Surgical outcomes of Endoscopic Anterior Cricoid Split and Balloon dilation as treatment for paediatric subglottic stenosis: A retrospective case series

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1. Declaration

I, Dr Louisa Brownell, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree at this or any other university.

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2. Cover Letter

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3. Abstract

Objective: Subglottic stenosis (SGS), congenital or acquired, can present as life-threatening airway emergencies or ongoing respiratory symptoms in paediatric patients. In resource-limited settings, identifying a first-line surgical option to definitively manage SGS, as opposed to permanent tracheostomy, is the ideal. The aim of this study is to review endoscopic anterior cricoid split with balloon dilation (EACSBD) as the first-line definitive treatment option for selective SGS cases, in a resource-limited setting, and to retrospectively compare outcomes with published literature.

Study design: Retrospective Case Series

Setting**:** Tertiary Paediatric State Hospital in Cape Town, South Africa.

Methods**:** Medical records of children with SGS managed with EACSBD from Jan 2020 to July 2021 were reviewed. Data collected included preoperative characteristics, intraoperative findings, postoperative course, and clinical outcomes. Successful treatment was defined as resolution of symptoms with no baseline respiratory distress. Institutional ethical approval was obtained prior to commencement.

***Results*:**

Eight patients aged between 3-17 months (mean age of 6,8 months) were identified. Cotton-Myer grades ranged between 1-3. The aetiology of the subglottic stenoses were: 4 acquired, 3 congenital, 1 mixed. Five patients did well with no further intervention necessary. One patient required a single follow-up laryngoscopy and balloon dilation. Overall, 6 patients (75%) had successful treatment and remained symptom-free. All congenital SGS (3/8) patients were successfully treated. Two patients failed EACSBD for reasons unrelated to the procedure. One patient (1/8) remained intubated for 41 days post-operatively and required a tracheostomy for respiratory failure secondary to severe pulmonary tuberculosis. Three children had post-operative aspiration, two resolved with speech therapy. One child went home on nasogastric feeding. No procedural complications were reported.

***Conclusion*:** This is the first study from sub-Saharan Africa to describe a series of EACSBD in selective paediatric SGS. All congenital cases in our cohort were successfully treated, contributing to an overall success rate of 75%. EACSBD is therefore a safe and effective surgical option for selected paediatric subglottic stenosis. It is well-suited for resource-limited settings by offering a definitive solution that may avert a tracheostomy. However, it should be used with caution in patients with additional laryngeal pathology, those with higher risk of aspiration, and in cases of co-existing lung disease. Careful patient selection is therefore essential to achieve optimal outcomes.

Keywords: Subglottic Stenosis, Paediatric Endoscopic Airway, Endoscopic Anterior Cricoid Split, Balloon Dilation, Limited Resource Setting, Croup

4. Introduction

Subglottic stenosis (SGS) is a narrowing of the subglottic airway i.e. below the glottis and above the first tracheal ring. It is a common cause of paediatric airway obstruction. The incidence of SGS is reported to be in the range of 1-8% after intubation [1]. SGS is classified as acquired (most common) or congenital stenosis [2].

Acquired SGS due to long-term or prior endotracheal (ET) intubation accounts for the vast majority (90%) of cases [3]. Avelino at al classified the acquired SGS into acute and chronic i.e., acute SGS - diagnosed and treated up to 30 days, and chronic SGS - diagnosed and treated more than 30 days after extubation or tracheostomy [4]. An increased incidence of acquired SGS occurred in the 1960's due to greater rates of prolonged mechanical ventilation in premature Neonatal ICU (NICU) children [5]. ET intubation compromises laryngeal mucosal capillary-refill pressure, leading to mucosal oedema and scar formation [6,7]. Longer durations of intubation, together with poor sedation are associated with higher relative risk of developing SGS [8]. Other risk factors for SGS are difficult intubation, earlier gestational age, prematurity, low birth weight, systemic infection, and any mucosal injury conditions (e.g. reflux) [9,10,11,12]. Improved NICU airway practices since the late 1960's have led to declining incidence of SGS [13,14,15]. However, SGS still remains a common cause of paediatric respiratory distress [16].

Congenital SGS is a subglottic airway diameter of less than 4mm in a term new-born due to defective canalisation of the cricoid cartilage [9,17], and may include other embryologic failures [9] identified at endoscopy. The membranous type is typically milder, circumferential, soft and dilatable, contrasting with the dense cartilaginous type - the latter more difficult to treat [9].

SGS may present with impending respiratory arrest or with stridor unresponsive to medical treatment. Milder forms may manifest as recurrent upper respiratory infections. Infants may also remain largely asymptomatic and remarkably tolerant for weeks or

months even with worsening subglottic disease, and eventually present with very advanced chronic SGS [9].

