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# Ultrasound and Video-Bronchoscopy to Assess the Subglottic Diameter in the Pediatric Population

#### Dr. Murad Husein

Department of Otolaryngology, McGill University, Montreal

July, 2001

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements of the degree of Master of Science

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0-612-75318-2



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## **Acknowledgements**

I would like to acknowledge the following individuals for their help and support in their respective capacities.

Dr. Manoukian and Dr. Platt, as my principal supervisors, for their guidance in formulating and carrying out the project and also for their assistance in editing the manuscript.

Dr. Yves Patenaude, as a collaborator, for his help in coordinating and carrying out the ultrasound measurements and for his expertise on the use of ultrasound.

Dr. Chantal Giguere, as a collaborator, for her guidance in conceptualizing the project at its earliest stages.

Dr. Suzanne Drouin, as a collaborator, for her help in performing the ultrasounds with Dr. Patenaude.

Miss Isabelle Morin, as a statistician consultant, for her help in analysis of the data.

Mrs. Nasrin Vellani, for her help in editing the manuscript of the thesis.

Department of Otolaryngology and Department of Otolaryngology Research Committee, McGill University, for their support in arranging and carrying out this project.

#### Abstract

Objective measurement of the subglottic lumen is still lacking in clinical practice. The objective of this study is to evaluate the accuracy of ultrasound and video-bronchoscopy in measuring the subglottic diameter in the pediatric population. This was a blind, prospective clinical study. Ten children undergoing non-life threatening bronchoscopy had their subglottic diameters measured with ultrasound, video-bronchoscopy and endotracheal tube sizing.

Ultrasound and video-bronchoscopy strongly correlated with endotracheal tube sizing in measuring the subglottic diameter. Ultrasound had measurements that were always smaller while video-bronchoscopy had measurements that were slightly larger than endotracheal tube sizing. Video-bronchoscopy may be more accurate than endotracheal tube sizing as the latter method will often underestimate the size of the lumen due to its own limitations. The smaller values obtained by ultrasound suggest it is not ideal to give absolute measurements in this area, but rather a potential tool to detect change of lumen size on follow-up.

## Abrégé

Les mesures objectives du diamètre sous-glottique sont toujours manquantes dans la pratique clinique actuelle. L'objectif de cette étude est d'évaluer l'éfficacité de l'échographie et de la vidéo-bronchoscopie dans le mesurement du diamètre sous-glottique chez la population pédiatrique. Cette étude clinique était prospective et à double insu. Le diamètre sous-glottique a été mesuré chez dix enfants subissant une bronchoscopie par échographie, vidéo-bronchoscopie, et par la grosseur du tube endotrachéal.

L'échographie et la vidéo-bronchoscopie ont grandement correlés avec la grosseur du tube endotrachéal lors du mesurement du diamètre sous-glottique.

L'échographie démontrait des mesures qui étaient constamment plus petites que la grosseur du tube endotrachéal, alors que la vidéo-bronchoscopie démontrait des mesures plus grandes que la grosseur du tube endotrachéal. La vidéo-bronchoscopie est probablement plus précise que la grosseur du tube endotrachéal puisque cette dernière habituellement sous-estime le diamètre sous-glottique. Les valeurs plus petites obtenues par l'échographie ne sont pas idéales pour le mesurement exacte du diamètre sous-glottique mais fournissent un outil pratique pour suivre l'évolution de celui-ci.

#### Introduction

Subglottic pathology is a common cause of pediatric upper airway obstruction with pathology ranging from congenital to inflammatory. The three most common pathologies that are seen in the pediatric population in this region of the airway are subglottic stenosis, subglottic hemangiomas and croup, also known as laryngotracheitis<sup>1</sup>. Pathology of this region results in stridor and ultimately airway obstruction, as can be explained by the anatomy of the subglottis.

The subglottis is a funnel-shaped region extending from the insertion of the conus elasticus into the free edge of the vocal cords above to the inferior margin of the cricoid cartilage below<sup>2</sup>. The most inferior portion, namely, the cricoid cartilage, is the narrowest portion and is circular in shape. This signet shaped ring has its narrowest portion at the level of its inferior ledge. Any mucosal edema is at the expense of the intraluminal diameter due to the presence of the complete cartilaginous ring at this level. The subglottic airway rapidly increases in size during the first two years of life, yet the subglottis remains the narrowest portion of the upper airway until 8 years of age<sup>3</sup>. A subglottic diameter of 4 mm or less in a full-term neonate is considered to be narrowed<sup>4</sup>.

## **Subglottic Pathologies**

A brief description of the three most common subglottic pathologies are presented below to provide insight into the nature and pathophysiology of these disease processes and their relation to the subglottis.

#### **Subglottic Stenosis**

Subglottic stenosis can be classified into congenital versus acquired. Congenital subglottic stenosis, as its name implies, is stenosis or narrowing of the subglottis which is present at birth. There is no history of endotracheal intubation or other apparent causes of the stenosis. The stenosis is typically membranous but may also be cartilaginous in nature. The membranous type is a fibrous soft-tissue thickening of the subglottic area due to increased fibrous connective tissue or hyperplastic mucous glands. The stenosis is circumferential with the narrowest portion located 2 to 3 mm below the level of the true vocal cords<sup>4</sup>. The most common congenital cartilaginous abnormality of the cricoid cartilage is the elliptically shaped cricoid cartilage according to the series by Holinger<sup>5</sup>.

Acquired subglottic stenosis is narrowing of the subglottis that occurs due to injury, often secondary to trauma from endotracheal intubation or prolonged intubation<sup>6</sup>. The stenosis is usually fibrous in nature. The pathophysiology of acquired subglottic stenosis is explained by a sequence of events that begins after endotracheal intubation. The endotracheal tube causes pressure necrosis of the subglottic mucosa, leading to mucosal edema and ulceration. Secondary infection and perichondritis leading to chondritis and cartilage necrosis ensues. Healing occurs by secondary

intention with proliferation of granulation tissue and deposition of fibrous tissue into the submucosa causing subglottic stenosis<sup>4,6</sup>.

Diagnosis is based on history, physical examination and bronchoscopy to directly visualize the location and extent of stenosis. Treatment varies from observation in mild congenital subglottic stenosis to surgical reconstruction in more severe cases of acquired stenosis. Objective imaging of the stenosis is necessary for reporting between institutions, treatment planning and ultimately follow-up of the stenosis.

#### Subglottic Hemangioma

Subglottic hemangioma is the most common neoplasm of the infant airway<sup>7</sup>. Infants often present at the age of 6 weeks, while 85% will present before the age of 6 months. Stridor is the most common symptom. The stridor is usually intermittent and biphasic but may progress to be constant. The diagnosis of recurrent croup is often mistakenly made due to the similarity in presentation. Insidious onset of respiratory distress often occurs with an increase in size of the hemangioma. Dyspnea, feeding difficulties, and failure to thrive may also be present. Symptoms are usually worse after the onset of an upper respiratory tract infection, further causing the confusion with viral croup. The lesion will typically enlarge for up to one year of age and then gradually decrease in size, with time to complete involution varying<sup>7,8,9</sup>.

The typical location of subglottic hemangiomas are the left lateral wall of the subglottis, although it may be posterior or circumferential. Fifty percent are associated with cutaneous hemangiomas <sup>7,8,9</sup>.

Initial diagnosis may be suggested with a combination of history, physical exam(cutaneous lesions) and plain film Xray(smooth posteriorly based swelling on lateral radiograph). Definitive diagnosis of an airway hemangioma is by direct laryngoscopy or bronchoscopy<sup>8</sup>. The classical appearance on bronchoscopy is of a pink or bluish, smooth and sessile mass arising from the lateral wall of the subglottis.

