Dental treatment of children using propofol and a laryngeal mask

J.S.J. VEERKAMP*, T. PORCELIJN**, R.J.M. GRUYTHUYSEN*

ABSTRACT

Aim Sedation regimens for toddlers and preschoolers are still open for further studies. Propofol is rapidly finding its way into medical routine. The aim of this pilot study was to re-evaluate the need for sedation in young children and to further investigate the use of propofol as an intravenous agent combined with the use of a flexible laryngeal mask for treatment of the youngest group of dental patients. Methods A randomised clinical trial with 54 children involved was conducted comparing one group receiving propofol sedation only with a study group receiving propofol with the use of a reinforced laryngeal mask. Assessments were made as to depth of sedation, quantity of propofol used, desaturations and recovery times. Results The use of a laryngeal mask improved the treatment conditions by decreasing the number of desaturations during treatment ($p \leq 0.001$, $t=5.74$). When using a laryngeal mask, the average amount (in ml) of propofol used was significantly higher ($p \leq 0.016$, $t=-2.22$) and the average waking up time in minutes significantly longer ($p \leq 0.016$, $t=-2.23$). Conclusion It was also found that deepening the sedation to be able to insert the laryngeal mask effectively reached such a level that it should be renamed as anaesthesia, thereby possibly limiting its use to hospital settings. The study supported, however, the safety aspects of the laryngeal mask.

KEY WORDS: Propofol, Laryngeal mask, Dental sedation, Dental anaesthesia

Introduction

Restorative dental treatment often means a considerable effort for toddlers and preschoolers up to four years of age. The child has very limited cognitive capacities and is unable to deal with the invasive nature of a dental treatment. A complex matter like a restorative dental treatment cannot be fully understood. The child also has limited coping abilities and from a psychological point of view at this age dental treatment should be adapted to this [Corah et al., 1985]. As a consequence, most of the children showing disruptive behaviour during dental treatment are between three and six years of age [Christen, 1977; Klingberg and Berggren, 1992]. Behaviour problems tend to decline with increasing age [Mussen, 1973; Bush, 1987; Klingberg and Berggren, 1992].

Retrospective research attributes most of dental fear to treatments during early childhood [Stouthart and Hoogstraten, 1990]. Direct conditioning associated with aversive treatment experiences in childhood [Milgrom et al., 1995] supports the use of treatment strategies that do not create a potentially stressful memory for the mentally unripe. Even at a preschool age the possibility of latent inhibition in the development of dental anxiety is suggested [D'avey, 1989] and therefore supports the idea of performing dentistry in young children in the least provocative way and at the latest possible moment. At a later age children should be able to cope with dental treatment more easily, having developed more cognitive capacities, or possibly being trained in learning how to manage aversive stimuli [Weinstein and Nathan, 1988]. It is, therefore, advised by authors to perform extensive restorative dental treatment in very young or mentally handicapped children with the support of some form of sedation [Weinstein and Nathan, 1988; Needleman et al., 1995; Wright et al., 1995].

The type of sedation chosen depends on the legislation in a specific country and the ideas and facilities of the operating dentist [Wright et al., 1995]. Mostly oral, rectal, intravenous or nasal sedation is chosen combined with some form of physical restraint and the use of nitrous oxide [Needleman et al., 1995]. Nitrous oxide is used to
augment the effect of the sedation of young children and to attenuate the child’s behaviour [Shapira et al., 1992; McCann, 1996; Houpt et al., 1996]. Moreover, in measuring the atmospheric concentrations of nitrous oxide during treatment, are reported in room air concentrations that exceed safety limits in most countries [Henry and Jerryl, 1990; Davies and O’Keefe, 1995]. Oral and intranasal sedation techniques have proven and specific benefits, but also drawbacks [Moore et al., 1984; McCann et al., 1996]. Various sedation regimens have been studied with reported success rates up to 90% [Moore et al., 1984; Shapira et al., 1992; Fuks, 1994; Needleman et al., 1995; McCann et al., 1996]. No conclusive relations were found between a patient’s behaviour and a specific drug regimen [Houpt, 1993a; 1993b]. The combination of limits to the success rates of oral and intravenous sedation regimens, recently developed guidelines and increasing malpractice insurance costs, create a barrier for paediatric dentists, though undoubtedly needed, to further study the possibilities of pharmacological support of the restorative treatment for young children.