Surgical decision-making depends on patient factors, disease severity, surgeon skill set and available resources. In minimal resource settings, theatre time, equipment and advanced specialized surgical airway expertise may not be readily available. Furthermore, post-operative follow-up for clinical review may present challenges for patients and practitioners. Thus, a first-line surgical option to definitively manage SGS that is safe and effective, simple and quick to perform, and avoids long-term tracheostomy and its sequelae is ideal.

Surgery for SGS can be open, endoscopic, or a combination. Tracheostomy is an acceptable, reasonable option if endoscopic or open procedure experience is unavailable. It bypasses the stenosis and allows laryngeal rest. By immediately relieving the upper airway obstruction, it facilitates weaning and liberation from the ventilator. However, it does not address the underlying disease. Tracheostomy care can successfully be performed at home, provided proper teaching and support is offered, but is not without risk, and a definitive procedure that liberates the child from tracheostomy is most certainly desirable.

Open airway reconstruction is recommended for persistent SGS, particularly with severe stenosis (grade 3-4); with cartilage involvement; and/or when scar tissue is present. It involves either expansion with laryngotracheal reconstruction or cricotracheal resection. These procedures have excellent decannulation rates [18], but are not simple and traditionally not feasible in resourced-limited settings. Success depends largely on good patient selection; specialised surgical skills; a coordinated multidisciplinary team; experienced intraoperative surgical and anaesthetic teamwork; meticulous postoperative care; strong Paediatric ICU (PICU) support with facilities for prolonged ventilation; and institutional ability to manage potentially severe post-operative complications. Secondary procedures and follow up are also often needed [19,20,21].
Furthermore, an external scar is undesirable.

Endoscopic treatment aims to expand the stenotic segment through scar excision (laser or “cold steel”) with or without dilation (rigid or balloon dilation) [22]. Laser excision carries a risk of thermal injury and repeated rigid dilation may further insult already traumatised subglottic tissue [23].

Endoscopic balloon dilation (EBD) as a primary stand-alone procedure is increasingly attractive and has taken centre-stage in the last decade and is the standard of care at the Red Cross War Memorial Children’s Hospital (RCWMCH). EBD is minimally invasive, avoids complexities of open surgery, leaves no external scar, has shorter procedure times, low complication rates and may avoid tracheostomy and laryngotracheal reconstruction [24]. It is highly successful in acute acquired paediatric SGS - Avelino et al demonstrated 100% success rates [4]. It is less successful (39%) in chronic acquired cases (more mature scar tissue) or in higher SGS grades 3-4 [4,24]. EBD alone is therefore not indicated for congenital cartilaginous stenosis or thick SGS scars [25]. Other drawbacks of primary EBD include the need for multiple repeat dilations, and a need for regular endoscopic surveillance [24]. In a few, selected cases when circumferential oedema, dense scar or narrowed cricoid cartilage ring is not sufficiently addressed by balloon dilation alone, a cricoid split, either open or endoscopic, is necessary. An endoscopic anterior cricoid split (EACS) is less invasive and carries less risk than open surgery. In our institution, EACS is therefore performed in a select group of suitable SGS candidates.

Endoscopic cricoid split (ECS) achieves surgical expansion by cutting through the narrowed cartilaginous cricoid ring either anteriorly alone, or anteriorly and posteriorly, to release the firm, circumferential stenosis, thereby widening the subglottic calibre.
This may include incising the first tracheal ring. To ensure distraction, it is followed by balloon dilation before the patient is reintubated for 5 days to maintain distraction. Endoscopic Anterior Cricoid Split with Balloon Dilation (EACSBD) technique was first described by Mirabile et al in 2010 [26]. Although small numbers, EACSBD was reported to be safe and effective (83%) with no residual respiratory symptoms or grade

0-1 SGS on follow up. EACSBD was suggested as first line treatment for most grades of stenosis with possible extension to more difficult-to-treat cases with cartilaginous congenital stenosis, or more chronic acquired SGS. As patient selection is limited, only a handful of retrospective studies with small numbers of EACSBD have subsequently been published, but all with good success rates, higher in the acute stenosis, and less so in the chronic acquired groups [26,27,28]. It would therefore appear that EACSBD is efficient and safe, with minimal post operative complications. The endoscopic nature of EACSBD avoids the morbidity of open approaches and does not preclude tracheostomy or other laryngotracheal reconstruction options, should it fail. Post procedural repeat balloon dilations have been reported [26,27].

At RCWMCH, the Division of Otorhinolaryngology manages a high volume of airway diseases in children, including laryngotracheal stenosis. Children of various ages and aetiologies present with subglottic stenosis, and are managed as above – endoscopically, open or a combination of both. The objective of our study was to retrospectively review our local case series of children managed at RCWMCH, who underwent EACSBD as definitive therapy for SGS; to compare our outcomes to the limited international literature. In doing so, to determine whether EACSBD is suitable in resource-limited settings as first-line definitive treatment by analysing metrics that lead to high burden requirements such as duration of ICU stay, time to discharge, need for repeat dilations, and tracheostomy.

