Detection of Respiratory Adverse Events in Pediatric Dental Patients Sedated With 0.75mg/Kg of Midazolam and Oxygen by Continuous Pretracheal Auscultation: A Prospective Randomized Controlled Trial

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Purpose: *Sedation is becoming more commonplace for pediatric patients undergoing minor procedures. Fortunately, electronic monitors have contributed to a reduction in the associated respiratory adverse events (RAEs). To test the hypothesis that adding the pretracheal stethoscope (PTS) to standard monitoring methods (SMMs) may improve RAE detection in sedated pediatric dental patients, the frequency of RAEs detected by SMMs (i.e. visual observation, capnography, and pulse oximetry) was compared to that detected by SMMs alongside continuous PTS auscultation.* ***Study design:*** *A prospective, randomised, controlled trial was performed with 100 pediatric patient participants of ASA≤2, who were scheduled to receive dental treatment under 0.75 mg/kg and oxygen. Patients were randomised into Groups A (n=50; SMMs) and B (n=50; SMMs+PTS). Inclusion criteria were behavioral management problems and intolerance to dental treatment despite behavioral management techniques or nitrous oxide administration. Exclusion criteria were high-risk conditions for RAEs, altered mental status, gastrointestinal disorders, parental refusal of conscious sedation and failure of previous conscious sedation. An anesthesist was present throughout the dental treatments.* ***Results:*** *RAEs were detected in 10 (20%) and 22(44%) Group A and B patients respectively (p=0.01). The majority of RAEs within Group B were detected by PTS auscultation (n=19). Capnography produced 13 and 15 false-positive results in Groups A and B respectively, whereas the PTS produced 4(8%) false-positive results in Group B (p=0.009).* ***Conclusions:*** *PTS was found to be useful for detecting RAEs during pediatric dental sedation with 0.75mg/kg midazolam and oxygen, in the presence of an anesthesist.*

Key words: *dental; sedation; monitoring; respiratory; pediatric.*

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INTRODUCTION

The use of invasive and non-invasive diagnostic and minor surgical procedures for pediatric patients who require either conscious or deep sedation has increased in the last decade. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Society of Anesthesiologists (ASA), the American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD) have published various guidelines with the aim of reducing sedation-associated risk in children and thereby ensuring safe practice in patient monitoring .[1-4]

Despite substantial efforts on behalf of the AAP Committee on Drugs and the JCAHO to promote guidelines which ensure safe practice and to reduce the risk associated with sedation in children [4, 5], adverse events associated with sedative administration still occur. These events mainly fall under the category of respiratory compromise and become apparent as hypoventilation, apnea, airway obstruction, and laryngospasm. The frequency of adverse events however is declining due to the use of continuous electronic monitoring [6, 7] in addition to traditional physiological monitoring methods for the conscious sedated patient such as assessment of tissue color, chest movement, signs of increased respiratory effort, pulse and respiratory rates, as well as use of the stethoscope for heart and breath sound auscultation [8, 9]. However, neither electronic nor clinical assessment methods are free of limitation when it comes to detecting child airway occlusion.

Anaesthetists traditionally monitored ventilation and cardiac output by auscultation of breath and heart sounds with a stethoscope. The advantages of this method include low cost, simplicity of application, maintenance of the anesthesist's attention to the patient, and affordance of the possibility for early detection of cardiovascular depression or breathing circuit disconnection.[10] However, these techniques have been criticised as being part of a bygone era which has given way to modern technologies such as pulse oximetry, capnography and invasive cardiac monitoring. [11] Current trainee anesthesists therefore tend to use pulse oximetry and capnography as substitutes rather than supplements to stethoscope auscultation.

None of the aforementioned committees have, to the present, issued any recommendations for the routine use of the pretracheal stethoscope (PTS) amongst standard monitoring methods (SMMs) during either conscious or deep sedation in pediatric patients.

We hypothesised that addition of the PTS to SMMs (i.e. visual observation, capnography, and pulse oximetry) may improve detection of respiratory adverse events (RAEs) in children undergoing dental procedures under 0.75 mg/kg midazolam and oxygen sedation.

In order to test the hypothesis, this study aims to compare the frequency of RAEs as detected by SMMs versus SMMs with continuous auscultation using the PTS in pediatric dental patients receiving 0.75 mg/kg midazolam and oxygen sedation.

