INFORMATION TO USERS

This manuscript has been reproduced from the microfilm master. UMI films the text directly from the original or copy submitted. Thus, some thesis and dissertation copies are in typewriter face, while others may be from any type of computer printer.

The quality of this reproduction is dependent upon the quality of the copy submitted. Broken or indistinct print, colored or poor quality illustrations and photographs, print bleedthrough, substandard margins, and improper alignment can adversely affect reproduction.

In the unlikely event that the author did not send UMI a complete manuscript and there are missing pages, these will be noted. Also, if unauthorized copyright material had to be removed, a note will indicate the deletion.

Oversize materials (e.g., maps, drawings, charts) are reproduced by sectioning the original, beginning at the upper left-hand corner and continuing from left to right in equal sections with small overlaps.

Photographs included in the original manuscript have been reproduced xerographically in this copy. Higher quality 6" x 9" black and white photographic prints are available for any photographs or illustrations appearing in this copy for an additional charge. Contact UMI directly to order.
NOTE TO USERS

This reproduction is the best copy available.
NEW MODALITIES TO MEASURE THE SUBGLOTTIC DIAMETER

Chantal Margaret Giguère, M.D.C.M.

Department of Otolaryngology

McGill University, Montreal, Quebec, Canada

July, 1999

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements of the degree of Master of Science (M.Sc. – Otolaryngology)

© Chantal Margaret Giguère, M.D.C.M., 1999
The author has granted a non-exclusive licence allowing the National Library of Canada to reproduce, loan, distribute or sell copies of this thesis in microform, paper or electronic formats.

The author retains ownership of the copyright in this thesis. Neither the thesis nor substantial extracts from it may be printed or otherwise reproduced without the author’s permission.

L’auteur a accordé une licence non exclusive permettant à la Bibliothèque nationale du Canada de reproduire, prêter, distribuer ou vendre des copies de cette thèse sous la forme de microfiche/film, de reproduction sur papier ou sur format électronique.

L’auteur conserve la propriété du droit d’auteur qui protège cette thèse. Ni la thèse ni des extraits substantiels de celle-ci ne doivent être imprimés ou autrement reproduits sans son autorisation.

0-612-55060-5
ABSTRACT

The objective measurement of the subglottic lumen has been a problem for many years. To date, no proposed system for this measurement has been adopted universally. The aim of this study was to evaluate, for the first time, B-mode ultrasound and a new video-bronchoscopic technique in the measurement of the subglottic lumen diameter.

This was a blind prospective animal study of 62 recently sacrificed rabbits. Different standardized diameters of the subglottis were measured on each intact animal using ultrasound followed by a video-bronchoscopic technique. These measurements were compared with the corresponding direct caliper results once the subglottis was surgically exposed.

Statistical analyses revealed clinically significant convergent values between both indirect (ultrasound and video-bronchoscopic) and direct (caliper) measurements. The study results clearly demonstrate that B-mode ultrasound and this new video-bronchoscopic technique are both precise measuring modalities for the subglottic lumen diameter.
ABRÉGÉ

La mesure objective de la région sous-glottique demeure un problème depuis plusieurs années. À ce jour, aucun système proposé pour cette mesure n’a été adopté universellement. L’objectif de cette étude était d’évaluer, pour la première fois, l’ultrason à mode-B et une nouvelle technique vidéo-bronchoscopique pour mesurer le diamètre de la région sous-glottique.

Cette étude prospective à simple insu, portait sur 62 lapins récemment sacrifiés. Différents diamètres prédéterminés de la région sous-glottique, ont été mesurés sur chaque animal, d’abord par ultrason puis par une technique vidéo-bronchoscopique. Ces mesures ont été comparées aux résultats correspondants obtenus à l’aide d’un compas de précision lorsque la lumière sous-glottique a été exposée chirurgicalement.

L’analyse statistique des résultats a révélée des valeurs convergentes, cliniquement significatives, entre les mesures obtenues par les méthodes indirectes (ultrason et vidéo-bronchoscopie) et celles obtenues par le compas de précision. Ces résultats démontrent clairement que l’ultrason à mode-B et cette nouvelle technique vidéo-bronchoscopique sont deux méthodes précises pour mesurer le diamètre de la région sous-glottique.
PREFACE

This thesis represents original work generated by the author during the fourth year of Residency Training in the Department of Otolaryngology, Head and Neck Surgery at McGill University, Montreal, Quebec, 1998-1999. The study described in this thesis document was performed at the Montreal Children's Hospital, under the supervision of Dr. J.J. Manoukian, pediatric otolaryngologist, Associate Professor, Department of Otolaryngology, McGill University. The clinical use of B-mode ultrasound and of a video-bronchoscopic technique in the measurement of the subglottic lumen diameter is an original idea of Dr. J.J. Manoukian. The experimental protocols to validate both of these instruments have been conceived and developed by both myself and Dr. Manoukian. Dr. Yves Patenaude, specialized in pediatric ultrasonography, Assistant Professor, Department of Radiology, McGill University, assisted in the definition of the ultrasound research protocol and performed all of the B-mode ultrasound measurements. Dr. Robert Platt, Associate Professor, Department of Biostatistics, McGill University, has assisted in data analysis. The animal specimens were obtained through the efforts of Mr. N. Battaglino. Technical assistance in caliper and video-bronchoscopic measurements was performed by Maria Battaglino. Editorial help was provided by Maria Battaglino as well as Dr. Zubin Panthaki. This project was supported financially by the Otolaryngology, Head and Neck Surgery Research Fund, McGill University. The work contained herein has been recognized with the First Prize – Clinical Science Research at the Annual Montreal Children's Research Institute Competition (May 12, 1999) and First Prize – Basic
Science Research at the *Annual James D. Baxter / McGill University Department of Otolaryngology Resident Research Competition* (June 3, 1999). In addition, this project was selected to be presented in the Poliquin Xomed Resident Research Competition of the *Canadian Society of Otolaryngology – Head & Neck Surgery 53rd Annual Meeting* held in Halifax, Nova Scotia (June 20-23, 1999) and in the Resident Research Competition of the *Association d'Oto-rhino-laryngologie et de Chirurgie Cervico-Faciale du Québec*, to be hosted at the Hotel Omni, Montreal, Quebec (November 5-7, 1999).
ACKNOWLEDGEMENTS

This research project would not have been possible without Dr. J. J. Manoukian's innovative ideas. I feel fortunate that he saw in me the potential to develop and pursue this area of investigative interest.