Treatment modalities range from observation to surgical excision and tracheotomy for airway protection<sup>9</sup>.

Objective imaging of the subglottis would allow a more accurate characterization of airway compromise, leading to appropriate treatment. In addition, objective imaging would allow follow-up of lesions based on careful observation or treatment given.

#### Laryngotracheitis

Laryngotracheitis or viral croup is the most common cause of acute stridor in children. An estimated 3 to 5% of children have at least one episode of croup<sup>10</sup>. It is related to a viral inflammation of the larynx and subglottis that may extend down into the trachea and bronchi. The mucosa of the vocal folds and subglottis become erythematous and swollen causing a decrease in the total diameter of the subglottic area<sup>10</sup>. Parainfluenza viruses are the principal infectious agents although a number of other viruses have been implicated including influenza A, and respiratory syncytial virus<sup>11</sup>. Characteristically, the child is between 6 months and 3 years of age with a seasonal preponderence, being in the fall or winter. The child presents with a harsh, barking cough and biphasic stridor after a few days of a typical viral upper respiratory

obstruction requiring emergent treatment. The duration of the illness varies from 3 to 5 days<sup>12</sup>. Diagnosis is suggested by history and physical exam. Plain film Xray is used to aid in the diagnosis. The anteroposterior view classically shows a "steeple sign" in the subglottic area as demonstrated by a narrowing of the subglottic region<sup>13</sup>. In severe cases, diagnosis may be confirmed by direct laryngoscopy at the time of endotracheal intubation.

Treatment of laryngotracheitis is based on the severity of disease and ranges from observation to medical treatment with steroids and racemic epinephrine. In severe cases, endotracheal intubation may become necessary<sup>12</sup>.

Objective imaging for croup would allow a more accurate depiction of the extent of airway compromise and subsequently affect treatment decisions. In addition, atypical or recurrent croup could be evaluated for the presence of other lesions with a similar presentation, as in subglottic hemangiomas.

As can be appreciated by the similarity and potential severity of these various conditions, rapid diagnosis in a non-traumatic and accurate manner is necessary.

Agitation of the child or placement of the child in the recumbent position is contraindicated due to the possibility of precipitating complete airway obstruction.

Objective assessment of this area would provide clinicians with information that would allow decisions to be made with greater confidence.

## **Subglottic Imaging: Past and Present**

Currently there is no standard way to measure and uniformly classify lesions of the subglottis. The present methods used to evaluate the subglottis rely on techniques that use radiation, sedation or even general anaesthesia. All of these methods are not ideal in evaluating a child with a precarious airway, as they could potentially lead to further airway compromise. Classification of this region is not universally accepted and is hampered by the lack of objectivity in measurement.

Literature review pertaining to the evaluation of the subglottis, has demonstrated a growing interest in the ability to accurately and safely measure the subglottic lumen. Initially, Chevalier Jackson designed laryngeal forceps for the measurement of the subglottic diameter of those patients with a history suggestive of subglottic narrowing <sup>14</sup>. Unfortunately, these forceps were not widely available, nor would they be effective in severely stenotic airways. The laryngeal forceps also required the use of general anaesthesia. Since that time a number of methods have been proposed to assess and possibly classify lesions of the subglottis. These include plain X rays <sup>15,16</sup>, tracheobronchography <sup>17</sup>, balloon tracheoplasty <sup>18</sup>, rigid bronchoscopy <sup>19,20</sup>, CT and Cine-CT<sup>21,22,23,24,25</sup>, MRI<sup>23,24,26</sup>, photometrics using video-bronchoscopy <sup>27</sup> and most recently, ultrasound <sup>1,28,29,30</sup>.

Plain films are commonly used in practice to give an overall picture of the airway. The "croup series" is the standard set of films that includes the anteroposterior, lateral, and inspiratory/expiratory views. This set of films is commonly used in practice

for evaluating the presence of laryngotracheitis(croup). Pathology such as subglottic hemangiomas may also be visualized with this technique. In 1987, Grundfast et al., presented a system for the classification of subglottic stenosis with the initial assessment being made with plain radiography<sup>31</sup>. Limitations include radiation exposure, movement artifact, magnification artifact, and limited ability to carry out a dynamic study<sup>15,16</sup>. Another problem is the limited ability to give detailed information about the airway, its mucosa and lesions present within the airway. A modification of plain X rays is tracheobronchography. Tracheobronchography uses a low-osmolar, non-ionic contrast agent injected via the endotracheal tube and dispersed using an Ambu-bag<sup>17</sup>. Chest radiography is then used to evaluate the airway. In addition to the limitations seen on plain films there is the need for an endotracheal tube and risk of reaction to contrast. This method is seldom used.

Balloon tracheoplasty is an innovative technique employed by Hebra et al. 18, in which balloon-tipped angioplasty catheters were used during bronchoscopy. The balloons are inflated at the level of the stenosis thereby giving an approximate volume of the subglottis based on the amount of air required to cause obstruction of the airway at that level by the balloon. Approximate diameter and length of stenosis could be evaluated with this technique. An obvious limitation includes obstruction of the airway during measurements. No data was presented in this study regarding the accuracy of the measurements by this technique.

The gold standard for evaluating the subglottis today is via rigid bronchoscopy <sup>19,20</sup>. Bronchoscopy is a technique that is performed with the patient under general anaesthetic. The instrument can be flexible with the use of fiberoptics or

rigid with the use of an open tube. This instrument is passed orotracheally while the patient is under a general anaesthetic. The rigid bronchoscope has many applications including the initial evaluation of the tracheobronchial tree, removal of foreign bodies or even airway control in airway obstruction<sup>19</sup>. The drawbacks of this type of examination include the use of general anaesthesia in a potentially precarious airway, and the requirement of an operating theater with a surgeon and anesthesia staff being present. To further complicate the use of bronchoscopy, a lack of uniformity in measuring and classifying the subglottis exists between different institutions. Cotton et al., initially proposed using bronchoscopy and subjectively classifying the stenotic segment based on percentage of perceived obstruction<sup>32,33</sup>. This was plagued with imprecision due to the subjective nature of "eyeballing" the lumen. In 1994, Cotton and Myer III, proposed the use of endotracheal tube diameters in conjunction with a modification of the previously mentioned classification schema<sup>34</sup>. The endotracheal tubes would be used to determine the approximate dimension of the firm subglottic stenosis. This dimension would then be compared to the expected normal airway diameter for the patient's age to derive the percentage of obstruction. In this method, endotracheal tubes are placed by intubation, either by the Anaesthetist or the Otolaryngologist. Positive insufflation demonstrates whether an air-leak is present or not. An air-leak at less than 10 cm H<sub>2</sub>O implies the tube used is too small and is subsequently replaced with one size larger. This procedure of tube sizing is continued until a leak pressure between 10 and 25 cm H<sub>2</sub>O is achieved, indicating the right tube size. Once the right tube size is determined, the outer diameter of the tube is assessed by inspecting the packaging of the endotracheal tube<sup>34</sup>. Assessment is hindered by the

inherent limitations of endotracheal tube sizing. The endotracheal tube is a circular structure that is being used to assess a region that may not be circular, as in the case of an elliptical cricoid cartilage or asymmetric lesion in the subglottis. Further, no description of the shape of the stenosis and length of the stenosis is ascertained by this method. Lastly, this method often requires multiple intubations, increasing the risk of trauma and obstructing an already compromised airway. Cotton and Myer III, also mentioned that this method is only to be used for firm, mature subglottic stenosis<sup>34</sup>, hence its applicability to other types of lesions is limited.

