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Prevalence of permanent vocal cord paralysis after anterior cervical decompression and fusion at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH)

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Prevalence of permanent vocal cord paralysis after anterior cervical decompression and fusion at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH)

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand in partial fulfilment of the requirements for the degree of Master of Medicine.

Johannesburg, 2018

DECLARATION

I PAUL MARULE KGAGUDI declare that this Research Report is my own, unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Orthopaedic Surgery at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

(Signature of candidate)

28 day of February 2016

at WITS.

DEDICATION

This is dedicated to my parents Ramahudu and Mamoloto, my Mmasetshaba and our kids Puno, Baledi and their soon to be sibling.

ABSTRACT

Background: Anterior Cervical Discectomy and Fusion (ACDF) is a successful procedure performed by Orthopaedic surgeons for various pathologies that affect the cervical spine. It is however not without complications. The commonest neurological complication is Recurrent Laryngeal Nerve (RLN) injury leading secondarily to permanent Vocal Cord Paralysis (VCP).

Aims and Objectives: The aim of this study was to assess the prevalence of permanent VCP post-ACDF at our Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) spinal unit. To study objectives are: 1) To correlate demographic, pathological and peri-operative patient factors to post-operative hoarseness and vocal cord paralysis and 2) To establish an association between post-operative hoarseness and clinical laryngoscopic cord status.

Study design: This is a retrospective with prospective recall.

Methods: Patients who underwent the procedure of ACDF at CMJAH from January 2012 to June 2016 were recruited telephonically to participate voluntarily. Our research study specific questionnaire was administered to the patients who consented for the study together with a post-operative direct laryngoscopy, performed by the Ear-Nose-Throat (ENT) specialist to assess vocal cord function.

Results: Only 23 patients presented for participation. Post-operative hoarseness was present in 5 cases (23%). The likelihood of which was higher in white women who had ACDF for a degenerative cause involving two or more vertebral levels. However, our study found none of the cases had vocal cord paralysis.

Conclusion: Post-operative hoarseness is common after ACDF, affecting almost a quarter of those who undergo the procedure. A white woman undergoing ACDF for a degenerative cause affecting multiple cervical spine levels is at risk, especially if being operated on the left hand side of the neck with a transverse incision. Although hoarseness suggests VCP, the relationship between the two is not always one of cause and effect. The former can exist due to other causes unrelated.

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NOMENCLATURE

ACDF- Anterior Cervical Discectomy and Fusion

C6 & C7 VERTEBRAE- Sixth & Seventh Vertebrae

CMJAH- Charlotte Maxeke Johannesburg Academic Hospital

CNS- Central Nervous System

ENT- Ear Nose Throat

LCS- Laryngoscopic cord status

POH- Post-operative hoarseness

RLN- Recurrent Laryngeal Nerve

VCP- Vocal Cord Paralysis

ZAR- South African Rand

CHAPTER ONE

1.0 Introduction

1.0.1 Background

The neck housing the cervical spine is a complex part of the human body. It connects the head to the body and acts as a conduit for vital structures. The small size of the neck and its anatomical relations has both medical and surgical implications in the case of pathology. Importantly the vital structures namely nerves, arteries, veins, air and food conduits are a challenge to a surgeon contemplating to perform neck surgery around this region.[1,2,3,4] One such surgery is Anterior Cervical Discectomy and Fusion (ACDF) performed mostly by an orthopaedic spine surgeon. There is a possibility of profound disability to the patient should any of the tissues be damaged. Recurrent Laryngeal Nerve (RLN) injury is one such complication of ACDF leading to vocal cord paralysis with consequential hoarseness of the voice, choking and difficulty in breathing. Technically, the size of the nerve (difficult to visualise) is a factor as well as its varied course through the tissues especially on the right hand side of the neck. Figure 1.1 and Figure 1.2 below display the intimate nature of structures of the neck in the antero-posterior plane and in an axial slice view through the substance of the neck respectively.

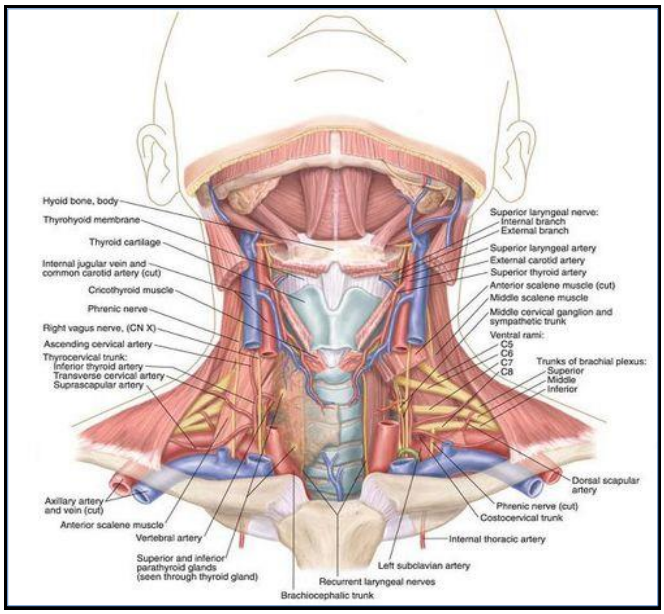


Figure 1.1 Anterior view of the neck.[5]

