Use of deep laryngeal oxygen insufflation during laryngoscopy in children: a randomized clinical trial

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Abstract

Background: Brief periods of haemoglobin oxygen desaturation are common in children during induction of general anaesthesia. We tested the hypothesis that oxygen insufflation during intubation slows desaturation.

Methods: Patients 1–17 yr old undergoing nasotracheal intubation were enrolled and randomly assigned to one of three groups: standard direct laryngoscopy (DL); laryngoscopy with Truview PCD videolaryngoscope (VLO2); or laryngoscopy with an oxygen cannula attached to the side of a standard laryngoscope (DLO2). The co-primary outcomes were time to 1% reduction in $S_pO_2$ from baseline, and the slope of overall desaturation vs time. All three groups were compared against each other.

Results: Data from 457 patients were available for the final analysis: 159 (35%) DL; 145 (32%) DLO2; and 153 (33%) VLO2. Both VLO2 and DLO2 were superior to DL in both time to a 1% reduction in $S_pO_2$ from baseline and the overall rate of desaturation (all $P<0.001$). The 25th percentile (95% confidence interval) of time to a 1% saturation decrease was 30 (24, 39) s for DL, 67 (35, 149) s for DLO2 and 75 (37, 122) s for VLO2. Mean desaturation slope was 0.13 (0.11, 0.15)% s$^{-1}$ for DL, 0.04 (0.02, 0.06)% s$^{-1}$ for DLO2 and 0.03 (0.004, 0.05)% s$^{-1}$ for VLO2. We did not find a correlation between decrease in $S_pO_2$ percentage and BMI or age.

Conclusions: Laryngeal oxygen insufflation increases the time to 1% desaturation and reduces the overall rate of desaturation during laryngoscopy in children.

Clinical trial registration: NCT01886807.

Key words: anesthesia; apnoeic oxygenation; laryngeal oxygen insufflation; nasotracheal intubation; paediatric patients
Editor’s key points

- Haemoglobin oxygen desaturation is common and rapid in children during laryngoscopy for tracheal intubation.
- The effect of oxygen insufflation on pulse oximetry measurements during laryngoscopy was studied in 457 children undergoing nasotracheal intubation.
- Deep insufflation of oxygen slowed desaturation when used with either direct or video-assisted laryngoscopy compared to direct laryngoscopy alone.

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concentration was then decreased to 2–2.5%, and subjects were mask ventilated for the next 3 min with 70%–30% N2O–O2.

Subjects were randomly assigned to one of the following three groups: (i) standard direct laryngoscopy (DL); (ii) laryngoscopy with Truview PCD videolaryngoscope (catalogue #4127; Truphatek, Netanya, Israel; VLO2); or (iii) laryngoscopy with an oxygen cannula attached to the side of standard laryngoscope (DLO2). Randomization was based on computer-generated treatment allocations (Research Randomizer, Version 4.0 at http://www.randomizer.org) that were maintained in sequentially numbered sealed envelopes. Randomization was 1:1:1, without stratification or blocking. The envelopes were opened immediately before induction of anaesthesia.

Laryngoscopy was performed routinely in the DL group. In the VLO2 group, oxygen was insufflated through the integrated channels in the blades at a rate of 2 litre min⁻¹ for blade sizes 0 and 1, and at a rate of 3 litre min⁻¹ for blade sizes 2 and 3 according to TruView manufacturer’s recommendation. In the DLO2 group, a size 4.0–5.0 tracheal tube was taped with sterile dressing to the left side of the laryngoscope blade, such that it did not obscure the view. During laryngoscopy, oxygen was insufflated through this tube at a rate of 2 litre min⁻¹ for blade sizes 1 and 2, and at a rate of 3 litre min⁻¹ for blade size ≥3, such that relative sizes of the blades from each group would have similar O2 flow.

After preoxygenation, the face mask was removed and the designated laryngoscope blade immediately inserted into the patient’s mouth. Nasotracheal intubation was accomplished using the technique described by Watt and colleagues. Briefly, a nasal RAE tracheal tube (Mallicknrodt, Pleasanton, CA, USA) was telescoped into a size 10 or 12 F red rubber catheter as it passed from the nares into the pharynx. Magill forceps were then used to retrieve the red rubber catheter and facilitate placement of the nasotracheal tube tip into the trachea under direct vision or video guidance.