There is a need for pharmacological support of the dental treatment of mentally very young patients. Research should focus on techniques safe for both patients and personnel and combining the 100% success rate of a general (hospitalised) anaesthesia and the ease and comfort of a regular dental treatment [Poswillo, 1990; Houpt, 1993a; A.S.A., 1996].

General anaesthesia uses combinations of drugs that are administered to ensure a safe procedure. For sedation, a single drug procedure might have benefits for a child’s health since the effect of a sedative agent does not interfere with other drugs given and it prevents the risks of a delayed recovery. With the modern drug propofol (2,6 di-isopropophenol, Diprivan®) these ideas are more within reach [Moore et al., 1994]. It is a fast acting sedative, with only side effects known during long continuous infusion of children with upper respiratory track infections [Parke et al., 1992]. Propofol has a short half-life period of 0.5-1 hour and no known reports of post-operative nausea [Sarasin and Ghoneim, 1996; Cillo, 1999]. Patients have no recollection of the treatment afterwards irrespective of the level of sedation. It is vital that the operator controlling the treatment of the sedated patient is fully aware of the signs and symptoms of both sedation and anaesthesia [Candelaria and Kuhen, 1995].

Propofol has proven good results in conscious sedation and ambulatory surgery [Marche et al., 1991; Rosenberg, 1995]. It is in fact useful in minor procedures with spontaneous ventilation and it is sometimes combined with nitrous oxide [Short et al., 1994; Oei-Lim, 1997], though few randomised clinical trials have been completed concerning this supplement [M oore et al., 1994; Merola et al., 1995]. Comparing propofol with one of the routine sedatives tips the balance easily to the newer drug [Stephens et al., 1993]. In adult patients a self-administering procedure reduces the amount of propofol needed and improves patients and surgeons satisfaction [Girdler and Rynn, 2000]. In children between four and ten years of age a high infusion rate and, as a consequence, a slower recovery is reported [Short et al., 1994].

In an earlier study the importance of the maintenance of an open airway [Veerkamp et al., 1997] was stressed. Protecting the airway is the most important issue in paediatric dental sedation. During the last few years the Brain laryngeal mask, LMA [Brain, 1984], has provided good results for this purpose [Brincombe and Brain, 1997]. Increased arterial saturation is reported, compared with conventional nasal mask anaesthesia [Baille et al., 1991]. The LMA was approved in 1991 by the U.S. Food and Drug Administration as a device to assist in the management of paediatric and adult airways. The development of a flexible, reinforced, laryngeal mask in 1992 lead to its use for deeper sedated patients [Pi nosky et al., 1998] and for restorative dental treatment. The combination of an open airway and a silicone cuff, covering the posterior part of the larynx, combines the ease of insertion and the quality of the seal of the glottis (Fig. 1).
The aim of this pilot study was, therefore, to further investigate the use of propofol as an intravenous agent combined with the use of a flexible laryngeal mask for treatment of the youngest group of dental patients.

Materials and methods
In this study 57 healthy (ASA I) children (30 boys) between 24-45 months were selected. The children were chosen from a larger group, who had been referred to a centre of special dental care. During a separate screening visit psychological intervention (desensitisation, modelling) did not seem to be very promising, because of the child's young mental age and limited cognitive capacities. The children had severe dental decay, most of the cases caused by nursing bottle caries. Stopping the sweetened comforter habit was an absolute condition for entering the restorative program. The treatment was based on normal standard routines: the affected teeth were treated restoratively if possible or otherwise extracted.

From the initial group 54 children participated in the study. Three were subsequently not selected and switched to full in-hospital anaesthesia, two due to nut allergy problems and one because of an airway illness without any possibility to postpone dental treatment. Every child required restorative or surgical dental treatment in at least three sextants. The children were to be treated after infusion of propofol, one group ensuring an open airway using a reinforced laryngeal mask (RLMA group n=35), and the other group without the use of the laryngeal mask (control group n=19).