MATERIALS AND METHOD

The trial was designed as a prospective, randomised, controlled study, and was approved by the Local Ethics Committee (Bnai Zion Medical Center, Haifa, Israel) and conducted at Bnai Zion Medical Center, Haifa, Israel. Figure 1 summarises patient flow as elaborated below. A total of 100 healthy children aged between 5 and 10 years, with behavioral management problems and inability to tolerate dental treatment under behavioral management techniques or in combination with nitrous oxide) were recruited. These children were due to undergo dental treatments which mainly consisted of restorations, stainless steel crown and space maintainer placement, fissure sealant application and preventative care. A full verbal and written explanation of the study was provided to both children and parents and informed consent was obtained prior to commencement of the study.

Patient recruitment occurred between August 2012 and May 2014. All patients were evaluated by a senior pediatric dentist and were randomly divided by sealed envelope technique into two groups of 50 patients. Group A patients were sedated with 0.75mg/kg of midazolam mixed in apple or grape juice orally and were monitored by SMMs. The dose of midazolam used was established as optimal in previous research.[12] Group B patients were sedated exactly as above, and were monitored by SMMs with the addition of continuous auscultation with a PTS (II pediatric stethoscope) with an extension attached over the sternal notch.

Children were excluded from the study if they fulfilled any of the following criteria:

- A high potential risk for airway adverse events conferred by features such as obesity, snoring, stridor, sleep apnea, maxillofacial malformations, history of previous airway difficulty, gastroesophageal reflux, or acute reactive airway disease
- Altered mental status
- Gastrointestinal disorders which could affect absorption of the midazolam
- Parental refusal of conscious sedation
- Failure of previous conscious sedation

Clinical technique

Parents were requested to complete a questionnaire on their child's past medical history and children were fasted as per general anesthesia guidelines (i.e. solids and milk-containing drinks withheld for 6 hours, and clear fluids withheld for 2 hours prior to induction). Following oral midazolam administration as described above, a eutectic mixture of local anesthetics (EMLA) cream was applied to the dorsa of both hands and intravenous cannulation was performed at 20-30 minutes prior to dental treatment for vascular access should urgent resuscitation be required. Topical anesthetic (Benzocaine 20%) was applied to the gingival mucosa 3-4 minutes before injection of local lidocaine (2%) at a maximal dose of 4 mg/kg as required. All patients continuously received supplemental oxygen at 2L/min via nasal cannulae with a proboscis extending over the narices and an aspiration port for continuous CO_2 sampling. Patients were connected to the oxygen supply as soon as they felt comfortable following midazolam administration and for the entire duration of the treatment procedure. Additionally, oxygen saturation levels and heart rate were monitored by pulse oximetry. All dental procedures were performed by the same specialist pediatric dentist, whereas all monitoring (i.e. visual observation, capnography, pulse oximetry) was controlled by a resident anesthesiologist and PTS auscultation was undertaken by a consultant anesthesist who was blinded of the study design.