Dr. Yves Patenaude has been an invaluable collaborator in the realization of this study. His expertise in pediatric ultrasound imaging has been a powerful resource which I relied upon. Furthermore, he has been a pleasure to work with.

I am grateful to Dr. B. Segal for his constructive criticism and useful feedback during this research project.

Maria Battaglino has been a constant source of support throughout this year. Her refreshing presence and optimistic attitude has made this undertaking enjoyable.

My dear friend, Dr. Zubin Panthaki, has been extremely helpful and encouraging in the preparation of all my presentations related to this project as well as in the realization of this thesis document.

Finally, and most importantly, I am indebted to my family for their constant support and guidance throughout my life endeavors.
#TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSTRACT</td>
<td>i</td>
</tr>
<tr>
<td>ABRÉGÉ</td>
<td>ii</td>
</tr>
<tr>
<td>PREFACE</td>
<td>iii</td>
</tr>
<tr>
<td>ACKNOWLEDGEMENTS</td>
<td>v</td>
</tr>
<tr>
<td>TABLE OF CONTENTS</td>
<td>vi</td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td>1</td>
</tr>
<tr>
<td>BACKGROUND</td>
<td>3</td>
</tr>
<tr>
<td>Pediatric Subglottis</td>
<td>4</td>
</tr>
<tr>
<td>Pediatric Upper Airway Obstruction</td>
<td>5</td>
</tr>
<tr>
<td>Previous and Current Methods of Subglottic Diameter Measurement</td>
<td>7</td>
</tr>
<tr>
<td>Ultrasonography</td>
<td>12</td>
</tr>
<tr>
<td>1. B-mode ultrasound</td>
<td>13</td>
</tr>
<tr>
<td>2. Use of ultrasonography for the upper airway</td>
<td>15</td>
</tr>
<tr>
<td>3. Acoustic shadow</td>
<td>17</td>
</tr>
<tr>
<td>PURPOSE</td>
<td>18</td>
</tr>
<tr>
<td>HYPOTHESES</td>
<td>19</td>
</tr>
<tr>
<td>MATERIALS AND METHODS</td>
<td>20</td>
</tr>
<tr>
<td>STATISTICAL ANALYSIS AND RESULTS</td>
<td>37</td>
</tr>
<tr>
<td>DISCUSSION</td>
<td>52</td>
</tr>
<tr>
<td>CONCLUSION</td>
<td>55</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>56</td>
</tr>
</tbody>
</table>
INTRODUCTION

Upper airway obstruction in infants and children is a common and distressing problem. The most common cause of subglottic obstruction in childhood is viral croup followed by subglottic lesions such as congenital or acquired subglottic stenosis or subglottic hemangiomas.

The subglottis is the narrowest region of the airway making it the most vulnerable site for obstruction in the inherently small pediatric airway. It is thus imperative to be able to measure the subglottic diameter in this age group. An objective way of measuring this region could help physicians in recognising and describing the severity of the narrowed lumen. This would also improve and standardise the current disparate ways of reporting results among clinicians and different institutions.

In cases of subglottic stenosis, knowledge of the subglottic diameter would be of great value in classifying the lesion, thus aiding in management decisions and meaningful comparisons of results with other therapeutic modalities. In the treatment process of severe croup and subglottic lesions, a precise and accurate measurement of the remaining airway could provide important information in the assessment of response to therapy and degree of regression of the lesions.

Many methods of measuring the subglottic region have been proposed over the years including radiography, computed tomography (CT), magnetic resonance imaging (MRI) and most recently, cine-CT. These imaging modalities all have disadvantages and limitations in assessing the airway size of the pediatric patient.
Rigid bronchoscopy, performed in the operating room under general anaesthesia, remains the gold standard and the most effective method for evaluating the relative dimensions of the subglottic airway\(^{2,10,11}\). Since interpretation of airway size is imprecise, subjective and often inaccurate\(^9\), several systems have been suggested for measuring the subglottic area at the time of rigid bronchoscopy\(^2,12,13,14,15\). However, none have proven to be universally applicable and useful nor has the accuracy of their measurement been determined.

Diagnostic ultrasonic instruments have been available in the medical field for the past four decades. The use of currently available ultrasound transducers could provide the physician with the measurement of the subglottic region in a non-invasive, rapid, painless, safe, atraumatic, inexpensive and dynamic fashion.

In cases where rigid bronchoscopy is indicated, the use of a video-bronchoscopic measuring technique could determine the subglottic diameter in an accurate and rapid way.

This study represents the **first attempt to evaluate the capability of B-mode ultrasound and a new video-bronchoscopic technique in measuring the subglottic diameter.**
BACKGROUND

Pediatric Subglottis

Pediatric Upper Airway Obstruction

Previous and Current Methods of Subglottic Diameter Measurement

Ultrasonography
THE PEDIATRIC SUBGLOTTIS

The upper airway is defined by the otolaryngologist as the airway above the lung parenchyma. The lower part of the laryngeal cavity or subglottic space extends from the level of the vocal folds to the lower border of the cricoid cartilage. Its upper part is elliptical in form, but its lower part widens and becomes circular in shape and continuous with the cavity of the trachea. It is lined with mucous membrane, and its walls consist of cricothyroid ligament above and the inner surface of the cricoid cartilage below. In this study, the subglottic lumen is defined as the air-filled area at the lower border of the cricoid cartilage.