More recently, the increased popularity of CT and MRI has lead to their usage in the assessment of the larvnx<sup>21-26</sup>. CT has been shown to correlate well with the measurements obtained by bronchoscopy in assessing the subglottis<sup>20</sup>. These imaging modalities are accurate yet are often impractical in the Pediatric setting. Typically, CT and MRI require the patient to lie motionless for a period of time<sup>21,22,23,24,25</sup>. Children under the age of 4-5 usually require sedation for the CT scan<sup>23</sup>. The advent of the cine-CT has reduced the scan time, but up to 20 minutes is still required in the scanning facility<sup>28</sup>. To do this the Pediatric patient would need to be sedated. This is contraindicated in assessing an airway that may already be compromised. In addition, CT utilizes a significant amount of radiation, being equivalent to 200 plain X-Rays. MRI, like CT, is limited in the assessment of the subglottis for similar reasons as above. Advantages to MRI include better ability to image soft-tissue and no radiation exposure. Duration of scan time and requirement for sedation are the major limitations. Children under the age of 7-8 years usually require sedation for MR studies<sup>23</sup>. MRI has the further disadvantage of not being readily available yet. Neither CT nor MRI provides

dynamic assessment of the airway<sup>23</sup>. Cine-CT is able to give a dynamic study, yet due to time in the scanner and limited availability is still not ideal<sup>28</sup>.

#### **Ultrasound**

The use of ultrasound in medicine is not new. This mode of imaging has proven to be a fast, noninvasive procedure with no ionizing radiation in imaging various parts of the body.

Ultrasound is defined as high frequency mechanical waves that humans cannot hear. These mechanical waves have frequencies that are greater than 20000 Hertz<sup>35</sup>.

Anatomic imaging with ultrasound is carried out by a pulse-echo technique. The pulses of ultrasound are generated by a transducer that is applied to the skin of the patient. The pulse produces echoes at organ boundaries and tissue interfaces. The return of the echoes are captured by the transducer and presented on the display of the sonographic instrument<sup>36</sup>. By knowing the speed of the echo a display of the tissue depth can be realized by measuring the time of return of the echo. Not all of the pulse will reflect back at the initial interface, but will go on to deeper structures before reflecting back.

As a result, a depiction of all the structures in line of the pulse is formed by the reflection of the pulse; this is known as a scan line. An anatomic image is composed of many scan lines. B scale scans involve translating the location of the various structures into a brightness scale. M mode scans translate reflector motion in time. Real-time imaging involves the rapid sequential display of ultrasound images resulting in a

moving display. This type of imaging requires rapid, repeatable, sequential scanning of the sound beam through the tissue<sup>37</sup>. Shadowing is caused by high attenuation objects in the sound path, making visualization of objects that are present distal to the initial object difficult to perform.

There is no known risk to the use of ultrasound in humans<sup>38</sup>. Currently, ultrasound is used in a number of areas in medicine for both diagnostic and therapeutic procedures. Examples include, prenatal ultrasound examining for defects in utero and ultrasound guided needle biopsy of thyroid lesions. Clinical application of ultrasound examination of the larynx began in the 1960's by a few investigators<sup>28</sup>. Their work was limited by the available technology at the time. Today, computerized ultrasonography allows the imaging of the actual anatomic structures whereas, in the past, only tracing or glottograms of the vibratory patterns of the vocal cords were available<sup>28</sup>. To date, the clinical use of ultrasound in the neck has focused on solid and cystic structures and avoided examining the airway. The reason for this is that ultrasound cannot pass through calcified cartilage, which makes it of little use in adults due to the common presence of thyroid cartilage calcification<sup>29</sup>. Secondly, the acoustic shadow of air in the posterior subglottis has limited evaluation of this area due to shadowing<sup>28,30</sup>.

Even so, sonographic assessment of the larynx has now been well established. The cricoid cartilage appears as a round hypoechoic structure, thus its lower border is used as a reference point to localize and image the subglottic region<sup>30</sup>. Limited studies are available regarding the measurement of the subglottic lumen with ultrasound as it is believed the subglottic air shadows the evaluation of the posterior portion of the subglottis.

In 1998, Giguere and Manoukian demonstrated the ability to successfully measure the subglottic lumen in the normal animal model with ultrasound<sup>1</sup>. The hyperechogenic air column was used to measure the subglottic diameter in three different dimensions. This study carried out at McGill University was a landmark study in the evaluation of the subglottis with ultrasound. The applicability to utilize this technology in a clinical model in the pediatric population and with the presence of lesions in the subglottis is still lacking in the literature.

## Video-Bronchoscopy

The technique of rigid bronchoscopy was described earlier. More recently, rigid rod telescopes using fiberoptics are being used in conjunction with the open tube rigid bronchoscopes that permit easier and more detailed visualization of distant structures. This technique is performed in the operating theatre with the child under a general anaesthetic. The rigid bronchoscope and the rod telescope within it are introduced orotracheally into the patient. The fiberoptic telescope in conjunction with the rigid bronchoscope allows a more detailed evaluation by projection of the image onto a television monitor<sup>19</sup>. This image can be recorded on a videocassette or a video-printer. This method of examination is also termed video-bronchoscopy. Video-bronchoscopy is similarly a technique that is routinely used to give an overall picture of the subglottis and lower airways. Although it is used in everyday practice, its use as an objective

way to measure the subglottis is lacking in the literature. As discussed earlier, rigid bronchoscopy is currently the gold standard in assessing the upper airway. The subjectivity that is inherent in evaluation of diameters in question may possibly be overcome with the use of video-bronchoscopy. Jones et al., using this technique with the name of photometrics demonstrated the applicability of this technique in giving accurate measurements in a cast model<sup>27</sup>. Giguere et al., in addition to assessing ultrasound also found video-bronchoscopy to be a reasonable method to evaluate the subglottis in sacrificed rabbits<sup>1</sup>. As in the case of ultrasound, there is a paucity of literature as it pertains to the use of video-bronchoscopy in assessing the subglottis in the pediatric population.

## **Objectives**

The results of Giguere et al., suggest that a further look at ultrasound and video-bronchoscopy would be beneficial to possibly apply them to the pediatric population for the objective evaluation of the subglottis. The ability to use ultrasound to evaluate the subglottic region in the pediatric population would provide a non-traumatic, quick method of examination that does not require the use of sedation or radiation. In the case of video-bronchoscopy, validation of this technique would ensure an accurate and reproducible method of evaluation of the subglottis when bronchoscopy is deemed necessary. This would foster a more universal approach to the description and ultimate treatment of lesions in this area.

The objective of this study is to look at the utility of video-bronchoscopy and ultrasound in comparison to the present standard of assessing the subglottis in the pediatric population, namely, endotracheal tube sizing.

#### **Materials and Methods**

This double-blinded prospective clinical study was carried out at the Montreal Children's Hospital, McGill University. The Otolaryngologist performing the video-bronchoscopic measurements of the subglottis and the ultrasonographer were blinded to each other's results. Similarly, the Anaesthesist performing the endotracheal tube measurements was blinded to the ultrasound and video-bronchoscopic results.

Comparisons were made between video-bronchoscopy, ultrasound, and the current standard of measuring the subglottic in the pediatric population, namely, endotracheal tube sizing. The study received approval from the Scientific Merit and Ethics Review Boards of the Montreal Children's Hospital, McGill University. Each patient enrolled was first consented to participate in the study.

The study consisted of a total of 10 patients who underwent an elective or emergently booked rigid bronchoscopy during a period from July 1, 2000 to February 28, 2001. Patients had an ultrasound of the subglottis within 24 hours prior to the bronchoscopy or within the operating theatre prior to commencement of the bronchoscopy. Endotracheal tube sizing was performed after completion of the bronchoscopy and prior to the patient being awakened from general anaesthesia.