5. Research Methods and Study Design

1.1 Study Design

A retrospective case series of paediatric SGS patients who underwent EACSBD at Red Cross War Memorial Children's Hospital in Cape Town, South Africa (tertiary paediatric ENT unit) from Jan 2020 to July 2021 was done. Informed consent was not required due to the retrospective nature of the study. Ethical approval was granted by the Human Research Ethics Committee of the University of Cape Town (reference number: HREC Ref 469/2020). Data was collected from patient medical records and included patient demographics, birth weight, indication for hospital/ICU admission,

underlying medical/systemic condition, preoperative characteristics, endoscopic findings, post-procedure intubation time, complications, follow-up duration and symptoms, further airway interventions. These findings were recorded on a clinical research form (Addendum 3) and were known only to the investigators. The patients identities were anonymized before uploading onto a digital spreadsheet for ease of comparison. Descriptive statistics with univariable analysis were used to describe demographics, clinical characteristics, surgical findings, clinical course and final outcomes. Data were presented as mean +/- standard deviation and median with categorical variables presented as frequency and percentages. Success of EACSBD was measured by resolution of respiratory distress without the need for further airway interventions i.e., avoidance of tracheostomy or airway surgery was considered successful and secondly by adequate expansion of stenotic airway.

1.2 Subject Population

Paediatric SGS cases treated with EACSBD were identified. Patients selected for EACSBD were patients that on visual assessment of the airway (either in theatre or emergently) had evidence of SGS. These patients presented with either emergent upper airway obstruction (requiring intubation in theatre), or recurrent episodes or unresolving episodes of croup, failed extubation or inability to wean off oxygen. Exclusion criteria were children a) older than 18 months at time of procedure; b) syndromic; c) EACSBD for indications other than SGS and; d) with a tracheostomy or open airway reconstruction.

1.3 Surgical Procedure and Postoperative Management

Endoscopic Anterior Cricoid Split: Under general anaesthesia while breathing spontaneously, the patient was gently placed into microlaryngeal suspension using the Benjamin-Lindholm laryngoscope, followed by topicalization of the airway with local anaesthetic. In the event of apnoea, rescue intubation for ventilation was performed following first pass for diagnosis using a Hopkins telescope (usually 0^0 2,7mm for rescue intubation as well). Diagnosis and grading of SGS using the Cotton-Myer classification,

and other airway abnormalities if seen, were recorded [29]. A standard sickle knife or microlaryngeal scissors was used to make a vertical midline incision through the anterior cricoid cartilage and mucosa - the endoscopic anterior cricoid split. An assistant palpated the anterior neck externally to judge incision depth and to stabilize the cricoid. Distally the first tracheal ring was divided and proximally the incision was limited to the infraglottis [30]. Balloon dilation was then performed with an age appropriate (5-7mm occlusive or non-occlusive) balloon. The size of balloon was determined by using the age-appropriate ETT (outer diameter plus 2mm). Balloon dilation was performed twice for 120 seconds, unless premature desaturation occurred. The earlier cases (patients 2, 3 and 4) had dilations using occlusive balloons, while the remainder were dilated with nonocclusive balloons that permitted ventilation during dilation. This improved the quality of airway management and has become the institutional standard of care [31]. The subglottic stenosis and subsequent expansion were measured according to the modified Cotton-Myer Grading system for subglottic stenosis (1-4). Further assessment of successful expansion was made by intubating with an uncuffed ETT. When the ETT passed easily, and still allowed for a leak at 20mmHg, this indicated that sufficient diameter expansion of the subglottis had been achieved. Subglottic expansion was measured by international standards that includes the modified Cotton-Myer staging system (of 1-4). Nasal intubation using a half sized larger uncuffed ETT was performed before transfer to PICU for 5 days of ventilation under sedation. Anti-reflux medication was also initiated. All patients received 24 hours of peri-extubation intravenous steroids. Patients were extubated on day 5 and supported with CPAP or supplemental oxygen, with adrenaline nebulisation for post-extubation stridor.

1.4 Evaluation of Outcomes

Institutional standard of care following EACSBD typically entails routine endoscopic evaluation at 6 weeks. Other outcomes included: persistent stridor or respiratory distress, need for endoscopy, and repeat dilation or tracheostomy. Factors that would contribute to effectiveness in resource limited settings included: duration of ICU stay, time to discharge, need for repeat dilations, and tracheostomy. However, during the COVID-19 pandemic (effectively March 2020 until July 2021), theatre and hospital access were

disrupted for non-urgent or non-emergent cases, and surveillance endoscopy and follow-up did not formally resume until October 2021 when the COVID19 lockdown was eased to Level 1, and patients were managed according to clinical symptoms. This interruption of routine surveillance resulted in variable follow-up periods for patients.

6. Results

A total of eight patients aged between 3-17 months (mean of 6,8 months, SD:11.67) were identified. Five were female, and 3 were male. Half (50%) were premature births (n=4), 37,5% were term babies (n=3), and 12,5% (n=1) was unknown gestational age. Weight at time of EACSBD ranged from 4,35-10 kg (mean of 6.82kg, SD1.85). Cotton-Myer SGS ranged between Grades 1-3. The aetiology of the SGS were: 4 acquired cases, 3 congenital cases, 1 mixed case (diagnosis based on a combination of clinical history and endoscopic findings). EACSBD indications included: 4 recurrent croup cases, 2 emergent stridor/upper airway obstruction cases, 1 failure to wean off non-invasive HiFlo (high flow oxygen therapy) case, and 1 failed extubation case. Preoperative ventilation requirements varied - 5/8 cases (62,5%) were ventilated: 4/5 were on non-invasive ventilation (2 on continuous positive airway pressure, 2 on HiFlo nasal canula); 1 intubated patient was on positive pressure ventilation. The remaining 3/8 cases were on room air (37,5%). *Preoperative characteristics and indications are described in* ***Table A. 1****. Direct laryngoscopy findings are presented in* ***Table A.2.***

No procedural complications following EACSBD were recorded. *Postoperative course and clinical outcomes are presented in* ***Table A.3***. Overall, 6/8 patients (75%) had successful treatment and remained symptom-free. Five patients did not require further airway interventions. They did not require follow-up scopes and were considered clinically well. All congenital SGS (3/8) patients were successfully treated with no additional interventions required. One patient (patient 1) required a single follow-up laryngoscopy and balloon dilation. The remaining 7/8 had successful subglottic expansion. Two of eight (patient 4 and 8) had complex post-operative courses unrelated to the EACSBD. Patient 4 was diagnosed with Pulmonary Tuberculosis (PTB) and received a tracheostomy for prolonged ventilation for respiratory failure. The subglottis

was patent and of adequate calibre. Patient 8 had persistent aspiration thought to be secondary to a type 1 laryngeal cleft, but was lost to follow-up.

Post-operative intubation ranged from 4-41 days (mean of 10 days, SD:11.77). Patient 4 had prolonged intubation (41 days) for respiratory failure. If patient 4 is excluded from the analysis, the post-op intubation ranged from 4-8 days (mean of 5,57 days, SD:4.6). The number of days in PICU postoperatively ranged from 4-41 days (mean of 12 days, SD:12.99). If patient 4 is excluded here, the PICU stay ranged from 6-10 days, (mean of 8 days, SD:4.4). The number of days in hospital after EACSBD ranged from 7-100 days (mean of 28.13 days, SD:29). Patient 4's total hospital stay was 100 days.

Three children (37.5%) had post-operative aspiration (patients 5, 7, and 8), two resolved with speech and swallow therapy (patients 5 and 7). Patient 8 had a prolonged 42-day hospital stay due to ongoing aspiration and intermittent stridor. Further assessment for definitive feeding or breathing options were discussed with the parents, who refused, and the child was discharged home with nasogastric feeding. He was lost to follow up.

The duration of post-operative hospital stay ranged from 7-100 (mean of 28.1 days, SD:29). If patients 4 and 8 with complex post-operative findings are excluded from analysis, the duration of would range from 7-21 days (mean of 13,8 days, SD:15.2). Mean post-operative follow-up ranged from 1-16 months (mean of 4,6 months, SD:5.3); follow-up was significantly affected by the COVID-19 pandemic. Two patients had post-operative endoscopies (patient 1 and 4). Patient 1 had a residual Cotton-Myer grade 3 SGS. A single repeat balloon dilation was performed successfully. This patient's total follow-up duration was 10 months. Patient 4's follow-up endoscopy was during tracheostomy surgery for prolonged ventilation and was found to have a Cotton-Myer grade 3 SGS and glottic web, attributed to the 41 days of prolonged intubation. The total follow-up duration for patient 4 was 16 months, the tracheostomy was still present at the end of this follow-up period but was eventually decannulated with no airway intervention needed.

7. Discussion

There is a paucity of literature on EACSBD, and even less related to resource-limited settings. To be suitable for resource-limited settings, EACSBD needs to be effective, safe and easy to perform. It should preferably not require specialized equipment or very advanced surgical skill or involve prolonged hospital stays and post-operative attendance. Most importantly, it should provide patient and family satisfaction and be culturally and socially acceptable. From our small case series EACSBD appears well suited to limited resource settings - successfully treating SGS as a first line option, avoiding tracheostomy or further airway procedures, without precluding open airway options, should EACSBD fail.