Once the trachea was intubated, correct placement of the tracheal tube was confirmed with end-tidal CO2. The study was stopped when: (i) the trachea was intubated and a capnography trace obtained; (ii) oxygen saturation decreased to 90%; or (iii) signs of cardiac instability were evident. Tracheal intubation was not delayed for study purposes.

Methods

With institutional review board approval, we enrolled patients at Children’s Health: Children’s Medical Centre Dallas between June 2013 and July 2014. We obtained written consent from parents and written assent from children 10 yr and older. We enrolled children (age 1–17 yr), who had an ASA physical status I–III, who were undergoing dental rehabilitation with general anaesthesia and nasotracheal intubation. We excluded patients with significant cardiorespiratory disease or recent respiratory infection, those at risk for pulmonary aspiration, and those with known or suspected difficult airway.

Protocol

Anaesthesia was induced with sevoflurane 8% in oxygen 100% by face mask. An i.v. cannula was inserted and rocuronium 0.6 mg kg⁻¹ given. Fentanyl and propofol were also available for use at the discretion of the anaesthetist. The sevoflurane...
primary outcomes for each subject. The time to 1% decrease in SpO₂ from baseline was calculated as the elapsed time (in seconds) between baseline (SpO₂ in the first second of intubation) and a reduction of 1% in SpO₂ (e.g. from 100 to 99%). Overall desaturation rate was assessed based on repeated second-by-second SpO₂ measurements, and is intended to describe the average rate of SpO₂ decrease, ignoring non-linearity of the SpO₂–time relationship. Desaturation rate is the slope coefficient of the linear trend of desaturation throughout the laryngoscopy period, measured as the percentage per second (see ‘Statistical analysis’ for more details). Previous studies on desaturation also reported a linear desaturation rate, making our methods consistent with the literature.

Subject characteristics, airway assessment, and anaesthetic information were recorded. Blood pressure and heart rate were recorded before laryngoscopy and at 1 min intervals for 10 min starting at the time of laryngoscopy.

Statistical analysis

We followed a modified intent-to-treat approach, which we define as including for analysis all randomized subjects who received any of the study interventions.

Primary outcomes

Desaturation was characterized using two outcomes: time to a 1% decrease in SpO₂ from baseline; and overall rate (slope) of desaturation over time. We considered a given intubation technique (DLO₂ or VLO₂) better than DL if it was found to be non-inferior (i.e. not worse) on both outcomes and superior on at least one. We defined a priori the noninferiority Δ for time to 1% reduction as 5 s [or 1.05 if using hazard ratio (HR)] and for desaturation slope as 0.05% s⁻¹.

We used joint hypothesis testing to control type I error at 0.025 across all noninferiority and superiority testing¹² comparing VLO₂ and DLO₂ with DL on primary outcomes. Given that noninferiority was required for both outcomes, no Bonferroni correction was made [α=0.025, 95% confidence intervals (CIs)]. However, Bonferroni correction was used for superiority testing because superiority on either outcome (given noninferiority on both) was sufficient [α=0.0125, 97.5% CI]. We further adjusted for interim analyses and two pairwise comparisons within primary hypotheses (VLO₂ vs DL and DLO₂ vs DL). We call these the 95% CI for noninferiority and 97.5% CI for superiority.

We first estimated the treatment effect (CI) for each outcome. We used Cox proportional hazards regression to compare groups on time to 1% saturation decrease, estimating a hazard ratio for
VLO₂ and DLO₂ vs DL, and censoring at intubation if saturation never reduced more than 1%. We reported 25th percentile Kaplan–Meier estimates for 1% saturation decrease from baseline instead of the 50th percentile (median) because many subjects never decreased by 1%. We used a random slope mixed-effects model with repeated measures to assess the treatment effect on overall rate of desaturation, adjusting for within-subject correlation (autoregressive) and restricted to saturations before reaching 90%. We then evaluated noninferiority of VLO₂ and DLO₂ to DL on each outcome. Noninferiority vs DL was claimed for an outcome at the 0.025 significance level if the upper limit of the 95% CI was below the corresponding noninferiority Δ. Second, if noninferiority was concluded for both outcomes, we proceeded to one-tailed superiority tests on each.