#### Step 1: Ultrasound Measurements

Once the patient is induced under general anaesthesia, the ultrasound measurements are acquired. The patient is breathing spontaneously and is oxygenated via a mask and bag, but is not intubated. Measurements were carried out with a linear 7.0 transducer at 10 Megahertz frequency with a B-mode real time device (Figure 1, model Acuson, Aspen). Resolution is 0.1 mm. All measurements were carried out while the patient was lying in a supine position. The ultrasound probe was placed on the neck in the fashion described below to acquire the luminal diameters of interest (Figure 2). This was preceded by the identification of the vocal cords followed by the lower edge of the hypoechogenic cricoid cartilage so as to ensure the accurate measurement of the subglottis. At this level three measurements are taken (Figure 3).

- 1) Left to right diameter. The probe is placed in the midline of the anterior neck, perpendicular to the skin of the patient, acquiring an image of the subglottic air column on the two dimensional screen. A right and left point is selected by the ultrasonographer at the extreme edges of the hyperechogenic air shadow, with the distance between the two being the left-right diameter of the subglottic lumen.
- 2) Right oblique diameter. The probe is placed on the left side of the neck at an angle of 45 degrees from the longitudinal midline, resulting in an image of the right oblique diameter. A measurement of the air column is similarly carried out as above.

3) Left oblique diameter. In similar fashion to (2), the probe will be placed on the right neck at an angle of 45 degrees from the longitudinal midline. The image of the left oblique diameter is acquired and measured.

#### Step 2: Bronchoscopic Measurements

After completion of the ultrasonographic measurements the intended bronchoscopy is carried out. Once the diagnostic or therapeutic bronchoscopy is completed, measurements of the subglottis are carried out. A pediatric bronchoscope and rod telescope is utilized. The size is determined by the age and size of the patient. The subglottis is identified by the presence of the complete ring of the cricoid cartilage. This is accomplished by initially passing the bronchoscope into the trachea and visualizing the posterior wall as the bronchoscope is slowly withdrawn. The trachea has a posterior defect in the cartilage that results in a posterior bulge of tissue. The subglottis is successfully identified by the disappearance of this bulge and the presence of the complete cartilaginous ring of the cricoid as mentioned earlier.

Once the subglottis is visualized, a #5 suction catheter is passed through the video-bronchoscope until its distal tip is visualized. The catheter is then placed to touch the cricoid cartilage at its inferior ledge. The screen aperture is adjusted to allow complete visualization of the subglottic lumen (Figure 4). The bronchoscope is then removed from the patient with care not to disturb the protruding suction catheter. The bronchoscope and telescope are then placed over a metric rule with the tip of the suction catheter touching the rule (Figure 5). This will allow for scale measurements to be

carried out as diameters measured on the subglottic images are scaled to the ruler images. The rule is a standard metric rule with 1 mm increments.

After completion of the bronchoscopy a tape of the subglottic images and the ruler are examined to determine the left-right, right oblique and left oblique diameters by placing a ruler to first the lumen picture and subsequently to the ruler picture to derive a measurement. This portion of the study was carried out in the Audio-Visual Department of the Montreal Children's Hospital to ultilize the editing videocassette machine as the operating room video-bronchoscopy system did not possess a video-printer device.

#### Step 3: Endotracheal Tube Measurements

Once the bronchoscopy is complete, the endotracheal tube sizing of the subglottis is carried out. As described by Cotton et al., a conservatively chosen endotracheal tube is passed through the level of the subglottis and the audible leak pressure is determined (Figure 6). If an audible leak less than 10 cm H<sub>2</sub>O is present, the endotracheal tube is removed and replaced with the next larger size. An acceptable audible leak pressure is between 10 cm and 25 cm. If a leak pressure is greater than 25 cm, the endotracheal tube is replaced with one that is one size smaller. This process is repeated until the appropriate endotracheal tube size is obtained. The outer diameter of the endotracheal tube is verified from the packaging of the tube (Figure 7). This method will provide a single diameter measurement as the endotracheal tube is considered to be circular in shape.

Three comparisons were carried out. Ultrasound, the endotracheal tube outer diameter and the video-bronchoscopic method were compared. Paired t-tests were used to determine whether a statistically significant difference in estimated diameter was present. The diameter measurements between the various techniques were tested for association with the Pearson Correlation Coefficient. SAS statistical software was utilized for the analysis.

For the comparison between the outer diameter of the endotracheal tube and the ultrasound method, the smallest of the three ultrasound measurements was used. This was done as, theoretically, the endotracheal tube could not pass through the subglottis unless it was able to pass through the narrowest diameter of the subglottis. The smallest ultrasound measurement should thus approximate the smallest diameter of the subglottis and hence the outer diameter of the endotracheal tube.

Similar comparisons were also carried out between the outer diameter of the endotracheal tube sizes and the smallest bronchoscopic measurement. Lastly, ultrasound measurements were compared to the video-bronchoscopic measurements of the same diameters. In this comparison the left-right, right oblique, and left oblique diameters were measured and compared between the two methods.

## **Results**

A total of 10 patients underwent bronchoscopy and were enrolled in the study. One patient could not have endotracheal tube sizing due to the presence of a posterior tracheal mass obstructing the airway. Measurements of the subglottis were made with video-bronchoscopy and ultrasound. Of note, the superior tracheal mass of this patient was visualized on ultrasound as a hyperechoic mass, demonstrating the ability of ultrasound to identify and outline an airway mass. The pathology for this lesion returned as a granular cell tumor. The ages of the patients ranged from 1 year to 20 years of age. The average age was 6 years. See Table 1 for details.

The study can be divided into three parts: the comparison of video-bronchoscopy to endotracheal tube sizing; the comparison of ultrasound measurements to endotracheal tube size; and the comparison of video-bronchoscopy to ultrasound measurements.

Video-Bronchoscopy to Endotracheal tube outer diameter

Video-bronchoscopic measurements were carried out for the left-right diameter, right oblique diameter and left oblique diameter. The smallest diameter of the three was compared to the outer diameter of the endotracheal tube for the corresponding patient. The smallest diameter of the three video-bronchoscopic measurements was used as the

endotracheal tube would only be able to pass through the smallest diameter of the subglottis. .

Comparison was conducted using confidence intervals and a paired T-test to compare if the difference between video-bronchoscopic measurements and endotracheal tube size was significant.

It was found that the smallest video-bronchoscopic measurements were always larger than the corresponding endotracheal tube size. The difference between the two modalities had a mean of 1.9 mm, with a 95% confidence interval 0.5 to 3.3 mm. The paired T-test demonstrated this difference to be statistically significant with a p-value of 0.01. This suggests that a small difference may exist.

Pearson's correlation coefficient supported a very strong, positive relationship between the two measurement modalities (r=0.98, p<0.0001). Refer to Table 2 for further results and Graph 1 for Pearson's correlation scatter plot.

#### Ultrasound to Endotracheal tube outer diameter

In similar fashion, a comparison of the smallest of the three diameters measured by ultrasound was compared to outer endotracheal tube diameter for the corresponding patient. Comparisons were conducted using confidence intervals, paired T-test, and Pearson's correlation coefficient as above.

It was found that the endotracheal tube size was larger than the minimum ultrasound measurements in all nine patients. The mean difference between the two modalities was -2.6 mm, with the endotracheal tube size being larger. The 95% CI was

-3.5 to -1.7 mm. The paired T-test demonstrated this difference to be statistically significant with a p-value of 0.0001.

Pearson's correlation was similarly carried out and also demonstrated a very strong, positive correlation between the two modalities (r=0.95, p<0.0001). Refer to Table 3 for further results and Graph 2 for Pearson's correlation scatter plot.