Assessment criteria

Physiology

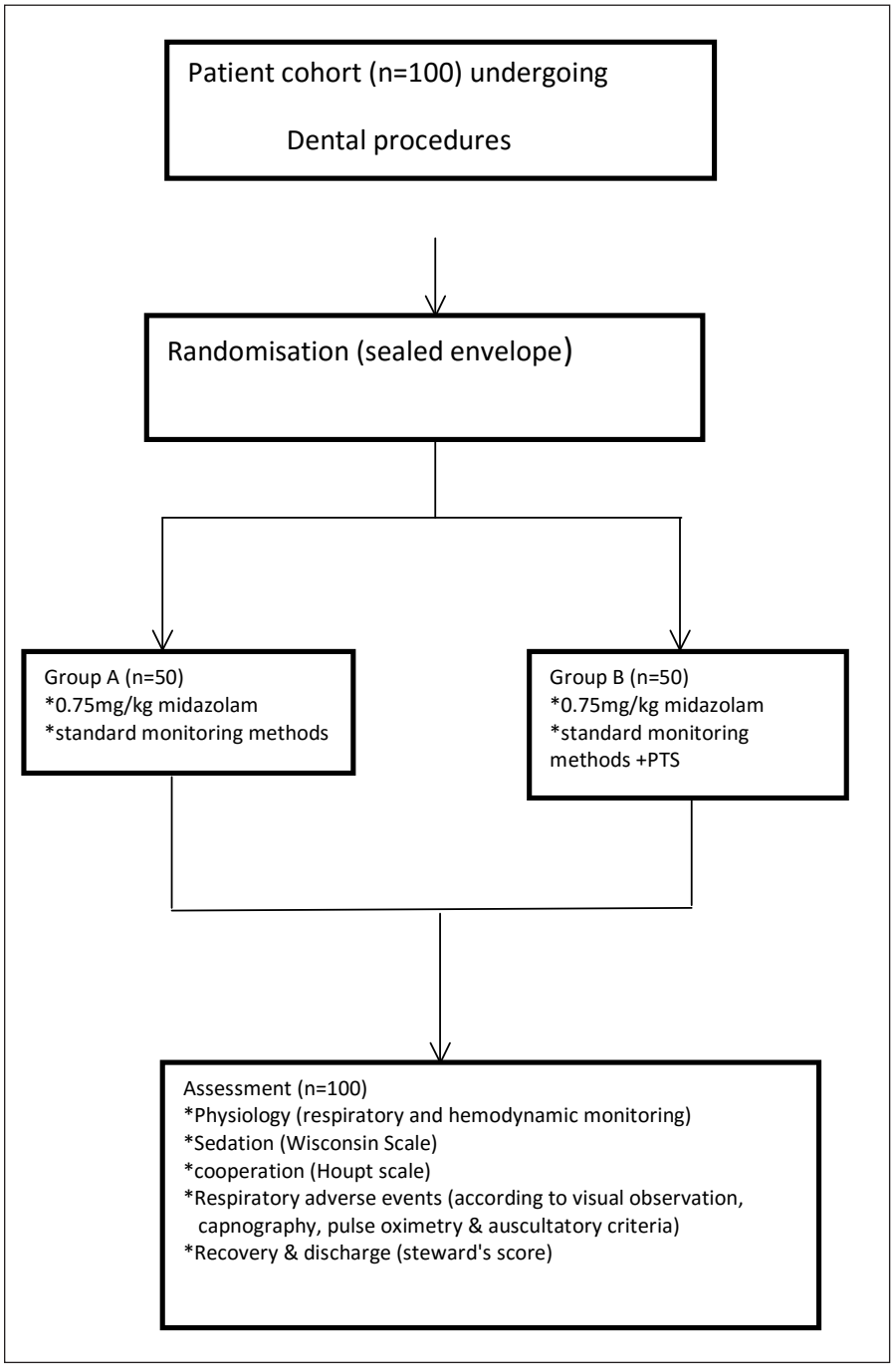
In addition to continuous visual observation, the physiological status of all patients was assessed by monitoring heart rate, respiratory rate and oxygen saturations immediately prior to midazolam administration, as well as by continuous CO_2 sampling (Smart MAC-Line O_2 $ETCO_2$ sampling lines, Oridion Medical Inc., Needham, MA, USA). All respiratory and hemodynamic vital signs were obtained and recorded at 5 minute intervals during treatment and at 15 minute intervals in both the pre and post-treatment areas.

As mentioned previously, Group B patients were additionally monitored by continuous auscultation by the blinded consultant anesthesist using the PTS attached over the sternal notch during treatment.

Level of sedation

The Wisconsin sedation scale [13] was used at 15-minute intervals by the anesthetist. The scale contains four categories: *1. Inadequate:* Patient is anxious, agitated, or in pain; *2. Minimal:* Patient spontaneously awake without stimulus; *3. Moderate:* Patient in drowsy state, eyes open or closed, but easily arouses

Figure 1: Participant flow



to consciousness with verbal stimulus; *4. Moderate-deep:* Patient arouses to consciousness with moderate tactile or loud verbal stimulus; *5. Deep:* Patient arouses slowly to consciousness with sustained painful stimulus; *6. Anesthesia:* Patient is unresponsive to painful stimulus . Satisfactory sedation was defined by a Wisconsin sedation score between 3 and 5.

Cooperation during treatment

The Houpt Behavior Rating Scale (HBRS) [14] was used continuously by the assistant pediatric dentist in order to evaluate patient cooperation. The scale contains six categories: *1. Aborted:* No treatment rendered; *2. Poor:* Treatment interrupted, only partial treatment was completed; *3. Fair:* Treatment interrupted but eventually completed; *4. Good:* Difficult but all treatment was performed; *5. Very good:* Some limited crying or movement; *6. Excellent:* No crying or movement. Children who displayed excessive movement or who struggled during treatment were gently manually restrained by either the assistant or the parent. Satisfactory behavior was defined by a HBRS value of at least 4.

