Mucosal injury During Nasotracheal Intubation for Dental Procedures in Children-Does the Tube Design Matter?

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1. Title: Mucosal injury during nasotracheal intubation for dental procedures in children-does the tube design matter?

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3. **Design: Prospective randomized controlled trial**

Abstract:

Extensive dental procedures in children frequently require general anesthesia due to lack of cooperation. In most cases, nasotracheal intubation (NTI) is necessary to preserve an unobstructed surgical field for the dental surgeon and to allow alignment assessment post repair. Advancing an appropriately sized breathing tube through the nares can cause significant trauma to the nasal mucosa resulting in bleeding, swelling and postoperative congestion and pain (7). Children are uniquely predisposed to these complications given the presence of adenotonsillar hypertrophy, narrow sinus passages, and friable mucosa! layer (7,9). To our knowledge, there has not been any study investigating choice of nasal tracheal tube (NTT) and degree of mucosa l damage in this patient population.

Background:

Several techniques have been suggested to reduce trauma during NTI, some of which are now adopted widely. These include lubrication of the nasal mucosa (17), softening of the tracheal tube by prewarming (1), and induced nasal mucosal vasoconstriction (4,5). The design of the NTT tip has been shown to impact the degree of trauma during NTI in the adult population (2,3,6,16). The Parker NTT (Parker Flex-Tip™ Tracheal Tube, Parker Medical via Mercury Medical, Clearwater, FL 33762) has a flexible distal tip that is mid line, curved and tapered. This shape theoretically facilitates its sliding past obstructions encountered in the airway such as the nasal turbinates, arytenoids and vocal cords, rather than being hung up on them and causing trauma (6). Use of Parker NTT in adult patients has been demonstrated to facilitate intubations via the fibreoptic, oral and nasotracheal pathways (2,3,6,16). While there are convincing studies in adults that demonstrate that the design of the NTT tip can impact the degree of trauma during NTI, to our knowledge no similar studies have been conducted in children.

Specific Aims:

To investigate the impact of NTT tip design on mucosa! injury during NTI in children undergoing dental procedures under GA

Null Hypothesis:

Choice of NTT in children requiring NTI for dental procedures has no impact on the degree of nasal mucosa! injury.

Primary Outcome:

Mucosa! damage as quantified by presence and severity of bleeding immediately after passage of the NTT through the nasopharynx.

Secondary Outcomes:

Presence and degree of impingement of the NTT during NTI.

Postoperative epistaxis as defined as ongoing nasal bleeding in the recovery unit (PACU), presence of post-extubation croup in the PACU, and time to discharge from the PACU.

Research Protocol:

Inclusion criteria: children between the ages of 3-11, ASA 1-3, presenting to Wolfsons Children's Hospital (WCH) for dental procedures requiring general anesthesia with NTI.

Exclusion criteria: ASA >3, known bleeding disorder, recent or ongoing treatment with blood-thinning medicines, frequent epistaxis, active URI/congestion/rhinorrhea, craniofacial abnormalities prohibiting NTI, known difficult airway, prior nasal surgery/trauma, or allergies to any of the medicines used in this study.

Preop: eligible patients will be identified by their dentist and receive a brochure detailing the study during their dentist visit. Eligibility will be confirmed by one of the study investigators or selected research personnel (study nurse/nurse practitioner) on the day of surgery and consent obtained with the parents.

Preoperative anxiolysis will be at the discretion of the anesthesiologist, but should be limited to oral or intravenous midazolam, dexmedetomidine, or intramuscular ketamine, and not include any medicines administered intranasally.

Intraop: cases are assigned exclusively to one of the study investigators, but may involve the presence of trainees (anesthesia residents, fellows or assistants).

Induction: pre-oxygenation followed by mask induction using 6-8% Sevofluorane in Nitrous oxide/O2 (60/40) followed by IV placement (22-24g), Fentanyl lmcg/kg, Propofol 1-3mcg/kg, Rocuronium 0.6mg/kg.

Nasal Prep: Oxymetazoline (Afrin, Merck Consumer Care, lnc) nasal spray, 1 pump each nostril. Using the smallest pediatric sized flexible fibreoptic scope, nostril patency and degree of choanal obstruction (as defined by adenoid size, which is known to vary by patient age (8,9,10)) will be assessed avoiding tactile trauma to the nasal mucosa. Unless it is deemed not patent or significantly diminished in size, the R nostril will be preferably selected for intubation as most standard NTT are designed in favor of R-sided **NTI.**

NTT prep: NTT size will be chosen based on the formula 'age+16/4 -0.5' for a cuffed NTT which has been validated previously (12). For patients with Trisomy 21, the formula will be uniformly adjusted to select an NTT one size down from calculated to accommodate a smaller midface skeleton (13,14,15). Since children with Trisomy 21 make up a large part of the dental surgery population, it would be impractical to exclude them from the study. A simplified table is included below(*) to define starting NTT size for both Down syndrome and other children by age. The selected NTT will be softened in sterile warm saline (1) for at least IOmin prior to insertion into the nasopharynx. Immediately prior to insertion the NTT tip will be lubricated with Lidocaine Hydrochloride USP 2% jelly (©Akorn, Incorporated I 1925 W. Field Court, Suite 300, Lake Forest, Illinois 60045).