A dentist performed the dental treatments together with an anaesthetist, after written informed consent from the parents and a preoperative screening. The latter protocol included possible contraindications such as any recent airway illness, known allergies like nut allergy [Ewan, 1996], diabetes mellitus or sickle cell anaemia. In any case, where a recent airway illness was reported, the treatment was postponed if possible.

Treatment procedure and level of sedation
The treatment protocol was based on the guidelines of the Council of the European Federation for the Advancement of Anaesthesia in Dentistry [EFAAD, 1994] and the British Society of Paediatric Dentistry [BSPD, 1996]. In addition the guidelines for deep sedation in paediatric dental patients, as defined for the American Academy for Pediatric dentists [AAPD, 1996] and the Dutch Consensus Committee for sedation and anaesthesia [Knappe and van Everdingen, 1996] were scored as follows:

1 - conscious and alert;
2 - drowsy;
3 - eyes closed, responding to verbal commands;
4 - eyes closed, responding to physical stimuli;
5 - eyes closed, unable to be woken by physical stimuli.

It should be noted that a level 5 score is generally accepted as being anaesthesia.

The parents and their child were asked to be in the clinic 30 minutes before starting the treatment, for a final checkup and to remove the topical anaesthesia cream (EMLA®). The parents had previously administered the cream at home to the dorsum of the right hand and foot under an occlusive dressing, following written instructions. The anaesthesiologist started treatment by creating an intravenous access. The intravenous line was kept in place for the propofol infusion throughout the treatment. The sedation was induced by administering a propofol bolus based on the body weight via a Graseby anaesthesia syringe pump, sufficient to sedate the child to a level that enabled the operating dentist to perform dental treatment without physical restraint. If the child still proved to be too agitated to insert the RLMA or to perform routine dental treatment, additional propofol was given via the infusion pump. The anaesthesiologist’s aim was to keep the propofol concentration as low as possible, but sufficiently deep to ensure an undisturbed dental procedure.

All patients were allowed to breathe spontaneously. To ensure an undisturbed open airway, a reinforced flexible laryngeal mask (RLMA) was inserted (Fig. 1, 2) in the research group. In the control group the position of the head and chin was checked carefully (Fig. 3). Blood pressure, pulse-rate, arterial oxygen saturation (SaO₂) and expired carbon dioxide (pCO₂) were monitored. The anaesthetist assessed the quality of the sedation. Data concerning oxygen desaturation, possible intra-operative and postoperative complications were registered. Following known criteria we defined a desaturation as every oxygen saturation level <92% for a period of 20 seconds. When desaturation occurred, the position of the head and neck, the laryngeal mask (if needed) was
checked and the chin lifted, if necessary. All treatment procedures were performed under local anaesthesia and with the use of rubberdam.

End of the treatment. A few minutes before ending the dental treatment the anaesthetist stopped the infusion. The laryngeal mask was removed shortly after finishing the dental treatment after the assessment that all protective reflexes were still present, breathing was undisturbed and SaO2 remained above 95%. The child was monitored until it woke up and was able to stand freely and reacted adequately to mother’s questions. Written post operative instructions were given and the anaesthetist contacted the parents six hours later, to check on the child’s condition. The children returned for a checkup visit approximately four weeks later.

Statistical analysis. All treatment results were analysed using a correlation matrix and exact probability tests, SPSS/PC+V 4.0 [Norusis, 1990].

**Results**

Most of the children were treated because of nursing bottle caries; the major part of the dental treatment had to be performed in the upper jaws. Most of the affected teeth could be restored using stainless steel crowns, amalgam or composite resin restorations. No significant differences were found concerning sex, age, body weight or number of restored or extracted teeth (Table 1). Variation in the propofol dose was not related to the child’s age or body weight (p=n.s.).

On injection of the local anaesthesia and placing of the rubberdam, pain and an increase of the pulse rate were a frequent occurrence. All children reacted by moving their hands or feet a little at the irritating moment, but never their head. After ending the stimuli, movements and pulse rate quickly returned to normal. The average level of sedation is given in Figure 4 and the average percentage of oxygen saturation in

<table>
<thead>
<tr>
<th></th>
<th>LMA (n=35)</th>
<th>Control (n=19)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (months)</td>
<td>37.5 ± 5.7</td>
<td>38.9 ± 5.7</td>
<td>0.90</td>
<td>n.s.</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>14.8 ± 2.1</td>
<td>14.6 ± 1.5</td>
<td>-0.39</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

n.s. = not significant

**TABLE 1** - Description of treatment groups by age and body weight for groups receiving propofol sedation.
Figure 5. No significant differences were found between the saturation levels (p=n.s.).