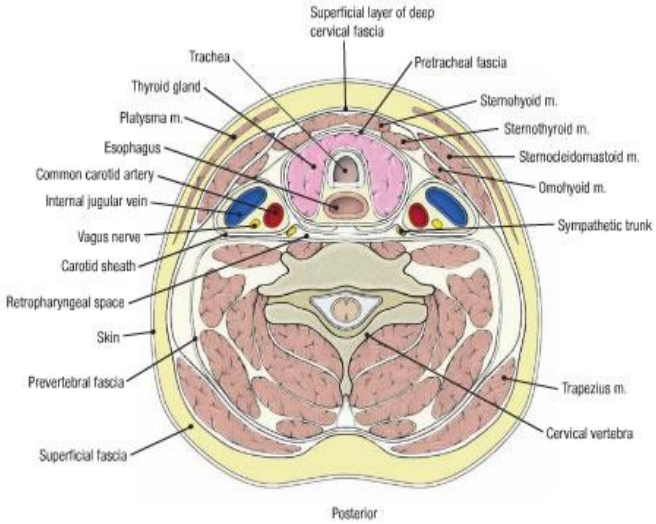


Figure 1.2 The cross-sectional view of the neck.[6]

1.1 Literature review

Anterior Cervical Discectomy and Fusion (ACDF) is a documented treatment option for cervical spine fractures and other pathologies such as myelopathy, radiculopathy and disc herniation about the neck.[7,8,9,10,11,12,13,14] This is overall a successful procedure in the experienced hands but not without complications.[1, 7,8,9,10,11,12,13] The range of complications following this procedure are reported between 8.4 – 19.3%.[8,9,14] Vocal Cord Paralysis (VCP) secondary to Recurrent Laryngeal Nerve (RLN) injury is the commonest and most important complication post-ACDF but probably is under-reported.[9,10] By definition VCP is the inability of the vocal cords to perform their primary functions of protecting the airway and fine-tuning phonation, two clearly important daily functions. Quite alarming is the litigation rate in the USA for VCP post-surgery across all surgical disciplines. Shaw *et al*. (2009) found that more than US$18 million were paid out for 112 cases of litigation. The main reason cited being surgical negligence, failure to recognise VCP and consent related issues.[15] Currently with the South African state's limited resources we are obviously exposed to at least two aforementioned factors which could lead to greater financial burden to the health budget. Thus far there is no data in South Africa on the topic of VCP post-ACDF, especially on the rate of VCP secondary to RLN palsy that can be inflicted during ACDF.

The RLN arises from the Vagus nerve on both sides of the neck. [2,3,4] However the RLN on the right hand side of the neck has a short and oblique course that puts it at risk of injury secondary to stretch.[9,10,11,12,16,17,28] Significantly it supplies the intrinsic muscles of the Larynx, which are involved in vocal cord motion required for phonation. Unilateral paralysis of the vocal cords may lead to a spectrum of complaints ranging from hoarseness to aspiration. Bilateral paralysis is rare, only described by Nikandish *et al*. (2013) in one case report post-ACDF with grave implication where the patient required tracheostomy for severe respiratory failure in order to prevent death.[2,22] The vocal cords and muscles are depicted in Figure 1.3

below.

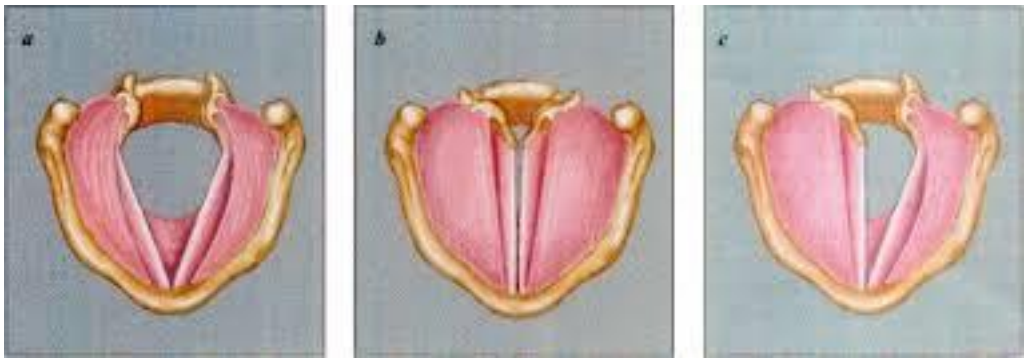


Figure 1.3 Clinical vocal cord variations. **A**: normal vocal cord relaxed, **B**: normal cord during phonation and **C**: Paralysed left cord during phonation.[18]

The subjective incidence of VCP post-ACDF is estimated at 0.07 – 11% in the literature. [9, 10,11,12,13,14] This figure doubles up to 24% with objective assessment of vocal cord status via laryngoscopy.[12,15] The recurring reason for the discrepancy is that some patients are asymptomatic and, therefore, but also for the fact that the symptoms are variable. Jung *et al*. (2005) reported that two thirds of patients with vocal cord paralysis are asymptomatic and can only be detected objectively with laryngoscopy. The symptomatic group of patients had permanent (0.15 – 3.5%) or temporary (0.98 – 8%) cord paralysis and usually presenting with Post-operative Hoarseness (POH) immediately post-operatively.[13,14,16,17] This is secondary to trauma to the nerve during operation ranging from stretching to complete transection of the nerve. Statistically most cases are temporarily impaired and will recover within one to three months with a small percentage resolving only latest by six months.[10,11,16,17] Those who recover during this period being probably cases secondary to benign mechanisms such has compression, stretching and oedema of the RLN.[7,16,17,22,23,24,25]

