacy of nitrous oxide as the single analgesic agent used during restorative treatment of primary molars using RA technique.

Conclusions

The benefits of N_2O includes analgesic and sedative properties. Nitrous oxide at 35-50% concentration was found to be an effective analgesic agent to perform Class I and Class II restorations on primary molars with no pulp involvement in caries lesions, attesting no need for local anaesthesia administration to achieve good pain control.

Further studies are recommended to verify adequate pain management with N_2O administrated in the RA technique as the single analgesic agent during restorative procedures on carious primary molars without pulp involvement.

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