The number of desaturation periods during each treatment was significantly reduced when using the laryngeal mask (mean 0.37±SD 0.83) when compared with the control condition (mean 2.84±SD 1.77). The significantly lower number of desaturations (p<0.001, t=5.74) during treatment resulted in a safer treatment condition. Using the laryngeal mask resulted in a significantly greater amount of propofol used during induction as well as during the total treatment. The average amount of propofol used during the actual treatment and the total average amount of propofol, however, did not differ suggesting the main effect be based on a deeper sedation during the initial setting of the treatment.

The time, necessary for waking up, is also given in Table 4 and varied between 5 to more than 30 minutes. After this the children needed an extra time of 10 to 60 minutes (average: 30 minutes) before they were able to play, walk around independently and were allowed to leave the Department. During the short time checkup and several weeks later no discomfort was reported.

Apart from basic reactions on pain stimuli (e.g. injection) during sedation there was no perceptible child behaviour, for an obvious correlation between the total treatment time and the total amount of propofol used (0.762, p≤0.001). There was also a moderate correlation between the total amount of propofol used and the volume per minute (0.497, p≤0.002). No further correlations of any importance were found.

Discussion
In this group of children reported on here most of the carious teeth were affected by early childhood caries. This confirms the importance of the need of extensive behavioural changes to prevent dental decay in this young age group [Veerkamp and Weerheijm, 1996]. In young children and toddlers, sedation is a difficult concept to define. In general, a sedated patient should be able to respond and to maintain its protective reflexes [Merola et al., 1995]. For young children or mentally handicapped people of comparable developmental level, however, the acceptance of the sedated state is difficult. There is a developmentally based inability to understand the concept of the relaxed, dreamy feeling of being sedated [Mussen, 1973; Bush, 1987]. As a consequence, the sensation of sedation is interpreted by a child as one of two possibilities: being awake or asleep, and it tends to act accordingly [Veerkamp et al., 1997].

Sedation or anaesthesia? Earlier reports have questioned the level of propofol used for sedation. This is confirmed by this study. In our control group the sedation level sometimes exceeded the third sedation level (Fig. 4), which, for the Netherlands, is described as the upper limit of non-anaesthetists.
Dental sedation for children. In particular, the deeper sedation levels created more breathing problems, that disappeared when using the RLMA. However, when using the RLMA, sedation turned into anaesthesia. Because of the amount of propofol necessary to insert the laryngeal mask, the children did not respond to verbal commands anymore and only reacted to physical stimulation. Breathing, however, was spontaneous and undisturbed, as long as the open airway was guaranteed. Using the reinforced laryngeal mask, the child was able to breathe freely, without saliva or moisture reaching the vocal cords, resulting in defensive reflexes. This way a stable oxygen saturation was nearly guaranteed (Fig. 5).

In the course of the study, the efficacy of the reinforced laryngeal mask made the operators decide to stop the treatment where the RLMA was not used as soon as possible. Therefore, the size of the control group was limited to a minimum needed for statistical analysis.

The deeper sedation needed for the insertion of the RLMA is demonstrated by the higher amount of propofol used during induction of the treatment, as given in Table 2. During the rest of the treatment, however, the same dose of propofol was used to maintain the same level of anaesthesia. The higher dose of propofol seemed a disadvantage, but it should be noted that the higher amount of propofol resulted in quieter treatment conditions. The longer time needed to wake up (Table 2) seemed to be a combination of patients’ comfort and the slightly higher initial propofol dose.