EACSBD is not indicated in all cases with SGS, and careful patient selection is key. In our study 100% success was achieved in congenital SGS - requiring no further intervention. EACSBD appears to be more effective than EBD alone in congenital SGS, as reported in the literature [28]. In acquired SGS cases, our study achieved a 75% success rate; 1 child was still symptomatic despite an expanded subglottis and required a tracheostomy for ventilation requirements. The other patient had a laryngeal cleft that resulted in refractory aspiration, worsening the stridor. These 2 cases emphasize the lower success rate with EACSBD in children with pre-existing lung disease and those with a higher risk for aspiration. Our study concurs with Mirabile's study, highlighting selection towards congenital cases as they have better outcomes, and to consider extending EACSBD to chronic cases, but with careful selection [26, Table A.4].

Of note, only one patient (SGS grade 3) required repeat balloon dilation (12,5%). This is much lower than similar reports in the literature: Mirabile et al.'s study of 18 patients found 83% required 1-7 repeat EBDs [26, Table A.4]; Carr et al's study of 9 patients found 78% required 1-2 repeat EBDs [27, Table A.4]; and in Blanchard et al.'s cohort of 7 patients, 100% required 1-4 repeat EBDs [33, Table A.4].

The COVID-19 pandemic may have also contributed to the lower rate, especially if at follow-up patients were deemed clinically well, surveillance scoping was deferred. This

raises a relevant point regarding the need for multiple routine surveillance scopes, provided patients are clinically well. It stands to reason that fewer number of repeat procedures is advantageous to patients with regards to follow-up. This study demonstrated good success rates with far less repeat surveillance scopes than is reported in the literature. However, due to the small number of patients, studies with larger numbers of patients and longer duration of follow up would provide more insight.

EACSBD appears suitable as first line treatment for congenital SGS and acutely acquired SGS. It can be used in emergent cases and in SGS that presents less severely, with unresolving respiratory symptoms. EACSBD can be used in more established grades 1-3 SGS and extubation failure cases [27]. The two failed cases requiring tracheostomy (one of which was a failed extubation case) were chronic acquired cases that closely resemble failures described by Carr [27, Table A.4] i.e. other significant laryngeal abnormalities (laryngeal cleft with aspiration) or chronic lung disease (pulmonary tuberculosis with collapse lung) and are less likely to benefit from EACSBD. Importantly however, a huge benefit of EACSBD is that it doesn't preclude other open airway interventions should it fail and can be considered prior to planning more extensive surgery.

EACSBD was performed with relative ease for an otolaryngologist, using regular microlaryngoscopy and cold steel equipment. The procedure is certainly quicker than open airway surgery, and requires less advanced skills. Carr et al. and Mirabile reported EACSBD procedure time as approximately 30 minutes vs 80 minutes for open procedures [26,27].

Post-operative intubation and sedation in PICU are important considerations especially in resource limited settings. Open airway surgeries require prolonged intubation and airway stenting [5,34]. This study's post-operative intubation period was only 10 days (even with more complex cases included). EACSBD is relatively safe and there were no direct postprocedural complications. Mirabile et al.'s post-operative intubation period was 2 weeks [26, Table A.4], Carr et al duration was 5 days [25, Table A.4]. Some literature has even suggested shorter durations (as short as 2 days) of post-operative

intubation [33,35, Table A.4]. Further work is needed to determine optimal duration of intubation.

Two patients had minor post-operative aspiration which resolved with speech therapy. One patient with refractory aspiration due to a laryngeal cleft was sent home on nasogastric feeds and was lost to follow-up. In this case, it was likely that the cleft and increased risk of aspiration was under-appreciated pre-operatively.

The endoscopic anterior split carries a significantly reduced cost compared to the open airway reconstruction and/or tracheostomy insertion. The microlaryngeal scissors and sickle knife already form part of the microlaryngeal set and is not an added expense. Furthermore, this expense can be offset against the significant reduction of theatre and anesthetic time and shorter post-operative PICU ventilation period (when compared to open airway surgical alternatives). Again, EACS is less resource-intensive than open airway surgical options. Balloon laryngoplasty is already practiced in this setting. The paper does not mention any specific balloon of choice. Any balloon dilator currently in use for endolaryngeal balloon laryngoplasty that is available, can be used. Furthermore, it is standard of care to use balloon laryngoplasty for addressing laryngotracheal stenosis endoscopically. The paper is not intending to emphasize the balloon dilation as a minimally resourced option, rather the EACS as definitive surgery in this setting.

While the alternative of widely available tracheostomy is cheaper upfront, long-term care costs (tube changes, cleaning, infection risk, supplies, caregiver time and resources) may lead to higher long-term costs for caregiver and institutions, as well as speech, cosmetic and stigma concerns associated with tracheostomy.

Limitations of the study include its retrospective nature, variable follow-up periods and deviation from routine follow-up due to the COVID-19 pandemic. The follow-up duration ranged from 1 -16 months (mean of 4,6 months, SD:5.3), so that longer term outcomes could not be determined. Comparative studies follow up durations also vary greatly, the largest study from Chen et al [28] ranged from 0,5- 7 years, the Mirabile et al study [26] follow-up duration was 4-45 months (median value +/- SD: 15,3 +/- 11,9),

while Carr et al's [27] mean follow-up duration was 10 months (range 4-22 months). Despite the small numbers, this study adds to the international literature as it is the first to assess outcomes for EACSBD in a resource-constrained, developing world setting.

8. Conclusion

EACSBD is safe, easy to perform, minimally invasive and has low complication rates. It is effective in treating both acquired and especially congenital SGS, where it can strongly be considered as first-line treatment. EACSBD appears to be well suited to resource-limited settings where theatre time and/or access is limited, there is lack of advanced open airway expertise, and challenges with patient follow-up for routine surveillance scopes or for clinical review. Successful EACSBD avoids further complex interventions and averts a tracheostomy (and sequalae of both). If unsuccessful, these options are still available. Furthermore, multiple routine surveillance scopes may not be required, provided the patient is clinically well. This may reduce the number of follow-up appointments.

However, careful patient selection for successful outcomes, is vital, and post-operative PICU and multidisciplinary support are essential. Chronic acquired SGS, co-existing significant laryngeal or tracheal abnormalities, and pre-existing lung disease that may require prolonged ventilation, are risk factors for poorer outcomes. Larger studies are needed to further refine the optimal management SGS.

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	Proof reading, edits, and final corrections
	Liaison with research departments
	Liaison with institution and ethical board for approval
Co- supervisors:	Initial guidance on paper structure Initial guidance on paper direction
	Proof reading and corrections

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Tables

Table A.1 Preoperative Characteristics and Indications for Airway Intervention

Patient	Gender	Premature	Birth Weight (kg)	Comorbidities	History of croup	Pulmonary function preop	Indication for EACSBD*
1	Female	Yes	2,92	Mild HIE	Yes	CPAP	Recurrent croup
2	Female	Yes	1,72	None	Yes	RA	Emergent, persistent stridor
3	Female	No	2,93	Aortopulmonary window biventricular hypertrophy	No	CPAP	SGS seen during cardiac surgery, unable to wean from CPAP
4	Female	Yes	2,96	Pulmonary Tuberculosis	No	Intubated	Failed extubation
5	Male	Unknown	2,89	None	Yes	HFNC	Recurrent croup
6	Male	No	3,1	None	Yes	HFNC	Recurrent croup
7	Female	No	2,8	Tracheomalacia	No	RA	Upper airway obstruction
8	Male	Yes	unknown	History supraglottoplasty	Yes	RA	Recurrent croup

HIE- Hypoxic Ischemic encephalopathy, CPAP- continuous positive airway pressure, DL- direct laryngoscopy, RA- room air, HFNC- high flow nasal canula, SGS-subglottic stenosis

*Indications for surgery taken directly from the operative notes

Table A.2 Direct Laryngoscopy Findings

Patient	Age at EACS (months)	Weight at EACS (kg)	Type of stenosis	SGS grade	Associated laryngeal abnormalities	Balloon size (mm)	ETT size post operative (mm)	Duration intubation (days)
1	9	8,6	Acquired (chronic)	3	Subglottic cysts	7	4,0	4
2	4	4,35	Congenital	2	Subglottic cysts	5	3,5	5
3	4	4,35	Congenital	2	None	5	3,5	6
4	3	5	Acquired (chronic)	1	Subglottic ulceration	5	3,5	41
5	7	8,2	Mixed	3	None	6	3,5	6
6	4	7,1	Congenital	3	Tracheomalacia, SGP performed at time of procedure	Not documented in records	3,5	5
7	7	6,8	Acquired (acute)	2	None	6	3,5	8
8	17	10	Acquired (chronic)	2	Laryngomalacia, SGP performed at time of procedure, laryngeal cleft type 1	6	4,0	5

SGP- supraglottoplasty

Table A.3 Postoperative course and clinical outcome

Patient	Duration PICU stay (days)	Duration hospital stay (days)	Complications	Follow-up duration (months)	Additional scope	Additional interventions required	Respiratory outcomes
1	6	12	None	10	Yes	Repeat balloon dilation x1 for residual CM Gr3 SGS	Clinically well
2	10	13	None	1	No	None	Clinically well
3	7	10	None	1	No	None	Clinically well
4	41	100	Failed extubation	16	Yes	Incision glottic web, residual CM Gr 3 SGS tracheostomy	Tracheostomy, but well
5	10	20	Aspiration, resolved with ST	5	No	None	Clinically well
6	7	7	None	2	No	None	Clinically well
7	8	21	Aspiration, resolved with ST	1	No	None	Clinically well
8	8	42	Aspiration, inspiratory stridor	1	No	Recommended tracheostomy, NGT, lost to follow up	Continued stridor and aspiration

SLT- speech and language therapy, NGT- Nasogastric tube, PICU-Paediatric Intensive Care Unit, CM- Cotton Myer, SGS- Subglottic stenosis

Table A.4 Summary of Published Studies on Endoscopic Anterior Cricoid Split and Balloon Dilation

Reference (year)*	Study design	Patients (n)	Age range at EACSBD (months)	Results
Our Red Cross Hospital Study (2022)	Retrospective Case Series – EACSBD grade 1-3 SGS	8	3-17	6/8 patients (75%) successful: 1/6 patient: 1 repeat balloon dilation. 5/6 patients: no further airway intervention. 3/8 congenital SGS patients: 100% successful & no further intervention. 1/8 patients: tracheostomy for prolonged ventilation from Pulmonary Tuberculosis 1/8 refractory aspiration-lost to follow-up.
Carr et al. (2018) [27]	Retrospective Case Series – EACSBD grade 2 and 3 SGS	9	2-23	1 patient: no further intervention. 7 patients: repeat balloon dilations. 1 patient: tracheostomy.
Chen et al. (2017) [28]	Retrospective Case Series – EBD alone vs EACSBD (acute acquired SGS, chronic acquired and congenital SGS)	56	1 – 144	EACSBD in acute acquired SGS (n=3): success 95.5%. EACSBD in chronic acquired SGS (n=6): success 66.7%. EACSBD in congenital SGS (n=28): success 85.7%.
Blanchard et al. (2014) [33]	Retrospective Case Series – endoscopic vs open intervention for paediatric SGS	16 (8 patients EACSBD, 8 patients open laryngeal surgery)	1.4 – 55.7	EACSBD patients (n=8): 5 patients extubated immediately postoperatively, 2 intubated 10-15 days. 2 patients: 1 repeat balloon dilation. 1 patient: multiple repeat balloon dilations. 1 patient: 2 additional endoscopic procedures. 1 patient: LTR.
Horn et al. (2012) [35]	Case Series: EACSBD in Infants with failed extubation	3	1 – 14	1 patient (acquired SGS): extubated postop day 2 – no further intervention. 1 patient (acquired SGS): extubated postop day 2 – required deroofing of cysts. 1 patient (acquired SGS and tracheobronchomalacia): self-extubated day 1, re-intubated and tracheostomy.
Mirabile et al. (2010) [26]	Retrospective Case Series: EACSBD in paediatric SGS	18	1-101	4 patients (22.2%): 1 repeat balloon dilation. 14 patients (77.7%): multiple repeat balloon dilations. Treatment successful in 83% (n=15).

EBD- elective balloon dilation, SGS – subglottic stenosis, LTR laryngotracheal reconstruction

*Successful treatment defined as no respiratory distress and grade 0-1 SGS on surveillance scope

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Addenda

Addendum 1: Original ethics approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

15 September 2020

HREC REF: 469/2020

Dr S Peer
Division of Otorhinolaryngology (ENT Surgery)
H-53 OMB
Email: shazia.peer@uct.ac.za

Dear Dr Peer

PROJECT TITLE: SURGICAL OUTCOMES OF ENDOSCOPIC ANTERIOR CRICOID SPLIT IN CHILDREN AT RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL: A RETROSPECTIVE REVIEW

Thank you for your response letter, addressing the issues raised by to the Faculty of Health Sciences Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020 & 06 July 2020.

Approval is granted for one year until the 30 September 2021.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.

HREC/REF:469/2020sa

Addendum 2: Extension of ethics approval

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.03.2025
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	20/3/2024

Note: Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.
Please clarify your plan for research-related activities during COVID-19 lockdown.
Please use the latest form found on our website:
http://www.health.uct.ac.za/fhs/research/humanethics/forms

RESEARCH ETHICS COMMITTEE
19 MAR 2024
FACULTY OF HEALTH SCIENCES
UNIVERSITY OF CAPE TOWN

Comments to PI from the HREC
We are in the final steps with this study. The data was already collected by June 2023. The student was preparing for final college exams late 2023, hence the delay in data analysis and writing up of the thesis. The student is now completing the final draft for submission for MMED that will take place by April 2024.