#### Ultrasound to Video-Bronchoscopy measurements

The difference between video-bronchoscopic measurements for the left-right, right oblique, and left oblique diameters and corresponding ultrasound diameters was examined for all 30 measurements (ten patients with three different measurements for each patient). Analysis was carried out using, confidence intervals, paired T-test, and Pearson's correlation coefficient. For discussion purposes, the analysis will focus on the right oblique measurements. Refer to table 3 for values for all the left oblique and left-right diameters.

In 100% of the cases video-bronchoscopy values were larger than the ultrasound measurements. The 95% confidence interval for mean difference for the right oblique diameter measurement for video-bronchoscopy and ultrasound is 1.9 to 6.2 mm. Paired T-test indicated this difference to be significant with a p-value of 0.002. Pearson's correlation coefficient demonstrated a strong, positive correlation (r=0.86, p=0.0015). Refer to Table 4 for further results and Graph 3 for Pearson's correlation scatter plot.

#### Discussion

The subglottis is the narrowest portion of the pediatric larynx. The subglottis is a funnel-shaped region that is narrowest at its inferior segment, namely the cricoid cartilage. The lumen at the midlevel of the cricoid cartilage is normally elliptical, while at the inferior margin the transverse and antero-posterior diameters are equal due to the ring configuration of the cricoid at this level<sup>5</sup>. Due to the presence of the complete ring, any mucosal edema is at the expense of the intraluminal airway, further reducing the airway at its most narrow point. Subglottic pathology ranges from circumferential as in laryngotracheitis and subglottis stenosis to focal as in a subglottic hemangioma.

Assessment of this region of the airway ideally should be able to differentiate the various pathologies that may be present and estimate the effect they have on the lumen of the airway. To do this an objective method of measurement is required along with an appropriate classification schema that can aid in prognosis and management. As mentioned earlier, an attempt at objective measurement of the subglottis first began in 1932, when Gabriel Tucker developed an instrument for making endoscopic measurements of the infant larynx and subglottis 14

Since that time a number of proposed methods of measurement have surfaced including plain films<sup>15,16</sup>, tracheobronchography<sup>17</sup>, bronchoscopy<sup>19,20</sup>, balloon tracheoplasty<sup>18</sup>, CT and Cine-CT<sup>21,22,23,24,25</sup>, MRI<sup>23,24,26</sup>, Photometrics using Video-Bronchoscopy<sup>27</sup> and most recently ultrasound<sup>1,28,29,30</sup>.

Bronchoscopy is currently the standard in assessing the subglottis and upper airway<sup>19,20</sup>. In recent years the addition of the fiber-optic rod telescope into the

bronchoscope has allowed a magnified picture with a high degree of resolution. The image is broadcast on a television screen in the operating theatre that can be video-taped or photographed. Assessment of the diameters in question remained subjective due to the examiner estimating the size of the lesion based on a magnified image. Cotton proposed the classification of mature subglottic stenosis with the Grades I to IV depending on the visualized stenosis<sup>32,33</sup>. This subjective assessment has been shown to predict decannulation of tracheotomized patients. Jones et al. proposed the idea of photometrics along with bronchoscopy to give an improved objective measurement of the diameters in question<sup>27</sup>. By standardizing the distance from the objective of the endoscope to the stenotic area, the cross-sectional area could be measured when a graduated grid that was held against the video screen. His data was based on studies carried out on a plaster cast. Giguere et al. using a similar approach progressed to using video-bronchoscopy (photometrics) of the subglottis of sacrificed rabbits<sup>1</sup>. No

Data regarding the use of ultrasound in assessing the subglottis is also sparse. In the 1960's clinical application of ultrasound in evaluation of the larynx was attempted by various investigators<sup>28</sup>. Technology at the time was limited and did not allow a complete examination of the area. Computerized ultrasonography became available in 1983. This newer technology enabled the assessment of anatomic structures of the larynx instead of a tracing on an oscilloscope<sup>28</sup>. Garel et al. commented on laryngeal ultrasonography in children<sup>30</sup>. They mentioned that ultrasound provided two advantages compared to plain films, namely, better tissue differentiation and ability to perform a dynamic study. Mention was made of ultrasound to perform subglottic

assessment and evaluate lesions such as congenital stenosis and subglottic hemangiomas. Limitations commented on by the authors included the limited ability to see the posterior aspect of the cricoid due to subglottic air. No results or statistical analysis was demonstrated in the paper. The first study to focus on the use of ultrasound specifically for evaluating the subglottis was carried out at McGill University in 1999 by Giguere et al<sup>1</sup>. In this study ultrasound was found to be an accurate method that strongly correlated with caliper measurements of the subglottis in sacrificed rabbits with a normal subglottis. The measurements were based on the hyperechogenic air column being used to give a diameter measurement of the subglottis. This provided the impetus for this study, which involved the comparison of ultrasound to video-bronchoscopy and endotracheal tube sizing in assessing the subglottis of the pediatric population. The advantages of ultrasound in assessing the subglottis are numerous. These would include a rapid, painless, and non-invasive modality that could serve as a means of screening the acutely ill child, following up on a longstanding lesion or assessing the impact of the pathology during respiration. The result would be a reduction in the use of invasive procedures such as bronchoscopy to initially screen for or follow-up of chronic lesions of the subglottis.

In this study ultrasound was compared to endotracheal tube diameters in a double-blinded, prospective fashion. Results demonstrated that ultrasound consistently underestimated the subglottic diameters in question, but was strongly correlated with the endotracheal tube sizing. This implies that although ultrasound may indeed underestimate the absolute value of a subglottic diameter, it does seem to follow the endotracheal tube sizing, in that a larger diameter in endotracheal tube size was

similarly found to be larger on ultrasound and vice-versa. Clinically, this would suggest that ultrasound might be more of a tool to assess change over time as in a chronic lesion as opposed to giving information on absolute diameters. None of the patients had subglottic pathology and as such data on assessment of these lesions is still limited. In one patient a granular cell tumour of the posterior trachea was visualized with ultrasound, indicating it may be an effective means to visualize lesions of the airway.

Similarly video-bronchoscopy was compared to endotracheal tube sizing. Video-bronchoscopy was found to have a strong and positive correlation to endotracheal tube sizing. Video-bronchoscopy was also found to have measurements that were slightly larger than the endotracheal tube size. This difference may be explained by inherent problems with endotracheal tube sizing itself. The endotracheal tube is a circular structure that is being used to assess a region that may not be circular, as in the case of an elliptical cricoid cartilage or asymmetric lesion in the subglottis. The audible air leak is a testament that the tube does not perfectly fit the contour of the subglottis. This would be expected otherwise the endotracheal tube would have been extremely difficult and traumatic to insert into the patient. Further, no description of the shape of the stenosis and length of the stenosis is ascertained by this method. In addition, this method often requires multiple intubations, increasing the risk of trauma and obstructing an already compromised airway. Lastly, the subglottis remains the narrowest portion of the pediatric airway until eight years of age, after which the level of the vocal cords is the narrowest region. The endotracheal tube sizing method does not take this into account and consequently can mistakenly measure the opening at the level of the vocal cords in children who are older than eight years of age rather than the

subglottis for which the measurement was initially intended. The video-bronchoscopic method is not limited by this and would only measure the true subglottic diameters as direct visualization of the subglottis is performed during measurement. In addition, the endotracheal tube method is suggestive of the cricoid being a perfect circle, which is not the case in many situations<sup>5</sup>. As such, the video-bronchoscopic technique may actually be measuring a diameter that the endotracheal tube cannot assess. In the same regard video-bronchoscopy can evaluate many diameters at the same level due to the observer choosing what to measure. For example, if the observer finds an irregular shaped lesion in the subglottis, he/she can measure the area of the airway unaffected by this lesion and the airway that is affected, comparing the two. This would give more information regarding the absolute and relative reduction in airway diameter.