Though the use of propofol in adult sedation often ends up with promising results [Oei-Lim, 1997; Ruiz and Coldwell, 2000], in young children using propofol should be reformulated as anaesthesia, based on their reactions on the level of sedation. The presence of an anaesthetist is a consequence of the European guidelines on sedation and anaesthesia [BSPD, 1996; EFAAD, 1994] and should follow the protocols given in every individual country. The use of a RLMA, however, seems mandatory for a safe and adequate treatment procedure. The need for further research is stressed by the lack of correlations between the other parameters. As in this study, no significant correlation was found between the propofol dose and the child’s body weight, it seems that other factors are of vital importance in assessing a dose-response curve. The lack of a relation between the initial propofol dose and that required to maintain the sedation underlines the complex nature of dental anxiety or arousal during dental treatment. A consequence might be to aim research in developing an instrument for pre-registering the child’s temperament [Klingberg and Broberg, 1998] and study the relation with the propofol initially used or as a maintenance dose.

Comparing the average saturation level did not give a significant difference between the experimental and control condition (Fig. 4), possibly due to the skewed distribution of the curve when a short moment of desaturation occurred. Comparing the number of desaturations results is a better representation of the actual situation. It should be noted that a safe treatment method is not proven solely by a sufficiently high average level of oxygen saturation, but merely by

<table>
<thead>
<tr>
<th></th>
<th>LMA (n=35)</th>
<th>Control (n=19)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Propofol given in ml</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) Induction</td>
<td>7.08 ± 2.41</td>
<td>5.63 ± 1.21</td>
<td>-2.95</td>
<td>0.005*</td>
</tr>
<tr>
<td>2) Total ml treatment</td>
<td>49.9 ± 16.9</td>
<td>40.3 ± 14.1</td>
<td>-2.22</td>
<td>0.016*</td>
</tr>
<tr>
<td>3) Ml/min treatment</td>
<td>0.49 ± 0.15</td>
<td>0.51 ± 0.14</td>
<td>0.38</td>
<td>n.s.</td>
</tr>
<tr>
<td>4) Total ml/min</td>
<td>0.59 ± 0.17</td>
<td>0.60 ± 0.16</td>
<td>0.35</td>
<td>n.s.</td>
</tr>
<tr>
<td><strong>Treatment time in minutes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total time</td>
<td>87.8 ± 29.7</td>
<td>76.9 ± 29.9</td>
<td>-1.66</td>
<td>n.s.</td>
</tr>
<tr>
<td>Waking up time</td>
<td>22.5 ± 8.7</td>
<td>17.7 ± 6.8</td>
<td>-2.23</td>
<td>0.016*</td>
</tr>
</tbody>
</table>

*significant if p < 0.05

Table 2 - Consequences of using a laryngeal mask for sedation with propofol for sedation in children.
the absence of problems occurring, such as periods of desaturation. The RLMA seems to be an important attribute in preventing those periods. In particular oxygen saturation, dropping as a result of moisture irritating the vocal cords, can be prevented by the use of the RLMA. To further increase the saturation level some authors advice the use of additional oxygen [Rohlffing et al., 1998], but an undisturbed airway is most important.

In this explorative study we improved the possibilities of propofol as a single sedative drug for toddlers in an ambulatory setting by using a reinforced laryngeal mask. In combination with a RLMA, propofol always enables the dentist to perform an undisturbed dental treatment while the child’s airway is taken care of. The higher concentration of propofol needed to enable treatment under safe circumstances with the RLMA however definitely brings the treatment to an anaesthetic level. The concept of an ambulatory purpose for this treatment method thereby becomes questionable. The method seems to benefit the patient, but in-hospital use might be needed. It would be helpful if additional protocols be developed. Nevertheless, propofol seems to be a particularly useful drug. Its quick onset, patient’s short recovery time, effectiveness in all patients treated and the good limitations of the potential risks are all promising and in agreement with recent findings [Hertzog et. al.,1999]. A ditional research on selecting patients and protocols is mandatory.

Conclusion

The use of a Reinforced Laryngeal Mask improves the breathing conditions during dental treatment of toddlers by ensuring an undisturbed open airway. This study indicates that its use is mandatory in these types of procedures.

The use of propofol in the dental treatment of toddlers in combination with a laryngeal mask deepens the sedation to such a level that it should be reformulated as anaesthesia. More studies on protocols are mandatory.

References


EFA A.D. Recommendations by the council of the European Federation for the Advancement of Anaesthesia in Dentistry concerning European standards for anaesthesia, analgesia and sedation in dentistry. Trier, Germany; Sept. 1994.


Hertzog JH, C ambell JK, D alton HJ, H auer GJH. Propofol