A post hoc analysis assessed whether differences between the three laryngoscopy methods on the primary outcomes depended on subject age. Specifically, we assessed the interaction between age and study group in both Cox proportional hazards regression (time to 1% reduction in saturation outcome) and random slope mixed effects (overall saturation rate outcome) models used in the primary analysis.

Secondary analyses
We compared VLO₂ and DLO₂ on each primary outcome using the same methods described above. We also compared groups on mean desaturation slope after an initial 1% reduction from baseline using a random slope model as above, including only saturations before reaching 90%. We compared groups on the proportion reaching 90% saturation using two-tailed χ² tests for superiority. We evaluated the association between time to 1% reduction in saturation from baseline and age and BMI using Cox regressions. Type I error was restricted to 5% for secondary analyses using Bonferroni correction. Interim analyses were planned at every 25% of maximal planned enrolment using a group sequential design testing efficacy and futility. We used a γ spending function (γ=−4 for efficacy, −2 for futility) to maintain the significance level for primary hypotheses at 0.025 and power at 90%.

Sample size considerations
Sample size was based on assessing superiority on the primary outcome of time to 1% reduction in saturation from baseline because this analysis required more subjects than the rate of desaturation. Assuming a median time to event of 35 s for DL (based on preliminary data) and an exponential distribution, a per-group sample size of 169 was needed to detect a hazard ratio of 0.65 compared with DL at the 0.00625 significance level (0.0125/2 pairwise comparisons) with 90% power. Adjusting for interim analyses gave a total of n=546.

Results
Among 1518 patients screened for eligibility, 482 patients were randomized (Fig. 1). According to modified intent to treat, 25 subjects were excluded because they did not receive the study intervention, for the following reasons: equipment or software failure (n=21), vomiting during induction (n=2), lack of resources (n=1), and withdraw of consent (n=1).

Seven subjects (1.5%) crossed over to DL and were included and analysed according to their randomized allocation, again according to modified intent to treat: n=2 DLO₂ subjects underwent DL because of improper blade size choice and because of complications from taping the oxygen cannula to the blade; n=5 VLO₂ subjects underwent DL because of vomiting (n=1), lack of space to manoeuvre the tracheal tube in the airway (n=2), or difficulty in obtaining a view (n=2).

Interim analyses were conducted after enrolment of 142, 263, and 393 total subjects to assess efficacy and futility (Fig. 2). By 263 subjects, the primary outcome comparisons had all crossed into the efficacy region. Recruitment continued to increase precision of the treatment effects; final enrolment was a total of 482 subjects.

Data from 457 subjects were available for final analysis, as follows: 159 (35%) randomized to DL, 145 (32%) randomized to DLO₂, and 153 (33%) randomized to VLO₂. The randomized groups were visually balanced on baseline variables (Table 1); thus, no baseline variables were included as covariables in the analyses.

Primary outcomes
Both DLO₂ and VLO₂ were found to be noninferior to DL on both primary outcomes, namely the time to 1% decline and overall slope (all P<0.001). We thus proceeded with one-tailed superiority testing and found that both DLO₂ and VLO₂ were also superior to DL on both outcomes (all P<0.001; Table 2 and Fig. 3). Hazard ratio estimates indicated that VLO₂ (HR 0.18) and DLO₂ (HR 0.16) were considerably slower and less likely to decrease 1% from baseline compared with DL (Table 2). Estimated overall desaturation slope was −0.10 slower for each group vs DL (Table 2). We therefore conclude for our primary hypothesis that VLO₂ and DLO₂ techniques are each more effective than DL intubation, because superiority was found for both outcomes in each comparison. Kaplan–Meier curves of time to 1% saturation reduction from the baseline are given in Fig. 4. A figure displaying individual saturation data by randomized group is reported in a Supplementary Figure S2.

In a post hoc analysis, we found no evidence of interaction between age and study group for either primary outcome (P-value of 0.76 for time to 1% reduction in saturation and 0.56 for overall desaturation rate).
Secondary outcomes

The VLO₂ and DLO₂ groups did not differ on either the time to 1% reduction in saturation (P=0.63) or the overall desaturation rate (P=0.26; Table 2). The desaturation rate (slope) after the initial 1% reduction in DL subjects (n=142) was significantly higher than for VLO₂ (n=57) and DLO₂ (n=40; both P<0.001). No difference in desaturation rate after the initial 1% reduction was found between DLO₂ and VLO₂ groups (P=0.08; Table 2). The risk of desaturation (yes or no) was significantly lower for DLO₂ and VLO₂ compared with DL (both P<0.001; Table 2). The DLO₂ and VLO₂ groups did not differ on desaturation incidence (P=0.70).