Laryngoscopy is performed as an outpatient procedure. The patient is consented to have the procedure done as it is deemed invasive and uncomfortable. A flexible direct laryngoscope is passed through the mouth or one nostril after a local anaesthetic spray and medical lubricant

to assess the vocal cords (see Figure 1.4). The patient is instructed to gently swallow the flexible tube in order to aid the visualisation of the cords. To assess paralysis the patient is asked to produce high-pitched notes so as to strain the cords and show any asymmetry in cord motion.



Figure 1.4 Direct flexible laryngoscopy showing the vocal cords**.**[19] A doctor (person on the right) is performing direct laryngoscopy on a patient and visualising it on a monitor.

Chen *et al*. (2014) performed laryngoscopy for vocal cord assessment in patients presenting with symptoms suggestive of vocal cord paralysis post-ACDF and documented 0.47% permanent VCP. Hypothetically they missed all the asymptomatic cases as explained earlier.[11,16,17] This implies that the true incidence of permanent VCP was not evaluated in their work as some of the asymptomatic but paralysed cases were missed. That paved the basis of our research study as we planned to perform post-operative laryngoscopy on all participants regardless of the status of their vocal cords in order to capture the true incidence permanent VCP in our clinical setting post-ACDF.

1.1.1 The Surgical procedure

The anterior approach of the neck was first performed for oesophageal diverticula surgery by Lahey *et al*. (1950).[7,8] Cervical spine application was subsequently reported by Smith *et al*. (1958) for the treatment of cervical radiculopathy.[7,8,9,10,11,12,13,14] The Smith-Robinson approach named after the latter, involved the removal of the disc at the affected level with replacement by a horse-shaped iliac auto-graft. To date the procedure had variable modifications by other surgeons involving variations in graft type, size and whether or not plate stabilisation is required.[7,8]

Intra-operatively the surgery involves either a vertical or horizontal incision for adequate exposure along the anterior border of the Sternocleidomastoid muscle followed by blunt tissue dissection to a plane between the carotid sheath laterally and trachea-esophageal relationship medially to get access to the anterior spinal column. The type of incision being dictated by both the level of the spinal column and number of spinal column units involved, this aids the surgical exposure and lowers the risk of RLN injury. VCP has been noted to increase when both lower spinal levels are involved, especially C6/C7 vertebral level and if 4 or more vertebral levels are involved in the operation.[11,12,13,14,17] Anatomically this surgical operation can be performed on either the left or the right hand side of the neck. It is proposed that an approach on the left hand side is safer in view of the unpredictable course of the nerve on the right hand side of the neck. The nerve has a short and oblique course on the right hand side of the neck with a high risk of injury thereof [9,10,11,12,16,17] (see Figures 1.5 and 1.6)

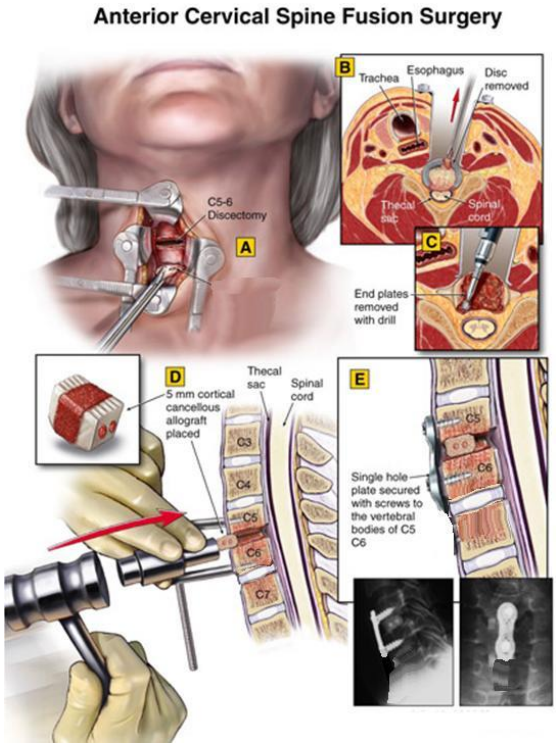


Figure 1.5 Dissection of the neck to anterior vertebrae **A**, Cross-sectional view of **A**: B, Vertebral endplate debridement **C**, Inter-positional graft insertion **D**, Buttress plate application **E** with X-ray results.[20]