Lastly, a comparison between video-bronchoscopy and ultrasound was also carried out. Ultrasound consistently demonstrated smaller diameter measurements for all three diameters measured for all patients compared to video-bronchoscopy. As in the comparison with the endotracheal tube sizing, ultrasound correlated with video-bronchoscopy in a positive and strong manner. The results give further confidence that ultrasound is a good method to follow the airway and lesions over time.

### **Summary**

Objective assessment of the subglottis would enhance the ability to make decisions on the management of children that present with both acute and chronic lesions of this area. This study has made a first attempt to validate video-bronchoscopy assessment of the subglottis in the pediatric population. Preliminary results are very encouraging for this method but further data is needed to provide conclusive evidence to this effect. Video-bronchoscopy may actually prove to be more accurate than the current method of evaluation of this area by endotracheal tube sizing and may prove to be the "gold standard" in the future.

Assessment of the subglottis using ultrasound was also attempted for the first time in a pediatric clinical model. Results tend to indicate that ultrasound is better in assessing relative diameters and as such changes as opposed to absolute diameter measurements. This could prove to be applicable in following chronic lesions such as subglottic hemangiomas or subglottic stenosis. Further data is needed to assess the efficacy of ultrasound with the presence of lesions in the subglottis.

Once an objective method of assessing the subglottis is found, the use of a standard classification method to assess lesions and luminal diameters would allow a more universal approach to a global problem. This study presents the first attempt to utilize objective measurements of the subglottis in the pediatric population using ultrasound and video-bronchoscopy. Further data is needed to apply these modalities to the present classification schema, as presented by Cotton. This would allow a more universal approach to reporting and treating lesions in this complex area.

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# **TABLES**

#### **Tables**

Table 1 Demographic Data of Patient Population

Variable		Value
Age:	Average Range	6.1 years 1 to 20 years
Sex:	Male	5
	Female	5

Table 2 Video-Bronchoscopic vs. Outer Diameter of Endotracheal Tube

Variable		Value
Mean	VB	8.14 mm
	ET	6.58
SD	VB	3.85 mm
	ET	2.16
Median	VB	6.90 mm
	ET	5.50
Paired T-statistic	(VB vs. ET)	3.16
<i>p</i> -value		0.01
95% CI		0.51 to 3.32
99% CI		-0.12 to 3.96
Correlation	(VB vs. ET)	0.98, p< 0.05

VB = video-bronchoscopy, ET = endotracheal tube

Table 3 Ultrasound vs. Outer Diameter of Endotracheal Tube

Variable		Value	
Mean	US	3.93	
	ET	6.58	
SD	US	1.04	
	ET	2.16	
Median	US	3.80	
	ET	5.50	
Paired T-statistic	(US vs. ET)	-6.84	
<i>p</i> -value		0.0001	
95% CI		-3.54 to -1.75	
99% CI		-3.94 to -1.35	
Correlation	(US vs. ET)	0.96, <i>p</i> <0.05	

US = ultrasound, ET = endotracheal tube

Table 4 Video-Bronchoscopic vs. Ultrasound Measurements

Variable		LR	RO	LO
Mean	VB	8.30	8.25	8.44
	US	4.19	4.22	4.35
SD	VB	4.06	3.79	3.82
	US	0.96	0.97	1.66
Median	VB	6.90	6.90	7.00
	US	3.95	3.90	3.85
T statistic	VB vs.US	4.00	4.25	4.67
p-value		0.003	0.002	0.001
95% CI		1.79 to 6.43	1.88 to 6.18	2.11 to 6.07
Correlation	VB vs. US	0.88*	0.86*	0.76*

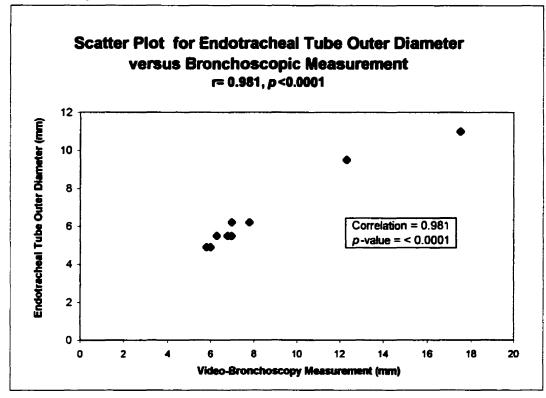
VB = video-bronchoscopy, US = ultrasound, LR = left to right diameter, RO = right oblique diameter, LO = left oblique diameter

<sup>\*</sup> Significant at p=0.05

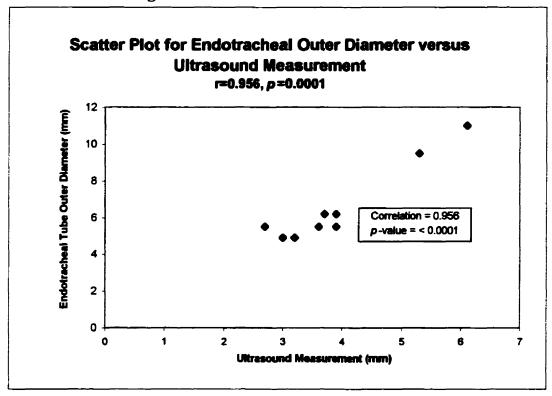
# **GRAPHS**

#### Graphs

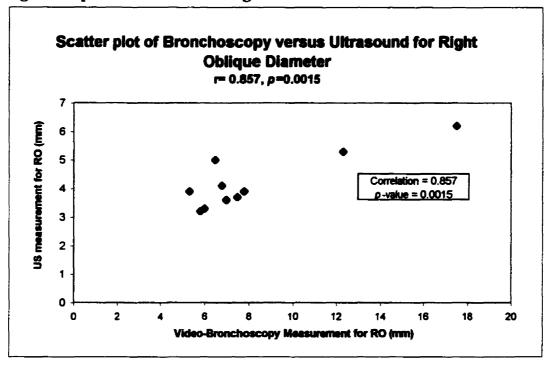
Graph 1: Scatter Plot of Endotracheal Tube Outer Diameter vs. Video-Bronchoscopic Measurement of the Subglottis



Graph 2: Scatter Plot for Endotracheal Tube Outer Diameter vs. Ultrasound Measurement of Subglottis



Graph 3: Scatter Plot of Video-Bronchoscopy vs. Ultrasound Measurements of Right Oblique Diameter of the Subglottis



# **FIGURES**

Figure 1: Patient is breathing spontaneously and is oxygenated via a mask and bag, but is not intubated. Measurements are carried out with a linear 7.0 transducer at 10 Megahertz frequency with a B-mode real-time device.



Figure 2: The ultrasound probe is placed on the neck with initial identification of the vocal cords followed by the hypoechogenic cricoid cartilage. The three measurements are taken at this level, namely, the left-right diameter, left oblique diameter, and the right oblique diameter.



Figure 3: Ultrasound image acquired during measurement of the subglottic lumen. The hyperechogenic air column is marked at the level of the subglottis by the calipers as outlined by the cross-hairs. The accuracy of the digital caliper system is 0.1 mm.

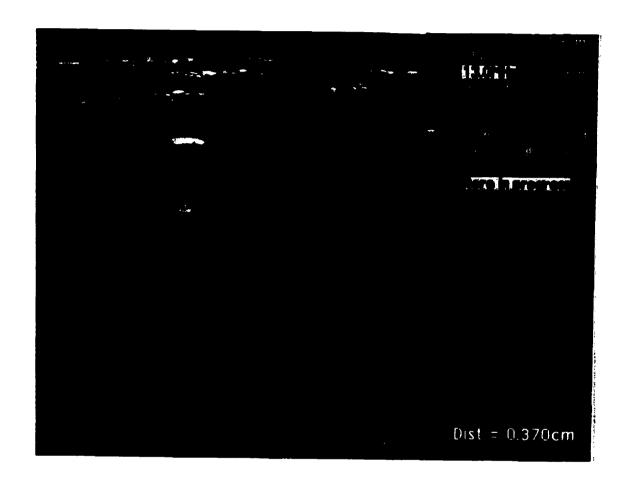


Figure 4: The subglottis as visualized by the video-bronchoscopic instrument. The suction catheter is passed distal to the tip of the bronchoscope to touch the inferior ledge of the cricoid cartilage. This will serve as a distance marker to allow scale measurements with a metric ruler as seen in Figure 5.

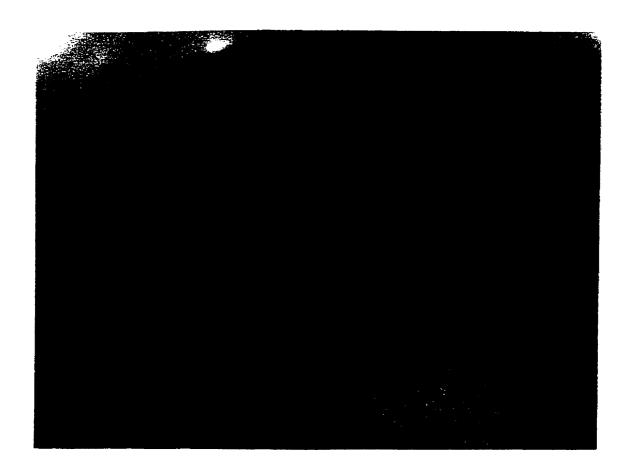


Figure 5: The metric ruler as visualized with the video-bronchoscopic instrument. Note the suction catheter tip touching the metric ruler to allow scale measurements of the subglottis from Figure 4. The increments on the ruler are 1 mm.

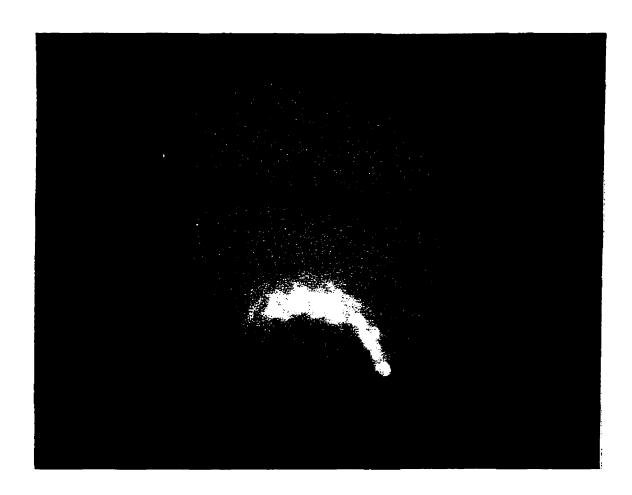
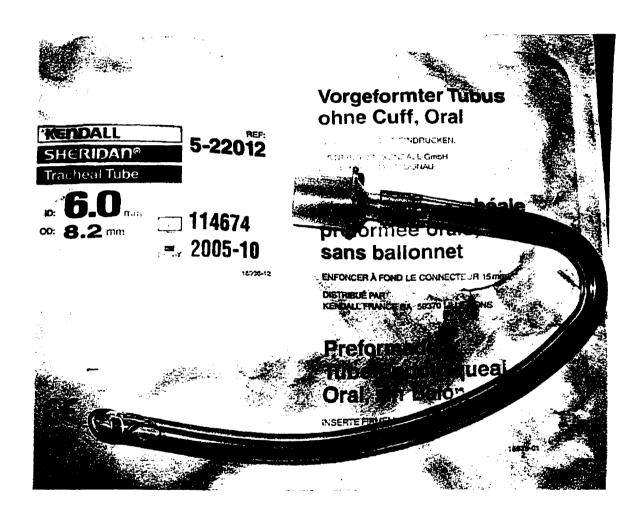


Figure 6: Endotracheal tube sizing technique to assess subglottic diameter. Assessment for air leak is carried out after conservatively chosen size of endotracheal tube is placed. Pressure for audible air leak is determined by a member of the Anaesthesia team placing a stethoscope over the anterior neck, and a second member positively insufflating the air bag to determine at what pressure an air leak is audible.



Figure 7: Once an appropriate endotracheal tube size is found as measured by an air leak between 10 and 25 cm water, the packaging of the endotracheal tube is examined to retrieve the outer diameter size in millimeters. The manufacturer guarantees the accuracy to +/- 0.15 mm.



# **APPENDICES**

### Measurement of the Subglottic Lumen by Ultrasound Consent Form (Age of Assent of 7 years)

You are having something called a bronchoscopy to check your breathing passage. This will be done while you are sleeping.

This study involves using an imaging machine called an ultrasound to take pictures in an area of the neck called the subglottis. If the ultrasound works, it will help to check for problems in this area of the neck of children.

At the same time as the bronchoscopy is being done, the ultrasound can be done. This involves placing a camera probe on your neck while you are sleeping. It takes a total of three to four minutes. This is not painful and there are no extra needles. There are no risks or benefits involved.

You are not forced to enter the study. You will receive the same care if you decide to have the ultrasound or not. If you say yes, you may still at anytime change your mind. If you have any questions, feel free to ask Dr. Manoukian or your parents/guardian, who can ask for you.

#### **Consent**

I have read and understood the information regarding the study and agree to participate. I understand entering the study is voluntary and that I can say no at anytime.

Name	
Signature	Date
Name of Parent or Guardian	
Signature of Parent or Guardian	Date _

Name		
Signature	Date	
Principal Investigator: Dr. Manoukian		
Signature	Date	

We would like to thank you for taking the time to consider this project.

### Mesure de la Lumière Sous-glottique par Échographie Formulaire de Consentment (pour jeune de 7 ans)

Vous allez subir un examen appelé bronchoscopie, qui sert à évaluer votre système respiratoire. Ceci sera fait alors que vous dormez.

Cette étude implique l'utilisation d'une machine de formation image appelée échographie pour prendre des photos dans une zone du cou qu'on appèle la région sous-glottique. Si l'échographie fonctionne, elle aidera à vérifier les problèmes dans cette zone du cou des enfants.

L'échographie peut être faite pendant que la bronchoscopie est réalisée. Ceci implique le placement d'une sonde d'appareil-photo sur votre cou pendant que vous dormez. Cela prend un total de trois à quatre minutes. Ce n'est pas douloureux et il n'y a aucune aiguille supplémentaire. Il n'y a aucun risque ou avantage d'impliqué.

Vous n'êtes pas forcé de participer à l'étude. Vous recevrez les même soins que si vous décidiez d'avoir les ultrasons ou non. Si vous acceptez d'y participer, vous pourrez néanmoins n'importe quand changer d'avis. Si vous avez quelque question que ce soit, sentez-vous libre de la poser au Dr. Manoukian ou à vos parents/tuteur, qui peut nous la demander.

#### Consentement

J'affirme avoir lu et compris l'information concernant l'étude et j'accepte de participer. Je comprends que ma participation à l'étude est volontaire et que je peux changer d'avis à n'importe quel moment.