Several important anatomic differences exist between the infant and adult airway. One of these is the infantile larynx, which, unlike adults', is funnel-shaped with the narrowest region at the subglottic lumen, a difference that lasts up through eight years of age. The subglottic region is formed by the relatively unyielding cricoid cartilage. The mucosal lining is loosely attached to pliant, non-fibrous submucosa. Therefore, mild changes in this area can result in critical narrowing of the airway. Normally, the full-term neonate has a subglottic diameter of 4.5 to 5.5 mm. In premature babies, it is approximately 3.5 mm. A subglottic lumen diameter is said to be narrowed when it measures less than 4 mm in a full-term neonate or less than 3.0 mm in a premature infant. Hence, even a small amount of mucosal edema in these narrow airways can lead to significant obstruction. In a newborn, 1 mm of edema can reduce the area to 40%-50% of normal, whereas edema must be approximately 3 mm thick in the adult to produce the same effect.
Viral croup, congenital or acquired subglottic stenosis and subglottic hemangiomas are the most common causes of subglottic obstruction in childhood. Croup is viral in origin and seasonal in nature. It afflicts most commonly children between the ages of 6 months and 2 years. Diagnosis is usually clinical and confirmed by radiographic croup series. In the early stages of the medical treatment process of severe croup, a precise and accurate measurement of the residual airway could yield information as to the response to therapy when clinical improvement may not yet be readily apparent. These patients, as well as those who present with recurrent, prolonged or atypical croup, need to be further investigated to rule out underlying subglottic pathology. Hence, the additional importance of measuring the diameter of this region once the infectious process has resolved.

Subglottic stenosis may be congenital or acquired. Most commonly, the stenosis is circumferential and symmetric, with the smallest diameter located 2 to 3 mm below the vocal cords. The exact incidence rate is unknown because the diagnostic criteria of subglottic stenosis are not uniform. There is a lack of common understanding and universal agreement in the assessment of the severity of subglottic stenosis. The diameter measurement of the subglottic airway would help in the classification of these lesions. In turn, this would allow for meaningful comparisons of management decisions and treatment results with other therapeutic modalities.
Subglottic hemangiomas generally develop within the first two months of life. They have an initial rapid growth phase which subsides by one year of age, causing intermittent airway obstruction and very often, acute respiratory distress. Treatment of this lesion must be tailored to the degree of airway obstruction it has caused. Knowledge of the remaining subglottic airway diameter is also important in the follow-up of the patient's treatment process. It would allow for precise assessment of lesion regression as well as aid in the tapering of oral steroids when medical therapy is the chosen therapeutic modality.

Many authors have recognised the importance of measuring the subglottic diameter. Physicians need an objective method of making this measurement to be able to evaluate and precisely describe the severity of a narrowed lumen. A standardised way of reporting subglottic lumen compromise is necessary to facilitate communication of results between clinicians and institutions.
PREVIOUS AND CURRENT METHODS OF SUBGLOTTIC DIAMETER MEASUREMENT

Many publications have articulated the difficulties with current diagnostic techniques of predicting the subglottic lumen diameter. Although several imaging modalities have been suggested to make this important measurement, they all have disadvantages and limitations in the pediatric patient.

Traditionally, initial assessment of subglottic airway obstruction in infants and children is done by radiographic croup series. The natural contrast of air against soft tissues allows for easy recognition of important structures in the airway. The AP, (antero-posterior), view of the upper airway is often useful in revealing a unilateral process causing deviation of the airway or impression on the airway as seen with a subglottic hemangioma. This view can also demonstrate a circumferential narrowing of the airway as seen in subglottic stenosis or croup. Radiography has been employed to measure the length of a region of subglottic narrowing and the diameter of the trachea in children.

A major problem in radiographic evaluation of the pediatric patient has been the small size of the airway. If magnification is used to try to compensate for this small size, there can be potential errors caused in the measurement of the airway diameter. Another drawback of radiography is the hazy soft-tissue contrast with the air created by the subglottic edema in cases of croup. Occasionally, subglottic stenosis may have a similar appearance. Since there is a lack of a sharp delimitation of the subglottic region, diameter measurements of this area are not accurate. Radiation exposure is another disadvantage of plain radiographs. Very often, poor
film quality and movement of the patient results in unnecessary repeated exams, thus further radiation exposure.

Computed tomographic (CT) and magnetic resonance (MR) imaging have gained increasing importance in the assessment of the airway. There are multiple indications for CT or MR imaging including evaluation of masses intrinsic or extrinsic to the airway, vascular airway compression and congenital airway anomalies. Both imaging modalities can provide excellent detail of the airway and can assess the size, location and extent of airway lesions with precision. It has been suggested that CT may be adequate for the assessment of subglottic narrowing. It may be useful in determining the length of a stenotic segment and the diameter of the trachea.

CT and MR imaging have several disadvantages. Sedation is contraindicated in children with a compromised airway and is unfortunately frequently needed for both CT and MR imaging. Children below the age of 5 years usually require sedation for CT studies. Because the MR examination is longer, children under 8 years of age require sedation. Furthermore, pulse oximetry and vital signs need to be closely monitored during and after the examination. Moreover, these imaging methods are non-dynamic studies, therefore, when measuring the subglottic diameter, errors can be made since the latter varies with the respiratory cycle.

Cine-CT has already been used in the radiological assessment of upper airway lesions and can provide tracheal diameter measurements which are highly reproducible. This new imaging modality has a number of inherent advantages. Images are obtained non-invasively and without the need for sedation. The images
are obtained very rapidly with less than 3 seconds of actual scan time. However, the
total time the child will spend in the scanning room will approach 20 minutes.

Cine-CT is not yet widely available. Furthermore, as with any type of CT
scanning, the patient is exposed to radiation.

CT, MR imaging and Cine-CT are expensive, require qualified technicians
and have time constraints. They also are performed with the patient lying in the
supine position which is not always favourable in children with upper airway
compromise.

The Gold Standard and most effective method for evaluating the relative
dimensions and conditions of the subglottic airway is rigid bronchoscopy. Several systems have been suggested for measuring the subglottic area diameter at
the time of rigid bronchoscopy, since subjective interpretation of airway size is often
inaccurate and imprecise.