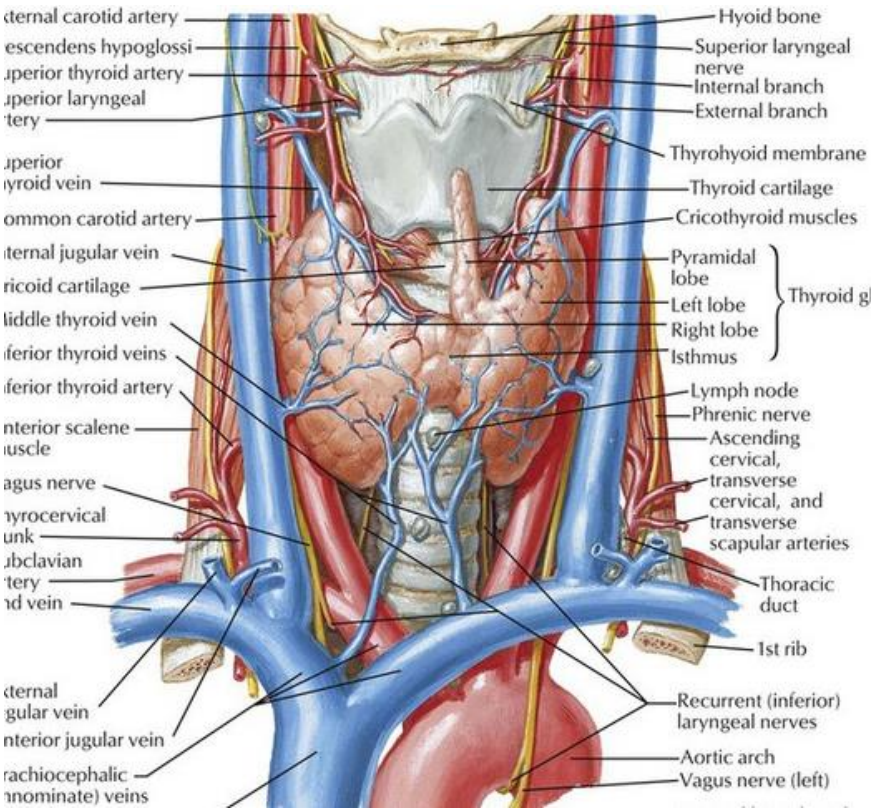


Figure 1.6 Anatomy of the recurrent laryngeal nerve at the neck, viewed from antero-posterior.[21]

1.2 Study significance

At CMJAH for ACDF we use the right hand side approach as a routine and, therefore our patients are hypothetically at a higher risk of RLN injury and VCP. This study has been planned to determine this risk and other factors that may increase the risk of VCP. The results of this work will act as crucial feedback to the CMJAH spinal unit with regards to the safety of the procedure at our centre. Our results will allow us to conclude whether those inflicted functionally develop any subjective patient dissatisfaction as per the data collection sheet (see Appendix **C**). Finally the question of routine use of laryngoscopy post-ACDF will be considered as a potential question for future research direction.

CHAPTER TWO

2.0 Research Question

What is the prevalence of permanent vocal cord paralysis after anterior cervical decompression and fusion at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH)?

2.1 Aim and Objectives

Aim

- The aim of the study is to determine the prevalence of permanent Vocal Cord Paralysis (VCP) in our South African population after anterior cervical spine surgery.

  Permanent VCP - VCP persisting for more than 3 months post-ACDF

Objectives

- To document the prevalence of permanent vocal cord paralysis post-ACDF
- To correlate demographic data to VCP
- To correlate pathology to VCP
- To correlate peri-operative factors to VCP
- To determine a relationship between POH and clinical laryngoscopic cord status

CHAPTER THREE

3.0 Inclusion and Exclusion Criteria

3.0.1 Inclusion

Patients treated with anterior cervical discectomy and fusion with

- Smith-Robinson approach
- Normal pre-operative speech
- No Central Nervous System (CNS) dysfunction
- Consenting to study participation
- 18 years and above

3.0.2 Exclusion

Patients with

- Alternative surgical approach to the neck
- Pre-operative CNS dysfunction
- Other vocal cord pathology (polyps)
- Less than 3 months post-surgery

3.1 Materials and Methods

Permission to perform this study was granted by the WITS HEALTH HUMAN RESEARCH ETHICS COMMITTEE clearance number: **M160865**, the CMJAH hospital manager and relevant academic head of units. This was a review of patients who had Anterior Cervical Discectomy and Fusion (ACDF) at CMJAH from January 2012 to June 2016. From the theatre record books a total of 70 ACDF cases were performed during this period. Men and women above the age of 18 years who had undergone ACDF during the study period were invited telephonically to participate voluntarily. All our study-participants did not have pre-operative laryngoscopy but they were asked if they had any pre-operative hoarseness as this was an exclusion criterion for the study. Only 23 patients operated during the above-mentioned period availed themselves for participation. At presentation the patients were informed further of the components of the study via the information sheet in Appendix **A** and a consent form in Appendix **B** was signed before participating in the study. The patients' medical files and surgical notes where consulted for demographic details (race, gender and age), peri-operative parameters (surgical indication, number of levels involved, side of surgical approach, the type of incision and duration since surgery). The impact of the above factors was associated with the two outcomes of the study i.e. post-operative hoarseness and the laryngoscopy status of the vocal cords. An ENT specialist performed the laryngoscopy assessment with a direct flexible laryngoscope at the ENT outpatients department. Normal vocal cord status was defined as symmetrical movement of the vocal cord while vocal cord paralysis was diagnosed if there was loss of movement of the vocal cord in question. The results were recorded on the data collection sheet shown in Appendix **C**, they were kept anonymous and confidential by assigning a study specific identification number per patient for example **ACDF004** signified the fourth patient during data collection. As most of our patients were referred from distant areas, a compensatory transportation fee was offered on a per distance rate per participant at the end of the research session.