The time to 1% reduction in saturation from baseline was not associated with BMI [based on only n=225 because of missing BMI data, P=0.92, estimated HR for increase of 5 kg m⁻² of 1.01 (0.70, 1.47) or age [P=0.03, HR for 1 yr increase in age of 0.92 (0.83, 1.03)]. Median [first, third quartiles] intubation time varied among the groups: 74 [60, 88] s for DL, 91 [70, 113] s for DLO₂, and 110 [88, 139] s for VLO₂.

Discussion

Our original primary hypothesis was that time to reach S₉₀ of 90% was prolonged by supplemental oxygen. But upon reviewing results of the first interim analysis, it became apparent that very few subjects in the oxygenated groups reached S₉₀ of 90%, creating serious issues for analysis and interpretation. We thus replaced the original primary outcome with co-primary measures of desaturation.

A 1% decrease in S₉₀, although not clinically significant, is a harbinger of a more rapid desaturation to come. Both the 1% decrease in saturation from baseline and the rate of desaturation should be considered together when comparing different intubation techniques.

We chose to use a starting oxygen concentration of 30% and nasotracheal intubations in an effort to simulate situations of prolonged intubations in the face of limited O₂ supply and maintain oxygen saturation closer to the inflection of the haemoglobin-oxygen dissociation curve. When we were designing the study, we found that very few patients preoxygenated with 100% oxygen desaturated, even when no supplemental oxygen was given. At a time when the fundamental use of oxygen is being questioned, the authors felt that administering 30% oxygen and having as prerequisite to stop the study when saturation reaches 90% provided a reasonable level of safety.

Subjects in both the deep laryngeal oxygenation groups (DLO₂ and VLO₂) took on average more than twice as long to desaturate 1% as subjects intubated conventionally (~70 vs 30 s). The difference between laryngoscopy with and without supplemental oxygen was both highly significant statistically and of clinical importance. Furthermore, the rate of overall desaturation was three- to four-fold faster without supplemental oxygen, again a difference that was both highly significant and of clear clinical importance.

There was, however, no important difference between the two oxygenation approaches for either the time to 1% desaturation or the overall desaturation rate. Our results indicate that even an ad hoc system of providing deep laryngeal oxygen during intubation is sufficient. Previous apnoeic oxygenation studies have used a nasal cannula. Oxygen insufflation through conventional nasal prongs is suboptimal, because the effective fractional inspired O₂ is low and proximal airway obstruction can prevent the open column of gas into the trachea.

Cook and colleagues evaluated blood oxygen partial pressure during apnoeic oxygenation via a tracheal tube in 28 paediatric patients. They reported that O₂ partial pressure decreased 4.1 (95% CI 2.7, 5.6) kPa min⁻¹, which is more than three times the rate reported in adults. They further concluded that after adequate preoxygenation, apnoeic oxygenation maintained adequate saturation in children for at least 10 min. Kernisan and colleagues found that after preoxygenation, apnoeic oxygenation with an oxygen flow of merely 0.1 litre kg⁻¹ min⁻¹ prevented desaturation for 3 min, whereas desaturation otherwise occurred after 116 s in patients weighing <10 kg and in 217 s in those weighing >20 kg. Based on a study on 61 patients between 1 month and 12 yr of age, Kinouchi and colleagues concluded that S₉₀ decreases to 95% more quickly in younger than in older children.

Although we did not identify an association between age or BMI and desaturation, our study included only a narrower range of each and was not powered for either outcome. Available data nonetheless suggest that use of apnoeic oxygenation in younger patients is less effective, probably because they have an increased oxygen consumption on a per kilogram basis compared with adults.