Gabriel Tucker in 1932 developed an instrument for making endoscopic
measurements of the infants' larynx and subglottis, emphasizing the need for an
effective tool to make this important measurement. The device is a modified
laryngeal forceps with a millimeter scale that relates forceps opening to a
measurement on the scale. Unfortunately, these types of forceps are not useful in
small, severely narrowed airways, nor are they widely available.

Hebra et al, in 1991, advocated an innovative approach to determine the
diameter of an airway stricture using balloon-tipped angioplasty catheters during
standard bronchoscopy. However, complete obstruction of the airway is caused by
the inflated balloon during the diameter measurements which is a concern in patients without a pre-operative tracheotomy. Furthermore, experience with this method was not discussed.

The most commonly used grading system for laryngo-tracheal stenosis is by Cotton in 1984, with its modifications by Cotton et al in 1989. The percentage of obstruction is determined by bronchoscopy and grades I to IV are attributed based on the perceived percentage of obstruction and its anatomic location. The intent of this classification was not to estimate the diameter of the subglottic lumen, but to provide a simple four-category system of grouping patients to facilitate analysis and discussion of their cases.

Myer III et al, in 1994, proposed another system of airway stenosis classification in which endotracheal tubes were used to determine the size of an obstructed airway. The size of endotracheal tube, that passes through the stenosis and gives an audible leak pressure between 10 and 25 cm H₂O, is compared to the expected size for the patient’s age. The percentage of obstruction is determined from this comparison. The stenoses are then classified into four grades. As stated by the authors of this proposed system, “the precision and resolution between the smallest endotracheal tube sizes is inadequate for the accurate description of subtle changes in the dimensions of small airways”. Furthermore, manipulation of the various endotracheal tubes, as well as multiple intubation attempts, may lead to laryngotracheal trauma or inflammation, further worsening the already compromised airway. Finally, although their method assesses the percentage of obstruction, diameter of the subglottic region was not addressed in their study.
Despite the number of predictive studies published on the assessment of the subglottic lumen dimensions, no proposed system to measure the subglottic diameter has been adopted universally.
ULTRASONOGRAPHY

B-mode ultrasound

Use of ultrasonography for the upper airway

Acoustic shadow
B-MODE ULTRASOUND

For the past three decades, ultrasound’s unique imaging characteristics have made it an important and versatile medical imaging tool. The flexibility and safety associated with its use has made this imaging modality very appealing.

Ultrasound, as applied to diagnostic instrumentation, is defined as high-frequency sound waves, inaudible to humans, over 20KHz\(^20,21,\)\(^22\). The most useful frequencies for medical ultrasonic imaging lie in the 1 to 10 MHz range\(^23\), allowing good resolution by the short wave length and good penetration by the limited frequency\(^24\). The acoustic waves are transmitted by hand-held transducers placed on the surface of the tissue to be scanned.

B-mode ultrasound accomplishes anatomic imaging with a pulse-echo technique, where pulses of ultrasound are generated by a transducer and transmitted into the patient. Reflections (echoes) produced at tissue boundaries are returned to the transducer, where they are detected and presented on a two-dimensional image display\(^25\).

B-mode real-time ultrasound allows assessment of both anatomy and motion\(^26\) (FIGURE 1). It has an image freeze-frame feature which is of great value in the measurement procedure as it permits any image to be instantly held stationary\(^27\). Linear dimensions are commonly measured from ultrasonic images. Measurements are accomplished by superimposing electronic caliper markers onto the dimensions of interest in the image displayed. The distance is presented in millimeters of tissue.
Figure 1. B-mode ultrasound real-time device. Model Acuson, Aspen.

(Serial No. 30156)
USE OF ULTRASONOGRAPHY FOR THE UPPER AIRWAY

In the early 1970s, a few investigators approached the possibility of using ultrasound in the clinical laryngeal examination. However, due to the crude technology available at that time, their work was limited. In the past, only tracing or ultrasonic glottograms of the vibratory patterns of the vocal cords were available, whereas today, computerized ultrasonography allows us to image the actual anatomic structures. Despite major technological advances, ultrasound of the larynx was not pursued because it was believed that the air in the larynx would reflect most of the ultrasonic beam, hence not allowing reliable ultrasound transmission.

In 1987, Raghavendra et al. reported the incidental identification of the larynx while performing ultrasound of the thyroid gland. Subsequently, they described the normal sonographic anatomy of the larynx with particular reference to the vocal cords in 41 healthy adult subjects.

It is only in the past decade that ultrasound has been used to image the larynx of children. Garel et al. studied normal sonographic anatomy of all the laryngeal structures as well as the subglottis. They found that ultrasound was very useful for evaluating functional disorders and space occupying lesions of the larynx in infants and children. It is said to be an easy and reproducible, non-invasive imaging technique that also allows dynamic visualization of the larynx. In imaging the subglottic area, the cricoid cartilage is an excellent reference point since it appears as a round hypoechoic structure. However, Garel et al. state that the subglottic air creates an acoustic shadow (hyperechoic) that prevents seeing the posterior aspect of the cricoid, so that the antero-posterior subglottic diameter cannot
be well appreciated\textsuperscript{10}. In their study, no measurements were assessed.

It is this acoustic shadowing that occurs with air that provided the impetus for the first part of our study.
ACOUSTIC SHADOW

Ultrasound scanners rely on the detection of echoes. To produce the latter, a reflective interface must be present. Acoustic interfaces are present at the junction of materials with different physical properties. When ultrasound passes from one medium to another, a certain amount of the incident sound energy is reflected. The difference in the acoustic impedances of the materials or tissues forming the interface determines the quantity of reflection or backscatter. Interfaces of tissue with air have large acoustic impedance differences therefore reflect almost all the incident energy.

Acoustic shadowing occurs distal to any highly reflective or attenuating surface. The interface between tissue and air acts much like a highly reflective object, creating a large shadow that obscures distal structures. Because it is generating many echoes, it is depicted as white and it is referred to as hyperechoic. When total acoustic shadowing occurs, the margins of the shadow are easily visible.

It is the central postulate of the first step in this work that B-mode ultrasound can determine the diameter of the subglottic lumen by the acoustic shadow created by the air in the latter (FIGURE 4). The measurement of the acoustic shadow width is presumed to be equivalent to the true diameter of the subglottis being scanned.
PURPOSE

The lack of an accurate and universally adopted measuring system for the prediction of the subglottic lumen diameter provided the impetus for this investigation.

The purpose of this study is to objectively test, evaluate and validate the precision of B-mode ultrasonic measurements as well as videobronchoscopic measurements for the assessment of subglottic diameter in an animal model.

Diagnostic tools that have the ability to perform this task could provide physicians and the specialized otorhinolaryngologists with invaluable instruments in recognizing and describing the severity of a narrowed subglottic lumen, which, in turn, will aid in management decisions.
HYPOTHESES

Based on the literature reviewed, there is currently no universally adopted tool available to measure, with precision, the subglottic lumen diameter.

The following hypotheses were formulated accordingly:

1. It is possible to estimate the subglottic lumen diameter, with a high degree of precision, using a B-mode ultrasound probe.

2. It is possible to estimate the subglottic lumen diameter, with a high degree of precision, using a video-bronchoscopic technique.

To verify these hypotheses, a three-step experiment was devised. The first step consisted of measuring the subglottic diameters by B-mode ultrasound in the rabbit animal model. The second step consisted of measuring the subglottic diameters by a video-bronchoscopic technique in the same animals. The third and final step consisted of measuring the corresponding diameters (previously measured in steps 1 and 2) directly on the surgically exposed subglottic lumens using calipers as a gold standard.
MATERIALS AND METHODS

This blind prospective animal study was carried out at the Montreal Children's Hospital, McGill University.

The study group consisted of 62 recently sacrificed rabbits. All animal airways were free of disease and lesions, with no evidence of laryngo-tracheal trauma or injury. The rabbits were skinned prior to the start of the study to allow for a smooth neck surface, similar to that of the human's, (FIGURE 2).

Figure 2. The rabbit animal model.

The research was conducted over multiple sessions, studying approximately 10 rabbits per session. Each animal underwent three consecutive steps within a maximum time of two hours. Between each step, the rabbits were stored in a cool and humid area.
STEP I: Ultrasound Measurements

With the rabbit lying in the supine position and with a transducer placed perpendicular to the neck, a transverse ultrasound scan was performed (FIGURE 3). The vocal cords were initially identified followed by the lower edge of the hypoechogenic cricoid cartilage.

Figure 3. Ultrasound transducer placed perpendicular to the animal’s neck.
At this level, the air-tissue interface in the subglottis creates a large shadow (Figure 4). The margins of the latter are easily visible and were used in our study to determine the diameter of the lumen. All measurements were made by superimposing electronic calipers at the extreme edges of the acoustic shadow created by the air column located in the subglottic area. The distance was presented in millimeters of tissue.

Figure 4. Acoustic shadow created by the subglottic air column.

White arrows indicate the visible, extreme margins of the shadow where the electronic calipers were placed.
At the level of the lower edge of the cricoid cartilage, three separate measurements were taken.

1) With the probe placed in the midline of the anterior neck, (FIGURE 5), an image of the subglottic air-column was captured on the 2-dimensional screen. A right and left point was selected by the ultrasonographer at the extreme edges of the hyperechoic shadow. The distance between these two points represented the “left to right” (LR) diameter of the subglottic lumen.

**Figure 5.** Ultrasound transducer placed perpendicular and in the midline of the animal’s neck to obtain the LR (left to right) diameter.
2) With the probe placed on the right side of the neck at an angle of 45° from the vertical longitudinal midline, (FIGURE 6), a second image of the subglottic air column was captured on the screen. Two points were selected at the extreme edges of the hyperechoic shadow. The distance between these two points represented the “right oblique” (RO) diameter of the subglottic lumen.

Figure 6. Ultrasound transducer placed on the right side of the animal's neck at a 45 degree angle to obtain the RO (right oblique) diameter.
3) With the probe placed on the left side of the neck at an angle of 45° from the vertical longitudinal midline, (FIGURE 7), a third image of the subglottic air column was captured on the screen. Once more, two points were selected at the extreme edges of the hyperechoic shadow. The distance between these two points represented the "left oblique" (LO) diameter of the subglottic lumen.

Figure 7. Ultrasound transducer placed on the left side of the animal's neck at a 45 degree angle to obtain the LO (left oblique) diameter.

The ultrasonic measurements were carried out with a linear 7.0 transducer at 10 megaHertz strength and B-mode real time device (model Acuson, Aspen, Serial No. 30156), (FIGURE 1). The resolution was 0.1 mm.

All ultrasound scans were performed by the same pediatric ultrasonographer.
**STEP II: Video-Bronchoscopic Measurements**

Rigid video-bronchoscopy was performed on every rabbit using a 3.5 mm inner diameter (ID) by 20 cm pediatric bronchoscope with a 0 degree telescope (FIGURE 8). The telescope was connected to a Sony Trinitron Color Video-monitor via the Olympus MH-99E video camera. Pictures of interest of the subglottic lumen were captured and printed with a Sony Color Video Printer (FIGURE 9).

**Figure 8.** Video-bronchoscopic set-up.
1. Pediatric bronchoscope (3.5 mm x 20 cm)
2. Video camera
3. Light source
4. Suction catheter in bronchoscope side port
5. 20 cm, 0 degree telescope
Figure 9. Video-bronchoscopic set-up.
1. video monitor
2. video printer
Calibration of the video-bronchoscopic instrument

A small suction catheter was introduced in the side port of the bronchoscope containing the telescope. This catheter was advanced passed the distal end of the bronchoscope until, when applied perpendicular and touching a ruler, at least 6.5 mm could be visualized in the circular visual field of the telescope on the video monitor, (FIGURE 10). At that time, the proximal point of entry of the suction catheter in the side port was marked and a picture of the ruler captured on the video monitor was printed. This print out image served as a scale for the following measurements, (FIGURE 11). The suction was then pulled back into the bronchoscope. The video camera used for this procedure was constantly kept at its lowest magnification.

Figure 10. Calibration of video-bronchoscopic measuring instrument. Ruler visualized on the video-monitor
Figure 11. Printed picture of the ruler to serve as a measuring scale.
Arrow indicates suction catheter tip.
Procedure

All the animal heads were removed by transecting the neck immediately above the tip of the epiglottis to allow easier introduction of the rigid bronchoscope. The larynx and trachea were suctioned delicately. Bronchoscopy was then performed, (FIGURE 12), and the subglottic area was identified using the "ledge" formed by the lower edge of the cricoid cartilage as a reference point. The suction catheter was then advanced in the side port to the previously marked point on the proximal end of the suction. The bronchoscope was then advanced or withdrawn to allow the tip of the suction catheter to contact the subglottic "ledge", (FIGURE 13). At that time, a second picture was captured and printed, (FIGURE 14). The initial ruler picture was then superimposed onto the subglottic lumen print out to serve as a measuring scale. Four diameter [LR, RO, LO and an antero-posterior diameter (AP)] measurements were determined according to eight selected points on the subglottic lumen picture, (FIGURES 15, 16).

All bronchoscopies were performed by the same physician as well as the point determinations. The measurement increments were of 0.25 mm.
Figure 12. Video-bronchoscopy being performed. The true vocal cords are visualized on the video-monitor.
Figure 13. Video-bronchoscopy being performed. The bronchoscope and side-port suction catheter are advanced to contact the subglottic shelf.
Figure 14. Dark arrows indicate the tip of the suction catheter in contact with the subglottic shelf.

Figure 15. Subglottic lumen with 8 points selected on the subglottic shelf.
Figure 16. Four different diameters of the subglottis to be measured.
   AP – Antero-posterior
   LO – Left oblique
   LR – Left to right
   RO – Right oblique
STEP III: Caliper Measurements

As a gold standard, subglottic lumen diameters of each rabbit were measured using calipers. A cut was made flush with the lower edge of the cricoid cartilage, thus exposing the subglottic lumen of interest, (FIGURE 17).

Figure 17. Surgically exposed subglottic lumen.
Two different observers took the following four diameter measurements of the subglottic area with the use of calipers: LR, RO, LO, and AP, (FIGURE 18). To ensure the precise nature of these measurements, the tips of the calipers were placed to touch the mucosal lining of the subglottic lumen without distorting the latter. All selected diameters corresponded to the previous ones taken by ultrasound (excluding AP) and video-bronchoscopy. The caliper opening was measured against a metric ruler with a precision of 0.25 mm.

**Figure 18.** Schematic representation of 4 different diameters of the subglottis to be measured.
STATISTICAL ANALYSIS AND RESULTS

In order to give a clear explanation of the results, the study was analysed in two parts.

The first part consisted of assessing the validity of ultrasound measurements. The association between the estimates obtained using the ultrasound and the calipers as well as the difference between the two measurements, were evaluated by student's \( t \) test, Pearson's correlation coefficient and simple linear regression model.

In the second part, the same statistical analysis was carried out for assessing the validity of video-bronchoscopy measurements. Due to a technical difficulty, this measuring modality was not performed on the two first rabbits.

All variables, tests, correlation and regression analyses were calculated for the four different diameters (LR, RO, LO, and AP). For discussion purposes and clarity of the data presentation, the statistical analysis will be focussed on the RO diameter results. However, all diameter results are represented in the following tables and figures.

In both parts, interrater (interobserver) reliability was assessed for the caliper measurements by having the same estimate obtained by two different observers at the same point in time. Interrarer differences, on average, did not exceed the margin of error of the caliper measurement.
Part I: Ultrasound Data Analysis

The difference between the ultrasound diameter measurements and that measured by the calipers was calculated for all 186 observations (62 rabbits and three different diameter measurements for each animal). The RO mean (standard deviation) for the caliper measurements was 5.06 mm (0.47 mm) and that of the ultrasound was 5.12 mm (0.57 mm). The mean difference was 0.06 mm with a 95% CI (-0.01 to 0.14). Student's *t* test showed that this difference was not statistically significant (p=0.08) (Table 1). Variability observed in subglottic lumen diameters of the 62 rabbits by both diagnostic modalities is illustrated in FIGURE 19.

In 65% of the total 186 observations, the ultrasonic measurements overestimated the caliper measurements (Table 1). This suggests that there was a tendency for the ultrasound to produce estimates that were slightly larger than those obtained by calipers. The comparison of caliper versus ultrasonic measurements, rearranged in ascending order of subglottic lumen diameter size, is shown in FIGURES 20, 21, and 22.

Pearson's correlation coefficient supported a strong and positive relationship between the two measurement methods (r=0.86).

Simple linear regression model was also utilized to critically evaluate the association between the measurements obtained by the ultrasound and those obtained by the calipers. This analysis assessed the ultrasonic measurement as a predictor of the caliper measurement. The model revealed that $R^2=0.74$, which indicates a very good fit.
Table 1: Comparison of caliper (direct) measurements vs. ultrasonic (indirect) measurements.

<table>
<thead>
<tr>
<th>Variable</th>
<th>LR</th>
<th>RO</th>
<th>LO</th>
<th>AP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>Cal.</td>
<td>4.84</td>
<td>5.06</td>
<td>5.05</td>
</tr>
<tr>
<td></td>
<td>US</td>
<td>5.06</td>
<td>5.12</td>
<td>5.11</td>
</tr>
<tr>
<td>Std. Dev.</td>
<td>Cal.</td>
<td>0.49</td>
<td>0.47</td>
<td>0.47</td>
</tr>
<tr>
<td></td>
<td>US</td>
<td>0.57</td>
<td>0.57</td>
<td>0.61</td>
</tr>
<tr>
<td>Median</td>
<td>Cal.</td>
<td>4.88</td>
<td>5.00</td>
<td>5.00</td>
</tr>
<tr>
<td></td>
<td>US</td>
<td>5.00</td>
<td>5.15</td>
<td>5.00</td>
</tr>
<tr>
<td>Minimum</td>
<td>Cal.</td>
<td>4.00</td>
<td>4.00</td>
<td>4.00</td>
</tr>
<tr>
<td></td>
<td>US</td>
<td>3.90</td>
<td>3.90</td>
<td>3.70</td>
</tr>
<tr>
<td>Maximum</td>
<td>Cal.</td>
<td>6.00</td>
<td>6.00</td>
<td>6.00</td>
</tr>
<tr>
<td></td>
<td>US</td>
<td>6.10</td>
<td>6.20</td>
<td>6.20</td>
</tr>
<tr>
<td>Range</td>
<td>Cal.</td>
<td>2.00</td>
<td>2.00</td>
<td>2.00</td>
</tr>
<tr>
<td></td>
<td>US</td>
<td>2.20</td>
<td>2.30</td>
<td>2.50</td>
</tr>
<tr>
<td>T statistic (US vs Cal)</td>
<td>4.64</td>
<td>1.75</td>
<td>1.41</td>
<td>NA</td>
</tr>
<tr>
<td>P-value</td>
<td></td>
<td>0.00</td>
<td>0.08</td>
<td>0.16</td>
</tr>
<tr>
<td>95% CI for diff.</td>
<td>0.12, 0.30</td>
<td>-0.01, 0.14</td>
<td>-0.02, 0.14</td>
<td>NA</td>
</tr>
<tr>
<td>Correlation (US vs Cal)</td>
<td>0.78*</td>
<td>0.86*</td>
<td>0.85*</td>
<td>NA</td>
</tr>
<tr>
<td>R-Squared</td>
<td></td>
<td>0.61</td>
<td>0.74</td>
<td>0.73</td>
</tr>
<tr>
<td>Max. Error</td>
<td>US</td>
<td>0.075</td>
<td>0.035</td>
<td>0.035</td>
</tr>
<tr>
<td>Percent ≥ Cal.</td>
<td>US</td>
<td>0.76</td>
<td>0.65</td>
<td>0.56</td>
</tr>
</tbody>
</table>

*Significant at p=0.05

Note 1: AP was not done with ultrasound

Note 2: R-squared is from linear regression model.

Note 3: Max Error refers to highest difference in 95% CI divided by the narrowest width by caliper (4.00).

Note 4: Percent ≥ Cal. signifies the percentage of ultrasound measurements that have overestimated the caliper measurements.
Note 1: Width is in mm

Note 2: Mean diameter measurement with range is shown.

C = caliper measurement

US = ultrasound measurement

**Figure 19.** Variability in subglottic lumen diameters of the 62 rabbits.
Figure 20. Comparison of caliper (C3) vs. ultrasonic (US) subglottic left-to-right (LR) diameter measurements, (arranged in ascending order of subglottic size).
Figure 21. Comparison of caliper (C3) vs. ultrasonic (US) subglottic right oblique (RO) diameter measurements, (arranged in ascending order of subglottic size).
Figure 22. Comparison of caliper (C3) vs. ultrasonic (US) subglottic left oblique (LO) diameter measurements, (arranged in ascending order of subglottic size).
Part II: Video-Bronchoscopic Data Analysis.

The difference between the video-bronchoscopic diameter measurement and that measured by the calipers was calculated for all 240 observations (60 rabbits and four different diameter measurements for each animal). The RO mean (standard deviation) for the caliper measurements was 5.06 mm (0.47 mm) and that of the video-bronchoscopy was 4.86 mm (0.40 mm). The mean difference was -0.18 mm with a 95% CI (-0.27 to -0.08).

Student's t test showed that this difference was statistically significant (p< 0.01) (Table 2). However, this difference is clinically insignificant for the maximal difference, with a 95% confidence, is extremely small (-0.27 mm). Variability observed in subglottic lumen diameters of the 60 rabbits by both diagnostic modalities is illustrated in FIGURE 23.

In an equal number of the total 240 observations, the video-bronchoscopic technique overestimated and underestimated the caliper measurements. The comparison of caliper versus video-bronchoscopic measurements, rearranged in ascending order of subglottic lumen diameter size, is shown in FIGURES 24, 25, 26, and 27.

Pearson's correlation coefficient supported a good and positive relationship between the two measurement methods (r=0.70).
Simple linear regression model was also utilized to critically evaluate the association between the measurements obtained by video-bronchoscopy and those obtained by the calipers. This analysis assessed the video-bronchoscopic measurement as a predictor of the caliper measurement. The model revealed that $R^2=0.49$, which indicates a good fit.
Table 2: Comparison of caliper (direct) measurements vs video-bronchoscopic (indirect) measurements.

<table>
<thead>
<tr>
<th>Variable</th>
<th>LR</th>
<th>RO</th>
<th>LO</th>
<th>AP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Cal.</td>
<td>4.84</td>
<td>5.06</td>
<td>5.05</td>
<td>5.20</td>
</tr>
<tr>
<td>Std. Dev. Cal.</td>
<td>0.49</td>
<td>0.47</td>
<td>0.47</td>
<td>0.51</td>
</tr>
<tr>
<td>Median Cal.</td>
<td>4.88</td>
<td>5.00</td>
<td>5.00</td>
<td>5.00</td>
</tr>
<tr>
<td>Minimum Cal.</td>
<td>4.00</td>
<td>4.00</td>
<td>4.00</td>
<td>4.00</td>
</tr>
<tr>
<td>Maximum Cal.</td>
<td>6.00</td>
<td>6.00</td>
<td>6.00</td>
<td>6.25</td>
</tr>
<tr>
<td>Range Cal.</td>
<td>2.00</td>
<td>2.00</td>
<td>2.00</td>
<td>2.25</td>
</tr>
<tr>
<td>T statistic (VB vs Cal)</td>
<td>0.78</td>
<td>-4.01</td>
<td>-3.75</td>
<td>-5.09</td>
</tr>
<tr>
<td>P-value</td>
<td>0.44</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>95% CI for diff.</td>
<td>-0.12, 0.05</td>
<td>-0.27, -0.08</td>
<td>-0.27, -0.07</td>
<td>-0.37, -0.16</td>
</tr>
<tr>
<td>Correlation (VB vs Cal)</td>
<td>0.71*</td>
<td>0.70*</td>
<td>0.69*</td>
<td>0.66*</td>
</tr>
<tr>
<td>R-Squared</td>
<td>0.51</td>
<td>0.49</td>
<td>0.48</td>
<td>0.44</td>
</tr>
<tr>
<td>Max. Error VB</td>
<td>0.03</td>
<td>0.068</td>
<td>0.068</td>
<td>0.093</td>
</tr>
<tr>
<td>Percent ≥ Cal: VB</td>
<td>0.58</td>
<td>0.49</td>
<td>0.49</td>
<td>0.42</td>
</tr>
</tbody>
</table>

*Significant at p=0.05

Note 1: R-Squared is from linear regression model

Note 2: Max Error refers to highest difference in 95% CI divided by the narrowest width by caliper (4.00).

Note 3: Percent ≥ Cal. signifies the percentage of video-bronchoscopic measurements that have overestimated the caliper measurements.
Note 1: width is in mm

Note 2: Mean diameter measurement with range is shown.

C = caliper measurement

VB = video-bronchoscopy measurement

**Figure 23.** Variability in subglottic lumen diameters of the 60 rabbits.
Figure 24. Comparison of caliper (C3) vs. video-bronchoscopic (VB) subglottic antero-posterior (AP) diameter measurements. (arranged in ascending order of subglottic size).
Figure 25. Comparison of caliper (C3) vs. video-bronchoscopic (VB) subglottic left-to-right (LR) diameter measurements, (arranged in ascending order of subglottic size).
Figure 26. Comparison of caliper (C3) vs. video-bronchoscopic (VB) subglottic right oblique (RO) diameter measurements, (arranged in ascending order of subglottic size).
Figure 27. Comparison of caliper (C3) vs. video-bronchoscopic (VB) subglottic left oblique (LO) diameter measurements, (arranged in ascending order of subglottic size).
DISCUSSION

Measurement of the subglottic lumen diameter using B-mode ultrasound based on the acoustic shadow has been shown, by this study, to be a very precise method of assessing the actual subglottic size. With 95% confidence, the maximum discordance between the direct (caliper) measurement and indirect (ultrasonic) measurement was less than a 7.5% difference (0.30 mm) (Table 1).

In our study, all direct measurements were taken with the use of manually adjusted calipers and a metric ruler. Human error was therefore introduced which could have been diminished by the use of digital calipers. The precision of the ultrasound electronic calipers is of a small fraction of a millimeter. However, ultrasound is clearly user-dependant thus, potential sources of error include imprecise selection of points to determine the diameter of the lumen as well as inaccurate placement of the ultrasonic transducer at a 45° angle on the neck (for the subglottic lumen is not always a perfect cylinder).

In 65% of all observations, the ultrasonic diameter measure overestimated the actual subglottic lumen diameter. The reasons for this bias are unclear, however, as previously stated, the ultrasonic values did not overestimate the caliper measurements by more than 0.30 mm (with a 95% confidence). This small value could not pose any clinical problem.

In this study, the rabbit model was selected due to its strikingly similar laryngeal anatomy to that of human's. Furthermore, the size of these animals' subglottis is comparable to that of a neonate.

Our results on these sacrificed animals were very good and demonstrated the
validity of ultrasound in measuring the subglottic lumen diameter. Nevertheless, further studies need to be performed on live animals or human subjects to verify the feasibility of this method in dynamic conditions.

The use of ultrasound in the measurement of the subglottic lumen diameter has several advantages. It is a non-invasive, atraumatic, inexpensive, portable, rapid and painless imaging modality to assess such a clinically important measurement. This modality avoids radiation exposure and alleviates the need for a general anaesthetic. Ultrasound could prove to be an invaluable dynamic measuring method, allowing for maximal and minimal airway diameter measurements according to the respiratory cycle. It may prove to be a good clinical follow-up tool for children with stable subglottic stenosis or in the treatment process of subglottic pathology. Finally, when rigid bronchoscopy is absolutely indicated, ultrasound may be used preoperatively or intra-operatively to precisely measure the subglottic diameter. This would be of particular importance when stenosis is due to a normal shaped but small sized cricoid. These congenital anomalies may be missed unless accurate measurements are made.

In the second part of our study, we demonstrated that a video-bronchoscopic measuring technique is also a precise method of estimating the actual subglottic diameter. With 95% confidence, the maximum discordance between the direct (caliper) measurement and indirect (video-bronchoscopy) measurement was less than a 9.3% difference (0.37 mm) (Table 2).

Student's t test demonstrated statistically significant (p<0.01) differences between caliper measurements and video-bronchoscopic measurements for three of
all four diameters. However, these differences are clinically insignificant for, with 95% confidence, the maximal difference for all diameter measurements is extremely small (0.37 mm). Furthermore, these differences could be partly attributable to the manually performed caliper measurements.

An obvious criticism of this proposed method of measuring the subglottic lumen is that of its subjectivity in the selection of points on the printed picture of the subglottis that subsequently determine the diameters to be measured.

Thus far, we have only studied this measuring technique on sacrificed rabbits. Hence, further research needs to be conducted on human subjects in order to further standardize its use. When rigid bronchoscopy is clinically indicated, this new method of measuring the subglottic lumen diameter may allow the otolaryngologist to make this important measurement in a rapid, atraumatic fashion. Subtle changes in lumen diameter could be detected with such a precise measuring modality.
CONCLUSION

The objective measurement of the subglottic lumen has been a problem for many years. To date, no proposed system for this measurement has been adopted universally. Neither ultrasound technology nor video-bronchoscopy have ever been used to assess the diameter of the subglottic lumen. This study represents the first attempt to document the validity of ultrasonic and video-bronchoscopic measurements for this purpose.

Our results have shown that both methods can provide measurements in a precise manner. We foresee that these objective ways of assessing the subglottic diameter will help physicians recognize and describe the severity of a narrowed lumen as well as report results in a standardized fashion.
REFERENCES