3.2 Variables

Outcome variables

- Post-operative hoarseness: any reported voice change after ACDF
- Laryngoscopic cord status: the status of the vocal cords after ACDF

Explanatory variables

- Gender
- Race
- Age

Independent variables

- Indication for surgery: the underlying cause of pathology to warrant ACDF
- Side of surgical incision: the side of the neck from which the patient is operated
- Number of vertebral levels involved: the number of vertebral units involved, one level being two adjacent vertebral bodies and their intervertebral disc
- Time since surgery: the time that has lapsed since the patient had ACDF

CHAPTER FOUR

4.0 Results

The majority of the participants in the study were males (15 patients) compared to females (8 patients). The average age of the participants was 43 years (range: 39 - 48 years). A total of 5 participants out of 23 had POH. Slightly more females (60%) had POH when compared to males (40%). Most of the participants were black Africans and they were the majority with POH. The proportion of participants with POH was the same between trauma and degenerative indication for surgery. The results indicated that patients who had right hand side neck surgical approach had POH higher (60%) than those who had left hand side neck approach (40%) and a similar finding could be observed in participants without POH. The number of vertebral levels operated and the type of surgical incision showed similar results. Time elapsed since ACDF doubled the presence of POH in the group that had been last operated two years prior. Laryngoscopic cord status was normal for all the study participants. Descriptive analyses of the demographic and clinical characteristics for permanent vocal cord paralysis post-ACDF were computed with STATA software version 14. Table 4.1 below illustrates the distribution of vocal cord status by demographic and clinical characteristics. Figure 4.1 displays the percentage distributions for variables that had a significant effect on the outcome of post-operative hoarseness.

Table 4.1: Distribution of permanent vocal cord paralysis by demographic and clinical characteristics

	Post-operative hoarseness		**Laryngoscopic cord status**	
	ABSENT (n = 18)	PRESENT (n = 5)	NORMAL (n = 23)	ABNORMAL (n = **0**)
Gender				
• **Male**	13 (72.22%)	2 (40%)	15 (68.18%)	
• **Female**	5 (27.78%)	3 (60%)	7 (31.82%)	
Age (years)	47.89 (S.D 2.8)	38.8 (S.D 1.7)		
Race				
• **African**	15 (83.33%)	4 (80%)	18 (81.82%)	
• **White**	2 (11.11%)	1 (20%)	3 (13.64%)	
• **Indian**	1 (5.56%)	0	1 (1.55%)	
Indication for surgery				
• **Trauma**	12 (66.67%)	2 (50%)	14 (63.64%)	
• **Degenerative**	6 (33.33%)	2 (50%)	8 (36.36%)	
Side of surgical approach				
• **Right side**	13 (72.22%)	3 (60%)	15 (68.18%)	
• **Left side**	5 (27.78%)	2 (40%)	7 (31.82%)	
Type of incision				
• **Transverse**	17 (94.44%)	3 (60%)	19 (86.36%)	
• **Vertical**	1 (5.56%)	2 (40%)	3 (13.64%)	
Number of levels involved				
• **One level**	15 (83.33%)	3 (60%)	18 (81.82%)	
• **Two or more levels**	3 (16.67%)	2 (40%)	4 (18.18%)	
Time since surgery				
• **3 – 12 months**	5 (27.78%)	1 (20%)	5 (22.78%)	
• **12 – 24 months**	6 (33.33%)	1 (20%)	7 (31.82%)	
• **> 24 months**	7 (38.89%)	3 (40%)	10 (45.45%)	

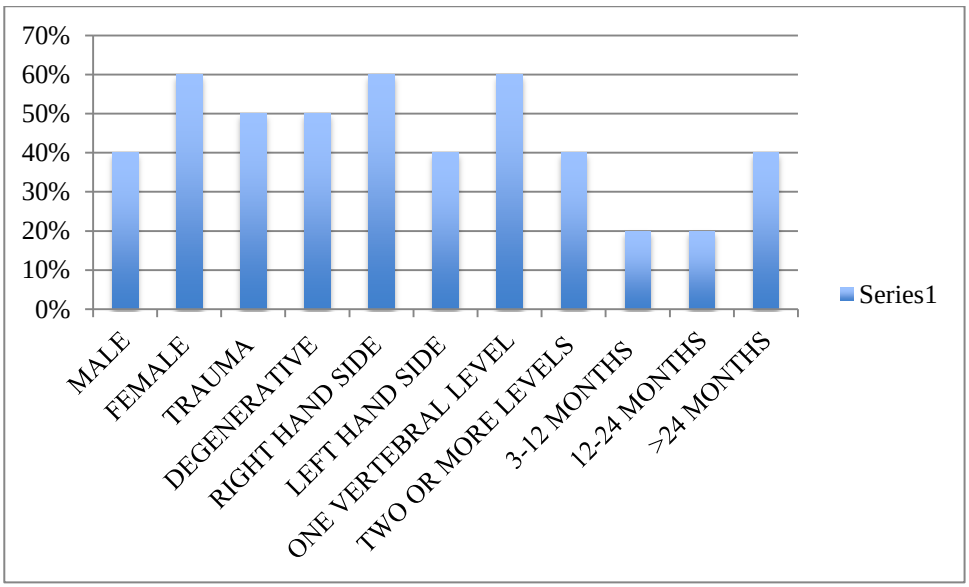


Figure 4.1 Percentage distributions per variable that had post-operative hoarseness post-ACDF

4.1 Statistical analysis

The presence of variables displayed in Figure 4.1 complicated the ability to detect any association between permanent cord paralysis and the explanatory variables. Furthermore, this hindered the achievement of the second objective of this study since all the participants had normal cord status at evaluation, limiting our variables further. We therefore, only quantified the prediction of post-operative hoarseness using odd ratios at 95% confidence interval. The analysis employed unconditional logistical regression model using only variable analysis to control confounder effect by combining main exposure variables with demographic and clinical characteristics as depicted in Table 4.2.

Table 4.2: Variable analysis showing odds ratio ratios for a relationship between post-operative cord status, demographic and clinical characteristics

	Post-operative hoarseness	
	Odds ratio	95 % Confidence interval
Gender • **Male**	1	
• **Female**	3.9	0.494 – 30.758
Race • **African**	1	
• **White**	1.25	0.1008 – 15.498
Indication • **Trauma**	1	
• **Degenerative**	2	0.223 – 17.893
Side of surgical approach • **Right side**	1	
• **Left side**	1.73	0.219 – 13.670
Side of surgical approach • **Transverse**	1	
• **Vertical**	11.33	0.764 – 167.970
Number of levels involved • **One level**	1	
• **Two or more levels**	3.33	0.378 – 29.389

The odd ratio of developing post-operative hoarseness amongst women was four times more compared to men (95% CI: 0.496 – 30.758). The participants who were whites had 25% higher chance of having POH compared to individuals who were of African origin. Participants with degenerative disease had twice the odds of having POH compared to those who had a traumatic cause. The side of surgical approach indicated that participants who were operated on the left hand side were more likely to develop POH than those operated on right hand side (OR: 1.73; 95% CI: 0.219 – 13.670). Patients who were operated with a vertical incision had about eleven times the odds of developing POH compared to those operated with a transverse incision (95% CI: 0.764 – 157.970). The participants who had more than one level operated had thrice the odds of developing POH (OR: 3.33; 95% CI: 0.378 – 29.389) compared to the ones with only one level.

CHAPTER FIVE

5.0 Discussion of results

The complication of vocal cord paralysis post-ACDF is significant and is well documented internationally. [9,10,11,12,13,14,16,17] VCP can be asymptomatic or symptomatic and debilitating to the affected patient.[10,14,16,17] The usual presentation of VCP ranges from the benign voice change problems (i.e. hoarseness) to the serious symptoms of choking that can either resolve or lead to death with airway obstruction early on if not acted upon.[17,25] Hoarseness is the most documented complaint in the literature post-ACDF and is reported to range between 0.07 – 11% , a smaller percentage compared to 23% (n = 5) reported by participants in our study. The subjective nature of the symptom of hoarseness and the small study-sample size could explain the discrepancy of results. Of the five patients who had hoarseness two had an underlying non-neurological causes of hoarseness in the form of cord polyposis for the one and reflux disease for the other, these being discovered only during laryngoscopy. Both patients denied any pre-operative spell of hoarseness. Scientifically speaking post-operative hoarseness from surgery related causes occurred only in three cases (13%) if we subtract the two aforementioned cases caused by unrelated conditions. The latter figure is more in keeping with the range reported in the literature of 0.07 – 11%.[9,10,11,12,13,14]

Demographically 80% of the patients with hoarseness were of African origin. This can only be explained by the fact that the study population was a reflection of the racial demographics of the country. Although trauma is deemed endemic in our country, it was not necessarily related to a higher risk of post-ACDF hoarseness. Ironically though there were more males who had ACDF for a traumatic cause. National Road accident figures correlate with our study results as they showed that middle aged males are more likely to be involved in motor-vehicular accidents leading to significant injuries and death in South Africa.[26] Even though more men were operated, women were four times more likely to have post-operative hoarseness, the is no obvious reason for this except to revisit the effect of the two non-neurological causes of hoarseness diagnosed at laryngoscopy. Pre-operatively a degenerative cause for ACDF was twice likely to lead to post-operative hoarseness but still had no impact of VCP, with trauma only having a 14% of that chance. This is reinforced in a study by Beutler *et al*. (2001) also showing a slightly higher rate of hoarseness (55%, 5 of 9 cases with hoarseness) for the degenerative group as compared to the trauma group (44%).[11]

Technically the course of the RLN on right hand side is susceptible to put patients at risk of cord paralysis secondary to it being unpredictable, this contraindicated with our study because even though 70% of the study population was operated from the right, none of them had cord paralysis. Most surgeons prefer the right hand side of the neck because it is easier to operate. They base their practice also on the fact that there is conflicting evidence as to whether right hand side neck surgery possess high risk for VCP as compared to the left hand side neck.[9,10,11,12,16,17,24] Beutler *et al*. (2001) showed no difference in incidence of vocal cord paralysis between the right hand and the left hand side of the neck.[11] Left hand side neck surgery in our study showed a higher rate likely for POH with no impact on VCP. If one takes the above into consideration as well as our post-ACDF rate of permanent VCP of 0% with a right hand side dominated surgical approach, it would seem that the right hand side should not be a risk factor for VCP during ACDF.