### Table 1 Baseline subject characteristics and intubation characteristics for three randomized groups. Values are reported as the mean (sd) or n (%), as appropriate. DL, direct laryngoscopy alone; DLO₂, direct laryngoscopy with cannula; VLO₂, Truview PCD laryngoscope

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>VLO₂ (n=153)</th>
<th>DLO₂ (n=145)</th>
<th>DL (n=159)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr; mean [minimum, maximum])</td>
<td>4.7 [1.5, 15]</td>
<td>4.4 [1.7, 16]</td>
<td>4.3 [1.2, 12]</td>
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<tr>
<td>≤3 yr old [n (%)]</td>
<td>43 (28)</td>
<td>53 (36)</td>
<td>64 (40)</td>
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<td>3–5 yr old [n (%)]</td>
<td>71 (46)</td>
<td>59 (41)</td>
<td>58 (37)</td>
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<td>&gt;5 yr old [n (%)]</td>
<td>39 (26)</td>
<td>33 (23)</td>
<td>37 (23)</td>
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<td>Female [vs male; n (%)]</td>
<td>72 (47)</td>
<td>71 (49)</td>
<td>71 (45)</td>
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<td>Weight [kg; mean (sd)]</td>
<td>20 (6)</td>
<td>20 (9)</td>
<td>20 (9)</td>
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<td>ASA physical status [n (%)]</td>
<td>I 73 (48)</td>
<td>70 (48)</td>
<td>80 (50)</td>
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<td></td>
<td>II 71 (46)</td>
<td>72 (50)</td>
<td>71 (45)</td>
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<tr>
<td></td>
<td>III 9 (6)</td>
<td>3 (2)</td>
<td>8 (5)</td>
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<tr>
<td>Heart rate [beats min⁻¹; mean (sd)]</td>
<td>110 (26)</td>
<td>114 (24)</td>
<td>110 (27)</td>
</tr>
<tr>
<td>Systolic blood pressure [mm Hg; mean (sd)]</td>
<td>99 (13)</td>
<td>98 (14)</td>
<td>97 (12)</td>
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<tr>
<td>Diastolic blood pressure [mm Hg; mean (sd)]</td>
<td>58 (14)</td>
<td>60 (14)</td>
<td>58 (12)</td>
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<tr>
<td>Oxygenation before laryngoscopy [%; mean (sd)]</td>
<td>99.7 (0.6)</td>
<td>99.4 (1.9)</td>
<td>99.6 (0.8)</td>
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</table>
Table 2 Results for primary and secondary outcomes. For the primary analysis, we compared VLO₂ and DLO₂ with DL on two outcomes: time to 1% reduction in saturation from baseline using Cox proportional hazard model; and overall desaturation rate (slope) via linear mixed effects model with repeated measures. For secondary analyses, the VLO₂ and DLO₂ groups were compared using similar models to those for the primary analysis; overall desaturation rate results are reported as the difference in mean slopes using the linear mixed effects model; for the incidence of desaturation (SpO₂ <90%) as desaturation relative risk using Pearson’s χ² test; for the age and BMI effect, the desaturation hazard ratio is reported for an increase of one unit in age or BMI using the Cox proportional hazard model. CI, confidence interval; DL, direct laryngoscopy alone; DLO₂, direct laryngoscopy with cannula; VLO₂, Truview PCD laryngoscope; SpO₂, haemoglobin oxygen saturation. *Kaplan–Meyer estimate 25th percentile along with adjusted 95% confidence limits were reported instead of the usual 50th percentile (median) because there were insufficient non-censored data for the DLO₂ group (not many patients experienced 1% reduction in SpO₂ from their baseline).
†Model-based mean slope estimates and difference in mean slopes were reported.
‡Median laryngoscopy time was reported as the median [first quartile, third quartile], in seconds. ¶Confidence limits reflect the Bonferroni adjustment for multiple pairwise comparisons, correction for several primary and secondary outcomes, and adjustment for five interim analyses in order to maintain the overall type I error rate at 2.5% for the primary and 5% for the secondary outcomes; all the reported CIs correspond to superiority tests. §Significant P-values corresponding to superiority tests.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>VLO₂ (n=153)</th>
<th>DLO₂ (n=145)</th>
<th>DL (n=159)</th>
<th>Estimate</th>
<th>P-value</th>
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<tr>
<td><strong>Primary outcomes</strong></td>
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<tr>
<td>Time to 1% saturation reduction (s)*</td>
<td>75 (37, 122)</td>
<td>67 (35, 149)</td>
<td>30 (24, 39)</td>
<td>Hazard ratio (97.5% CI)*</td>
<td>0.18 (0.11, 0.29)</td>
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<td>VLO₂ vs DL</td>
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<td>DLO₂ vs DL</td>
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<tr>
<td>Overall desaturation rate (% s⁻¹)†</td>
<td>0.03 (0.004, 0.05)</td>
<td>0.04 (0.02, 0.06)</td>
<td>0.13 (0.11, 0.15)</td>
<td>Difference in slopes (97.5% CI)†</td>
<td>−0.09 (−0.12, −0.06)</td>
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<td>VLO₂ vs DL</td>
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<td>DLO₂ vs DL</td>
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<td><strong>Secondary outcomes</strong></td>
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<td>(i) VLO₂ vs DLO₂</td>
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<td>Time to 1% saturation reduction (s)*</td>
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<tr>
<td>Overall desaturation rate (% s⁻¹)†</td>
<td>0.12 (0.04, 0.20)</td>
<td>0.19 (0.09, 0.29)</td>
<td>0.35 (0.30, 0.40)</td>
<td>Difference in slopes (97.5% CI)†</td>
<td>−0.07 (−0.19, 0.06)</td>
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<td>VLO₂ vs DL</td>
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<td>DLO₂ vs DL</td>
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<tr>
<td>(ii) Desaturation rate after initial 1% reduction (% s⁻¹)†</td>
<td>18 (12%)</td>
<td>15 (10%)</td>
<td>78 (49%)</td>
<td>Relative risk (95% CI)§</td>
<td>0.14 (0.05, 0.35)</td>
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<tr>
<td>VLO₂ vs DL</td>
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<td>DLO₂ vs DL</td>
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<td>(iii) Incidence of desaturation (SpO₂ &lt;90%)</td>
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<tr>
<td>VLO₂ vs DL</td>
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<td>Relative risk (95% CI)§</td>
<td>0.12 (0.04, 0.32)</td>
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<td>DLO₂ vs DL</td>
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<td>(iv) Age effect on time to 1% saturation reduction, for 1 yr increase</td>
<td>110 [88, 139]</td>
<td>91 [70, 113]</td>
<td>74 [60, 88]</td>
<td>Hazard ratio (95% CI)§</td>
<td>0.92 (0.83, 1.03)</td>
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<td>BMI effect on time to 1% saturation reduction, for 5 kg m⁻² increase</td>
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<td>Median laryngoscopy time (s)†</td>
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To our knowledge, this is the first report of use of the Truview PCD for nasal intubations in paediatric patients. We were unable to intubate four subjects (2.5%) assigned to the Truview PCD system, each of whom was subsequently intubated easily after conversion to direct laryngoscopy, a finding consistent with previous publications. A limitation of our analysis is that the primary outcome ‘overall desaturation rate’ was used to describe desaturation data, ignoring non-linearity of the \(S_pO_2\)–time relationship. That was done to simplify interpretation and make the results comparable to previously published ones.

In summary, deep laryngeal oxygen insufflation, whatever the delivery method, more than doubles the time to a 1% decrease in \(S_pO_2\) and reduces the overall rate (slope) of desaturation by more than a factor of three in apnoeic children. There is little cost or risk in providing supplemental laryngeal oxygen during intubation, and it provides clinically important protection against hypoxaemia. We thus recommend that deep laryngeal oxygenation should be considered when intubating children, especially those with limited reserves.

**Authors’ contributions**

Analysis: N.M., E.J.M.

**Supplementary material**

Supplementary material is available at British Journal of Anaesthesia online.
Acknowledgements
We would like to thank dental surgeons Neal A. Dean, DDS; Takanobu Fujita, DDS; Roland J. Garza, DDS, MSD; Erik K. Herrington, DDS, PhD; Brian L. Hochstein, DDS; Carolyn A. Kerins, DDS, PhD; Reena Kuba, DDS, MS; Michelle R. Lindsay, DDS; Allan R. Rapolla, DDS; and Robert E. Morgan, DDS, MSD, without whom this study would not have been able to be completed. We are also grateful to Roxana Ploski, BS and Joanna Dela Cruz, BS for helping with data collection.

Declaration of interest
None declared.

Funding
University of Texas Southwestern Medical Centre; Division of Paediatric Anesthesia Research.

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Handling editor: H. C. Hemmings