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PAEDIATRIC TRACHEOSTOMIES IN JOHANNESBURG:

A TEN YEAR REVIEW.

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Otorhinolaryngology (MMC022)

July 2012

Declaration by Student

I, Christopher Jacobs declare that this dissertation is my own work. It is being submitted for the degree of Master of Medicine (Otorhnolaryngology), in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.



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Decleration by supervisors

This dissertation is submitted for examination with my approval as University Supervisor/ Co-supervisor



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17 day of July , 2012.

Dedication

This dissertation is dedicated to

My wife,

Andrea Jacobs,

For all her love, support, and

encouragement throughout the

preparation of this study.

ABSTRACT

Introduction

A tracheostomy in the paediatric age group is a created clinical situation that demands highly specialized care.

Whilst the procedure itself may be performed as a lifesaving measure, the high level of care required to maintain this artificial airway is unfortunately associated with a higher morbidity and mortality than in the adult tracheostomy patient.

The successful management of these young patients with the burden of a tracheostomy airway requires the overcoming of many challenges, particularly those of a resource poor environment.

No standard protocol of care for these patients exists, with care practices and care related complications varying widely between institutions and regions.

Shifts in age and indication demographics have been noted internationally, with infants now comprising the largest age group, and prolonged intubation for ventilation the most common indication.

Aims

The aims of this study were to describe:

- The demographics viz. the age, indications, and outcomes for these patients - in the Johannesburg Public Hospital Sector, thus providing a basis for understanding the patient profile, and
- The particular clinical problems encountered in this local and regional setting.

Materials and Methods

- A retrospective study was conducted, selecting and evaluating data over a 10 year period from 1st January 2001 to 31st December 2010.
- All Patients in the age group less than 18 years of age were identified.
- These patients had undergone the procedure of tracheostomy in any of the four Johannesburg Academic Hospitals viz. Chris Hani Baragwanath Hospital, Charlotte Maxeke Johannesburg Academic Hospital, Helen Joseph Hospital, and Rahima Moosa Mother and Child Hospital.
- These patients were evaluated for age and for indication profiles, and for complications associated with the technical procedure and /or of the care of this artificial airway. Various factors were identified in ascertaining the effect on the final outcome.

Results of Case Identification:

- Complete clinical records were found for 70 patients. The ages ranged from 2 weeks (neonate) to 17 years, with a mean age of 7 years.
- Only 18.5 % of patients were infants (under 1 year of age), with the neonatal age group accounting for just 4% (n= 3) of cases.
- The largest proportion was the 5.1- 10 year age group (30% of cases).

INDICATIONS:

1. The most common indication group for tracheostomy were those with a potentially life threatening upper airway obstruction. These accounted for 67% (n = 47) of the cases.
2. Only 12% (n = 9) of cases were performed for prolonged intubation for positive pressure mechanical ventilation associated with respiratory disease.
3. Central nervous system disease associated with a depressed level of consciousness accounted for 14% (n = 10) of cases.
4. Five percent (n = 4) were indicated for surgical prophylaxis associated with potential upper airway compromise.

Specific indications within these groups showed that the highest numbers of tracheostomies were performed for subglottic stenosis of the laryngeal airway, accounting for 28% of cases, and severe head trauma (i.e. requiring airway protection for depressed level of conciousness), accounting for 12% of cases. Glottic stenosis consequent on repeated surgeries for excision or ablation of recurrent laryngeal papillomata accounted for 7% of cases.

MORBIDITIES:

A total of 65 morbidities were encountered in 41 patients.

- The most commonly encountered complication was tracheostomy tube / cannula obstruction with blood clots and/or thickened, desiccated pulmonary secretions - with 23 episodes accounting for 35% of complications.
- Nosocomial Pneumonia was the second most common complication, accounting for 33% of cases (n=22).
- Other complications included:
  - Operative site bleeding,
  - Accidental early decannulation,
  - Local wound infection,
  - Neck and chest wall surgical emphysema,
  - Exuberant granulation tissue formation, and
  - Cannula breakage with aspiration.

Complication rates in the neonatal and infant subgroups were significantly higher than in other age groups ($p = 0.0296$), with an average complication rate of 1.53 events per patient.

MORTALITY:

- An overall mortality rate of patients with tracheostomies was found to be 27%.
- The mortality rate associated directly with tracheostomy care accounted for 8.5%. Of these cases, 86% were due to cannula airways obstruction ($n = 5$).
- The mean age of the patients that died from acute cannula obstruction was 2.45 years (i.e. the toddlers).

IN-HOSPITAL STAY:

- The duration of in-hospital stay from day of procedure to release from in-hospital based care revealed a mean of 147 days (Range 5 – 1360 days).
- The largest percentage of patients (44%, n = 31) were admitted for a period of less than 1 month, however, prolonged admissions were noted, with 11% of patients (n = 8) admitted for a period of more than 1 year.
- A significant correlation of in-hospital stay was established with age - being inversely proportional to length of stay (r = -0.29); with the infant group having the longest mean duration of in-hospital stay (259 days).
- The overall discharge rate was 60%. Of the discharged patients, 57% were successfully discharged with tracheostomies in place for continued care in the home environment.

CONCLUSIONS

1. This study showed that the Johannesburg academic hospitals have not followed the international shift in age and indication demographics; infants do not constitute the majority of patients in our institutions, and upper airway obstruction, rather than prolonged intubation for ventilation, remains the most common indication for tracheostomy. Of the upper airway obstruction group, subglottic stenosis and laryngeal papillomatosis were the most common causes.
2. This study also showed that mortalities and morbidities occurred at a higher rate than reported in the literature, with an average 2.35 complications per tracheostomy year, compared to 0.12 complications per tracheostomy year of similar studies.[23]

   Cannula obstruction and nosocomial pneumonia were identified as the major complications affecting 32% and 31% of patients respectively, compared to 5- 14% and 1.7- 19.5% respectively reported in other institutions.[1,3,23,25,28] The tracheostomy related mortality rate of 8.5% was far higher than the average 1.47% reported in other institutions.[10]
3. Prolonged admissions were observed as a result of difficulties in instituting home based care.
4. Factors associated with improved outcomes included; age over 1 year, tracheostomy tubes with internal diameters of more than 4.5mm, the presence of inner cannulas in the tubes, shorter duration of admission, and the adjunct to surgery indication group.

CLINICALLY DERIVED RECOMMENDATIONS FROM STUDY:

Interventions aimed at addressing the identified areas may therefore be instituted.

These may include:

- Weekly fibre-optic endoscopy for prolonged intubation ventilated patients, to view time of progressive pressure injury to mucosa; and a lower threshold for tracheostomy in the older child.

- Refining the surgical technique of trainees, i.e. minimizing dissection of trachea and safe cannulation procedures. This includes minimizing mucosal injuries during the debulking procedures of laryngeal papillomata.

- Improving the training programmes of paediatric nursing staff involved in airway care.

- Establishing tracheostomy care units within the paediatric ward facilities.

- Establishing a formal tracheostomy home care program, through social workers, home nursing programmes, in collaboration with local or regional health provider facilities.

- Allocation of a specific budget for the provision of home tracheostomy care e.g. suction equipment - using of mechanically operated pumps; and the usual resuscitation equipment on standby.

- A greater availability of the more resilient, lighter weight and the longer lifespan Stainless Steel paediatric tracheostomy tubes with inner cannulas.

With these practical and pragmatic interventions it seems quite possible and feasible to improve the outcomes of children that require long term tracheostomy in the care of our institutions. These are generally children with good long term prognoses and thus potentially normal individuals in the long term.

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NOMENCLATURE

1. Decannulation – the accidental or deliberate removal of tracheostomy tube airway from the patient's trachea.
2. Infant – A child less than 1 year of age.
3. Neonate – A child less than 28 days of age.
4. Nosocomial pneumonia – pneumonia which was not present at the time of admission to hospital.
5. Pulmonary toilet – the evacuation of secretions (and debris) from the lower airways with a suction cannula.

List of Abbreviations

CNS – Central nervous system

HIV – Human Immunodeficiency Virus

HPV – Human Papilloma Virus

ICU – Intensive Care Unit

IMF – International Monetary Fund

LTB – Laryngotracheobronchitis (Croup)

LRT – Lower respiratory tract

MVA – Motor vehicle accident

PVA – Pedestrian vehicle accident

CHAPTER 1

1. INTRODUCTION

The first recorded tracheostomy on a paediatric patient was performed in 1620 by Mabicot.[1]
It has traditionally been used to bypass acute upper airway diseases and in particular obstructions caused by acute infections.[2,3,4] The procedure is often a life saving measure. There are, however, major difficulties in the paediatric age group, as it is associated with a two to three fold higher morbidity and mortality rate compared to adult patients.[2,3,5] These highly vulnerable young patients require specialized care – requiring the involvement of a multidisciplinary team, labour intensive nursing, and adequate equipment and facilities.[6] Out-patient or home care can be especially challenging.

Typically, optimal resources for care are often only available in first world settings. The public health care sector in South Africa in the main, represents a third world, under resourced and poorly educated environment.[7] This poses even greater challenges to the safe, successful management of these patients, particularly in the home-care setting.

There are no published data – in the last 25 years - on the overall outcomes of these patients in South Africa. During this time significant changes in the indications, age profile, and outcomes have been noted internationally.[3,8,9,10]

Published data has also established that tracheostomy practices vary widely across countries

and even between institutions in countries,[11] with no universally accepted standards of care.[1,12]

The primary aim of this study was thus to gain an understanding of tracheostomy care-related issues in the loco-regional setting. This will further ascertain how South African institutions have followed international trends. This study will also identify the complications encountered and particular challenges faced by our institutions. These findings would form a basis for possible future interventions in improving outcomes for this special group of patients.

CHAPTER 2

2. LITERATURE REVIEW

In this chapter the literature is reviewed, with presentation of important aspects relating to the tracheostomy procedure and after care in paediatric patients. Indications are discussed with historical indications compared to current practice. A shift in the age of patients is presented, and the complications of tracheostomies are discussed. Findings of local and international studies are presented. The chapter ends with discussion of tracheostomy home based care.

2.1 ANATOMICAL AND PHYSIOLOGICAL CONSIDERATIONS

The paediatric airway has several important anatomical differences compared to the adult airway, which places these patients at an increased risk for obstruction. The airway is a tubular structure, and the relevant physical principles governing flow through it are given in Poiseuille's law.[13] According to this law, resistance is inversely proportional to the radius of the tube to the fourth power. This means that small changes in the radius of the lumen result in very large changes in resistance to flow, hence increasing the work of breathing. This is of particular importance when the initial airway is of small diameter. For example as little as 1mm of narrowing in a 4mm diameter airway, will result in 16 fold increase in the airway resistance.[13]

The small tracheostomy tubes required are also at greater risk of obstruction. In order to be placed within the trachea, the outer diameter of a tracheostomy tube must be smaller than the

already narrow airway, and further reduction in the functional inner diameter depends on the thickness of the material used in its construction, and the presence of a removable inner tube. Partial or complete blockage of these small tubes may thus result in life threatening increases in airway resistance.

Other anatomical differences make the surgical aspects of paediatric tracheostomy insertion more challenging. These patients have a relatively short neck with significant amounts of subcutaneous fat. The larynx is also situated high up in the neck. This makes surgical exposure more difficult, and positioning the patient prior to the procedure, with adequate extension, is therefore important. In addition, the paediatric trachea is relatively soft and pliable, and this makes intra operative palpation difficult, and allows lateral displacement with retraction during surgery, with the potential for lung or vascular injury.[2]

Paediatric patients also have limited oxygen reserves, making loss of the airway during or after surgery particularly dangerous.[2]

The above mentioned factors all contribute to increased intra-operative and post-operative complications in the child.



Figure 1: A 4 year old boy with subglottic stenosis following intubation for burn injuries, showing tracheostomy in situ.

(Photograph: Author. Photograph used with patient consent).

2.2 SURGICAL TECHNIQUE

The tracheostomy procedure is performed ideally in the operating theatre, in a controlled, sterile environment.[14] The patient is placed supine, and the neck hyper extended. Important landmarks are identified, including the thyroid cartilage, cricoid cartilage, and sternal notch. A horizontal incision is made through skin and subcutaneous tissue, one third to one half the distance between the sternal notch and the cricoid cartilage. Subcutaneous fat is excised, and the strap muscles are divided in the midline, and retracted laterally. The thyroid isthmus is divided to expose the trachea. Stay sutures are placed in the trachea, which is then incised vertically through the 2nd and 3rd tracheal rings.[2] The tracheostomy tube is then inserted with the use of an obturator, and secured after confirmation of correct position.

2.3 TRACHEOSTOMY TUBES

2.3.1 Construction

Tracheostomy tubes are available in a wide range of materials, sizes, shapes, and variations in design.[15] Material used in their construction can be divided into the plastic group, composed of polyvinyl chloride or silicone, and the metal group, composed of stainless steel or silver[16] (See figures 2 and 3). Plastic tracheostomy tubes are softer, may be cuffed, and have a 15mm connecter port to allow attachment of ventilation tubing or humidification devices. Metal tubes are rigid, do not have cuffs or a connector port, and are also more expensive.[16] They do, however, have certain advantages, allowing for the inclusion of inner cannulas in smaller size tubes (discussed below).

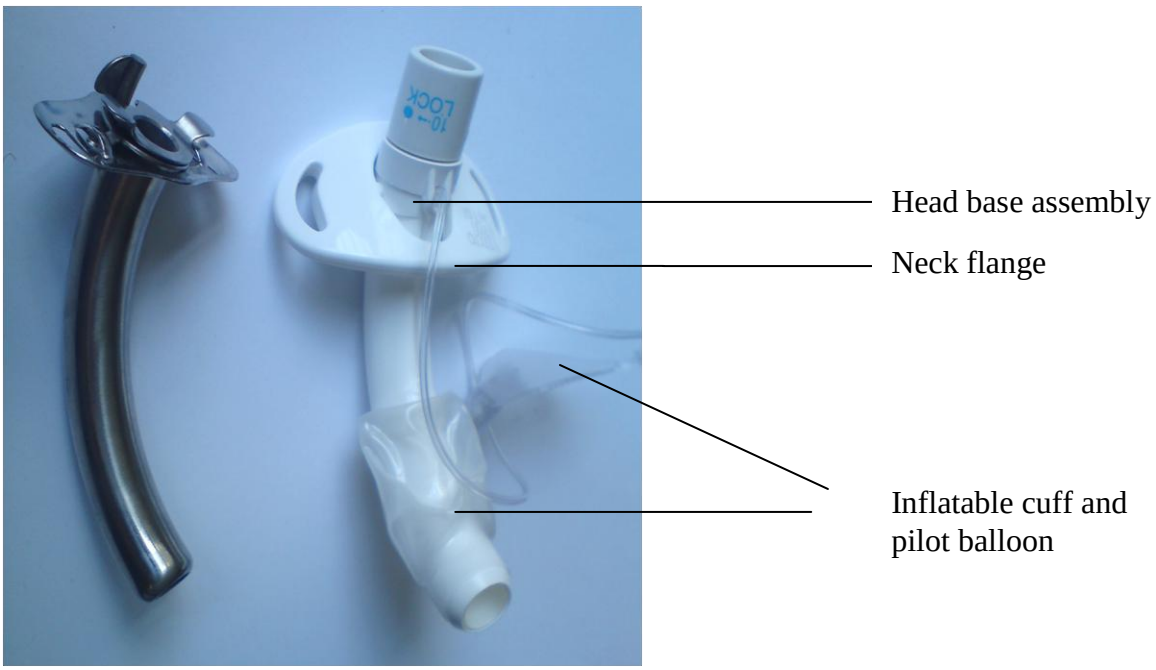


Figure 2: Adult type (cuffed, with inner cannula) plastic and metal tracheostomy tubes. (Photograph: Author).

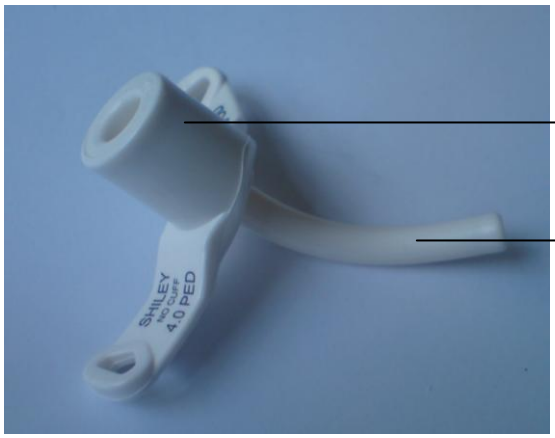


Figure 3: Paediatric type plastic tracheostomy tube (uncuffed, no inner cannula).

(Photograph: Author).

2.2.2 Inner Cannulas

An important variation in design is the inclusion of a removable inner cannula (see figure 4). These cannulas can be completely removed for thorough cleaning, while the outer tube remains safely in the patient's trachea. This is therefore an important tool in preventing cannula obstruction and its consequences. It also means that the tube can be cleaned without the use of expensive suction devices. Inner cannulas, however, decrease the inner diameter of a tracheostomy, as they effectively increase the total thickness of the tracheostomy tube wall. They are thus only available for larger size plastic tracheostomy tubes. With metal tracheosotomy tubes however, due to the strength of the metal, the walls of the tubes can be made very thin, thus allowing for the inclusion of an inner cannula in smaller size tubes without significantly altering the dimension of the tube.[17]

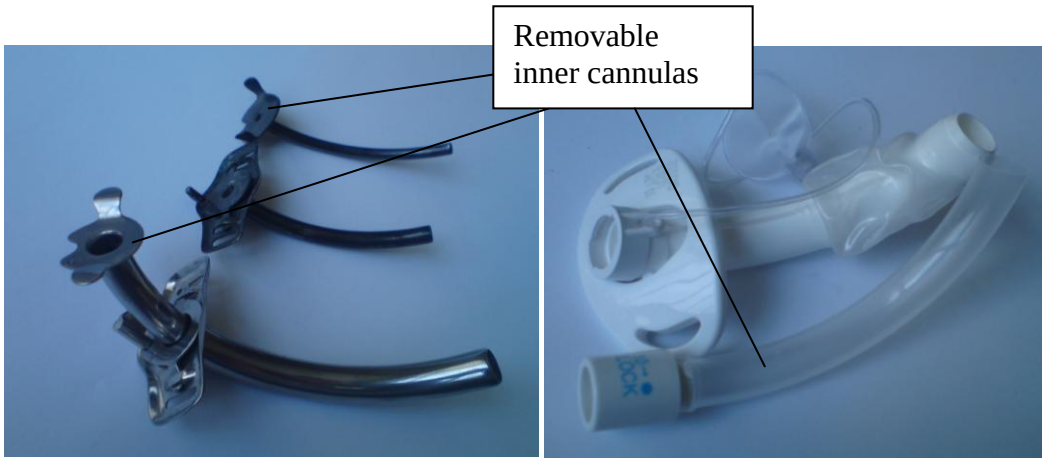


Figure 4: Metal and plastic tracheostomy tubes with removable inner cannulas.

(Photograph: Author).

2.3.3 Tube sizes

The correct size tracheostomy tube is usually dependant on the child's age. Tubes are allocated a size number according to the internal diameter of the tube. The exact dimensions for a particular size number tube, however, differ between manufacturers, and the correct size is therefore provided in table format by the manufacturer, showing sizes appropriate for age.[18]

Formulas based on age and weight may also be used to calculate the correct diameters of the tube. The most commonly used formula for the internal diameter is as follows: Internal diameter = (age/3) + 3.5, where age is in years. So, for example, a 3 year old child should therefore be fitted with a 4.5mm internal diameter tube.[18] In the case of tubes with inner cannulas, the tube size is based on the internal diameter of the inner cannula. Thus the outer diameters of the outer tubes are larger than a similar size tube without an inner cannula.

2.4 INDICATIONS

Tracheostomy may be required in the paediatric patient for several reasons. These can be grouped into three main categories, namely:

- Upper airway obstruction
- Prolonged intubation for ventilation
- Pulmonary toilet (clearing mucus and secretions from the airways through suctioning via the tracheostomy tube).[2]

In addition, it may be used;

- Prophylactical1y as an adjunct to major head & neck surgical procedures.[9,14]
- For airway protection in patients with depressed Central Nervous system (CNS) function.[1,16]

2.4.1 Upper airway obstruction

Upper airway obstruction may be caused by a broad spectrum of pathologies. These include:

- Infectious conditions, such as Acute Diphtheria, Acute Laryngo-tracheobronchitis (LTB, or croup), and Acute Epiglottitis
- Congenital abnormalities, such as Choanal Atresia, Laryngomalacia and Subglottic Stenosis.
- Trauma, including laryngeal fractures and inhalational injuries
- Neoplastic diseases, such as haemangioma, papilloma, and sarcoma
- Neurological diseases resulting in bilateral vocal cord paralysis.[9]

In this situation, the tracheostomy tube bypasses the obstruction, allowing inspired air to pass directly from the trachea to the lower airways.

2.4.2 Prolonged intubation for ventilation

A number of pathologies, including neuromuscular and respiratory problems, may necessitate prolonged ventilation, and may require tracheostomy.[8] In this situation, the use of tracheostomy avoids laryngeal trauma associated with prolonged trans-pharyngeal intubation.

Endotracheal tubes can result in pressure necrosis of the laryngeal mucosa, causing oedema, ulceration and inflammation, which results in scarring and stenosis.[9] This injury most commonly occurs in the posterior commisure of the glottis in adults.[13] However, in paediatric patients the injury occurs at the level of the subglottis, as this is the narrowest portion of the paediatric airway, and is an area that cannot be distended due to the complete cartilaginous ring of the cricoid.[13]

Intubation injuries have been clearly demonstrated in adult patients, in whom tracheostomy is generally recommended after 7- 10 days intubation.[13] In younger paediatric patients, however, prolonged intubation is better tolerated with fewer complications.[19] Newborn infants may be intubated for several months with minimal evidence of laryngeal injury.[9] Thus tracheostomy for prolonged intubation is usually employed in older children requiring ventilation, who have irreversible diseases.[9] In these children, it is recommended that tracheostomy be performed after 10-14 days of ventilation.[9]

However, it is noted that there is no widely accepted limit regarding length of intubation before performing tracheostomy, and the decision to tracheostomize the younger child must be individualised.[10,19] Fibreoptic bronchoscopy, performed on a weekly basis, may be used as a

tool to assess the upper airways for evidence of injury.[9] Where there is evidence of injury, tracheostomy is recommended.[9,10]

2.4.3 Pulmonary toilet / Access to LRT

In patients unable to clear airway secretions, such as those with neuromuscular disease, a tracheostomy assists in pulmonary toilet by allowing direct access to the lower airways with suction cannulas.[9] This reduces the build-up of secretions, thus decreasing the risk of atelectasis and pneumonia.

2.4.4 Surgeries requiring airway prophylaxis.

In certain surgeries, tracheostomy may be required to protect the airway from potential obstruction, or when prolonged recovery and ventilation is anticipated after a procedure.[9,14]

In this situation, the airway may not be immediately threatened, but may become compromised by possible bleeding or oedema during the early post-operative phase and recovery periods. Such operations include those of the head and neck, the airway, major neurosurgical and cardiac procedures.[9,14]

These tracheostomies are usually temporary and are removed relatively soon after recovery from surgery.

2.4.5 Airway protection for depressed level of consciousness.

A group of patients may require tracheostomy for airway protection due to a depressed level of consciousness. These patents have no airway obstruction, and no longer require ventilator support or pulmonary toilet, but cannot be safely extubated as they are unable to ‘centrally’ protect their airways. The real risk of aspiration requires that a safe alternative airway be created. Examples of such patients include those with severe head injuries, and central nervous system tumors.

2.5 SHIFT IN INDICATION

Infectious diseases have historically been the most common indication for tracheostomy.[2,3,4] In the early 1900's, infections such as diphtheria and poliomyelitis were common; however, the incidence of these conditions decreased in the 1940's and 1950's respectively after the introduction of vaccines.[9] Subsequently infections such as croup and epiglottitis became the most common indication for tracheostomy.[9] However, this has decreased since the 1980's as a result of utilizing endotracheal intubation to secure the airway in croup, and the introduction of the Haemophilus B vaccine decreasing the incidence of epiglottitis.[8] Overall, infectious disease has now become an uncommon indication for tracheostomy. A review of recent literature shows that the incidence of this indication has fallen from 50% to only 3%,[1,10] with some first world institutions not having performed a single tracheostomy for infectious indications for a 10 year period.[3]

A shift in indication has thus occurred in many first world centres, [10] and today the most common indication for paediatric tracheostomy is prolonged intubation for ventilation.[2,9] However, this has not been observed in third world countries, where upper airway obstruction remains the most common indication.[20]

In South Africa infectious aetiologies, particularly LTB (57% of cases), were by far the most common indication for tracheostomy 25 years ago.[21] One study has since been conducted, which showed that LTB only accounted for 21% of cases.[22] However, this is still a high percentage, with observation of current practice in the study hospitals suggesting that croup has very rarely required tracheostomy.

In other areas of Africa, laryngeal papillomatosis has been shown to be the most common indication.[20] Laryngeal papillomatosis is a condition in which warty out-growths develop on the laryngeal mucosa as a result of Human Papilloma Virus (HPV) type 6 and 11 infection. It is the most common benign neoplasm of the larynx in the paediatric population.[13] The majority of infections are thought to arise by vertical transmission during birth from mothers with genital papilloma. Airway compromise in these cases may arise as a result of papilloma itself, or as a result of the surgical management of papilloma, with laryngeal scarring and stenosis. High numbers of respiratory papilloma cases have also been observed in the study hospitals.

2.6 AGE GROUPS

Internationally, the age demographic has also shifted, with most tracheostomies now being performed in children under 1 year of age.[3,5,20,23] This has occurred due to increased survival rates of intensive care patients, particularly neonates, requiring tracheostomies for long term ventilation,[2,23] and increased numbers of tracheostomies being performed for congenital defects.[3] Again, this trend has not been seen in other third world countries.[20] Previously in South Africa, the largest number of tracheostomies was performed in the 13-18 month old age group.[21] No recent age demographics have been published.

2.7 COMPLICATIONS

Many complications may occur during or after tracheostomy placement, and these occur more commonly in younger patients, with the highest rates observed in premature infants.[24] Early studies demonstrated high complication rates,[9] highlighting the complexity of care required for successful outcomes. While management has improved, with better outcomes now documented, standards of care have not yet been formalized,[1] and no consensus on their optimal management exists.[12]

The complications can be arbitrarily divided into early and late groups. Early complications occur in the first month after the procedure, and late complications thereafter.[25]

Early complications are seen in 5-49% of cases,[9] and include infections, cannula obstruction, tube displacement, bleeding, subcutaneous emphysema, pneumothorax and pneumomediastinum. Late complications are seen in up to 100% of patients,[9] and include stomal or tracheal wall granuloma, suprastomal collapse, tracheomalacia, laryngotracheal stenosis, and tracheocutaneous fistula formation.[25]

Overall complication rates for inpatients in the literature vary in both developing and developed countries, as do the most commonly encountered complications. Several studies have shown zero mortality,[10,26] while others have demonstrated rates of up to 6%.[22]

In South Africa, the last study assessing inpatient morbidity and mortality rates was conducted at the Red Cross War Memorial Hospital in Cape Town from 1980-1985. In this study of 293

patients, Prescott et al showed a mortality rate of 1.7%. The most common morbidities were stomal granulation (17%) and suprastomal collapse (18%).[21] No more recent analysis has been published.

2.8 HOME CARE

Paediatric patients may require tracheostomies for long periods of time, or even permanently, depending on the primary disease. Home based care was developed in order to decrease prolonged hospital admissions, and is associated with numerous benefits. These include a more normal social development in a family environment, and potentially allowing for normal schooling of the child.[6,12] It also reduces the costs associated with hospital admission,[12] and decreases the risk of nosocomial infections.[6,26]

Home care has been shown to be safe,[6,25] and this form of management has been successfully practiced for more than 20 years in some centres now.[6] However, it is not without risk, and several conditions need to be met for its safe implementation.

A period of training for the caregiver (preferably both parents and an additional caregiver[25]) is required, which lasts on average 2-3 weeks.[6,26] This involves training on humidification, suctioning, tube changing, dealing with emergency situations including cardiopulmonary resuscitation,[26] and recognising complications such as chest infections, early on.[25]

The home environment must also be assessed for appropriateness of facilities including

running water and electricity.[26]

Finally, home care equipment must be provided, which includes a suction pump with backup battery, suction cannulas, humidifiers, and a spare tracheostomy cannula.[6] Home oxygen may also be required.[25]

Additional requirements include an assessment of the emotional stability and level of social support available to the care giver .[6]

This process is best organized within a formal tracheostomy homecare program, which includes a multidisciplinary team approach. The components of these teams vary in different centres, and may include an otolaryngologist, paediatric surgeon, specialists in intensive care, registered nurses, psychiatrist,[6] social workers,[27] and home care nurses.[14]

It is evident that this is a labour intensive exercise requiring many resources, which are typically limited in a third world environment. This was illustrated in a recent Turkish study by Ilce et al, who stated that home care could not be implemented in that country due to inappropriate home conditions.[4]

In South Africa there are many impediments to the successful employment of this management strategy, and thus questions arise as to its safety. This study aimed to further describe how these factors have affected the outcomes of patients in the study hospitals.

2.9 OBSERVATIONS AND HYPOTHESIS

High mortality rates of paediatric tracheostomy patients, particularly infants, have been observed in the study hospitals. International trends of demographic shifts in indication and age do not appear to have occurred, with very few tracheostomies performed for prolonged ventilation in infants. Home based care has been problematic, resulting in many prolonged hospital admissions.

The author's hypothesis was that age and indication demographic shifts would not correlate with international trends, and that complication rates would be higher than in reported studies.

2.10 AIMS AND OBJECTIVES:

The objectives of this study were:

- To describe the age and indications for tracheostomies in the paediatric population in Johannesburg, and
- To determine the complications of paediatric tracheostomies in the local setting.

CHAPTER 3

3. MATERIALS AND METHODS

Introduction

In this chapter, the methodology used in the study is explained. Details of the study location, design, time period, and study population are described. Data collection methods are detailed, and data analysis, including descriptive and inferential analyses, are explained. The chapter ends by addressing ethical considerations of the study.

3.1 STUDY LOCATION

This study was conducted at the Chris Hani Baragwanath Hospital, Charlotte Maxeke Johannesburg Academic Hospital, Helen Joseph Hospital, and Rahima Moosa Mother and Child Hospital. Paediatric patients who underwent tracheostomies in these hospitals were assessed.

3.2 STUDY DESIGN

The study was a retrospective clinical audit.

3.3 STUDY PERIOD

The study analyzed records from the last 10 years, from 01/01/2001 to 31/12/2010.

3.4 STUDY POPULATION

In this study paediatric patients were defined as those less than 18 years of age. All patients under 18 years of age who underwent tracheostomies in theatre, under general anaesthetic, were included in the study.

3.5 INCLUSION CRITERIA:

- Patients under 18yrs of age.
- Underwent a tracheostomy procedure in the study hospitals.

3.6 EXCLUSION CRITERIA:

- Patients over 18yrs of age.
- Tracheostomies inserted at other institutions.

3.7 DATA COLLECTION

Data was collected by identifying patients less than 18 years of age who had undergone tracheostomy in the theatre register of the otorhinolaryngology, emergency, burns unit, and paediatric theatres. These details were used to collect patient's files from the records departments.

Data from the time of surgery until the time of initial discharge from hospital was retrieved from patients' files, and included;

1. Date of surgery

2. Age at tracheostomy insertion
3. Indication for tracheostomy
4. Tracheostomy tube size and presence of an inner cannula
5. Tracheostomy related complications and mortalities as an inpatient
6. Decannulation date
7. Duration of hospital admission

Relevant data regarding previous and current tracheostomy related hospital practice was obtained through communication with the heads of department of otorhinolaryngology in the four hospitals, nursing staff, and involved allied disciplines.

3.8 DATA ANALYSIS

1. Data capturing

Data from patient records was captured onto a Microsoft Excel spreadsheet document.

2. Data cleaning and coding

Data cleaning was performed by examining extreme values, missing values, and grouping data for analysis. Extreme values were verified in the patient files, and were excluded if outside the research population inclusion criteria. Missing values were addressed by attempting to retrieve values from patient files. If data was not retrievable, this was recorded as missing, or patients were excluded from the analysis. Data was sub grouped for analysis as described below.

3. Importing data

Clean data was imported into the STATA version 10 statistics software program for analysis.

4. Data analysis

Descriptive and inferential statistical analyses were performed.

Descriptive Analysis

Descriptive analysis evaluated categorical and continuous variables.

Categorical variables were described, including:

- indication for tracheostomy insertion
- tracheostomy related complications
- tracheostomy related mortalities

For these variables, frequencies and percentages were calculated, and this information was presented in frequency tables, pie charts, and bar graphs.

Continuous variables were described, including:

- age
- duration of admission

For these variables, the standard deviation, mean, and range were calculated. The t test was used to calculate significance between subgroups.

These results were compared to publlished data.

Inferential Analysis

Inferential analysis was also performed:

Data was grouped for subgroup analysis, including grouping into;

- age ranges
- indication groups (upper airway obstruction, prolonged intubation for ventilation, adjunct to surgery, or depressed level of consciousness)
- tracheosomy tube size ranges
- presence of an inner cannula
- duration of hospital stay ranges

These groups were analyzed to ascertain which factors are associated with statistically significant improved outcomes.

Fisher's exact test was used to compare proportions and test for statistical significance. A p-value of less than 5% indicated statistical significance.

3.9 ETHICAL CONSIDERATIONS

Permission for the study was obtained from the Chief Executive Officers of the relevant hospitals.

Ethics clearance was obtained from the University of Witwatersrand Human Research Ethics Committee to conduct the study.

No informed consent was required for the research as it was a retrospective study.

Patient's identities were protected by assigning a code to each patient, which is available only to the author.

CHAPTER 4

4. RESULTS

Introduction

In this chapter, the results of the study are presented, including results for; age and indications, complications, hospital admission duration, and discharge rates. Results are presented in graphic formats, including pie charts, bar graphs and contingency tables.

General

Complete records for 70 patients could be found for the 10 year study period. The first objective of the study was to describe the age and indication demographics of the study population.

4.1 Age

The age range of patients was 2 weeks to 17 years, with a mean age of 7 years. Standard deviation was 5.45, with a median of 6 (see figure 5).

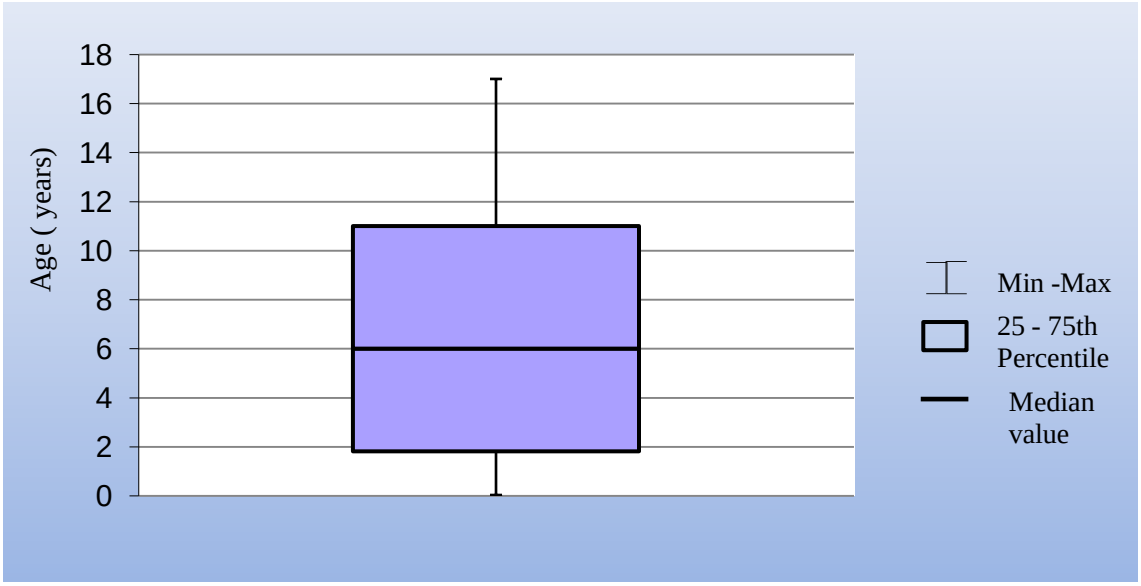


Figure 5: Box plot showing age of patients

Age range sub grouping showed that 18.5 % of patients were under 1 year of age, 24% between 1.1 and 5 years of age, 30% between 5.1 and 10 years of age, and 27% between 10.1 and 17 years of age (see figure 6). The neonatal age group (less than 28days old) accounted for only 4% (n= 3) of cases.

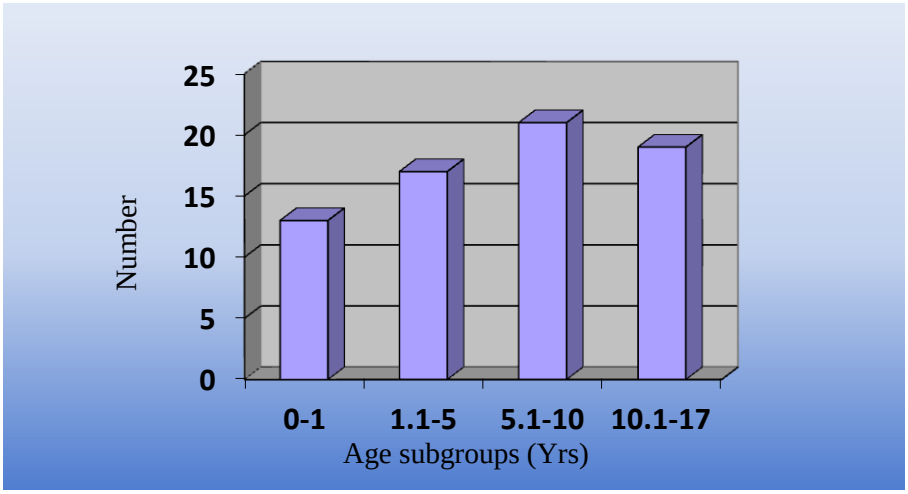


Figure 6: Age range distribution of patients.

4.2 Indication Groups

Indications were divided into 4 groups: Upper airway obstruction, prolonged intubation for ventilation and pulmonary toilet, adjunct to surgery, and airway protection for depressed level of consciousness. Of the 4 groups, upper airway obstruction was the most common group, accounting for 67% (n = 47) of cases. 14% (n = 10) were inserted for depressed level of consciousness, 12% (n = 9) for prolonged intubation for ventilation or pulmonary toilet, and 5% (n = 4) for surgical prophylaxis (see figure 7).

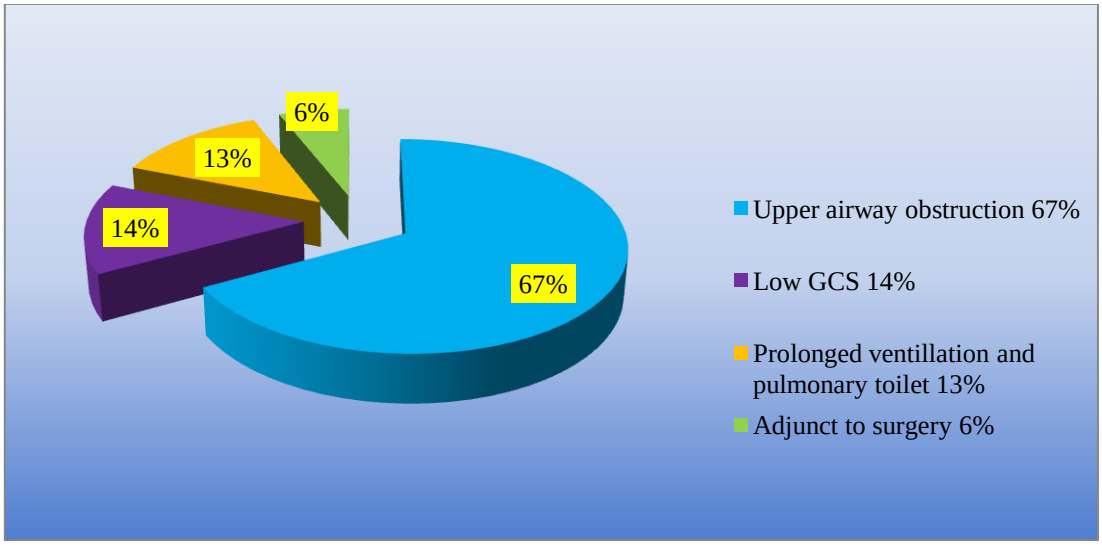


Figure 7: Indication groups for tracheostomy.

4.3 Indications

Assessment of the specific indications for tracheostomy showed the highest numbers were performed for subglottic stenosis (28%), head injuries (12%), and glottic stenosis post surgery for laryngeal papilloma (7%) (see figure 8). A wide variety of other conditions required tracheostomy, and these are presented in table format below (see table1).

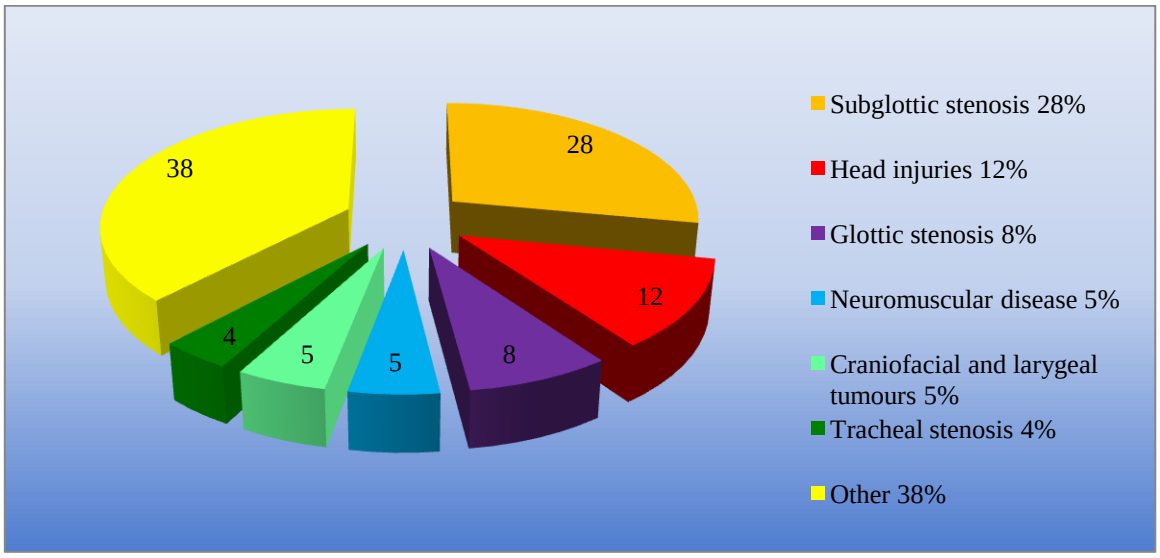


Figure 8: Major indications for tracheostomy.

Table 1: Indication groups, indications, and diagnoses requiring tracheostomy.

INDICATION GROUP	INDICATION	DIAGNOSIS	No	% of Total
Prolonged intubation for ventilation and Pulmonary Toilet			**9**	**0.129**
	Pulmonary disease	Attempted suicide	1	0.014
		Kyphoscoliosis, restrictive pnemopathy	1	0.014
		ARDS, pneumonia	1	0.014
	Neurological/neuromuscular disease	Guillain-Barre Syndrome	3	0.043
		Malignant hyperthermia	1	0.014
	Septicaemia	Ruptured appendix	1	0.014
		Burn injuries	1	0.014
Depressed level of consciousness			**10**	**0.143**
	Post neurosurgery	Brainstem glioma excision	1	0.014
	Head injury	Assault	1	0.014
		PVA/MVA	8	0.114
Upper Airway Obstruction			**47**	**0.671**
	Subglottic stenosis	Congenital	3	0.043
		Acquired	17	0.243
	Glottic stenosis	Post papilloma surgery	5	0.071
		Post trauma	1	0.014
	Subglottic oedema	Primary peritonitis, prolonged intubation	1	0.014
	Tracheal stenosis	Post prolonged intubation	3	0.043
	Laryngomalacia		2	0.029
	Craniofacial syndromes	Oromandibular-limb hypogenesis syndrome	1	0.014
		Treacher Collins syndrome	1	0.014
	Craniofacial and laryngeal tumours	Papilloma	2	0.029
		Oropharyngeal squamous carcinoma	1	0.014
		Complex laryngeal cyst	1	0.014
	Bilateral vocal cord paralysis	Hydrocephalus	1	0.014
		Post head injury	1	0.014
		Congenital	1	0.014
	Obstructive sleep apnoea	Morbid obesity	1	0.014
	Laryngeal trauma	Caustic ingestion	2	0.029
	Infections	Parapharyngeal abscess	1	0.014
		Supraglottitis	1	0.014
		Submandibular abscess	1	0.014
Adjunct to Surgery			**4**	**0.057**
	Head and Neck Tumours	Pleomorphic adenoma	1	0.014
		Mediastinal/cervical 30esmoids tumour	1	0.014
		Parapharyngeal neurofibroma	1	0.014
	Massive facial debridement	Mucormycosis	1	0.014
Total			**70**	100

The second objective of the study was to describe the complications encountered in the study hospitals, and to ascertain factors associated with improved outcomes.

4.4 Complications

A total of 65 morbidities were encountered in 41 patients. The most commonly encountered complication was cannula obstruction, with 23 episodes accounting for 35% of total cases. Pneumonia was the second most common complication, accounting for 33% of cases (n=22). Other complications included bleeding, accidental decannulation, wound infection, surgical emphysema, granulation, and cannula aspiration. (See table 2).

Table 2: Tracheostomy complications.

Complications	No	% Total
Cannula obstruction	23	0.35
Pneumonia	22	0.34
Bleeding	9	0.14
Accidental decanulation	3	0.05
Wound infection	3	0.05
Surgical emphyseama	2	0.03
Granulation	2	0.03
Aspirated cannula	1	0.02
Total	65	1

4.4.1 Complications in age subgroups

Complications were analyzed according to age subgroups. Complication rates in the infant age subgroup (< 1yr) were higher than in other age groups, with an average of 1.53 complications per patient. This group had a significantly higher complication rate compared to the other age groups (p = 0.0296, Fisher's exact test, two tailed). The 10.1 – 17 yr age group had the lowest complication rate with 0.37 complications per patient. (See table 3 and figure 9). The odds of a patient developing one or more complications in each age group was calculated and is presented in table 3 below.

Table 3: Relative complication rates for different age groups.

Age range	No. patients	No. complications	Average no. complications per patient	Odds of developing one or more complications
0 - 1yr	13	20	1.53	3.33
1.1 - 5yr	17	21	1.24	2.4
5.1 - 10yr	21	17	0.8	0.91
10.1 - 17yr	19	7	0.37	0.46

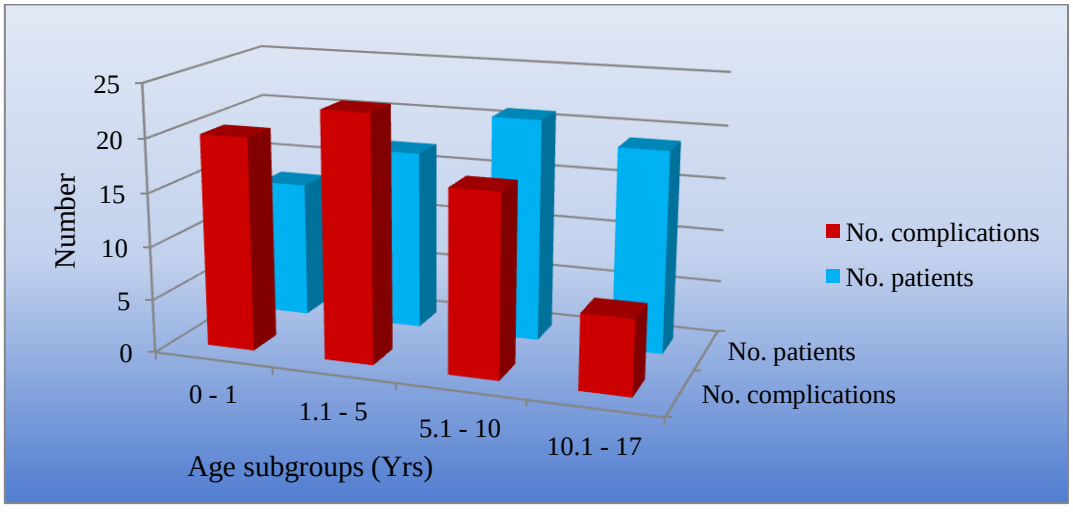


Figure 9: Number of complications compared to number of patients for age ranges.

4.4.2 Cannula obstruction

Cannula obstruction was further assessed. Tracheostomy tube diameters were compared in relation to obstruction episodes. (Tube diameters do not necessarily correlate with age, as patients of similar age may differ in size, and tubes may not have been correctly chosen for a patient's age). The internal diameters of all tubes in the study ranged from 3 – 6mm. Two groups were compared; a smaller tube size group consisting of tubes with internal diameters from 3 – 4.5mm, and a larger tube size group, with diameters from 5 – 6mm. A 2 x 2 contingency table was constructed (see table 4) and Fisher's exact test used to determine significance. A statistically significant higher incidence of cannula obstruction was found in the smaller tube group ($p = 0.0062$).

Table 4: 2x2 contingency table showing cannula obstruction in smaller and larger tube size groups.

	No cannula obstruction	**Cannula Obstruction**	**Total**
Tube diam. 3 - 4.5mm	11	13	**24**
Tube diam. 5 - 6mm	41	10	**51**
Total	**52**	**23**	**75**

Similarly, the role of inner cannulas in preventing obstruction was assessed. Tube diameter as a factor was excluded by assessing similar size tubes (5 – 6.4 mm internal diameter), and comparing the number of episodes of obstruction in tubes with and without inner cannulas (see table 5).

Table 5: 2 x2 contingency table showing cannula obstruction in tracheostomies with and without inner cannulas

	No cannula obstruction	**Cannula obstruction**	**Total**
Inner cannula	1	18	**19**
No inner cannula	9	23	**32**
Total	**10**	**41**	**51**

Fisher's exact test was used to determine significance. A statistically significant decrease in cannula obstruction episodes was demonstrated in the group of tracheostomies with inner cannulas ($p = 0.0468$).

The time of cannula obstruction after insertion of tracheostomy was also assessed. The majority of episodes (48%) occurred within the first month after insertion. To adjust for the higher number of patients admitted during the same period, the number of episodes per patient was calculated, and plotted against time. This revealed that the highest obstruction rate also occurred in the first month after insertion (0.16 episodes per patient), progressively decreasing with time thereafter (see Figure 10).

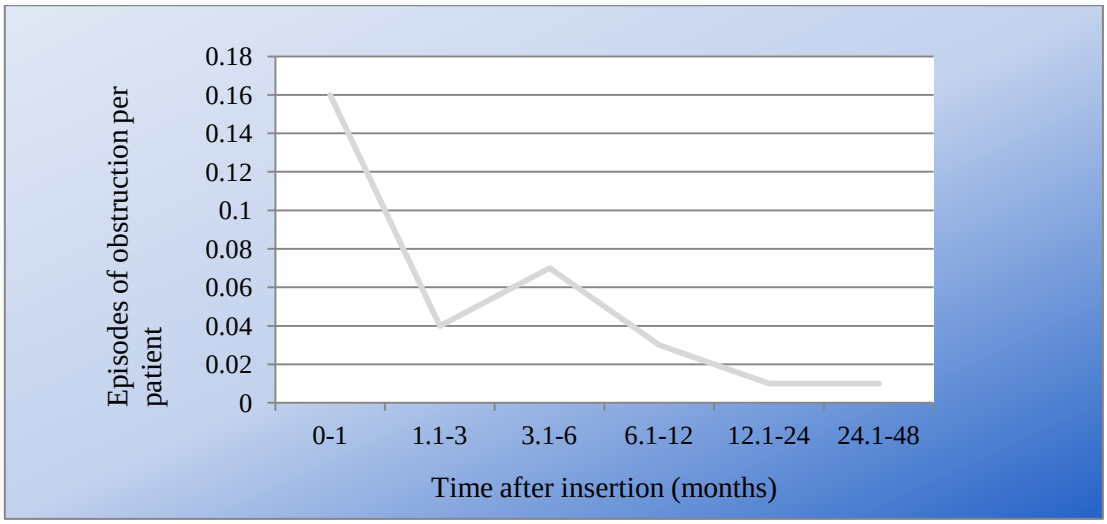


Figure 10: Episodes of cannula obstruction per patient as a function of time after insertion.

4.4.3 Nosocomial Pneumonia

Nosocomial pneumonia was the second most commonly encountered complication, with 22 episodes accounting for 34% of complications. Pneumonia was more common in the younger age groups, with 50% of cases occurring in the infant age group, and 32% in the 1.1 – 5yr and 5.1 – 10 year groups. No cases of pneumonia were reported in the over 10 year age group (see figure 11).

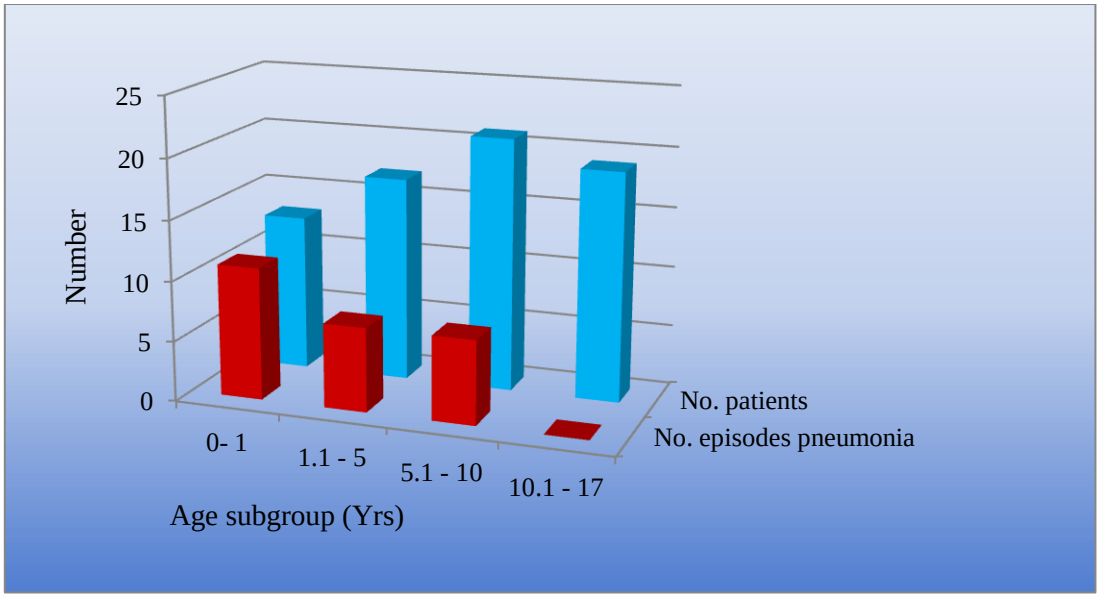


Figure 11: Episodes of pneumonia in different age groups.

Incidence of pneumonia was assessed in relation to duration of hospital stay. Four patients had multiple episodes of pneumonia, and these patients were all admitted for a period of more than 2 years. A strong correlation was established between duration of stay and episodes of pneumonia in affected patients (r = 0.851).

4.5 Mortalities

19 mortalities occurred in the 10 year study period, giving a mortality rate of 27%. Of these, 6 were attributable to the tracheostomy. This gives a tracheostomy related mortality rate of 8.5%. Tracheostomy related mortalities accounted for 31.2% of total mortalities.

Almost all of these cases were due to cannula obstruction (n = 5), with 1 case due to accidental decannulation (see figure 12). The mean age of the patients who died from cannula obstruction was 2.45years, with 4 of the 5 patients being under 2 years of age.

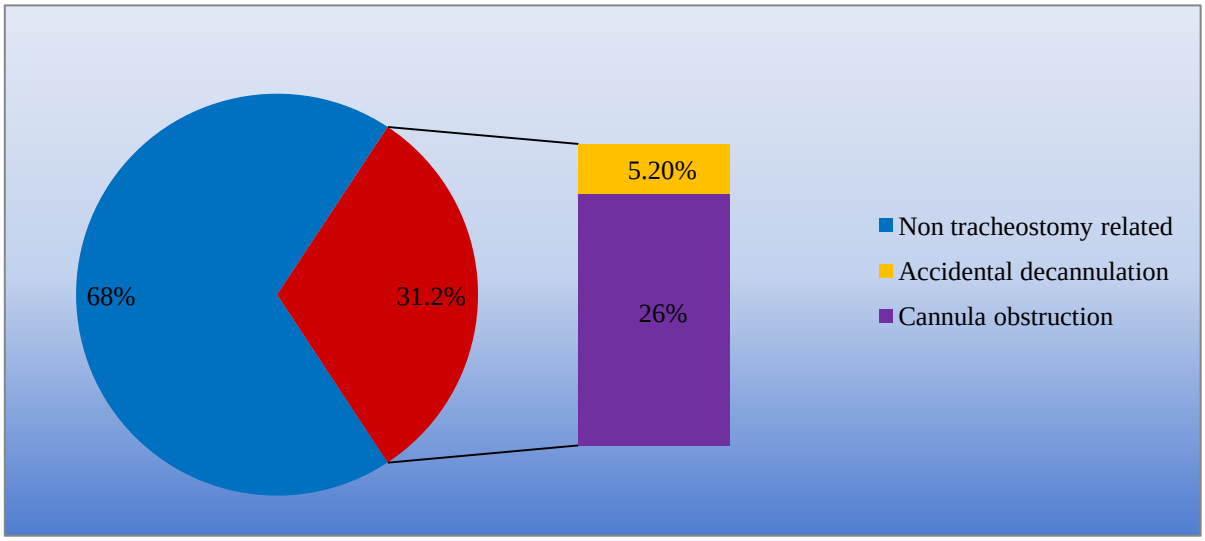


Figure 12: Mortalities: Tracheostomy-related and non trachostomy-related.

4.6 Duration of in-hospital stays.

The duration of hospitalisations revealed a mean of 147days (range 5 – 1360 days). A standard deviation of 274, and a median of 34 was calculated. Nine patients remained inpatients at the end of the study period. Subgroup analysis showed that the majority of patients (44%, n = 31) were admitted for a period of less than 1 month, with numbers tapering with time thereafter. Prolonged in-hospital stays were noted, with 11% of patients (n = 8) admitted for a period of more than 1 year (see figure 13).

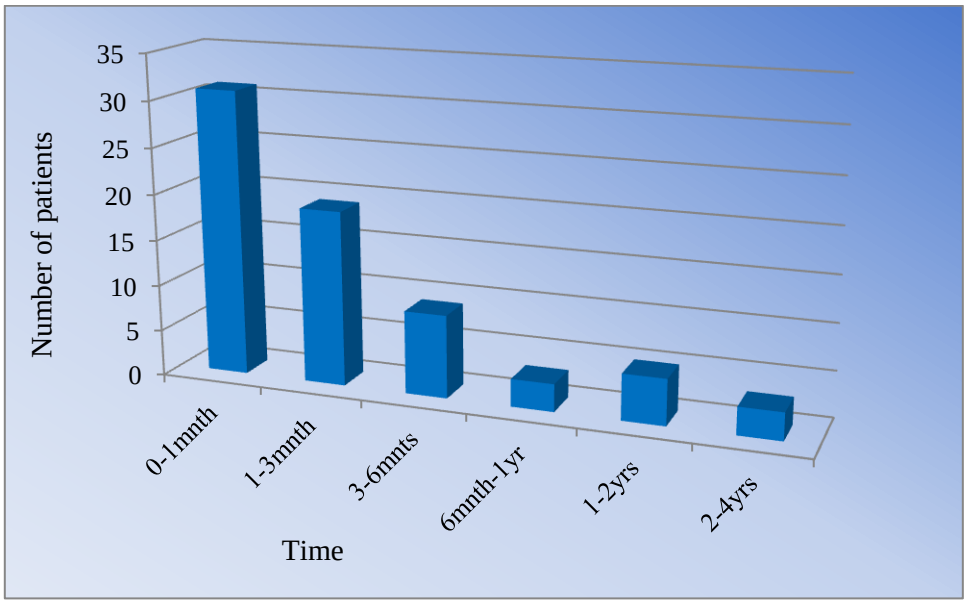


Figure 13: Number of patients admitted for time periods.

Age was assessed as a factor for duration of in-hospital stay. The infant age group had the longest duration, with a mean of 259 days, and the 10 – 17 year group the shortest stay with a mean of 25 days (see figure 14). A significant correlation was established whereby age was inversely proportional to length of stay (r = -0.29).

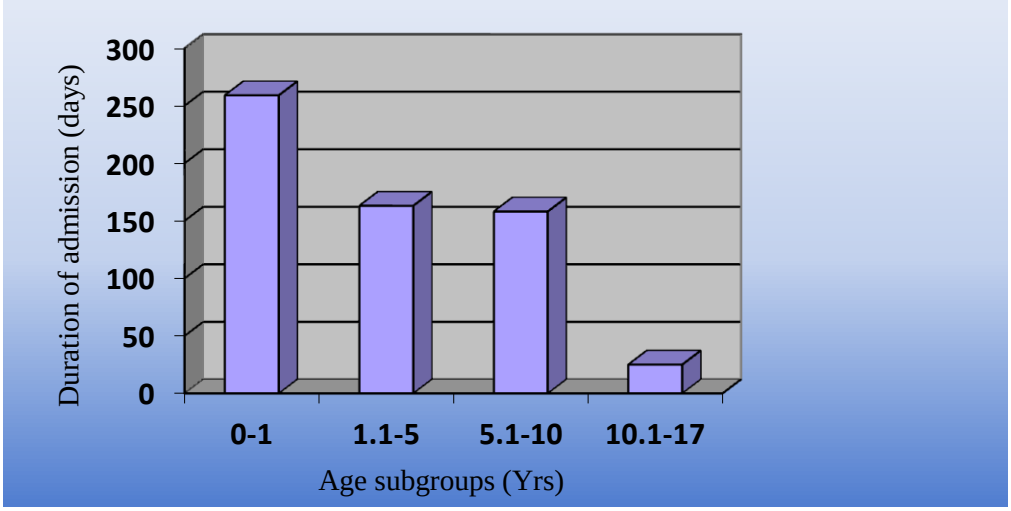


Figure 14: Mean duration of in-hospital stay for different age subgroups.

Comparison of an older and younger age subgroup was also performed by dividing the age range at the midpoint. The younger group thus consisted of patients less than 9 years of age, and the older group of patients 9- 17years. The mean duration of in-hospital stay for the younger group was 199 days, whereas that for the older group was only 26 days. This was a statistically significant difference (p = 0.0091, unpaired t test).

4.7 Discharge to home care

The overall discharge rate was 60% (27% mortality, 13% patients remaining as inpatients at the end of the study period). Of the discharged patients, 57% (n = 24) were successfully discharged with tracheostomies in place for continued care in the home environment, while the remainder were discharged post-decannulation. The average duration of in-hospital stay for these patients prior to discharge was 171 days. The average age of the discharged patients was 8 years.

4.8 Decannulation

25% (n = 18) of patients were successfully decannulated prior to discharge. The mean duration of tracheostomy prior to decannulation was 124 days (range 7 – 1090days).

4.9 Comparison of indication groups

The outcomes of the four different indication groups were compared in terms of number of complications, mortality rates, and duration of admission. These results are summarised in the table below (see table 6).

Table 6: Comparison of outcomes in indication groups.

	No. patients	Complications per patient	Mortality rate	Mean duration of admission (days)
Upper airway obstruction	47	1.14	0.19	196
Depressed level of consciousness	10	0.2	0.4	40
Prolonged intubation for ventilation	9	0.89	0.56	38
Adjunct to surgery	4	0.5	0.25	33

CHAPTER 5

5 DISCUSSION

Introduction

In this chapter the findings of the study are discussed. Particular focus is placed on findings in the study which differ from that of published data. The chapter first discusses the age profile and indications groups of patients. The upper airway obstruction group is further discussed with a focus on prominent indications, including laryngeal papillomatosis and subglottic stenosis. Differences in observations are discussed throughout, with comparison to other first and third world publications. The chapter ends with discussion on prolonged hospital admissions and home based care.

5.1 GENERAL

The aims of this study were to describe the age and indication demographics for paediatric patients undergoing tracheostomy in Johannesburg, and to assess the outcomes for these patients. The findings of the study are important because no standards of care for paediatric tracheostomised patients have been established,[1] and practices are noted to vary both between countries, and between institutions within countries.[11]

The study thus provides a platform to understand the local patient profile, and to identify complications particularly relevant to the local environment. These findings can then be used to improve tracheostomy care specific to the study institutions.

5.2 AGE

A shift in the age demographic over the last 25 years has been widely reported in the literature.[3,5,8,20,23] Advances in care of neonates, particularly premature neonates, has resulted in increased survival rates in this age group.[2] These patients may require tracheostomies for long term ventilation, or for upper airway obstruction due to acquired subglottic stenosis, occurring as a complication of intubation for infant respiratory distress syndrome, or prematurity.[23] An increasing incidence of tracheostomies for congenital birth defects such as laryngomalacia and craniofacial anomalies has also been noted.[5] A review of the indications shows that the number of tracheostomies performed for prematurity has increased from 28% to 58%, for congenital abnormalities from 6% to 23%, and for neuromuscular disease from 9% to 23%.[1]

As a result, most tracheostomies are now being performed in children under 1year of age.[13,23] In their study of 56 children under the age of 12, Shinkwin et al found that 70% of patients were under 1year of age, and of those 50% were less than three months of age.[23] This trend is not limited to first world environments, but has also been noted in some third world countries such as India[5] and Pakistan.[26]

It has not, however, been seen in other African countries, such as Nigeria, where the majority of patients (69.6%) fall in the 6-10 year age group.[20] Early studies in South Africa, showed the the largest number of tracheostomies were performed in the 13-18 month old age group.[19]

In this study, the age range was 2 weeks -17 years, with a mean of 7 years. Sub group analysis

showed that the infant group (less than 1 year) accounted for only 18.5% of cases, with the largest group (30% of cases) being the 5.1-10 year age group. The neonatal group (<28 days old) accounted for only 4% (n = 3) of the study population. Thus the shift in age demographic has not occurred in our institution.

This contrast may be explained by differences in policy for neonatal intensive care units, where very few tracheostomies are performed for prolonged intubation for ventilation. In addition, fewer procedures for craniofacial abnormalities are being performed in our institutions. The difference in observed age demographic is thus linked to the indication profile, which is discussed below.

5.3 INDICATIONS

Indications for tracheostomy in this study were divided into the following groups:

- Upper airway obstruction
- Adjunct to surgery
- Airway protection for depressed level of consciousness
- Prolonged intubation for ventilation and pulmonary toilet

5.3.1 Upper airway obstruction

Upper airway obstruction was the most common indication group, accounting for 67% of cases (n = 47). This group had the highest complication rate (1.14 complicaltions per patient), and the longest mean duration of admission (196 days). However, it was noted to have the lowest mortality rate (19%). Prominent indications in this group included subglottic stenosis and laryngeal papillomatosis.

5.3.1.1 Subglottic stenosis

Subglottic stenosis was the most common specific indication for tracheostomy in the study, accounting for 36% (n = 20) of cases. The vast majority of these cases were acquired stenoses, with only 3 cases of congenital stenosis reported. This is higher than in similar studies, with incidences of 19% and 20% reported.[8]

These rates represent a sharp rise from earlier studies from the 1970's, in which incidences of

0.2 – 5% were reported,[8] and may be attributed to improved survival rates of critically ill children undergoing prolonged intubation and ventilation.

Intubation is the major cause of subglottic stenosis. While the overall incidence of post-intubation stenosis is low (around 1%), it is the most common cause of acquired stenoses, accounting for 90% of cases.[13]

All cases of acquired subglottic stenosis in this study were due to prolonged intubation. This greater potential for injury in the older child was demonstrated, with a mean age of 6 years for post intubation stenosis cases.

Fibreoptic bronchoscopy has been used successfully to assess for intubation injuries early on, and thus avoid the potential complications.[9,10] This strategy was demonstrated in adult patients to reduce the tracheostomy rate for stenosis post long term ventilation to less than 5% .[10] Endoscopy is not routinely performed in the study hospitals, and may be a potential intervention to consider in attempting to reduce the incidence of subglottic stenosis. A lower threshold for tracheostomy for prolonged intubation for ventilation in older children may also be appropriate.

5.3.1.2 Recurrent Laryngeal Papillomata

Glottic stenosis was the indication for tracheostomy in 8 % of cases. 83% (n = 5) of these were as a result of surgery for laryngeal papillomatosis.

Airway compromise in papillomatosis cases may arise as a result of the papilloma growth itself obstructing the laryngeal lumen, or as a result of complications of surgical management of the papilloma. Papillomatosis tends to be resistant to treatment, and patients will typically require multiple debulking procedures at regular intervals. In the study institutions, this is performed using cupped forceps, or with the use of laser. However, injury to the larynx is a potential complication with each debulking episode, regardless of the modality.[13] This may cause scarring with fibrosis, resulting in airway narrowing.

All cases (n = 5) required tracheostomy for scarring of the larynx after multiple surgical debulkings, with no procedures being performed for emergency airway access due to papilloma obstruction.

An incidence of 7% is higher than that in reported literature, and represents an increase from earlier South African studies such as that of Prescott et al, who showed that papilloma accounted for only 1.3% of cases of tracheostomy.[21]

However, other areas of Africa show an even higher incidence. Adoga et al, in a Nigerian study, showed that laryngeal papillomatosis was by far the most common indication for tracheostomy in their institution, accounting for 46% of cases.[20]

A possible explanation for the high numbers of stenoses post-surgery seen in the study hospitals, is that many of these patients present after hours with airway obstruction and respiratory distress, and are taken to theatre as emergencies. The surgeon on call may be a less experienced trainee, and may be more likely to cause iatrogenic injuries to the larynx during

debulking.

There have been recent developments in the prevention of HPV infection. The introduction of a new quadrivalent vaccine in South Africa this year, effective against HPV types 6, 11, 16, and 18, may decrease the incidence of papilloma by reducing the maternal reservoir of HPV.[30] This is an exciting development, but follow up studies will be needed to evaluate the effectiveness of this intervention.

5.3.1.3 Upper Respiratory Infections

Worldwide, a decrease in the incidence of infectious disease requiring tracheostomy has been noted, and it is now an uncommon indication accounting for 0 – 5% of cases.[3,23,29]

In South Africa, a comparison of two studies from Cape Town illustrates this decreasing incidence. In their 1985 study, Prescott et al demonstrated that croup accounted for 57% of cases requiring tracheostomy. Mulwafu et al in a study from the same centre in 2007 showed that croup then accounted for only 21% of tracheostomies. However, this is still a far higher percentage of cases compared to international literature, where croup accounts for 4.3 - 5% of cases.[5,20,23] In their study, Mulwafu showed the need for tracheostomy in these patients was related to their HIV status. All patients (n=14) who failed to resolve the airway obstruction after an average 9 days of endotracheal intubation, and were then tracheostomised, were found to be HIV positive.[22] Thus the high incidence of tracheostomy for croup reflects the high prevalence of HIV in South Africa.

It would be expected then that Johannesburg hospitals would have a similar incidence of tracheostomy for this condition. However, this was not the finding in this study, where zero tracheostomies were performed in the 10 year assessment period for croup. The HIV status of patients did not form part of the assessment data in this study, and further studies may clarify the role it plays in our setting.

Despite infectious diseases being more prevalent in third world environments, the overall incidence of infections requiring tracheostomy in this study is also similar to that of other first world institutions, accounting for only 4.2% of cases (1 case of parapharyngeal abscess, 1 submandibular abscess, and 1 supraglottitis).

5.3.2 Adjunct to surgery

Four patients underwent tracheostomy for this reason, accounting for 6% of cases. These patients all had head and neck surgery, with excision of a large pleomorphic adenoma, a cervical desmoid tumour, and a parapharyngeal neurofibroma, and one case of massive facial debridement for mucormycosis performed. Patients in this group generally had good outcomes, with overall low complication rates, and the shortest mean duration of admission compared to the other groups (33days).

5.3.3 Airway protection for depressed level of consciousness

This group accounted for 10% (n = 6) of tracheostomies performed. Of the 6 cases, 5 were due to traumatic brain injuries (4 motor vehicle accidents (MVA)/ pedestrian vehicle accidents

(PVA), 1 assault), and 1 post neurosurgical removal of a brainstem glioma. There is a high incidence of road accidents in South Africa, and children are unfortunately not spared from the consequences. Other institutions in Africa have noted even higher rates of tracheostomy for head injuries as a result of traffic accidents, with rates of up to 15.2% reported.[20]

Violence is another serious problem in South Africa, with assaults resulting in serious brain injuries. This is more commonly seen in older children. The assault victim in this study was a 14 year old male. These finding are in keeping with other institutions, where over 75% of tracheostomies perfomed in the adolescent age group are for injuries, a third being due to traumatic brain injury.[19]

5.3.4 Prolonged intubation for ventilation and pulmonary toilet

In this study, only 13% (n = 9) of patients were tracheostomised for prolonged intubation for ventilation and zero patients for pulmonary toilet. This finding is dramatically different to that in published data, where prolonged ventilation is now the most common indication for tracheostomy in some centers, accounting for up to 26% - 61% of cases.[7,26] Increased survival rates of intensive care patients, particularly neonates, has resulted in increased number of tracheostomies for this group.[2,23] By contrast, in this study no tracheostomies were performed for prolonged intubation for ventilation in the neonatal or infant subgroups.

While other African countries have also shown a low incidence of tracheostomy for prolonged intubation for ventilation (11%), [20] some third world centres, such as in Pakistan, have demonstrated that this is by far the most common indication, accounting for as much as 61%

of tracheostomies.[26] In their study, Zia et al describe how financial constraints have influenced the need for early tracheostomy in their ICU.[26] The study demonstrated how this intervention resulted in a significant reduction in both the length of ICU stay, and the days of ventilation in these patients.[26] In addition to cost saving, shorter ICU stays decrease the risk of nosocomial pneumonia.[26]

Large patient volumes and financial constraints are clearly relevant to the South African public health sector, with constant demand for ICU beds. In the study hospitals, however, this management strategy has not been used. A conservative approach to tracheostomy has been adopted by the paediatric intensivists, which may be motivated by the perceived high complication rates of tracheostomies in these hospitals, and by the lack of universally accepted criteria in the literature regarding length of intubation prior to tracheostomy.[10] Prolonged intubations and its potential consequences as discussed, are the result.

5.4 COMPLICATIONS

A total of 65 complications were encountered in 41 patients. The accumulated duration of tracheostomy for the 70 patients was 27.6 years. This gives a rate of 2.35 complications per tracheostomy year. This is a far higher rate than reported in similar studies; Shinkwin et al, for example, reported a rate of 11 complications in 91.4 tracheostomy years (0.12 complications per tracheostomy year).[23]

The most commonly encountered complications were cannula obstruction (n = 23), and pneumonia (n = 22). Other complications included bleeding (n = 9), accidental decannulation (n = 3), wound infection (n = 3), surgical emphysema (n = 2), granulation (n = 2), and cannula aspiration (n = 1). This is a very different complication profile to that reported in the literature.

In a review of 21 large studies, Kremer et al showed that on average, cannula obstruction was reported in only 4% (range 0 – 14%) of cases, with pneumo-mediastinum (13.5%), accidental decannulation (5.4%), and pneumothorax (4.7 %) the most commonly encountered complications.[10] In contrast, no cases of pneumomediatinum or pneumothorax were recorded in this study.

5.4.1 Cannula obstruction

Cannula obstruction was the most commonly encountered complication (35 % of complications), with 23 episodes reported, thus overall affecting 32% of patients. This finding is concerning as it is far higher than in reported literature, with comparable studies reporting obstruction episodes in 5- 14% of patients.[1,3,28]

This complication is most commonly seen in younger patients with smaller tube sizes, as minimal crusting or secretions are required to occlude the tracheostomy lumen.[3] Michael reports that in neonatal patients, rates of up to 75% have been found.[1] Subgroup analysis in this study confirmed this pattern, with over half (52%) of cases occurring in the infant age group (internal diameter tube size 3-3.5mm). A statistically significant increased incidence of cannula obstruction was found in tubes less than 4.5mm in diameter ($p = 0.0062$).

Increased vigilance for this complication is therefore appropriate in younger patients. However, the study also demonstrated that obstruction is not limited to smaller tubes, illustrating the importance of meticulous cleaning and suctioning of tracheostomy tubes, regardless of size, to maintain patency.

The value of an inner cannula in preventing obstructive episodes was clearly demonstrated. The presence of an inner cannula in similar diameter tubes was associated with a significantly decreased incidence of obstruction ($p = 0.0468$). In the study hospitals, adult type Shiley tubes with inner cannulas are available in larger sizes for older children (adult type, size 4.0 -6.0), however, metal tubes are more expensive, and stock of appropriate sizes is often limited.

14 patients were fitted with the adult type Shiley tube, and 6 with metal tubes.

Tube obstruction is noted to be the commonest cause of tracheostomy attributed mortality in the literature.[23] Similarly in this study, obstruction accounted for 5 of the 6 tracheostomy related deaths (83%). In addition, a further 3 cases required removal of the tube and cardiopulmonary resuscitation to prevent additional mortalities.

The first month after insertion was identified by the study as a high risk period for obstruction, with almost half (47%) the cases occurring during this period. This may be due to initial inflammatory mucosal changes and loss of ciliary function as a result of inspiring non humidified air,[31] and the acute irritation of the tracheal mucosa by the tube, with increased mucous production.

However, obstruction was not limited to the early postoperative period, with episodes encountered as much as 2 years after insertion. Again, this underlines the importance of continuous tube care for the full duration of tracheostomy, as build up of secretions and resultant obstruction remains a potential threat.

The finding that almost a third (32%) of patients in the study experienced an episode of obstruction is concerning, particularly when it is considered that the infant age group accounted for only 18.5% of patients, with only 3 neonatal tracheostomies performed. Obstruction is caused by a buildup of dried secretions in the tube, leading to progressive narrowing of the effective internal diameter. This build up is prevented by the use of humidification, to loosen and decrease viscosity of secretions, and by regular suctioning of the

tube.[25]

These interventions form part of the nursing care in managing tracheostomised patients, and the findings of this study thus suggest that this area of care has been suboptimal. A factor affecting the quality of nursing care is that of the 4 study hospitals, only one has a dedicated tracheostomy ward, with experienced staff. Patients may be nursed in ICU, or in general paediatric wards, where tracheostomy care understanding may be inadequate.

Measures to correct this problem may include the use of formal training programs for staff, and the establishment of dedicated wards for these patients in all the hospitals. A greater availability of appropriate size metal tracheostomies would allow for more patients to be fitted with inner cannulas. This in turn may also decrease the incidence of obstruction episodes.

5.4.2 Nosocomial Pneumonia

Pneumonia was the second most commonly reported morbidity in this study, accounting for 35% of complications (22 episodes in 16 patients). On average, 31% of the study population had an episode of pneumonia. This is far higher than that reported by other authors. In their study of 56 patients for example, Shinkwin et al reported only 1 case of pneumonia (1.7% of patients affected) during a 10 year study period.[23] Others have reported rates of up to 19.5%.[25]

After placement of tracheostomy, several changes occur which may predispose to the development of lower respiratory tract infections. These include: bypassing the protective mechanisms of the upper airway, exposing the tracheal mucosa to atmospheric air, mucus stasis, a change in mucus pH, the tracheostomy tube acting as a foreign body, and trauma to the tracheal mucosa from manipulation of the tube or by suction catheters.[32]

Several studies have shown that bacterial colonization of the tracheobronchial airways after insertion of tracheostomy occurs in almost 100% of patients.[32,33,34]

This study showed an overall rate of 0.03 episodes of pneumonia per patient per year. Two of these patients were unable to adequately clear airway secretions; one as a result of head injury with depressed level of consciousness, and one as result of neuromuscular disease (Guillain-Barre Syndrome).

The high number of pneumonia episodes may indicate breeches of hygiene in nursing care.

While it is noted that bacterial colonization is difficult to prevent,[32] strict antiseptic techniques should nonetheless be practiced when dealing with tracheostomised patents, particularly during suctioning, to prevent the introduction of organisms into the lower airways. Nursing education in this regard is thus vital in preventing episodes of pneumonia.

Prolonged hospital admissions were also shown by the study to play a role, with prolonged length of exposure to hospital pathogens increasing the potential for developing nosocomial pneumonia. The study showed that half the patients admitted for more than one year experienced multiple episodes of pneumonia.

A description of the microbiological profile of the cases of pneumonia did not form part of this study, and further research is needed to compare these findings with that of other centres

5.4.3 Bleeding

Bleeding is reported to occur in 1.2% of patients.[10] In this study bleeding accounted for 14% of complications, affecting 13% of patients (n = 9).

Bleeding may be minor, or catastrophic. Intra operative bleeding may occur from injury to an aberrant vessel, or to the thyroid gland.[25] Minor bleeding from the wound in the early post operative period seldom requires more than simple haemostasis measures. Bleeding in the late post operative period is also usually minor, arising from granulation tissue, or as a result of tracheitis. However, massive bleeding may occur in the case of innominate artery erosion, which is fatal in as much as 75% of cases. This is the most common cause of late mortality,

and is seen in 0.6-0.7% of cases.[2]

In this study, 89% of cases (n = 8) occurred in the early post operative period, and all were minor episodes, with no mortalities resulting.

5.4.4 Accidental decannulation

Three cases of accidental decannulation occurred, one of which resulted in mortality. Accidental decannulation and cannula obstruction are noted to be the most common case of tracheostomy related deaths.[1] When this complication occurs early after surgery, the wound has not yet consolidated and formed a mature tract between the skin and trachea. Thus if decannulation occurs at this stage, the wound will collapse and resulting obstruction of the surgical airway. In addition, attempts at reinsertion of the tube may result in the creation of false tracts, and incorrect placement of the tip of the tube outside the tracheal lumen.[23] It is not clear what the reasons for the cases were, but possibilities include; inadequate or too loosely applied tracheostomy tape ties, inadequately suspended ventilation tubing, inadequate restraints and sedation of ventilated patients with self extubation, and inadequate length tracheostomy tube resulting in dislodgement from the tracheal lumen.

5.4.5 Cannula aspiration

This was an unusual complication occurring in a 2,5 year old male, with post intubation subglottic stenosis, with several comorbidities. During suctioning of the tracheostomy tube, it was noted that the cannula had become detached from the head base assembly, and had been aspirated. The child was not in respiratory distress, and was taken to theatre for bronchoscopic removal of the tube, which was found in the distal trachea with the tip in the right main bronchus. No further morbidity resulted.

It has been noted that with time, polyvinyl chloride (Shiley) tubes become less flexible and can develop cracks.[17] This patient had been admitted for a period of 736 days prior to the incident, although it is unclear how many times the tube had been changed in that period. Two paediatric and one adult patient with similar incidents with these tubes have been reported in the literature.[6,35] A design flaw appeared to be the problem, with the tracheostomy manufacturer stating that a recall of the tubes in question had taken place, and that a new design would be employed in the future.[35]

5.4.6 Incorrect size tube insertion

Tube sizes were appropriately selected in the majority of cases. In one particular case however, incorrect sizing resulted in significant morbidity. In the patient, an 11 year old boy, a size 8 adult Shiley tracheostomy tube was inserted by a department outside of otolaryngology.

The correct size would be a paediatric size 5.5 tube (no inner cannula, therefore smaller outer

diameter).[36] The outer diameter of the inserted tube was thus too large for the airway, causing extensive contact with the tracheal mucosa and resulting in excessive granulation tissue formation. The tube was tightly fixed at the stoma, and required a general anaesthesic in theatre to enable removal, and re-insertion of an appropriate size tube. No other tube size related morbidities were noted.

5.5 MORTALITIES

The study demonstrated a high overall mortality rate of 27%. This is not unlike other centers, with overall mortality rates ranging from 7.4 – 44%.[28] These high rates are explained by the fact that many patients requiring tracheostomy are critically ill, with poor prognoses, and often succumb to their primary disease. However, numbers of mortalities attributable to the tracheostomy are generally low; findings in the literature vary from 0 - 6%,[3,29] with an average rate from 22 large studies of 1.47%.[10]

Thus the finding of a more than fivefold higher tracheostomy related mortality rate (8.5%, n = 6) is concerning. Cannula obstruction was the reason for mortality in 5 of the 6 patients, again raising concern over the adequacy of nursing care for these patients. The higher risk of cannula obstruction in younger children with small tube diameters was again demonstrated; the mean age of these patients was 2.45 years, with 4 of the 5 being under 2 years of age.

5.6 AGE AS A RISK FACTOR

It has been well documented that the rate of complications increases with decreasing age, with the highest rate seen in the premature neonate group.[24] Higher rates of cannula obstruction and pneumonia in particular were noted in this study. Macrae showed that almost 50% of children less than 3 years of age experienced complications, whereas in those over 3 years, complications only occurred in 15 – 20% of cases.[37] This study confirmed this finding, however, the complication rates were higher; in children under 3 years complications occurred in 78% of patients with several patients experiencing multiple complications, while in the over three year age group, 47% of patients experienced complications. Mortality rates are also higher in younger patients; in the same study Macrae showed that 11% of mortalities in children <6 months of age were tracheostomy related, whereas no deaths were tracheostomy related in children over 6 months of age.[37]

In this study 36% of mortalities in children under 2 years of age were tracheostomy related, whereas in those older than 2 years, 25% were tracheosotomy related. These figures emphasize the greater risks, and therefore need for extra vigilance, in caring for younger children with tracheostomies, particularly the infant group.

5.7 PROLONGED IN-HOSPITAL STAY

Prolonged admissions were observed in the study, with a mean length of stay of 147 days (range 5 – 1360 days). Nine patients remained inpatients at the end of the study period. 16% of the patients were admitted for longer than 6 months, and 11% for longer than 1 year. The maximum length of stay was 1360 days (3.7 years).

This compares unfavorably with other institutions, despite the fact that very few (4%, n = 3) tracheostomies were performed for infants, typically requiring more resources and less likely to be discharged early,[11] and that few tracheostomies (13%, n = 9) were inserted for patients for prolonged intubation for ventilation, which constitutes a group with generally more severe medical conditions. The 8 patients admitted for longer than 1 year required only tracheostomy care, with no additional medical needs such as ventilation. The average age of these patients was 1.76 years. In contrast, a large study of hospitals from 22 states in North America showed that the average duration of hospital admission across all age groups was 50.2days.[11]

Nosocomial pneumonia was shown in this study to be a concerning complication related to prolonged admissions. While other complications may have an equal or greater incidence in the outpatient setting, nosocomial pneumonia occurs as a result of hospital acquired pathogens, and is thus linked to the duration of exposure to these pathogens.

Subgroup analysis showed that 50% of the cases of pneumonia occurred after 60 days of admission. 50% of the patients admitted for a period of over 1 year also experienced multiple episodes of pneumonia during their admission. It is thus apparent that a major portion of this

complication could be avoided if discharge rates were in keeping with those of other institutions.

Such prolonged admissions are as a result of the difficulties in establishing safe home based tracheostomy care for many patients, which is discussed in more depth under the home care section below.

The cost of suction machines is often the limiting factor preventing discharge of patients. However, this must be balanced against the far greater cost of prolonged admissions. Basic costs associated with admission need to be considered, but in addition, every episode of nosocomial pneumonia contracted is associated with additional costs with the requirement for expensive intravenous drugs, laboratory and radiological investigations, as well as increasing the work burden on the paediatric department, and nursing staff. Prolonged admissions result in more inpatients at any given time, thus dividing the nursing care, with less attention given to each individual. Suggested standards of care such as 24 hour one to one nursing[1] become impossible.

5.8 HOME CARE

In the South African public hospital setting, there are many impediments to the successful implementation of home care. In addition to the requirements of a period of training for the caregiver, provision of home care equipment, and assessment of the home environment for appropriateness of facilities such as running water and electricity,[6,28] studies have identified several other non medical impediments to discharge. These include; language barriers, parental unemployment, a family member with a disability, delayed funding approval, and lack of telephone facilities.[25,28] These factors are clearly relevant to the South African public sector environment, and would suggest tracheostomy home care to be problematic.

This study confirmed these concerns, with only 34% of patients successfully discharged with tracheostomies in place. Patients were only discharged after a prolonged period, with an average duration of admission of 171 days prior to discharge.

By contrast Graf et al, found the median time to discharge after completing tracheostomy care training in their institution was only 6.5 days (range 0 – 71 days).[28] In addition, patients who were decannulated prior to discharge, were kept as inpatients for a mean duration of 124 days prior to decannulation, rather than being discharged with tracheostomies to home care at an earlier time.

The findings of the study show that complications are more likely to occur in younger patients with smaller size tracheostomy tubes, and in patients who could not be fitted with tubes with an inner cannula. Discharge rates reflected these concerns, with younger children kept as

inpatients for longer periods. The mean age of the patients admitted for over 1 year was 1.7 years, whereas the mean age of the discharged patients was 8 years.

While the social circumstances in the South African public health care sector are particularly challenging, a recent study from Tygerberg Hospital in the Western Cape has shown that home care can be successfully employed, despite limited resources.[38] In this study, Vanker et al discuss how this was achieved through an established formal tracheostomy homecare program, and through the provision of home care equipment. Despite its success, the study revealed that an intensive contribution from the social work department was required to ensure appropriate discharge environments, adding to the burden of an already overloaded department.[38]

Other authors have shown that home care can be safely performed even in suboptimal circumstances in third world countries, in which home support services are not ideal. Alladi et al, in a study from India, and Zia et al, in a study from Pakistan, showed that this could be achieved with fortnightly change of tracheostomy tube,[5] and the provision of foot operated suction pumps.[5,26]

In the study hospitals, no formal tracheostomy home care program exists, with no formal multidisciplinary team, and no home care equipment, such as suction pumps and humidifiers, provided free of charge to patients. The availability of suction machines is particulary problematic. As these are not provided by the hospitals, parents are required to purchase them

privately, or may receive them by donation. Foot operated manual suction pumps are less expensive alternatives to electric pumps, and are in fact more appropriate in areas where electricity supply is inconsistent.[26] These have been used with success in other third world countries,[26] and this option may provide a more practical solution in the South African setting.

Suction machines allow for the clearing of airway secretions, and for cleaning of the tracheostomy tube to prevent obstruction, and thus form part of the recommended discharge criteria for these patients. However, this study demonstrated the value of an inner cannula in the tracheostomy tube, with significantly fewer episodes of obstruction occurring in these tubes ($p = 0.0468$). As these tubes can be removed from the patient for routine cleaning, or if an occlusion of the inner cannula has occurred, they may be an acceptable alternative to suction machines in carefully selected patients who do not require suctioning of the lower airways. Further research into home based care will be required to ascertain the safety of this strategy.

Because of the vast number of factors to consider in assessing whether a child can be safely discharged with a tracheostomy, it is clear that each patient must be assessed individually, taking all aspects into consideration before instituting home based care.

5.9 LIMITATIONS

This study may have been affected by the following limitations;

- All data had to be physically collected, as no electronic database exists in the study hospitals. Many patient records could not be found as a result of misfiling, loss, or incorrect capturing. This resulted in lower patient numbers for the study than could have otherwise been obtained.
- In addition, several patient records were incomplete, and did not contain adequate data, resulting in exclusion from the study.
- As a retrospective study, the study relied on accurate note keeping by the treating doctors, and it is possible that underreporting of complications may have occurred.

CHAPTER 6

6. CONCLUSIONS AND RECOMMENDATIONS.

Paediatric patients with tracheostomies represent a group of patients with very specific needs. Successful management of these patients requires overcoming many challenges, particularly in a resource poor environment. As tracheostomy practices and complications vary widely between institutions, this study provided a basis for understanding the patient profile, and particular problems encountered in the local hospital setting.

This study demonstrated that the Johannesburg academic hospitals have not followed the international shift in age and indication demographics. Infants did not constitute the majority of patients. Upper airway obstruction, rather than prolonged intubation for ventilation, remains the most common indication for tracheostomy, with subglottic stenosis and laryngeal papillomatosis the most common indications of this group.

Assessment of morbiditiy showed that cannula obstruction and nosocomial pneumonia were the major complications encountered, occurring at a far higher rate than that reported in the literature. Mortality rates were also higher than reported in other institutions, with almost all cases the result of cannula obstruction.

The first month after tracheostomy insertion was demonstrated to be a greater risk period, with the highest rates of complications occurring during this time. Prolonged in-hospital stays were

observed as a result of problems in instituting home care.

The study identified several factors impacting on outcomes. Age had a significant affect on outcome, with younger patients, particularly infants, shown to have higher morbidity and mortality rates, and longer durations of admission. Tracheostomy tube sizes, and the presence of an inner cannula both affected outcomes, with significantly fewer complications in tubes with internal diameters greater than 4.5mm, and in tubes with inner cannulas. Prolonged admissions also affected outcomes, with the number of episodes of nosocomial pneumonia correlating with duration of admission. Finally, indication groups were shown to affect outcomes; the upper airway obstruction group had the longest duration of stay, and the highest complication rate, but the lowest mortality rate, whereas the prolonged intubation for ventilation group had the highest mortality rate, and the adjunct to surgery group the shortest length of stay.

The study thus provides a basis for addressing the specific areas identified, in order to improve outcomes. Subglottic stenosis may be reduced by routine weekly fibreoptic endoscopy for ventilated patients, and a lower threshold for tracheostomy in the older child. Glottic stenosis post papilloma surgery may be decreased through refining the surgical technique of trainees.

Improved training of nursing staff involved in tracheostomy care is vital, and may decrease the incidence of cannula obstruction encountered. The establishment of tracheostomy wards in all the hospitals would further improve the quality of nursing care. Shorter in-hospital stays may be achieved through the establishment of a formal tracheostomy home care program, with particular emphasis on the role of the social work department. This will allow better

evaluation of patients and their potential discharge environments. An increased allocation of the hospital budget for the provision of home suction equipment is also required, with utilization of manually operated foot pumps as a more cost effective and practical option. A greater availability of metal tracheostomy tubes with inner cannulas may decrease cannula obstruction episodes, and further improve discharge rates. This will also in turn decrease the incidence of nosocomial pneumonia.

With these interventions it is possible that that improved outcomes for tracheostomised children in our institutions may be achieved.

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APPENDIX A

Filtered data

Filtered Data

Code	Date of surgery	Diagnosis	Age(yrs)	Indication	Indication group	Tube Size	Tube type	Complic.1	Days after insertion	Complic. 2	Days after insertion	Complication 3	Days after insertion	Mortality	Mort Complic	Days after trache	Discharged	With Tracheostomy	Duration in Hosp (days)
001	2006/07/24	Hydrocephalus with vc palsy	0.16	Bilateral vocal cord palsy	UAO	3	shiley	Pneumonia	33					yes	non trache related	35	no		35
002	2006/09/27	Papilloma	8	Glottic stenosis	UAO	5	shiley, 5 metal							no			yes	yes	75
003	2008/07/28	Assault, acute subdural haematoma	14	Low GCS	Low GCS	5.5	shiley							yes	non trache related	4	no		4
004	2008/07/16	Brainstem glioma	1	Low GCS	Low GCS	3.5	shiley							yes	non trache related	18	no		18
005	2009/10/16	Duodenal atresia	4	Subglottic stenosis post intubation	UAO	4	shiley, inner	Pneumonia	150		155			no			yes	yes	179
006	2010/01/26	PVA HI, intubated	8	Subglottic stenosis post intubation	UAO	5	shiley, 4 metal	CO	99	CO	225	bleeding tracheitis	18	no			no	inpt	339
007	2010/02/04	Kyphoscoliosis, pv post spinal decompression sx	16	PV	PV	5	shiley	Wound infection	11	bleeding	13	CO	1	yes	non trache related	13	no		13
008	2010/07/31	Papilloma, glottic stenosis post debulking	5.5	Glottic stenosis	UAO	5.5	shiley	Wound Infection	6								no	inpt	153
009	2007/10/01	Papilloma	1	Glottic stenosis	UAO	3.5	shiley	Pneumonia	30	Pneumonia	60	CO, Pneumonia, bleeding	3yrs	no			no	inpt	1187
010	2006/10/25	MVA head inj, intub	14	Subglottic stenosis post intubation	UAO	5.5	shiley							no			yes	yes	68
011	2003/05/03	Retropharyngeal abscess, intubated	1.5	Subglottic stenosis post intubation	UAO	3	shiley	CO	3	bleeding	6			yes	CO	13	no		13
012	2010/11/05	CP, laryngomalacia	0.67	Laryngomalacia	UAO	4	shiley	Wound Infection	5		153						no	inpt	56
013	2009/01/02	GBS	2	PV	PV	5	shiley	CO	17					yes	CO	17	no		17
014	2010/10/20	Flame Burns Face, prolonged intubation	9	Tracheal stenosis	UAO	5	shiley, 5 metal	Bleeding	10	CO				no			no	inpt	72
015	2010/07/30	Flame Burns Face, inhalation inj, prolonged intubation	5	Subglottic stenosis post intubation	UAO	5	shiley, 4 metal	CO	215					no			no	inpt	154
016	2009/03/23	Attempted suicide, pv	17	PV	PV	6	shiley inner	bleeding	7					no			yes	yes	32
017	2009/09/09	Parapharyngeal abscess	11	Parapharyngeal abscess	UAO	5	shiley							no			yes	no	29
018	2010/04/21	Pleomorphic adenoma	13	Adjunct to surgery	AS	5.5	shiley	CO	5					no			yes	no	7
019	2009/07/01	Burns neck, intub	1	Subglottic stenosis post intubation	UAO	4.5	shiley	Pneumonia	45					no			no	inpt	548
020	2003/04/15	MVA HI , low GCS	8	Low GCS	Low GCS	5	shiley							no			yes	yes	168
021	2004/12/13	Palilloma	6	Glottic stenosis	UAO	5	shiley, 4 metal	Pneumonia	232	bleeding	942	Pneumonia	1294	no			yes	yes	1360

022	2004/08/26	Congen subglottic steenosis	1.75	Subglottic stenosis congenital	UAO	4	shiley	Pneumonia	4					yes	CO	4	no		4
023	2008/09/11	MVA HI, intubated	17	Subglottic stenosis post intubation	UAO	6	inner							no			yes	yes	22
024	2003/05/07	ligation PDA, intubted	3	Subglottic stenosis post intubation	UAO	4	shiley							no			yes	yes	5
025	2002/11/01	Primary peritonitis, intubated	6	Subglottic oedema	UAO	6	portex							no			yes	no	24
026	2008/08/16	Dermatomyositis/ GBS	7	PV	PV	5	shiley	Pneumonia	25					yes	CO	28	no		28
027	2003/07/18	Ex prem nicu, ventillation	1	Subglottic stenosis post intubation	UAO	3.5	shiley	AD	1	Pneumonia	648	Pneumonia	25	no			yes	no	688
								CO	394										
028	2002/06/16	Cor pulmonale, prev ventillation, subglottic stenosis	2.5	Subglottic stenosis post intubation	UAO	4	shiley	Pneumonia	817	Pneumonia	933	granulation at trache site	1074	no			yes	no	1090
								aspirated broken trache	736	Pneumonia	996	AD	738						
029	2002/05/03	Supraglottitis	6	Supraglottitis	UAO	5.5	shiley	Pneumonia	28					no			yes	no	52
030	2010/07/07	Parapharyngeal neurofibroma	14	AS	AS	6	Inner							no			yes	no	8
031	2004/03/19	Congenital subglotic stenosis	1.75	Subglottic stenosis congenital	UAO	4	shiley							yes	non trache related	12	no		12
032	2001/01/15	Papilloma	2.5	Glottic stenosis	UAO	4	shiley	Pneumonia	226					no			yes	yes	436
033	2000/12/19	Subglottic stenosis post intubation	0.25	Subglottic stenosis post intubation	UAO	3	shiley	CO	3	bleeding	10			no			yes	yes	98
034	2009/01/30	Cystic supraglottic mass	0.083	cystic laryngeal lesion	UAO	3	shiley	CO	180	Pneumonia	228			no			yes	yes	456
035	2000/10/16	Papilloma, glottic +subglottic stenosis	4	Glottic stenosis	UAO	5	shiley							no			yes	yes	290
036	2007/10/26	Tracheobronchial tree papilloma	5	Papilloma	UAO	5	shiley, 4 metal							no			yes	yes	208
037	2008/10/10	PVA, multiple brain contusions	8	PV	Low GCS	5	shiley							no			yes	no	70
038	2008/11/04	Laryngeal trauma	7	Glottic stenosis	UAO	5.5	shiley							no			yes	yes	39
039	2010/09/07	lobectomy, intubation	1.5	Subglottic stenosis post intubation	UAO	4	shiley	bleeding+ sx emphyseama	8	granultion tissue	30			no			yes	yes	66
040	2010/05/29	MVA, HI, ventillated	15	Tracheal stenosis	UAO	5	shiley							no			yes	yes	61
041	2010/12/13	Conj subglottic stenosis	0.25	Subglottic stenosis congenital	UAO	3.5	shiley	CO	3	Pneumonia	30			no			no	inpt	18
042	2010/12/17	caustic injestion	6	Supraglottic injury with oedema	UAO	5.5	shiley							no		13	yes	no	16
043	2010/11/21	MVA, polytrauma, HI	11	low gcs	Low GCS	8	shiley, inner	granulation tiss	20	required removal in OT	20			no			yes	no	60
044	2008/12/09	Myelomaningocoel, hydroceph, BVC palsy	0.167	Bilateral vocal cord palsy	UAO	3	shiley							yes	non trache related	10	no		10
045	2005/02/01	Treacher collins syndrome, tracheal stenosis post trache	6	Tracheal stenosis	UAO	5	shiley							yes	non trache related	716	no		716

046	2004/07/05	OSA, cor pulmonale, morbid obesity	10	OSA	UAO	4	shiley, inner	AD	2					yes	Accidental Decannulation	6	no		6
047	2003/10/10	Anaplastic astrocytoma	4	Subglottic stenosis post intubation	UAO	5	shiley							no			yes	no	31
048	2009/09/18	PVA, HI	6	Low GCS	Low GCS	4	shiley	Pneumonia	12					no			yes	no	32
049	2008/06/13	Oromandibular-limb hypogenesis syndrome	0.038	Micrognathia with uao	UAO	3	shiley	CO	3	CO	11	Pneumonia	46	yes	CO	50			50
050	2007/03/01	Submandibular abscess	15	Submandibular abscess	UAO	6	shiley, inner							no			yes	no	8
051	2003/01/03	MVA, DAI, multiple facial fractures, bilat vc palsy	5	Bilateral vocal cord palsy	UAO	6	portex, no inner	AD	44					no			yes	no	45
052	2003/05/03	Skull base fracture, DAI, intub	6	Subglottic stenosis post intubation	UAO	5.5	shiley	bleeding min	1	Pneumonia	15			no			yes	no	28
053	2003/06/03	Mediastinal/cervical desmoid tumour excision	10	AS	AS	5.5	shiley	Pneumonia	32					no			yes	yes	94
054	2004/11/04	MVA, HI, PV, tracheal stenosis	14	Tracheal stenosis	UAO	5.5	shiley							no			yes	yes	30
055	2005/07/28	Sq Ca oropharynx	8	Sq Ca oropharynx	UAO	5.5	shiley							no			yes	yes	156
056	2006/09/22	Bilat VC palsy congen.	0.083	Bilateral vocal cord palsy congenital	UAO	3	shiley	CO	104					no				yes	153
057	2007/01/07	MVA, PV	13	Subglottic stenosis post intubation	UAO	5.5	shiley	Bleeding	0					no			yes	yes	31
058	2007/02/01	Laryngomalacia	0.83	Laryngomalacia	UAO	3	shiley							yes	non trache related	54	no		54
059	2007/03/09	GBS	4	PV	PV	4	shiley	CO						no			yes	yes	27
060	2010/07/05	MVA, poltrauma, HI	17	Low GCS	Low GCS	6	shiley, inner							yes	non trache related	4			4
061	2000/04/19	GBS	16	Subglottic stenosis post intubation	UAO	6	shiley, inner	surgical emphyseama	2					no			yes	yes	34
062	2010/07/30	MVA, polytrauma, HI	17	Low GCS	Low GCS	6	shiley, inner							yes	non trache related	8	no		8
063	2007/07/18	PVA, polytrauma, HI	15	Low GCS	Low GCS	6	shiley, inner							no			yes		19
064	2007/11/02	Ruptured appendix, PV	10	PV	PV	5	shiley							yes	non trache related	15	no		15
065	2008/06/08	Malignant hyperthermia	15	PV	PV	6	shiley, inner							no			yes	no	16
066	2009/02/06	Burns with Inhalational burns, ARDS, pneumonia	3	PV	PV	4	shiley	AD	5								yes	no	60
067	2010/03/05	MVA HI	10	Low GCS	Low GCS	6	shiley, inner							no			yes	no	14
068	2010/12/17	Caustic injestion	6	Supraglottic injury with oedema	UAO	5.5	shiley							no			yes	no	22
069	2010/11/05	Mucormycosis	13	Mucormycosis, extensive surgery	AS	4	shiley, inner		14					yes	non trache related	21	no		21
070	2010/02/26	Septic burns	1.5	PV	PV	3.5	shiley	CO	120					yes	non trache related	136	no		136

APPENDIX B

Ethics Clearance Certificate

Ethics Clearance Certificate

M110457

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Christopher Richard Jacobs

CLEARANCE CERTIFICATE	**M110457**
PROJECT	Paediatric Tracheostomies in Johannesburg: A TenYear Review
INVESTIGATORS	Dr Christopher Richard Jacobs.
DEPARTMENT	Department of Otorhinolaryngology
DATE CONSIDERED	06/05/2011
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 07/06/2011 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr Lalenthra Naidoo

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementione research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...