Outcome measurement

RAEs were defined by the presence of any of the following criteria:

- *Observation:* Clinical signs of airway compromise or increased respiratory effort as a sign of upper airway obstruction
- *Capnography:* Absence of the end-tidal carbon dioxide ($ETCO_2$) waveform or an $ETCO_2$ partial pressure in excess of 50mmHg for at least 15 seconds in either case
- *Pulse oximetry:* Arterial oxygen saturation levels below 90% for at least 30 seconds
- *PTS auscultation:* Disturbances in the continuity or quality of inspiratory or expiratory sounds

Additionally, RAEs were rated in terms of severity according to the intervention required as follows:

- *Minor:* RAEs requiring only tactile patient stimulation
- *Moderate:* RAEs requiring external airway manoeuvres (EMs) such as jaw-thrust or chin-lift, and/or insertion of airway adjuncts
- *Severe:* RAEs requiring bag-valve-mask ventilation or endotracheal intubation due to depression of airway-protective reflexes during the treatment procedure

Recovery and discharge

All children were continuously observed in the postoperative care unit by a certified nurse until discharge. Procedure duration and time-to-discharge were recorded. Finally, children were discharged home after achieving the maximal value of 6 points on Steward's Simplified Post-Anesthetic Recovery Score [15] with provision of written and verbal post-treatment instructions to parents.

Data analysis

A sample size of 100 children (50 children per group) provided 95% power at a two-tailed α of 0.05 to detect a 0.5 episode difference between the two groups, assuming a common within-group standard deviation of 0.5-0.8.

Continuous data were compared using the paired t-test and Mann-Whitney nonparametric test, whereas discrete data were compared using Pearson's chi-squared and Fisher's exact tests. The significance of differences was defined as less than 0.05. Statistical analysis was executed using the SPSS software package (Release 17.0.2, SPSS Inc., 2009) and WINPEPI programs (2011, version 11.10).

RESULTS

A cohort of 100 children, comprising 53 boys and 47 girls aged between 5 and 10 years was recruited, allocated randomly and equally to Group A (n=50; SMMs) and Group B (n=50; SMMs+PTS), and completed the study. Patient weight ranged between 16 and 31kg, and the maximal cohort ASA score was 2 (Table 1). No statistically significant differences were detected between groups for age, weight, or ASA status (p= 0.563, 0.137, 0.78 respectively).

Patient sedation and cooperation

Time of onset of midazolam action ranged between 15 and 30mins, with no significant difference between groups (p=0.14; one-way ANOVA). Wisconsin sedation scores ranged between 3 and 5 throughout the treatment procedure (with the exception of one Group A patient, whose 45-minute Wisconsin score was 2, but whose procedure lasted 40mins) and were also similarly distributed between groups (p=0.81, 0.23, 1, and 0.14 at baseline, 15mins, 30mins, and 45mins respectively; one-way ANOVA).

HBRS values ranged between 2 and 5 during procedures, with satisfactory behaviour (as defined by a value of at least 4) throughout procedures achieved in the case of 24 and 19 Group A and Group B patients respectively. All children achieved a value of at least 4 on at least one interval measurement. HBRS values were similar between groups throughout procedures (p=0.149, 0.848, 0.27, and 0.75 at baseline, 15mins, 30mins, and 45mins respectively; one-way ANOVA). Table 2 summarises the cohort sedation and cooperation measurements.

Adverse events

RAEs were detected in 10 (20%) Group A patients. Within this group, RAEs were detected by observation in 3 patients and by capnography in 7 patients. None were detected by pulse oximetry. By definition, all RAEs in Group A were detected by SMMs. Capnography additionally produced false-positive RAE results in 13 cases.

RAEs were detected in 22 (44%) Group B patients. Within this group, none were detected by observation, none were detected by pulse oximetry, 3 were detected by capnography, and 19 were detected by PTS auscultation. In summary, 3 RAEs were detected by SMMs and 19 were detected by PTS auscultation. Additionally, false-positive results were produced in 15 (30%) and 4 (8%) cases by capnography and auscultation respectively. In Group B, as in Group A, all RAEs were moderate, requiring only EMs.

The difference in number of RAEs between groups was statistically significant (Pearson Chi Square Test Asymp. Sig. [2-sided] p= 0.01 (Table 3).

Table 1: Patient baseline demographic and clinical characteristics

	Group A (control)	Group B (Pretracheal stethoscope)	P-value*
Number of participants	50	50	-
Gender (Male:Female)	27:23	26:24	-
Age (years)**	7.27 ± 1.73 (5-10)	7.05 ± 1.69 (5-10)	0.56
Weight (kg)**	22.93 ± 3.82 (16-30)	21.68 ± 3.68 (16-31)	0.14
ASA**	1.22 ± 0.42 (1-2)	1.24 ± 0.42 (1-2)	0.78

*One-way ANOVA; **Mean ± SD (range)

Table 2: Sedation and cooperation profiles

		Group A (control)	Group B (Pretracheal stethoscope)	P-value*
Onset of Midazolam action (min)**		21.29 ± 4.22 (15-30)	20.00 ± 3.62 (15-25)	0.14
Wisconsin sedation score**	**Baseline**	4.29 ± 0.46	4.31 ± 0.47	0.81
	15 minutes	3.85 ± 0.48	3.73 ± 0.45	0.23
	30 minutes	3.44 ± 0.5	3.44 ± 0.50	1.00
	45 minutes	3.15 ± 0.42	3.29 ± 0.46	0.14
Houpt Behaviour Rating Scale**	**Baseline**	4.63 ± 0.69	4.88 ± 0.81	0.15
	15 minutes	4.17 ± 0.54	4.2 ± 0.60	0.85
	30 minutes	3.73 ± 0.59	3.88 ± 0.60	0.27
	45 minutes	3.54 ± 0.67	3.49 ± 0.71	0.75

*One-way ANOVA; **Mean ± SD (range)

Table 3: Respiratory adverse events & false-positive results

	Monitoring method		Group A	Group B	p-value*
RAEs##	**SMMs†**	**Observation**	3	0	-
		Capnography	7	3	-
		Pulse oximetry	0	0	-
		Subtotal	10	3	-
	PTS‡		N/A	19	-
	Total		10	22	0.01
False-positives	SMMs	Observation	0	0	-
		Capnography	13	15	-
		Pulse oximetry	0	0	-
		Subtotal	13	15	-
	PTS		N/A	4	0.009*
	Total		13	19	-

Pearson Chi Square Test Asymp. Sig. [2-sided]

*Significant difference in false positive episodes between capnography and PTS

** Respiratory adverse events

† Standard monitoring methods

‡ Pretracheal stethoscope

False positive cases detected by the capnography were comparable in both groups. However a significant differences found between PTS auscultation and capnography regarding false positive episodes in group B; P=0.009 (Table 3).

Procedure duration and time to discharge

Procedure duration ranged between 30 and 60 minutes in both groups (p=0.49). Time to discharge ranged between 80 and 120 minutes in both groups (p=0.12).

DISCUSSION

In 1985 (with revisions in 1992 and 2006), the AAP issued the first set of guidelines for the management of children receiving sedation and analgesia for diagnostic and therapeutic procedures.[5, 16, 17] A series of similar guidelines was later developed by anaesthesists in the USA (ASA guidelines for non-anesthesiologists in 1996 and 2002).[4, 18]

Many additional specialty groups in medicine and dentistry have developed and published monitoring guidelines in order to improve patient safety. Fortunately, these guidelines are largely similar and follow ASA principles.[4] There is strong consensus amongst consultants that monitoring ventilatory function by observation or auscultation reduces the risk of adverse outcomes associated with sedation and analgesia. According to ASA Practice Guidelines, consultant members are equivocal regarding the ability of capnography to reduce the risks associated with moderate sedation, agree that it may reduce risks during deep sedation and also believe that automated apnea monitoring may reduce risks during both moderate and deep sedation. In addition, there is strong agreement amongst members that oximetry during sedation-analgesia reduces the likelihood of cardiac arrest and death, as it is more reliable in the detection of hypoxaemia than clinical assessment alone.[4]

All guidelines for respiratory function monitoring share the following recommendations:

1. Oxygenation must be monitored continuously by pulse oximetry
2. Ventilation must be monitored periodically during moderate sedation, and continuously during deep sedation and general anesthesia

This study demonstrated a tendency towards higher RAE detection rates in patients sedated with 0.75mg/kg of midazolam and oxygen by introducing pretracheal auscultation to standard monitoring techniques. A significant RAE numbers were detected between the two groups (10 and 22). An anesthesist was present throughout the dental sessions.

The most finding on comparison of specific monitoring methods between the two patient groups is that most of the RAEs were detected by the introduction of the PTS to the SMMs in the group B patients. This may reflect the capability of PTS auscultation to detect RAEs before they become visually or electronically apparent. Such an interpretation would be consistent with current views that despite its relative simplicity, the stethoscope is unsurpassed in its capacity to provide instant information on airway patency, ventilatory effort and heart rate.[19] The time-lapse between auscultatory signs and capnographic or observational changes was not measured in this study, as detection of RAEs on auscultation mandates intervention regardless of other findings.

In comparing traditional (including auscultation) to electronic monitoring techniques, Crosswell et al. found that electronic techniques were more sensitive yet less specific than traditional techniques, and therefore recommended the combination of both methods for maximal patient safety.[20] In a subsequent study, Bennett et al. compared the sensitivity of auscultation vs. capnography in predicting oxygen desaturation (defined as $SaO_2 \leq 92\%$) during apneic episodes in deeply sedated or anaesthetised adults. Once again, capnography was found to be more sensitive yet less specific than PTS auscultation.[20] Our study results revealed that more RAEs were detected by capnography than by observation in group A and more RAEs detected by auscultation than by capnography monitoring in group B patients, in addition an approximately fourfold false-positive rate detected in capnography as compared to the PTS in group B . The fact that more RAEs were detected with the PTS than with capnography in the current study is in contradiction with their relative sensitivities, as determined by both investigator groups above. This contradiction may be a result of sample size and/or study design, as both Croswell et al. and Bennett et al. used multiple observers. It should be remembered however, that we used 0.75 mg/kg midazolam and oxygen for sedation.

Finally, a theoretical analysis based on the Australian Incident Report Study (AIMS) considered that the stethoscope (used alone) could have detected a maximum of 54% of 1,256 incidents. In fact, the stethoscope was only used in 65 cases and was the first instrument to detect an incident on only one occasion. However, these reported incidents involved patients under general anesthesia and included cardiovascular events such as cardiac arrest and arrhythmia in addition to RAEs. The authors concluded that the stethoscope had been superseded by the correct use of appropriate monitors, but that use of the stethoscope is a basic requirement and should be available wherever anesthesia is performed.[22]

The respiratory system is unfortunately less amenable to monitoring than the circulatory system during dental procedures under sedation. Although visual observation of respiratory function is important, it only provides information on respiratory effort as opposed to gas exchange.[23] Relying on visual observation of tissue colour only during these procedures is unsafe, due to the limitations imposed by the presence of dental paraphernalia and eye protection, patient restraint, hemoglobin levels, tissue pigmentation, ambient light and observer skill. Moreover, changes in tissue colour are late to appear in hypoxemia particularly in patient with oxygen supply.[20] In a study by Loeb et al. which assessed response times of anesthesia residents, it was found that 5 minutes may elapse before such a visual stimulus is detected during continual patient surveillance.[24] In our study, only three patients with RAEs were detected by observation in group A and no one in group B.

As pulse oximeters do not measure ventilation, they are typically subject to a lag of one minute, thus precipitous reductions and subsequent corrections in the partial pressure of arterial oxygen (PaO_2) may not be recognised promptly [25] Our findings revealed no case of RAEs by pulse oxymetry. Capnography on the other hand is easy to use in the setting of general anesthesia, but is limited by nasal cannula displacement and/or obstruction due to airway secretions during conscious sedation. Despite the occurrence of false-positive alarms during capnography such as resulted in our study, this method still considered an accurate monitor for detection of airway obstruction.[20]

Although continuous auscultation was once in routine use, it has been largely abandoned with the advent of electronic monitoring, reportedly due to availability of better monitoring, discomfort, inability to hear other sounds or people, and lack of freedom of movement.[26] Use of the PTS can also be limited by observer dependence. Arguments both for and against the use of the stethoscope were published as early as 1987. On one hand, it has been advocated that the stethoscope cannot provide any useful information beyond the presence or absence of breath sounds and cannot therefore reliably monitor ventilation.[11] On the other hand, the stethoscope has been defended as a simple and inexpensive instrument which extends the senses of anaesthesists, who are in fact the most important monitor in themselves.[10, 27]

CONCLUSION

PTS was found to be useful for detecting RAEs during pediatric dental sedation with 0.75mg/kg midazolam and oxygen, in the presence of an anesthesist.

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