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	12 March 2024		
HREC REF Number	469/2020	Current Ethics Approval was granted until	June 2022
Protocol title	Surgical outcomes of endoscopic anterior cricoid split in children at Red Cross War Memorial Children's Hospital: A retrospective review.		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	☐ Yes	X No	
If yes, could you please provide the HREC Reference number for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	A/Prof Shazia Peer		
Department / Office Internal Mail Address	Shazia.peer@uct.ac.za | Division of Otolaryngology, H-53 OMB, Groote Schuur Hospital, Observatory, 7925		

1.1 Does this protocol receive US Federal funding?	☐ Yes	X No

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Addendum 3: Data collection sheet

Endoscopic anterior cricoid split (EACS) in children: Retrospective Review

Clinical Research Form (CRF) No: [ ]

A) PATIENT DETAILS

Sex…… Date of birth ……Premature Yes [ ] No [ ]

Gender:…….. Race:……..

Weight at birth (kg)……

Age(weeks) and weight (kg) at EACS:……Weeks …….Kg

B) PRE-OPERATIVE ASSESSMENT

Clinical needs at initial diagnosis:

Pulmonary function and O_2 requirements prior to EACS: Fi O_2 (%) PEEP ( )

Previous intubations:

Number [ ] Duration [ ] (total number of days for all intubations divided by the number of intubations to get average)

Tracheostomy in-situ preprocedural? Yes ( ) No ( )

Diagnosis of subglottic stenosis:

Date of diagnosis: _____

Subglottic stenosis: congenital ( ) / acquired ( )

Other:_____

Associated aspects:

Syndromic child [ ] Non-syndromic child [ ]

If syndromic, elaborate: _____

Comorbidities: Yes ( ) No ( )

If yes, elaborate:_____

C) INTRA-OPERATIVE ASSESSMENT

Date of EACS:_____

Age(weeks) and weight (kg) at time of surgery:……weeks……kgs

Type of Anaesthetic: TIVA [ ] Gas [ ] Apnoeic and awake [ ] Paralysed [ ]

SURGICAL STEP 1: CONFIRM DIAGNOSIS:

- Diagnostic Laryngoscopy, tracheoscopy, bronchoscopy

  Telescope used: 30^0 or 0^0, 2.7mm or 4mm

  Other information:_____

- Associated airway conditions:

  Laryngomalacia [ ] Chronic Lung Disease [ ] Asthmatic [ ] OSAS [ ]

  Accessory (Pig) bronchus [ ] Abnormal carina [ ] Other: _____

  Subglottic Cysts: Yes [ ] No [ ] if yes, L [ ] R [ ] A [ ] P [ ]

- Baseline Grade of subglottic stenosis according to Cotton-Myer Classification (1-4)

  Grade 1 [ ] Grade 2 [ ] Grade 3 [ ] Grade 4 [ ]

  Other features: _____

  No. of dilations & Duration of each (in seconds): 1 [ ] , 2 [ ] , 3 [ ]

  SURGICAL STEP 2: Endoscopic Anterior Cricoid Split (EACS):

- EACS Technique: Cold steel / Laser
- If Cold Steel, type: microscissors / sickle knife / beaver knife. If Laser: CO_2 / Diode

  SURGICAL STEP 3: Post EACS balloon dilation:

- Balloon dilator size: _____ type: non-occlusive / occlusive dilator
- During occlusion of airway with balloon: (complete for each dilation)

  FIRST: Oxygen saturations [ ] Heart Rate [ ] BP [ ] Resp Rate [ ]

  Rescue ventilation: Yes [ ] No [ ] Rescue intubation Yes [ ] No [ ]

  SECOND: Oxygen saturations [ ] Heart Rate [ ] BP [ ] Resp Rate [ ]

  Rescue ventilation:Yes [ ] No [ ] Rescue intubation Yes [ ] No [ ]

  THIRD: Oxygen saturations [ ] Heart Rate [ ] BP [ ] Resp Rate [ ]

  Rescue ventilation:Yes [ ] No [ ] Rescue intubation Yes [ ] No [ ]

- ETT size achieved after EACS and balloon dilation:

  Grade 1 [ ] Grade 2 [ ] Grade 3 [ ] Grade 4 [ ]

  Airway sized: Yes ( ) No ( ) Size: _____

C) POST-OPERATIVE ASSESSMENT

Pulmonary function and O_2 requirements post-operative: Fi O_2 (%) PEEP ( )

Duration of intubation post operatively in days: _____ days

Extubation date:_____ To: room air / HiFloO_2 / CPAP / BIPAP

Number of days in ICU:_____ Number of days until discharge home:_____

Clinical outcome:

Was decannulation/ extubation achieved? Yes ( ) No ( )

Complications of procedure? Yes ( ) No ( )

If yes, elaborate_____

Duration of follow- up post operatively? _____

Repeat or other airway intervention required? Yes ( ) No ( )

If yes, elaborate_____