<del></del>	
Date :	
	Date :
Date :	
Date :	

#### Measurement of the Subglottic Lumen by Ultrasound Consent Form

#### Introduction

The long-term aim of this research project is to help in the diagnosis of problems in an area of the breathing passage called the subglottis in children and infants. This area lies right below the level of the vocal cords. Currently, to diagnose and investigate problems in this area, X-ray and bronchoscopy are used which, although are extremely useful, subject the child to radiation, sedation or general anaesthesia. This project is investigating the use of ultrasound as an alternative. Ultrasound is a form of imaging that utilizes sound waves to create a picture. It is quick, non-painful and does not involve giving the child any radiation, medication or needles. This form of imaging is already being used as a standard test in other parts of the body, for example as a routine test during pregnancy or for assessing gallbladder problems. Our research is to see if this form of imaging can also be used to look at and assess the airway (subglottis).

If you agree to participate, what will that involve?

If you agree to participate in this study, your child will proceed to have the bronchoscopy that is already scheduled at the Montreal Children's Hospital operating room. In addition, at the end of the procedure, a trained pediatric radiologist will perform an ultrasound of your child's neck. The ultrasound involves placing a probe on a specially designed pad made of gel that is in contact with the skin. The procedure will take a total of 3-4 minutes in addition to the scheduled bronchoscopy time. The benefits of this study are yet to be determined.

Risks involved in participating in this study. There are no risks associated with this study.

Will participation in this study affect my treatment? Participating will in no way affect your treatment.

Benefits of participating in this study

There are no potential benefits of participating in this study.

What happens if I want to withdraw from the study?

You are perfectly free to withdraw from this research project at any time you want to. Such withdrawal will in no way affect your treatment.

#### Confidentiality

We assure you that all information gathered during the course of this research project will be kept completely confidential. All data will be identified through a code number so we

will not know to whom the data relates. The results of the research will be published in scientific medical journals in an anonymous form. All data will be kept for a period of five years after which it will be destroyed.

#### Further Information

If you would like any more information or have any questions related to this study, please do not hesitate to call the Montreal Children's Hospital, Dr. Husein or Dr. Manoukian at 514-934-4400, ext. 4320. The hospital Ombudsman is Liz Gibbon. She may be contacted at 934-4400, ext. 2223, if there are any other concerns.

#### Consent

I have read and understood the information concerning this study and agree to participate. I understand that participation is entirely voluntary and that I may withdraw at any moment without it in any way affecting my treatment.

Name	
Signature	Date
Name of Parent or Guardian	
Signature of Parent or Guardian	Date
Witness Name	
Signature	Date
Principal Investigator: Dr. Manoukian	
Signature	Date

We would like to thank you for taking the time to consider this project.

### Mesure de la Lumière Sous-glottique par Échographie Formulaire de Consentement

#### Introduction

L'objectif à long terme de ce projet de recherche est de faciliter le diagnostic des problèmes dans un passage respiratoire chez les enfants appelé la région sous-glottique. Cette zone se trouve sous les cordes vocales. Présentement, pour diagnostiquer et étudier les problèmes dans cette zone, on utilise les rayons X et la bronchoscopie qui, bien qu'elles s'avèrent extrêmement utiles, exposent l'enfant à la radiation, à la sédation ou à l'anesthésie générale. Ce projet étudie l'utilisation de l'échographie comme alternative. L'échographie est une sonde de formation d'images qui utilise des ondes de sons pour créer une image. C'est un processus rapide, non-douloureux et n'implique pas de radiation, médicament ou d'aiguille. Cette forme d'échographie est déjà utilisée comme examen standard dans d'autres parties du corps, par exemple comme un test de routine durant la grossesse ou pour évaluer des problèmes de la vésicule biliaire. Notre recherche consite à déterminer si cette forme d'échographie peut également être employée pour regarder et pour évaluer les voies respiratoires sous-glottiques.

#### Qu'est-ce que ma participation impliquera?

Si vous acceptez de participer à cette étude, votre enfant subira une bronchoscopie qui était déjà planifiée à la salle d'opération de l'hôpital des enfants de Montréal. En outre, à la fin du procédé, un radiologiste pédiatrique qualifié exécutera des échographies du cou de votre enfant. L'échographie implique le placement d'une sonde sur couche de gel particulier en contact avec la peau. Le procédé prendra un total de 3-4 minutes en plus du temps de la bronchoscopie. Les avantages de cette étude restent à être déterminés.

#### Les risques encourus par cette étude :

Il n'y a aucun risque associé à cette étude.

#### La participation à cette étude affectera-t-elle mon traitement?

La participation affectera nullement votre traitement.

#### Les avantages de participer à cette étude :

Il n'y a aucun avantage potentiel à participer à cette étude.

#### Comment puis-je me retirer de l'étude?

Vous êtes parfaitement libre de vous retirer de ce projet de recherche à tout moment. Un tel retrait n'affectera nullement votre traitement.

#### Confidentialité

Nous vous assurons que toute l'information recueillie pendant ce projet de recherche sera maintenue entièrement confidentielle. Toutes les données seront identifiées par un numéro de code ainsi nous ne saurons pas à qui les données appartiennent. Les résultats de la recherche seront publiés dans des revues médicales scientifiques sous une forme anonyme. Toutes les données seront concervées pendant une période de cinq ans après quoi elles seront détruites.

#### Informations supplémentaires

Si vous désirez plus d'information ou avez n'importe quelle question sur cette étude, n'hésitez pas à appeler l'hôpital des Enfants de Montréal, le Dr. Husein ou le Dr. Manoukian au 514-934-4400 poste 4320. L'Ombudsman de l'hôpital est Liz Gibbon. Elle peut être contactée à 934-4400 poste 2223, si vous avez d'autres inquiétudes.

#### Consentement

J'affirme avoir lu et compris l'information au sujet de cette étude et j'accepte d'y participer. Je suis conscient du fait que la participation est entièrement volontaire et que je peux me retirer à tout moment sans affecter de quelque façon que ce soit, mon traitement.

Nom :		
Signature :	Date :	
Nom d'un parent ou tuteur :		
Signature du parent ou tuteur :		Date :
<b>Témoin</b> Nom :		
Signature :	Date :	
Investigateur Principal: Dr. Manoukian		
Signature	Date :	

Nous aimerions vous remercier de prendre le temps de considérer ce projet.

### MEASUREMENT OF THE SUBGLOTTIC LUMEN BY ULTRASOUND – Data Collection Form

Drs. M. Husein, J. Manoukian, R. Platt, Y. Patenaude, C. Giguere, S. Drouin

Clinical Arm		
Study No.:		
Date:		
Normal SG ( )		
Abnormal SG ( )		
Name:		
MCH #:		
Age:		
History:		
Operation Type:		
ULTRASOUND	BRONCHOSCOPE	<u>VIDEO</u>
Measurements:	Tube Size:	Measurements:
L-R: mm mm	<u>I.D</u> .	<u>L-R:</u>
R Oblique: mm	<u>O.D.</u>	R Oblique: mm
L Oblique: mm	Leak cm H2O	L Oblique: mm
Findings:	Findings:	Findings:

## MEASUREMENT OF THE SUBGLOTTIC LUMEN BY ULTRASOUND - Radiology Collection Form

Drs. M. Husein, J. Manoukian, R. Platt, Y. Patenaude, C. Giguere, S. Drouin

Clinical Arm
Study No.:
Patient's Unit#
Patient's Name
Sex: 1) Male 2)Female
Date:
Normal SG ( )
Abnormal SG ( )
ULTRASOUND
Measurements:
AP: mm
R Oblique: mm
L Oblique: mm
Dimensions of Lesion or Volume:
Echogenicity of Lesion:
Location of Lesion:
Additional Findings: