Evaluation of the Effect of Mouth Gag Application on Ultrasonographic Optic Nerve Sheath Diameter of Pediatric Patients Undergoing Tonsillectomy or Adenotonsillectomy: Observational study

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Abstract

Background: Mouth gag is usually used during Adeno/tonsillectomy surgeries, cleft palate repair, obstructive sleep apnea surgery and intraoral tumor excision. The placement of gag causes hemodynamic changes similar to laryngoscopy. The aim of this study is to evaluate the effect of mouth gag placement on optic nerve sheath diameter (ONSD) of pediatric patients. The secondary aim is to assess the relationship between neck extension for positioning of head and increase in ONSD measurement.

Methods: The trial is registered to Australian New Zealand Clinical Trials Registry with Trial ID: ACTRN12618000551291. This prospective, observational study was performed in a tertiary university hospital operating theatre between 01.05.2018-01.07.2018. Thirty-five children aged < 18 years, with ASA I status, and scheduled for adeno/tonsillectomy surgeries were prospectively included in the study. Measurements of ONSD were performed (T0) after induction of anesthesia, (T1) after endotracheal intubation, (T2) after the placement of mouth gag and (T3) 20 minutes after the placement of mouth gag. The degree of neck extension was assessed by the angle between the Frankfort plane and horizontal plane of the operation table in natural position.

Results: All participants completed the study. There were significant differences in ONSD values according to time (p < 0.001). The maximum increase in ONSD values was detected after intubation (0.69±0.06 mm) and immediately after mouth gag placement (0.67±0.07 mm). ONSD values continued to increase 20 minutes after the gag placement. There was no relation between degree of neck extension and ONSD values (b = 0.63, p=0.715)

Conclusions: Mouth gag application causes significant increases in ONSD measurements of children. Therefore, the duration of mouth gag application during surgeries might be limited. Trial registration: The trial is registered to Australian New Zealand Clinical Trials Registry with Trial ID: ACTRN12618000551291.

Background

Introduction of oral antibiotics in the 1960s dramatically decreased the rate of tonsillectomy (T) and adenotonsillectomy (AT) surgeries in time; however, T and AT remain as one of the most common surgeries performed in children worldwide. Traditionally, the head of the patient is positioned in extension and a mouth gag is placed for these surgeries (1). The Crowe-Davis mouth gag was initially designed for mouth opening and intraoperative anaesthetic agent delivery, then Boyle modified the original device to use mouth gag with endotracheal tubes (2). Although it provides advantage for access to the intraoral cavity, the placement of mouth gag results in hemodynamic changes similar to laryngoscopy which causes significant increases in the intracranial pressure (ICP) and intraorbital pressures (IOP) (3). Moreover, excessive mouth opening causes tonic contractions at muscles of mastication and postoperative pain in the temporomandibular joint (4).
Several previous studies evaluated the ultrasonographic measurement of optic nerve sheath diameter (ONSD) as a non-invasive, simple and rapid way to detect the pressure changes of intracranial compartment (5,6). The sheath around the optic nerve is an anatomical extension of the dura mater, and within the sheath, intracranial subarachnoid space extends through the optic nerve. Therefore, a rise in ICP is directly transmitted to the distensible subarachnoid space around the optic nerve. Although the measurement of ONSD has been used in different clinical scenarios in the current literature, there is no study evaluating the effect of mouth gag placement on ONSD measurements. Thence, the primary aim of this study is to evaluate the effect of mouth gag placement on ONSD of pediatric patients. The secondary aim is to assess the relationship between the degree of neck extension related to head positioning and increase in ONSD measurement.

Methods

This observational study was approved by XXXXXXXX Clinical Research Ethic Committee (approval number: XII) on 26.04.2018 and registered at anzctr.org.au (Trial ID: ACTRN12618000551291) and conducted in accordance with the current Declaration of Helsinki. Signed informed consents were obtained both from parents of all children and children themselves who were over 6 years of age. Patients between 3–18 years old with American Society of Anesthesiologists (ASA) physical status I-II and scheduled for a T or AT surgery were prospectively included in the study. The exclusion criteria were patients with known acute or chronic ophthalmic diseases, history of previous ophthalmic surgery, increased ICP, receiving ß blocker, calcium canal blocker, statin or nitrate treatment, more than one attempt for endotracheal intubation and duration of mouth gag application < 20 minutes.