Intubation procedure: for the purpose of this study we will intubate using the glidescope (Verathon Medical, ULC, Burnaby, BC, Canada) to mimic the standard practice of direct laryngoscopy while allowing for pictures of the oropharynx and NTT tip to be saved for later analysis. The glidescope will be inserted and positioned midline after which the prepared NTT is advanced through the selected nostril until visualization in the oropharynx. Quantification of mucosal bleeding (none, mild(blood on tracheal cuff only), moderate(blood on tracheal cuff and trace blood in the oropharynx), or severe(blood pooling in the oropharynx)) will be done at the time of intubation and verified at a later time by another study investigator based on the pictures taken. In the event of disagreement, a third investigator will make the final judgment based on the input from the prior evaluators. The presence and degree of impingement will be noted by the person intubating as follows: none (smooth passage without hang-ups), mild (single interruption in passage easily overcome by gentle rotation or angle change of the NTT), moderate (interruption in passage requiring re-passage of the tube, or more than one interruption in passage requiring readjustments) or severe (necessitating NTT down-size and/or multiple attempted re-passages). Tracheal intubation should then ensue using McGill forceps as necessary to guide the NTT through the vocal cords.

Maintenance: anesthetic gas admixture at the discretion of the anesthesiologist. Additional opioids and/or anxiolytics at the discretion of the anesthesiologist.

Postop: in the recovery unit (PACU), presence of persistent epistaxis, post-extubation croup, and the time to discharge from PACU will be noted.

Research Plan:

This will be a prospective, randomized controlled trial in children aged 3-llyrs undergoing dental procedures at WCH. We are looking to exclude the null hypothesis of no effect of NTT design by observing significant differences in the above-mentioned primary- and secondary outcome variables in the study-vs. control groups. A sample size of 80 patients (40 in each group) can detect the difference of the same magnitude between our study and control groups with a power of more than 98% at the level of significance of 0.05. Randomization to study (Parker NTT) vs. control (Standard NTT) will be computer generated and will be stratified by adenoid size. (Please refer to the Statistics Section below)

Recruitment will be facilitated by brochures handed out by our participating dental surgeons, and final enlistment will be done on the day of surgery.

Statistics Description:

Power and Sample Size Justification: The primary aim of the study is to compare the proportion of patients with the presence of at least mild {as defined in the intubation procedure section) bleeding between Parker NTT {study) and Standard NTT {control) groups. To our knowledge, no studies reported conducting research to assess the impact of mucosal injury in pediatric patients. A pediatric study {ref: El-Seify et al) reported a significant difference in the proportion of patients with the presence of bleeding between the control group {27.5%} and a similar method of our study group {7.5%). A sample size of 80 patients {40 in each group) can detect the difference of the same magnitude between our study and control groups with a power of more than 98% at the level of significance of 0.05. Randomization will be stratified by adenoid size.

Data Analysis: Collected data will be summarized by two groups. Categorical variables will be summarized by frequencies and percentages. Quantitative variables are summarized by mean and standard error of mean {SEM} or median and inter-quartile range, whichever is appropriate. A Chi-squared test or Fisher exact test will be used to compare the distribution of categorical variables, while two-sample t test or non-parametric Mann-Whitney U test will be used to compare the mean or median of quantitative variables. In addition to Chi-square/Fisher exact test, a logistic regression model will be used to compare the proportion of patients with the presence of at least mild bleeding between two groups. The analysis will be adjusted for the degree of obstruction and for other influential covariates in a multivariable logistic regression model. In addition, an ordinal logistic regression will be used to compare the severity of bleeding between two groups as long as the assumption of proportional odds met. Otherwise, a multinomial logistic regression model will be used for this purpose. The same analytical procedures will be used to compare the presence and the degree of impingement between two groups. Once again, univariable and multivariable logistic regressions will be used to compare Postoperative epistaxis and the presence of the extubation croup between two groups. Kaplan Meier survival plot and log rank test will be used to compare the distribution of time to discharge from the PACU. All tests are two -tailed at the level of significance of 0.05. The statistical software SAS, version 9.3 will be used for analyses.

Possible Discomforts and Risks: None beyond those incurred by standard practice

Possible Benefits: Identifying an easily implementable measure to reduce mucosa! trauma and pain in children requiring NTL

Conflict of interest: Nothing to disclose

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(*)

Cuffed NTT size selection chart based on the formula (age+16)/4 - 0.5 (rounded to nearest size) with exceptions for children with Trisomy 21 (tube down-sized by 1), and in the case of severe impingement (tube down-sized by 0.5)

Patient age (yrs)	NTT size, cuffed	NTT size, cuffed, children with Trisomy 21	NTT size, cuffed, in case of severe impingement	NTT size, cuffed, in children with Trisomy 21, in case of severe impingement
3-4	4.5	4.0	4.0	3.5
5-6	5.0	4.5	4.5	4.0
7-8	5.5	5.0	5.0	4.5
9-10	6.0	5.5	5.5	5.0
11	6.5	6.0	6.0	5.5