A transverse surgical incision along Langer lines is promoted as it heals better but in our study it was eleven times more likely to cause post-operative hoarseness. By comparison a vertical incision allows better visualisation of neck structures and therefore minimal tissue handling during surgery but it leaves behind an undesired surgical scar of which may not be a bad trade-off for the development of hoarseness with a transverse incision. Fountas *et al*. (2007) showed that the number of vertebral levels operated had no significance on the development of post-VCP and therefore post-ACDF hoarseness.[9] In our study if two or more vertebral levels were operated on, the patient was three times more likely to develop POH. This may be in keeping with the proposed mechanism of post-ACDF hoarseness development, as two or more vertebral level surgery takes longer to perform and, therefore the stretch induced insult on the RLN is sustained longer and hence the increased incidence of post-ACDF. [7,16,17,22,23,24,25] The only contradiction is that all our cases of hoarseness did not show actual VCP at laryngoscopy. Again this confliction of results can be explained and just be a reflection of the effect of a small study-sample size.

Permanent VCP post-ACDF is reported at a low 0.47% which is within the range 0.07 - 11%. Objective assessment with laryngoscopy the rate of VCP actually doubles to 24% due to improved identification of VCP in the asymptomatic cases which would otherwise be missed.[10,17] This is contrary to our study which had no cases of permanent vocal cord paralysis and it seems that the application of laryngoscopy post-ACDF did not have any effect even for the cases that had post-operative hoarseness. Scientifically one would have expected that in those cases at least the vocal cords would be paralysed and in keeping with

subjectively reported change in voice quality but it wasn't the case. In the literature Chen *et al*. (2014) diagnosed 13% more patients with VCP who were originally not aware of any subjective functional vocal problem, their results opposing our study.[17]

Almost three-quarters (74%) of our patients with hoarseness had been post-ACDF for more than a year at assessment. It is expected that the incidence of post-ACDF VCP would decline with time as some cases that are temporarily affected would resolve within three to twelve months post-surgery.[17] In our study though this is not the case, the reason for the increase could only be that the non-neurological causes of hoarseness in the form of vocal cord polyps and reflux disease skewed the results. In terms of risk factors for the development of VCP post-ACDF this puts out question again of whether in our South African context with limited resources we should do routine post-ACDF direct laryngoscopy examination. This will obviously have an impact on temporary VCP but if it comes to practice, will it help detect the real incidence of VCP in this population? A follow-up assessment after six months post-ACDF will define the discrepancy of the ones who progressed to permanent VCP. In our clinical settings this is a further burden on an already strained healthcare system in terms of resources? With our results is it even worth the trouble? In ideal conditions without the below mentioned limitations described in Section **5.1**, a large study-sample size may change our perspective completely and guide our practice when it comes to VCP post-ACDF.

5.1 STUDY LIMITATIONS

5.1.1 Small sample size

Loss to follow-up due to changed contact details was common. Unfortunately the record books indicated that some of the participants had passed on post-operatively. Inadequate theatre patients' records in the form of missing diagnoses, missing contact details and wrong operation entry had an additional negative impact on this study sample. A further group of patients could not participate in the study citing reasons such as being out of the country, living in a distant province as well as work related obligations preventing availability. A small number of patients expressed lack of interest to participate in the research due to undisclosed personal reasons.

CHAPTER SIX

6.0 Conclusion

Post-operative hoarseness is common after ACDF, almost a quarter of those who undergo the procedure end up being affected by this complication. Our study's findings suggested that patients who had right hand side neck surgical approach had POH higher (60%) than those who had left hand side neck approach (40%), and a similar finding could be observed in participants without POH. Moreover, patients who were operated with a vertical incision were speculated to have approx. Eleven times the odds of developing POH compared to those operated with a transverse incision (95% CI: 0.764 – 157.970). The participants who had more than one level operated had thrice the odds of developing POH (OR: 3.33; 95% CI: 0.378 – 29.389) compared to the ones with only one level. A white woman undergoing ACDF for a degenerative cause affecting multiple cervical spine levels is at risk, especially if being operated on the left hand side of the neck with a transverse incision. Moreover, it was also observed that the time elapsed since ACDF doubled the presence of POH in the group that had been last operated two years prior. Therefore, this study showed that demographic factors (race and female gender), pathological factor (multi-level degenerative disease) and peri-operative factors (left hand side approach and transverse incision) have an adverse relationship with POH. Although hoarseness suggests VCP, the relationship between the two is not always one of cause and effect. The former can exist post-ACDF due to other unrelated causes.

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List of Appendices

A. Patient information sheet

B. Patient consent form

C. ACDF data collection sheet

D. CEO permission letter

E. ENT permission to do research

F. Ethics clearance certificate

Appendix A

Patient information sheet

Title: The incidence of vocal cord paralysis post Anterior Cervical Discectomy and Fusion at Charlotte Maxeke Johannesburg Academic Hospital

Hello, my name is Paul Marule Kgagudi. I am a doctor as well as a postgraduate student at Wits University working toward becoming a specialist orthopaedic surgeon. An orthopaedic surgeon is a doctor that deals with broken bones, joints and other conditions that affect the bones in general. Part of our training program involves doing some research. I therefore would like to invite you to participate in my research study. Your availability for participation will be highly appreciated.