All children received preoperative medication with midazolam 0.5 mg kg$^{-1}$ orally (maximum dose of 15 mg) 15 minutes before the surgery. A standard monitoring was employed to all children with electrocardiography, non-invasive arterial blood pressure, pulse oximetry, bi-spectral index (BIS) (Datex-Ohmeda S/5 monitor M-BIS module, Helsinki, Finland), nasopharyngeal temperature, end-tidal CO$_2$ (EtCO$_2$) measurement and gas analysis. Anaesthesia was induced with intravenous propofol 1–2 mg/kg, fentanyl 1 mcg/kg and rocuronium bromide 0.6 mg/kg. When BIS score decreased under 60, the patients were intubated by an experienced anaesthesiologist at the first attempt. Anaesthesia was maintained with sevoflurane in 40% O$_2$ and 60% air mixture, and the inspired concentration of sevoflurane was targeted to maintain a BIS score between 40–60.

Following endotracheal intubation, the ear-nose-throat (ENT) specialist placed the Boyle-Davis mouth gag. The extension of mouth opening and head position of patients were adjusted by the same ENT specialist to enhance the exposure of (adenotonsils. When the placement of mouth gag was completed, operating room (OR) anaesthesiologists took a photograph of the neck extension in the lateral view. The degree of neck extension was assessed by the angle between the Frankfort plane and horizontal plane of the operation table in natural position (Frankfort plane angle). The angle was calculated by using an application (Angles in Photos, 2015 kublaidos) (Fig. 1). The anaesthesiologist repeated the calculation for two times for each patient and recorded the average value. A Frankfort plane was officially described
in the anthropologic conference in Frankfort in 1884. It is an imaginary line passing from left orbitale to left porion point and it has been used as a reference plane for cephalometric studies. Recently, Frankfort plane angle was used for the assessment of neck flexion-extension in the study of Kobayashi et al (7).

ONSD was measured by two investigators who had experience in over 50 cases. A linear 6–13 Hz probe (Fujifilm Sonosite, Bothwell, USA) was used for the sonographic measurements at four different time-points. A thick layer of water-soluble ultrasound-transmission jelly was applied over the left upper eyelid of each patient. Then the probe was gently placed over the eyelid without exerting excessive pressure. The probe was moved with careful attention to find the best image of optic nerve entering into the globe. The ONSD was measured 3 mm posterior to the globe (Fig. 2). The investigators measured ONSD 3 times from the same eye and recorded the average of these measurements at four different time-points: (T0) after induction of anaesthesia, (T1) after endotracheal intubation, (T2) after the placement of mouth gag and (T3) 20 minutes after the placement of mouth gag.

At each time-point, heart rate (HR), mean arterial pressure (MAP), EtCO2 and nasopharyngeal temperature (temp) were also recorded.

**Statistical Analysis**

We conducted the statistical analysis using the software Statistical Package for Social Science (SPSS), version 17 (made by SPSS Incorporated, located in Chicago, Illinois, USA). In the current study, the primary outcome was the change in ONSD measurement between T2 and T3. We relied on the assumption of observing a normal distribution of a dependent variable requires n >30, then we decided to include 35 patients with assuming possible drop-outs. The mean ONSD measurement in healthy pediatric population is 3.080.36 mm. An increase 0.3 mm in mean ONSD measurement (10% of mean ONSD value in healthy pediatric population) was considered as clinically significant (8). Considering a 0.05 significance level for type 1 error and 0.20 significance level for type two error, the collected data was sufficient for the power of statistical tests that were used. All continuous variables including age, weight, globe size, ONSD, EtCO2, Temp, HR, MAP are presented below as mean and standard deviation (SD), and the categorical variables, gender and T/AT, are presented as both numbers and percentile (%). The relationship between Frankfort plane angle and ONSD changes analyzed by regression model. Linear mixed model was used to observe the variation of repeated ONSD measurements and the other parameters (EtCO2, Temp, HR, MAP) over time. Moreover, post hoc analyses were performed using Bonferroni correction for multiple comparisons, since the time wise differences were statistically significant in all parameters observed.

**Results**

Totally 35 children were included in the study. The flowchart of the study is summarized in Fig. 3; 22 of them were male and mean age was 7.32.75 years. The demographic data of the patients were listed in Table 1.
Mean ONSD measurements at different time-points were listed in Table 2. The maximum increase in ONSD values was detected after intubation (0.690.06 mm) and immediately after mouth gag placement (0.670.07 mm). Pairwise Comparisons were used to assess the changes in ONSD measurements, and the differences were found significant at all time-points (Fig. 4).

Mean Frankfort plane angle was calculated as 130.417.5 (minimum 114.23 and maximum 144.65). We assessed the relation between Frankfort plane angle and mean ONSD changes between T2 and T3 time-points to evaluate the effect of neck extension on ONSD measurements. According to regression model, there was no relation between the degree of Frankfort plane angle and mean ONSD changes ( = 0.63, p = 0.715).

We summarized the hemodynamic parameters and other variables potentially affecting ICP, and consequently ONSD measurements, in Table 3. According to Pairwise Comparisons, the differences in EtCO₂ and body temperature were not significant over time. However, there were notable changes in mean heart rate and MAP values. The maximum mean heart rate (110±17 beats/min) and MAP values (91.211.3 mmHg) were recorded immediately after mouth gag placement (T2). Although the heart rate and MAP significantly decreased 20 minutes after the mouth gag application, mean ONSD measurements continued to increase.

**Discussion**

In the current study, we evaluated the effects of mouth gag placement and degree of neck extension on ONSD measurements. We detected significant increases in ONSD immediately after mouth gag placement and additionally ONSD values continued to rise 20 minutes after mouth gag application. However, the degree of neck extension as assessed by Frankfort plane angle had no effect on ONSD measurements.

The transbulbar sonography technique for the estimation of ICP by measuring ONSD of children was first described by Helmke et al (9). So far, several studies evaluated the reliability of ONSD measurements by concurrent magnetic resonance imaging and invasive methods (10–12). Steinborn et al (13) observed 99 healthy children and adolescents in order to determine the normal values of ONSD. They reported that the mean value for ultrasonographic ONSD measurements was 5.75 ± 0.52 mm. One year later, Steinborn et al (10) observed 56 children with normal ICP and 25 children with elevated ICP to determine a cutoff value for normal ONSD. In this study, the diagnosis of elevated ICP (ICP ≥ 15 mmHg) was based on different invasive measurement methods such as intracranial devices or lumbar puncture, concurrent imaging studies, and ophthalmologic findings. The researchers reported that the mean ONSD in patients with normal ICP was 5.77 ± 0.48 mm while it was 6.85 ± 0.81 mm in children with elevated ICP. They calculated the optimal cutoff value of ONSD as 6.0 mm for estimation of elevated ICP with a sensitivity of 82% and specificity of 74%. Similarly, Padayachy et al (14) analyzed 174 children and they reported that the optimal cutoff value for detecting an ICP ≥ 15 mmHg in the children > 1 year old was 5.49 mm with a sensitivity of 93.7%, specificity of 74.4% and for ICP ≥ 20 mmHg, the cutoff value of ONSD was
measured as 5.75 mm with a sensitivity of 85.9 %, a specificity of 70.4 %. In the current study, the mean ONSD value was under 5.49 mm (5.250.58 mm) even after endotracheal intubation. However, it was measured as 5.920.63 mm immediately after mouth gag placement and ultimately, it increased over 6.0 mm (6.280.55 mm) only 20 minutes after mouth gag placement. Recently, Lee et al (8) evaluated the effect of caudal block performed with two different volumes (1 vs 1.5 ml/kg) of ropivacaine on ONSD measurements of children. They reported that 19 patients probably experienced increased ICP 10 minutes after the caudal block and 12 of them had increased ONSD measurements even 30 minutes after the block. In our study, ONSD measurements of 19 patients were over 5.75 mm (range 4.9—7.3 mm) immediately after the mouth gag placement and 20 minutes later, the number increased to 31 (range 5.2 —7.4 mm). Therefore, a limitation might be concerned for the duration of mouth gag application.

Direct laryngoscopy is well known to cause marked stress response with hypertension, tachycardia, arrhythmias and a significant increase in ICP and IOP (15). These alterations may result in adverse events especially on cardiovascular and nervous systems (16). Previous studies evaluated different drugs (17) and intubation techniques (18,19) to attenuate this response. Previously, An et al (3) showed that mouth gag placement for exposure of pharyngeal tonsils during T/AT surgeries caused significant increases in heart rate and mean arterial pressure measurements of paediatric patients. The authors stated that these haemodynamic changes were similar to haemodynamic response caused by direct laryngoscopy. According to these data, we hypothesized that mouth gag placement during surgeries would cause a significant increase in ONSD measurements and ONSD values would probably remain to increase as long as the mouth gag application continued. In our study, mean ONSD value increased by 0.360.04 mm and passed the pathologic cutoff values in 20 minutes after mouth gag placement. The hemodynamic responses caused by laryngoscopy are believed to be induced by direct contact of the blade with the posterior third of the tongue, manipulation of the richly innervated epiglottis and insertion of endotracheal tube between the vocal cords (20). During mouth gag placement, a similar blade contacts directly to the tongue and the suspension system causes contractions in the muscles of mastication. As the oropharynx is a sensory organ capable of initiating sympathetic reflexes (21), the catecholamine release due to mouth gag application is not surprising. However, we found the effect of mouth gag placement on ONSD measurements much more significant than the effect of direct laryngoscopy. Furthermore, mean ONSD values continued to rise as long as the gag remained in the mouth. Whereas, increased ICP is known to reduce cerebral perfusion pressure and regional oxygenation that may result in postoperative neurological complications (22). Although mouth gag remains for a short time in usually healthy children during A/AT surgeries, it has to be kept in mouth for significantly longer durations during some other procedures such as cleft palate repair, obstructive sleep apnea surgery and intraoral tumor excision. Consequently, long term mouth gag placement may cause deteriorative results especially in patients with comorbidities during these longer procedures.

Previously, Panjabi et al (23) reported that a rotation of upper cervical spines over 20° in the sagittal plane exceeds the normal ranges of physiological motion. The authors calculated the angle by three reference lines passing through C1, C2 and C3 cervical spines in the radiologic view. According to these reference lines, Erden et al (24) reported that endotracheal intubation with Macintosh blade caused a maximum of
19.4 movement in C1/C2 spines. This brings the idea that excessive extension of neck during mouth gag application is likely to exceed the normal ranges of cervical motion. In addition, placement of mouth gag during ENT surgeries was shown to be associated with temporomandibular joint dysfunction, pain and trismus in the postoperative period. These adverse effects were reported to be related with the duration of gag application (25). Considering this information, we evaluated the effect of neck extension angle on ONSD measurements. However, we could not detect any relation between degree of neck extension and ONSD measurements of children according to regression model.

The main limitation of the study is that we couldn't have a chance to evaluate the postoperative impacts of increased ONSD. All participants were healthy children and the duration of mouth gag application was as short as 20 minutes in this study. Procedures with longer duration of mouth gag placement, such as intraoral tumor excision, would be more helpful in determining postoperative cognitive deteriorations. Secondly, we couldn't measure ONSD of the children prior to induction. The mean age of our children was 7 years and in most of the cases, we couldn't assess ONSD while the patients were awake. Last of all, the assessment of neck extension was based on Frankfort plane angle which was calculated by a phone application. The lines passing through Frankfort plane and horizontal plane of the operation table in natural position were drawn manually. Although we measured the angle three times for each patient, miscalculation is still possible.

**Conclusions**

Mouth gag placement causes significant increases in ONSD measurements of children. Therefore, the duration of mouth gag application might be limited during surgeries.

**Declarations**

**Ethics approval and consent to participate**

Ethical approval for this study was granted by the Mugla Sitki Kocman University Training and Research Hospital Biomedical Research Ethics Committee (approval number: XII) on 26.04.2018. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consents were obtained from the parents/guardians of all individual participants included in this study.

**Consent for publication**

**Not applicable**
Competing interests

The authors declare no competing interests.

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There was no study funding or competing interest.

Authors’ contributions

BA, MKT, AİU, SK, SGD conceptualised, designed, collected and analysed data. MKT & AİU helped with study design, guided data collection. BA & MKToversaw and assisted with data analysis. NA drafted the first manuscript with SGD. Subsequent drafts were reviewed and revised by BA, MKT, AİU, SK and SGD. All authors read and approved the final manuscript.

Availability of data and materials

Additional data available with request.

Abbreviations

ONSĐ: optic nerve sheath diameter

T: tonsillectomy

AT: adenotonsillectomy

ICP: intracranial pressure

IOP: intraorbital pressures

ASA: American Society of Anesthesiologists
**BIS:** bi-spectral index

**EtCO\(_2\):** end-tidal CO\(_2\)

**ENT:** ear-nose-throat

**OR:** operating room

**HR:** heart rate

**MAP:** mean arterial pressure

**SPSS:** Statistical Package for Social Science

**Temp:** nasopharyngeal temperature

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**Tables**

**Table 1. Descriptive variables of the patients**

| Variable            | Value          |
|---------------------|----------------|
| Male / Female (%)   | 22 / 13 (62.9 / 37.1) |
| Age (years)         | 7.3±2.75       |
| Weight (kg)         | 24.8±9.6       |
| Globe Size (mm)     | 2.16±0.1       |
| T/AT (%)            | 13 / 22 (37.1 / 62.9) |

T/AT: Tonsillectomy / Adenotonsillectomy

**Table 2. Optic nerve sheath diameter (ONSD) measurements and changes in measurements between time-points (values are presented as mean±SD)**
| Time-point | ONSD     | Significance* | Observed Power |
|------------|----------|---------------|----------------|
| T0         | 4.56±0.410.000 | 0.00          | 1.00           |
| T1         | 5.25±0.580.000 | 0.00          | 1.00           |
| T2         | 5.92±0.630.000 | 0.00          | 1.00           |
| T3         | 6.28±0.550.000 | 0.00          | 1.00           |

**ONSD Changes**

| Time-point Change | ONSD Changes |
|-------------------|--------------|
| T0-T1             | 0.69±0.060.000 |
| T0-T2             | 1.36±0.080.000 |
| T0-T3             | 1.71±0.070.000 |
| T1-T2             | 0.67±0.070.000 |
| T1-T3             | 1.03±0.060.000 |
| T2-T3             | 0.36±0.040.000 |

* p value was adjusted for multiple comparisons with Bonferroni test

T0: After induction of general anaesthesia, T1: After endotracheal intubation, T2: After mouth gag placement, T3: 20 minutes of mouth gag placement

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**Table 3: Hemodynamic parameters and other variables associated with intracranial pressure at different time-points**

| Time-point | EtCO₂  | Temp   | HR     | MAP    |
|------------|--------|--------|--------|--------|
| T0         | 35.1±2.6 | 36.5±0.12 | 99±18  | 79.6±9.3 |
| T1         | 36.5±2.6 | 36.5±0.13 | 109±16 | 87.89±10.9 |
| T2         | 36.9±2.6 | 36.5±0.11 | 110±17 | 91.2±11.3 |
| T3         | 36.8±2.7 | 36.5±0.09 | 97±19  | 80.2±10.2 |
| p value    | 0.995   | 0.879   | 0.00   | 0.00   |

* p value was adjusted for multiple comparisons with Bonferroni test

EtCO₂: end-tidal CO₂, Temp: Body temperature, HR: Heart rate, MAP: Mean arterial pressure

T0: After induction of general anaesthesia, T1: After endotracheal intubation, T2: After mouth gag placement, T3: 20 minutes of mouth gag placement
Figure 1

Calculation of degree of neck extension with Frankfort plane angle
Figure 2

The ultrasonographic measurement of ONSD 3 mm posterior to the globe
Figure 3

Flowchart of the study
Figure 4

Changes of optic nerve sheath diameter, end-tidal CO2, temperature, heart rate and mean arterial pressure of patients