My study is aimed at picking up the rate of hoarseness of voice and voice box paralysis following the commonly performed neck spine surgery at our spine unit at Charlotte Maxeke Johannesburg Academic Hospital.

For patients that are willing to be involved in the study a number of questions will be asked to check if they have noticed any change in the quality of their voice. This will be followed on with assessment of the voice box using a fine tube camera to assess as to why there is hoarseness. The camera will be used by Dr. Maharaj, he is an Ear-Nose-Throat specialist at Charlotte Maxeke Johannesburg Academic Hospital. He is a doctor that deals with conditions affecting the areas mentioned above.

The throat camera is performed at their clinic and usually inserted through one of the nostrils or mouth in order to see the back of the throat. A pain easing spray is used to make the procedure comfortable and painless but this spray may also affect tasting of food for a day or two after the procedure. If at any point you feel uncomfortable and want us to stop the procedure we will be willing and understanding to do so. This also applies to complete request to be removed from the study as we understand that some situations can only be fully apprehended only by being in. This won't change the way we would have normally treated you in the future at our hospital in general.

The study is completely confidential as your name will not be used but each patient will be given a study number attached to the patient information sheet in appendix A. Your participation is again highly valued as it will help us pickup how we are doing in terms of the procedure currently and whether we need to change anything for future patients. This will only be possible with your participation which is highly appreciated. This study will be approved by the Human Research Ethics and Post-graduate committees. For more information

feel free to contact myself at (011)-933-8000/078-428-8229 alternatively call either Dr. V. Maharaj on 076-120-4066.

For other queries please contact the following members of the Health Research Ethics Committee(Medical) at Wits: Prof. P Cleaton-Jones, Tel 011-717-2301, email. peter-cleaton-jones1@wits.ac.za Ms. Z Ndlovu/ Mr. Rhulani Mkansi/ Mr. Lebo Moeng; Administrative officers on 011-717-2700/2656/1244/1252 and respectively via email on zanele.ndlovu@wits.ac.za, Rhulani.mkansi@wits.ac.za & lebo.moeng@wits.ac.za

If you are happy with the information and the study is clear to you then we just need a signed consent form for u to be included in the study.

Sincerely,

Paul Marule Kgagudi

Appendix B

MMED STUDY CONSENT FORM

I,_____, give my consent to participate in the study named **"the incidence of vocal cord paralysis post Anterior Cervical Discectomy and Fusion at Charlotte Maxeke Johannesburg Academic Hospital"**. I have read and understand the content of the patient information sheet. I have been given enough information and the procedure is clear to me.

Signature of participant

_____

Signature of witness

_____

Date……..

Appendix C

Patient Study ID.	
Gender • **Male** • **Female**	
Age (years)	
Race • **African** • **White** • **Indian** • **Asian**	
Indication • **Trauma** • **Degenerative** • **Infection** • **Tumour**	
Levels of vertebrae involved • **One level** • **Two or more**	
Side of surgical neck approach • **Right side** • **Left side**	
Type of incision • **Transverse** • **Vertical**	
Time since surgery (months) • **3 – 12** • **12 – 24** • **>24**	
Post-operative Hoarseness • **Present** • **Absent**	
Laryngoscopy cord status • **Normal** • **Paralysed**	

Appendix D

Appendix D.

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Mr. J. Maepa
Office of the Clinical Director
Tell: (011) 488-3365
Email:johannes.maepa@gauteng.gov.za
13 June 2016

Dear Dr. Paul Marule Kgagudi

STUDY TITLE: The incidence of vocal cord paralysis post Anterior Cervical Discectomy and Fusion at Charlotte Maxeke Johannesburg Academic Hospita.

Permission to conduct the above mentioned study is provisionally approved. Your study can only commence once Ethics approval is obtained. Please forward a copy of your ethics clearance certificate as soon as the study is approved by the Ethics committee for the CEO's to give you the final approval to conduct the study.

Supported/~~not supported~~

Dr. M.I. Mofokeng
Clinical Director
DATE: 15/06/2016

Approved/~~not approved~~

Ms G. Bogoshi
Chief Executive Officer
Date: 20/06/2016

Appendix E

Appendix E

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

OTORHINOLARYNGOLOGY – HEAD NECK SURGERY

The Registrar
Faculty Health Sciences.
Wits Medical School.

Dear Mrs. S Benn

Re: Dr Paul Marule Kgagudi,
Registrar / Associate Lecturer in Dept. Orthopedics.
M.Med Research Project with Assistance from ENT Dept.

This is to confirm that the ENT Department has agreed to assist Dr Paul Kgagudi with his M.Med Research Project as stated on another attachment.

Please let the Ethics Team be aware of this undertaking.
Thank You

Regards

.....
ADJ PROF PC MODI
Academic Head
Friday, July 01, 2016

Appendix F

R14/49 Dr Paul Marule Kgagudi

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160865

NAME: (Principal Investigator)	Dr Paul Marule Kgagudi
DEPARTMENT:	Orthopaedic Surgery Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	What is the Incidence of Vocal Cord Paralysis at Charlotte Maxeke Johannesburg Academic Hospital(CMJAH)
DATE CONSIDERED:	26/08/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dimakatjo Ramushu
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	07/10/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 301, Third floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in August and will therefore be due in the month of August each year.

Principal Investigator Signature

Date 28/02/18

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES