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# Post-operative airway management of cervical spine surgery at Charlotte Maxeke Johannesburg Academic Hospital

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# Post-operative airway management of Cervical Spine Surgery at Charlotte Maxeke Johannesburg Academic Hospital




**Dr SM. Tlhabane**

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, 2021**

# Declaration

I, Dr Shadrack Morake Tlhabane 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)

**25 AUGUST 2021 in Johannesburg**

# Dedication

This study is dedicated to my mom, **Elizabeth Lepepe Tlhabane** for raising me to become the person I am today. You have been the pillar of strength. I would not have achieved this milestone without you. THANK YOU SO MUCH!!!!!!!

Moreover, I would like to dedicate this to my late grandmother **Rebecca Botang Tlhabane**.

Special thanks goes to my immediate and extended families for the tremendous support throughout my studies, my partner **Boitumelo Mokgatle**, my son **Kgosietsile**, my younger sister **Tebatso Tlhabane**, my aunt **Ellen Tlhabane**, and all my cousins **(Mangweng, Rebecca, Molefe and Nkami, and Gomotsegang**) for the support and patience during the difficult times of my studies.

Finally, I would like to send my special thanks to my uncle, **Stephens Tlhabane** and his family for their unwavering support.

# Presentations and publications arising from the research project

N/A

# Abstract

## INTRODUCTION

Cervical spine surgery is performed by both orthopaedic and neurosurgeons. The common procedure done for cervical spine pathologies is Anterior Cervical Discectomy and Fusion (ACDF) which has good and predictable outcomes, lower complication rates compared to the posterior approach. Despite satisfactory outcomes associated with ACDF, there are potential rare complications that can ensue. Although these complications are rare, they may be fatal. Risk factors associated with post-operative airway complications are well documented in the literature but guidelines on post-operative airway management are sparse. The anaesthetic practice at our health institution is for these patients to be admitted in an Intensive care unit (ICU) post-operatively.

## METHODS

Our hypothesis was that, not all patients undergoing cervical spine surgery require ICU admission post-operatively. These was a retrospective hospital based case series over a 10-year period (01 January 2007 – 31 December 2017) of patients who underwent cervical spine surgery at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). The socio-demographic data, the risk factors and outcome measures were analysed. The association between the risk factors and the outcome measures were also analysed.

## RESULTS

Majority of these patients (67.3%) were extubated immediately post-operatively, and 61.54% spend only one day in ICU/High care area (HCA) (overnight) and our re-intubation and tracheostomy rate was 7.79% and 1.92%, respectively. Mortality rate in our study was 13.46%. Overall, post-operative airway complication rate was 9.61%, slightly higher than what is reported in the literature. Risk factors that had statistical significant association with the outcome measures are summarised below. Operation time was associated only with increased risk of re-intubation (OR = 41.6, 95% CI = 1.4 – 1220.31, *p*-value = 0.031). Blood loss was associated with both increased number of days spend in ICU (*p*-value = 0.006) and delayed extubation (OR = 4.2, 95% CI = 1.09 – 16.24, *p*-value = 0.038). Bad neurological status was associated with both mortality rate (OR = 0.1, 95% CI = 0.02-0.60, *p*-value = 0.012) and

delayed extubation (OR = 6.75, 95% CI = 1.76 – 25.85, *p*-value = 0.005). Increased anaesthetic time was only associated with increased risk of re-intubation (*p*-value = 0.020).

Further analysis of neurological state after re-categorisation revealed statistical significant association with mortality rate (OR = 15.6, 95% CI = 1.60 – 151.26, *p*-value = 0.018) increased number of days spend in ICU (*p*-value = 0.002) and delayed extubation (OR = 6.9, 95% CI =1.68 – 28.41, *p*-value = 0.007)

## CONCLUSSION

Majority of the patients were extubated immediately post-operatively and only spend one day in ICU, and the study also showed overall low complication rate. Therefore, we conclude that not all patients undergoing cervical spine surgery should be admitted in ICU post-operatively. Stratification according to the risk profile of the patient should be performed and management of airway post-operatively should be individualised, and evidence based logical stepwise decision-making process based on the protocol/algorithm should be followed.

# Acknowledgements

My sincere gratitude goes to my Supervisors, **Dr Shazad Khan, Dr Maxwell Jingo and Prof Mkhululi Lukhele,** for the encouragement, guidance and support throughout the stages of this research project.

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# Nomenclature

**ACCF**: Anterior Cervical Corpectomy and Fusion

**ACDF**: Anterior Cervical Discectomy and Fusion.

**ACEP**: American College of Emergency Physicians

**AEP**: Asian Extubation Protocol

**ALL**: Anterior longitudinal ligament

**ASIA**: American Spinal Injury Association.

**BMI**: Body Mass Index

**C**: Cervical

**CEO**: Chief Executive Officer

**CI:** Confidence interval

**CMJAH**: Charlotte Maxeke Johannesburg Academic Hospital

**EBL**: Estimated Blood Loss

**ETT**: Endotracheal tube

**GDP**: Gross Domestic Products

**GP**: Gauteng Province

**HCA**: High Care Area

**HREC:** Human Research Ethics Committee

**ICU**: Intensive Care Unit

**IQR:** Interquartile range

**KZN**: Kwa-Zulu Natal

**mL**: Millilitres

**MMT:** Manual muscle testing

**OR:** Odds ratio

**RLN:** Recurrent laryngeal nerve

**SCM**: Sternocleidomastoid muscle

**SD:** Standard deviation

**SLN**: Superior laryngeal nerve

**USA**: United States of America.

**WC**: Western Cape

# CHAPTER 1

# 1. INTRODUCTION AND LITERATURE REVIEW

## 1.1 Background

Cervical spine surgery is performed by both orthopaedic and neurosurgeons. The procedure comprises decompression of the neural structures and fusion of the spinal column at one, two or more levels. Trauma, infections, tumours, deformities and degenerative diseases are the main reasons for cervical spine surgery. Cervical spine surgery can be approached anteriorly or posteriorly. Approach selection is influenced by location of compressive elements, type of the fracture, ligament injury and the overall alignment. The common procedure done for cervical spine pathologies is Anterior Cervical Discectomy and Fusion (ACDF) which has good and predictable outcomes, lower complication rates compared to the posterior approach.[1] The majority of patients seen in the United States of America's (USA) outpatient spine clinics are post Anterior Cervical Discectomy and fusion procedure.[2]

### 1.1.1 Posterior Cervical Spine Surgery

Posterior cervical spine surgery is an established procedure for the treatment of cervical myelopathy caused by multilevel spondylosis.[3] Spurling and Scoville reported satisfactory outcomes using posterior approach in the treatment of cervical radiculopathy more than a decade before Smith and Robinson described anterior cervical spine surgery.[4] Posterior approach allows for direct visualisation of the involved nerve root and permits decompression with or without fusion of the spinal column. It involves performing lamino-foraminotomy/laminectomy, which is the removal of bone from the adjacent lamina and facet joint overlying the compressed nerve root.[4,6] While this approach does not involve removal of the anterior lesions, literature has reported well to excellent outcomes.[4]

### 1.1.2 Surgical Technique

The patient is in sitting or prone position during surgery. The sitting position offers the advantage of decreased venous congestion and dry surgical field, however there is a risk of air embolus and cardiac complication associated with the sitting position.[4] Due to this complication, most surgeons prefer prone position. The prone position requires attention to details to maintain optimal alignment of the cervical spine and to avoid eye complications. Headframes and padded headrest present a risk of increased intraocular pressure, and this can result in optic nerve necrosis and subsequently loss of vision.[5] Therefore, Mayfield frame is used to secure a patient in prone position and prevent this complication. Reverse Trendelenburg position is important to avoid venous congestion.[6] The final position is checked using fluoroscopic image to confirm good alignment of the cervical spine, i.e. normal cervical spine lordosis.

After preparation and draping of the patient, a midline skin incision is made and nuchal ligament and deep fascia are divided. Dissection is carried close to bone to avoid muscle stripping and reduce bleeding. The intersspinous ligaments are preserved during the posterior approach. Sub-periosteal dissection of the para-spinal muscles is performed to permit direct visualisation of the laminae below and above together with the facet joint at the involved level. Care is taken to avoid damage to the adjacent facet capsule and to avoid dissection beyond the extent of the desired fusion.

### 1.1.3 Cervical Laminectomy Technique

Decompression of the neural elements using laminectomy technique starts at the lower inter-laminar space by elevating the ligamentum flavum from the dura using a blunt dissector, such as a Penfield dissector.[6] Kerrison ronguer is used to resect the ligamentum flavum. A laminar spreader is subsequently placed between adjacent laminae to increase surgical working space. In addition, Kerrison rongeuer is used to perform laminectomy on both sides, beginning at the notch where the lamina meets the lateral mass, and in a distal to proximal direction.[6] By lifting the dissected lamina posteriorly, a plane between the dura and lamina can be created using a Penfield dissector, and the lamina can be lifted from the dura.

Complete laminectomy allows dura to expand and permits the visualisation of the nerve roots of two levels into the intervertebral foramen.[6] Figure 1.1 demonstrates the laminectomy technique.

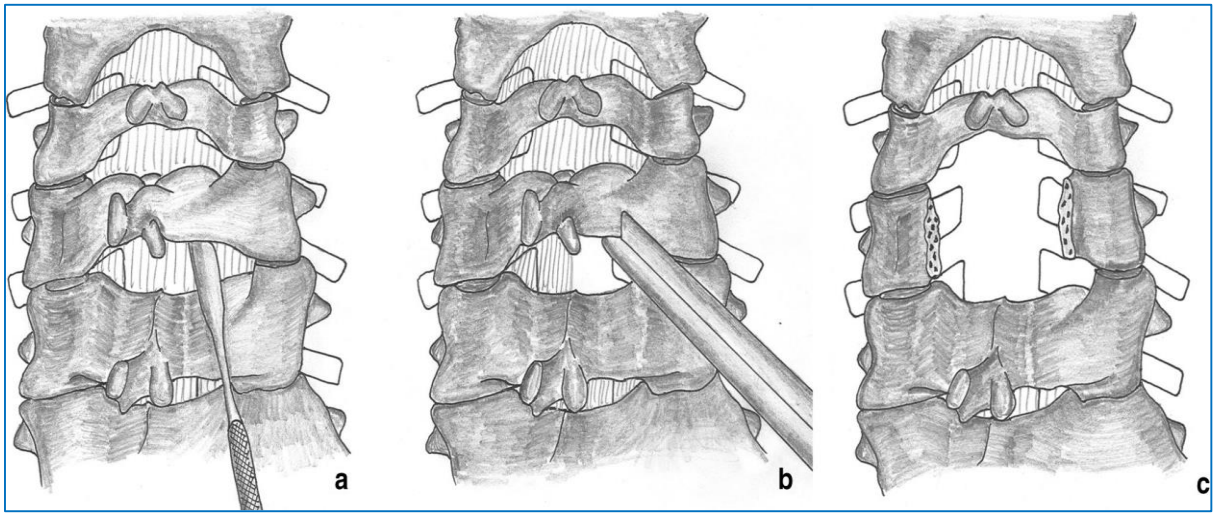



**Figure 1.1:** Images showing the demonstration of the laminectomy technique ("a" to "c") (adapted from Mayer M, Meier O, Auffarth A, *et al*.). [6]

### 1.1.4 Complications associated with posterior cervical spine surgery

Posterior cervical spine surgery has several advantages compared to the anterior approach namely, indirect decompression without destabilising the disc spaces, and less risk for post-operative instability.[3,7] However, this procedure is associated with a number of complications such as C5 palsy, axial pain, restriction of neck motion, peri-neural adhesion and loss of lordotic curvature.[3,7,8] C5 palsy is a debilitating complication post cervical decompression procedure where patients show weakness of the deltoid and biceps brachii muscle power.[3] The C5 nerve root is at risk due to its direct and short course as it exits the spinal cord, and this makes it susceptible to traction injury due to posterior shift of the decompressed spinal cord.[9] Yonenobou *et al*. (1991) reported 3.4% incidence of early post-operative C5 nerve root deterioration.[7] C5 nerve palsy predominantly involves motor function but may also have sensory and radicular pain.[9] Nakashima *et al*. (2012) defined C5 nerve palsy as post-operative deterioration of muscle power in the deltoid by one or more grades (determined by manual muscle testing (MMT) on the deltoid muscle, with or without involvement of the biceps

muscle), but no loss of power in other muscles.[10] Other complications associated with posterior surgery include, spinal cord injury, nerve root injury, complications associated with screw fixation, e.g. screw malposition, spring back closure and post laminectomy kyphosis.

Currier *et al*. (2012) reported the incidence of neurological complications to be 0.18%.[8] The incidence of neurological complications increases to 2.6% with correction of severe kyphotic deformity.[11] Neurological complications associated with kyphotic correction through posterior surgery can be mitigated by performing foraminotomy prophylactically in the presence of foraminal stenosis.[9] Correction of kyphotic deformity at C4/C5 level is also associated high risk of neurological complication due to the massive posterior shift of the spinal cord leading to C5 palsy.[11] Spinal cord monitoring is therefore, recommended in high-risk patients.

Complications associated with screw fixation has also been reported in the literature. Complications associated with screw malposition in the cervical spine surgery are vertebral artery injury and neurological fallout, however, the most common complication is injury to the vertebral artery. The incidence is related to the vertebrae being instrumented. Literature reports incidence of 0 – 4% for the atlas (C1) and 0 – 7% in the axis (C2).[12] The incidence of vertebral artery injury during instrumentation is reported as 1.3 – 4% for Margerl fusion. The risk of neurological fallout is low at 0.2% during C1/C2 fusion.[13] The risk of nerve root injury in the subaxial spine during lateral mass instrumentation is 1.3%.[14] Lateral mass fracture has also being mentioned in the literature as a complication for screw fixation in the subaxial spine.

Mochida *et al*. (1999) reported a 40% incidence of spring back closure after laminoplasty.[15] Hirabayashi first described open door laminoplasty in the 1970s. The procedure allows widening of the spinal canal without removing posterior cervical elements as opposed to laminectomy.[16] Laminectomy includes removal of the spinous processes, inter and supraspinous ligaments, laminae, and ligamentum flavum and loss of capsule of the facet joints that compromises the posterior stabilisers. The incidence of kyphosis after multilevel laminectomy is reported as 20%.[17] The phenomenon is known as postlaminectomy kyphosis. It is more common in younger population group as the older patients may have partially fused cervical spine and are more stable.

Combined anterior and posterior cervical surgery is recommended by some surgeons, especially in patients with multilevel cervical stenosis with severe kyphotic deformity. Anterior surgery allows thorough decompression, but sufficient stability can be difficult to achieve in

three or more disc levels. The incidence of pseudoarthrosis in patients undergoing only anterior cervical discectomy and fusion without posterior surgery with exposure of three or more levels is reported to be between 20 and 42%.[18] Bolesta *et al*. (2000) concluded in his series of three or four level anterior cervical discectomy and fusion with plate fixation that the pseudo-arthrosis rate was unacceptably high.[19] Other risk factors associated with pseudoarthrosis reported include smoking, osteoporosis, increased fusion levels and poor surgical technique, non-steroidal anti-inflammatory agents among others.

### 1.1.5 Anterior Cervical Spine Surgery

As previously, stated ACDF is the most commonly performed cervical spine surgery in the USA with satisfactory outcomes. Anterior cervical spine surgery permits efficient treatment for multiple spine pathologies, which include trauma, degenerative disease, infections, tumours and deformity correction, amongst others. It provides easy access while the outcomes are satisfactory in majority of cases. It constitutes one of the rewarding spinal procedures.[20] The initial reported techniques on cervical spine surgery were posterior based, however in the past 10-years, significant increase in the practice of this procedure has been noted.[21] The anterior approach was first described by Smith and Robinson in 1955 and has since become the standard of care for orthopaedic surgeons and neurosurgeons.[22] This approach has since been modified several times from the original technique.

## 1.2 SURGICAL TECHNIQUES

### 1.2.1 Patient Position

The patient lies supine with a bolster between the shoulder blades, to allow extension of the cervical spine and dropping the shoulder down from the surgical field. Extension of the neck allows opening of the intervertebral disc spaces, and jaws to move upwards to allow access to the cephalad aspect of the cervical spine.[21] The shoulders are pulled caudal to obtain better visualisation of cervico-thoracic junction. Gardner Wells tongs or Mayfield clamps are sometimes applied to control neck rotation particularly during deformity correction. Reverse Trendelenburg position reduces bleeding intra-operatively.[6]

## 1.2.2 Surgical Landmarks

Correct localisation of the skin incision is important for good cosmetic outcome and safe mobilisation of soft tissue during surgery to prevent complications. Improper skin incision may lead to inadequate exposure, and that may lead to incomplete decompression and difficulty with instrumentation. Anatomical landmarks and intra-operative fluoroscopic imaging are used to determine the correct level for surgical incision. Hyoid bone (C3/C4), thyroid cartilage (C4/ C5), cricoid cartilage (C6) and carotid tubercle (C6) are the anatomical structures that are used to determine the appropriate cervical vertebral level (see Figure 1.2a and b). Literature has also described the mandibular angle as anatomical landmark, and correlates to C2 /C3 intervertebral disc space and is independent of patient body habitus.[23]

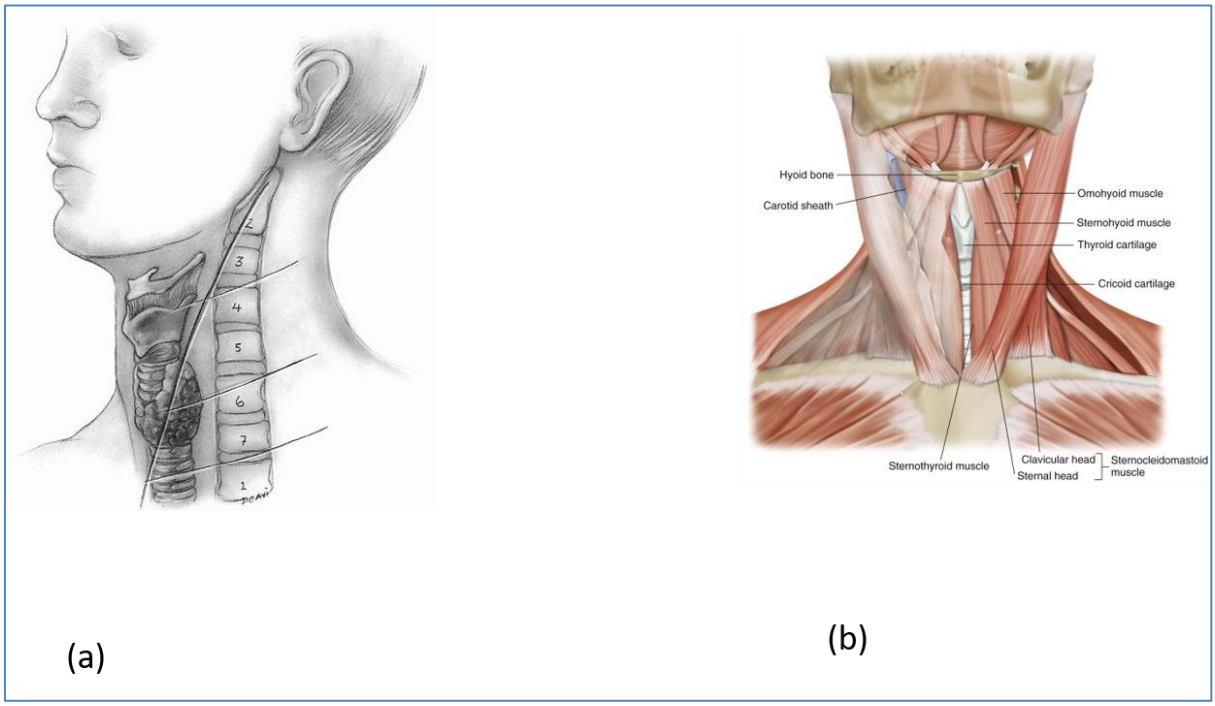



**Figure 1.2a:** Image from the side of the neck depicting the surgical landmarks that are used intra-operatively to identify the correct cervical level (adapted from Siemionow KB, Neckrysh S).[24] **Figure 1.2b:** Image from the front of the neck depicting the surgical landmarks that are used intra-operatively to identify the correct cervical level (adapted from Pait TG, Killefer JA, Arnautovic KI *et al*.).[25]

The prerequisite to performing anterior cervical spine surgery is good understanding of the anatomy around the head and neck, particularly the relationship between the neural elements,

vascular anatomy, bony anatomy and different cervical fascial layers. The platysma and external jugular vein lie outside investing layer of the deep cervical fascia. The pre-tracheal fascia encloses the thyroid gland, trachea and oesophagus anteriorly. It then blends with the carotid sheath, which contains common carotid artery, internal jugular vein, vagus nerve and deep cervical lymph nodes. The pre-tracheal fascia is sharply dissected to separate it from the carotid sheath. Superior and inferior thyroid vessels connect the carotid sheath with the midline. The prevertebral fascia encompasses the anterior longitudinal ligament (ALL) allowing entry to the disc space and vertebral bodies [26] (see Figure 1.3).

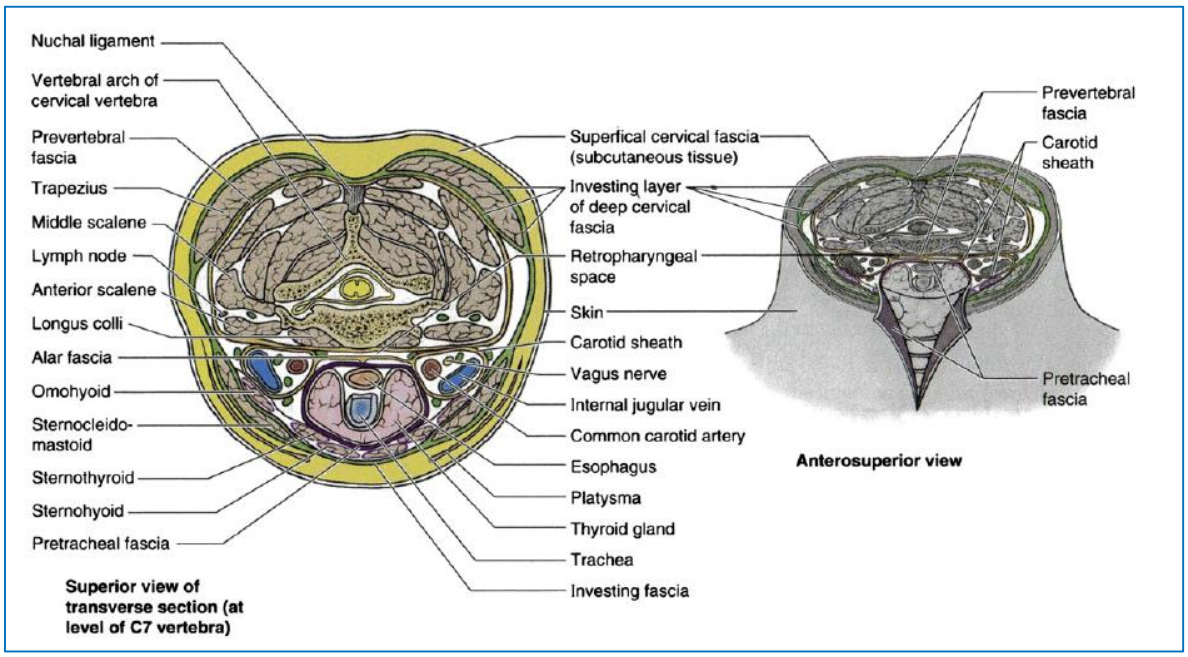



**Figure 1.3:** Images depicting cervical fascial layers that are encountered during anterior approach to the cervical spine (adapted from Siemionow KB and Neckrysh S).[26]

The risk of injury to certain important anatomical structures during this procedure is dependent on the level being operated. The vertebral artery is mostly in danger in the upper cervical spine, i.e. C2/C3 intervertebral disc level. Pait *et al*. (1996) during the cadaveric study found the shortest average distance to be at the cervical disc level of C2/C3 (i.e. 0.8 mm) when measured from the tip of the uncinate process to the medial border of the vertebral artery.[27] Therefore, caution is recommended when surgery is performed at this level. Superior laryngeal nerve (SLN) is particularly in danger at C3/C4 disc level due to its anatomy. Sympathetic trunk is particularly at risk at C6 level as it is situated 10.6 mm to 11.6 mm from the medial border of the longus colli.[28,29] Recurrent laryngeal nerves (RLNs) are the structures most in danger during

this procedure, particularly at C6/C7 level and cervico-thoracic junction. Both RLNs penetrates the larynx at or below C6 disc level.[21]

### 1.2.3 Surgical Approach

Appropriate level is identified using anatomical landmarks and confirmed with fluoroscopy before the surgical incision is made. A 3 to 5 cm transverse incision is then made at an appropriate level. Longitudinal surgical incision can also be used particularly when more extensile exposure is needed. The transverse surgical incision allows good exposure for one or three level surgery and good cosmetic outcome while longitudinal incision provides poor aesthetics.

The incision is made within the transverse skin tension lines. The fascia of the platysma muscle is encountered and incised in line with the skin incision and the platysma muscle fibres are the split longitudinally. The deep investing cervical fascia is then identified anterior to the anterior border of the sternocleidomastoid muscle (SCM), and subsequently incised. The SCM is retracted laterally and strap muscles (sternothyroid and sternohyoid) together with the midline structures (trachea, oesophagus) are retracted medially. The carotid sheath is identified by feeling the pulsation of the common carotid artery. The pre-tracheal fascia is then identified on the medial aspect of the carotid sheath and incised. The carotid sheath is retracted laterally together with the SCM muscle. The superior and inferior thyroid arteries are identified and ligated if necessary. A plane is then developed by blunt dissection to expose the prevertebral fascia and longus colli muscle covering the ALL. The longus colli muscles and ALL are split in the midline elevated subperiosteally to avoid injury to the sympathetic chain, and this exposes the cervical vertebrae. There are several methods that have been described in the literature to help identify the correct cervical level, which include the needle localisation and use of the radiopaque clamp on the ALL. The disadvantage of using hypodermic needle technique at the incorrect level may accelerate degeneration of the uninvolved disc. The needle identification of the level is recommended when more than two level ACDF is planned; where the danger of inserting a needle in the uninvolved disc is lower (see Figure 1.4). [21]

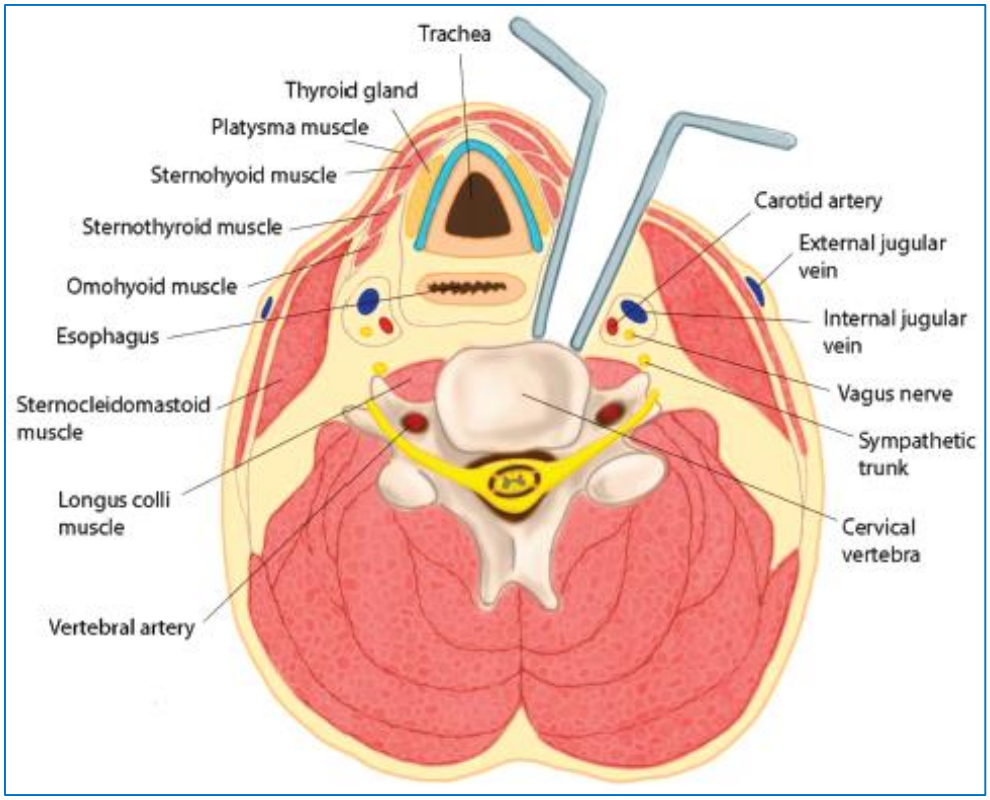



**Figure 1.4:** Anatomical cross section of the Smith Robinson approach (adapted from Razi A, Saleh H, DeLacure MD, *et al*.). [21]

## 1.3 Complications associated with anterior cervical spine surgery

ACDF is the most commonly performed cervical spine surgery with excellent results; however, it is associated with several complications. Despite satisfactory outcomes associated with ACDF, there are potential rare complications that can ensue. Anterior cervical corpectomy and fusion (ACCF) is associated with higher complication rate than ACDF.[30] The long list of complications associated with anterior cervical spine surgery includes infection, cerebrospinal fluid leakage, abscess and hematoma formation. Implant related complications have also been reported in the literature. Fountas *et al*. (2007) reported an incidence of instrumentation backout in 0.1% of their cases.[31] Although the complications are rare and have minor clinical significance, they may be fatal.

The reported incidence of post-operative airway complication after isolated anterior cervical spine surgery ranges between 1.7 and 6.1%.[32] Emery *et al*. (1991) reported a 2.8% incidence

of post-operative airway obstruction in their series of 108 patients after anterior decompression and non-instrumented fusion.[33] Manninen *et al*. (2007) reported a 1.2% incidence of post-operative airway obstruction requiring re-intubation in patients undergoing a cervical spine procedure.[34]

The two most common cause of post-operative airway compromise are prevertebral soft tissue swelling and laryngopharyngeal oedema.[33,34,35] Wound hematoma, abscess formation leakage of cerebrospinal fluid and failure of the construct are rare causes of airway complications post-operatively. Sagi *et al*. (2002) reported that post-operative airway complications requiring unplanned re-intubation or tracheostomy are rare.[35] However, patients who are at risk for post-operative airway complications after anterior cervical surgery must be identified pre-operatively, so that one can optimise airway management post-operatively. Even though these complications are uncommon, they require a prompt response whenever they occur, and failure to respond appropriately may result in a hypoxic brain damage or death. Risk factors for airway compromise following anterior cervical spine surgery include:

- More than three cervical levels exposure pre-operatively,
- Operation involving C3 – C4 or level above,
- Operation time longer than 5 hours,
- Estimated blood loss (EBL) greater than 300 millilitres (ml),
- Medical comorbidities,
- Combined anterior and posterior surgery
- High Body Mass Index (BMI).[18,32,35]

The risk factors for post-operative airway compromise have been well described in the literature, but guidelines on post-operative airway management are sparse.[36] Kim *et al*. (2017) found that the airway complication rate was low when an airway management protocol for stratifying a patient at risk was used in their series, and concluded that a patient with no risk factors is not likely to have airway complications.[32] Other complications that have been reported in the literature that are associated with anterior cervical spine surgery include neurological and vascular injury, dysphagia and injury to the cervical sympathetic trunk.[21,37,39]

Vertebral artery injury is uncommon but can results in devastating complications if it occurs. Vertebral artery injury can cause cerebrovascular accident, clot formation; neurological deficits

and sometimes death can ensue from exsanguination.[37] Iatrogenic injury to the vertebral artery during anterior cervical spine surgery is reported to be between 0.3 and 0.5%.[21] Obermuller *et al*. (2015) also reported the incidence of 0.3%.[38]

Prolonged and continuous retraction of the oesophagus may lead to dysphagia after anterior cervical spine surgery.[39] Post-operative dysphagia is reported to range between 2 and 60% depending on the number of factors.[39] Yew *et al*. (2019) reported that prolonged intra-operative surgical time, young patients and female gender were the risk factors during early post-operative time in contrast to pre-existing medical comorbidities that were responsible for persistent dysphagia.[40] Vaishnav *et al*. (2019) demonstrated that prolonged operating time was the only risk factor for post-operative dysphagia.[41]

Post-operative hoarseness of voice can occur as the results injury to the ipsilateral recurrent laryngeal nerve. The hoarseness of voice is as the result of paralysis of the ipsilateral vocal cords. The left recurrent laryngeal nerve has a predictable course in the neck as it ascends between the trachea and the oesophagus. Ebraheim *et al*. (1997) reported that the left RLN lies deep within the trachea-oesophageal groove, while the right RLN is located anterior and lateral to the trachea-oesophageal groove.[42] Theoretically, right RLN is mostly in danger during dissection due to its unpredictable course; however, there is no difference in this complication rate between the right and left sided surgical approach according to the literature.[21] Kilburg *et al*. (2006) in the retrospective analysis reported 1.9% and 1.8% incidence of right and left RLN injuries respectively in those who underwent ACDF.[43] Beutler *et al*. (2001) demonstrated similar results and reported 2.1% incidence of RLN injury.[44]

The superior laryngeal nerve (SLN) is also at risk of injury during anterior cervical spine surgery; however, there is paucity in the orthopaedic literature about the SLN. The SLN divides into two branches, before penetrating the thyrohyoid membrane. Burger *et al*. (1985) showed that the incidence of permanent SLN is 1%[45] and since then, literature-tracking injury to SLN has been limited.[21]

The sympathetic trunk lies closer to the medial border of the longus colli muscle at C6 (average distance of 10.6 mm) than at C3.[27] Civelek *et al*. (2008) reported that sympathetic chain lies about 11.6 mm from the medial border of longus colli at C6.[28] Due to this anatomical morphology, the sympathetic trunk is at high risk of injury at C6 level. Injury to the cervical sympathetic trunk present as Horner's, which is characterised by ptosis, meiosis and anhidrosis

on the same side. Literature reports incidence of Horner's syndrome to be between 0.2 and 4%.[21]

Intensive care unit (ICU) is a hospital unit that provides continuous monitoring and specialised care to acutely ill patients either medical or surgical, whose conditions are life threatening and require comprehensive care.[46] The American College of Emergency Physicians (ACEP) defines a critical illness or injury as the one that impairs one or more vital organ systems resulting in a high probability of imminent or life threatening deterioration in a patient's condition.[47] Critical care services are offered by ICU trained physicians as well as nursing personnel, and patients need to be admitted in critical care units, i.e. ICU or High Care Area (HCA) for these services to be rendered. It is an expensive and scarcely available resource. In 2005, ICU beds in the USA accounted for 15% of the hospital, the occupancy rates were estimated at 68% and the costs were roughly $82 billion, or 0.66% of the gross domestic products (GDPs).[48] The most recent estimated costs in the USA published in 2008 for critical care ranged between $121 − 263 billion (16.9 − 38.4% for hospital costs and 5.2 − 11.2% for national health care expenditure).[49] Moreover, due to this exorbitant cost scarcity of critical care services, the appropriate utilisation of ICU beds is essential. ICU in South Africa is expensive and is a resource-limited environment. The South African annual health expenditure for the year 2017/2018 was R187.5 billion, which is 13.5% of the total government's expenditure.[50,51] There are no statistics available in South Africa for the annual critical services expenditure.

South Africa has limited ICU resources available. The majority of these resources are found in the private sector and they serve the minority population. Bhagwanjee *et al*. (2007) found that only 23% of the public hospitals in South Africa have ICU/HCA facilities available compared to 84% of the private hospitals. Furthermore, the majority of these facilities are concentrated in three main provinces i.e. KwaZulu-Natal (KZN), Gauteng (GP) and Western Cape (WC).[52] The study also showed that 2.3% of all ICU beds across the provinces are not utilised by patients due to a lack of staff or equipment.

Scribante and Bhagwanjee (2007) found that 25.6% of the nurses working in ICU were ICU trained, of which 3.8% were neonatal ICU specialists.[53] Naidoo *et al*. (2013) concluded that due to limitations of critical care services in South Africa, there was a need for a triage protocol for ICU admission and discharge, and effective treatment guidelines and algorithms.[54] While

the risk factors associated with airway complications in patients undergoing cervical spine surgery are well documented in the literature, protocols that guide airway management post-operatively are sparse. Kim *et al*. (2017) developed the Asian Extubation Protocol (AEP) for patients undergoing cervical spine surgery, and to their knowledge, this was the first airway management protocol available for patients undergoing anterior cervical spine surgery.[32] The Asian Extubation protocol is presented in Figure 1.5 below.

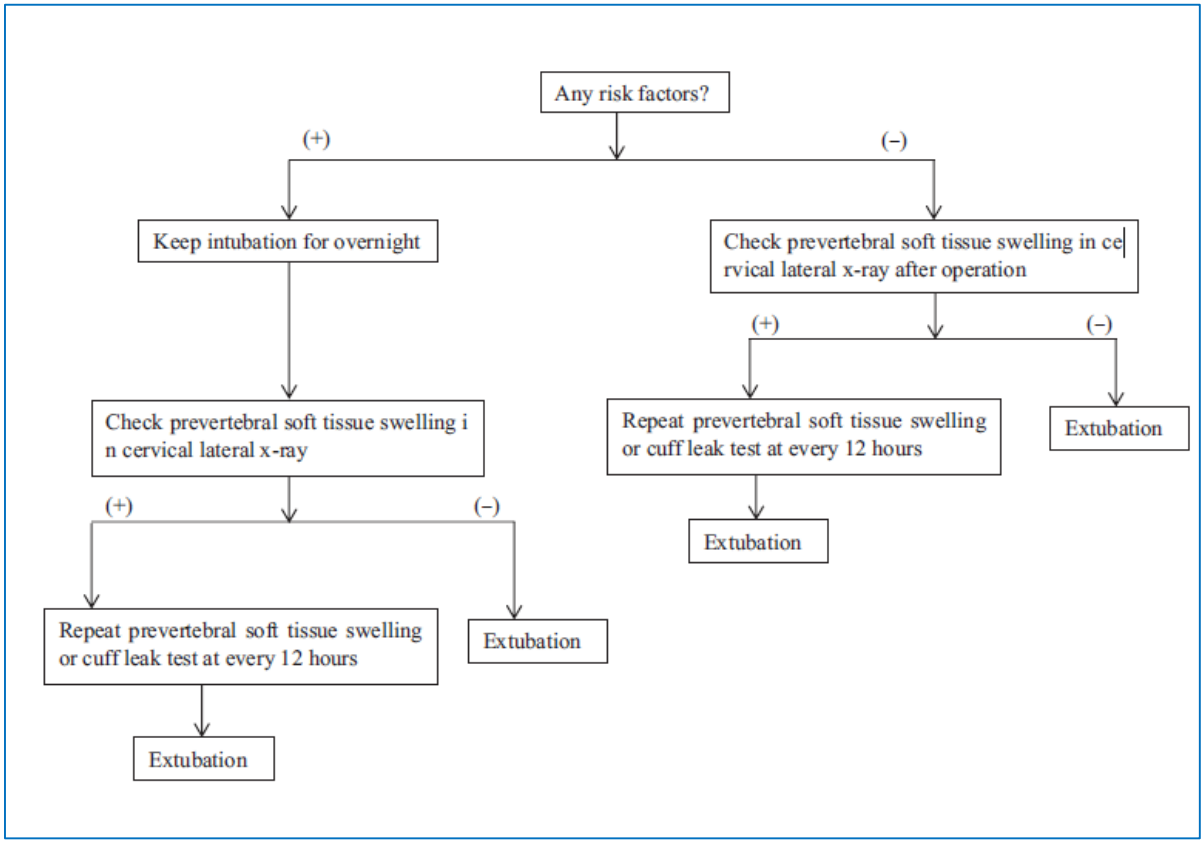



**Figure 1.5:** Asian Extubation Protocol.[32]

Currently, there is no standard airway management protocol available on ICU admission post cervical spine surgery at our health institution. The decision on airway management/ICU admission post operatively is left to the discretion of the anaesthetist. Currently, the practice is that ICU beds need to be made available before the patient undergoes surgery. Due to the exorbitant cost of ICU admission, a lack of ICU beds and trained personnel, together with long waiting periods for patients awaiting cervical spine surgery, it is essential to develop a standardised airway management protocol. Therefore, the aim of the study was to assess the

appropriateness of the current practice of post-operative airway management, assess the need for ICU admission post-operatively.

## 1.4 Study Aim and Objectives

The aim of the study was to review the appropriateness of the current practice of airway management in patients who underwent cervical spine surgery at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH).

The objectives of the study were to:

- To review the appropriateness of the current practice of airway management
- To determine the risk factors for airway compromise in our population.
- To determine the incidence of re-intubation and tracheostomy and death post-operatively.

# CHAPTER 2

# 2. METHODOLOGY

### 2.1 Null Hypothesis

Not all patients undergoing cervical spine surgery require ICU admission post-operatively.

### 2.2 Research Design

The study was a retrospective hospital based case series over a 10-year period, of patients both males and females above the age of 18 years who underwent cervical spine surgery at CMJAH.

### 2.3 Materials and Methods

The data of the patients who underwent cervical spine surgery at CMJAH were reviewed over a 10-year period (01 January 2007 – 31 December 2017). Patients were identified using the orthopaedic spine surgery register and their medical records were retrieved. Study numbers were assigned to each patient medical record. The pre-operative data including demographics, intra-operative and post-operative data were collected as shown in Appendix A, B, and C.

### 2.4 Selection Criteria and Sample size

#### 2.4.1 Inclusion Criteria

The inclusion criteria for the study were patients who were 18 years and older who underwent cervical spine surgery at CMJAH between 01 January 2007 and 31 December 2017. All patients who had cervical spine surgery at CMJAH during the set period were included regardless of their neurological status.

#### 2.4.2 Exclusion Criteria

The exclusion criteria were patients who had incomplete medical records, i.e. medical records in which notes were missing or incompletely recorded.

### 2.5 Data collection and analysis

The study included all patients who met the inclusion criteria set above in subsection 2.4. The sample size was 52 patients. Ethics clearance was obtained from Human Research Ethics Committee (HREC), Medical, University of the Witwatersrand (Clearance Number: **M181135**). Study numbers were used to protect the identities of the patients. The data collection sheet had three pages (see Appendices A, B and C). The first page (see Appendix A) contained pre-operative data which included demographics of the patients, indications for surgery, previous cervical spine surgery (anterior) and comorbidities of the patients. The second page contained intra-operative data (see Appendix B) which were mainly risk factors, for example operative surgical time, approach used amongst other variables. The third page (see Appendix C), contained post-operative data, which had primary and secondary outcome measures for example re-intubation and tracheotomy rate. The raw data were entered onto Microsoft Excel and analysed using Stata version 14.0.

### 2.6 Limitations

These was a retrospective study with a small sample size. This limitation was mitigated by the fact that the duration of the study was long, over a 10-year period.

# CHAPTER 3

# 3. RESULTS

STATA version 14.0 statistical package was used for data analysis. *P*-values < 0.05 were considered statistically significant. Final data were analysed on 52 patients.

### 3.1 Descriptive statistics

Descriptive statistics were used to analyse the sociodemographic profile of the patients, risk factors and outcome measure (see Tables 3.1 and 3.2 and Figures 3.1 to 3.8). These were reported as frequency and percentages for categorical variables and mean/standard deviation (SD) or median/interquartile range as appropriate for continuous variables.

#### 3.1.1 Demographics

Fifty-two patients were recruited, 39 males and 13 females. The majority of the patients included in our study were males (75%), and females only accounted for 25% of the study population. The racial profile of the study population included 44 Black, six Caucasian, one Indian and one Coloured. The median age was 30.5 years (with interquartile range of 23.5). The youngest patient was 18 years old with the oldest being 79 years old. There was equal number of patients below the age of 40 years (26 patients)) and those 40 years and older (26 patients).

**Table 3.1:** Socio-demographic characteristics of the patients

| | **Frequency** | **Percentage** |
|---|---|---|
| Gender | | |
| Female | 13 | 25.0 |
| Male | 39 | 75.0 |
| Race | | |
| Black | 44 | 84.62 |
| Coloured | 1 | 1.92 |
| Indian | 1 | 1.92 |
| White | 6 | 11.54 |
| Age (median = 30.5 years, IQR = 23.5) | | |
| Less than 20 years | 1 | 1.92 |
| 20 – 29 years | 12 | 23.08 |
| 30 – 39 years | 13 | 25.00 |
| 40 – 49 years | 11 | 21.15 |
| 50 – 59 years | 9 | 17.31 |
| 60 – 69 years | 4 | 7.69 |
| 70 years and older | 2 | 3.85 |

### 3.1.2 Risk factors

Figures 3.1 to 3.8 summarises the risk factors identified amongst our study population. Majority of the patients did not have any previous anterior neck surgery; only two patients (3.8%) out of 52 participants had previous surgery to the neck. One patient had previous thyroidectomy and the other patient was documented as previous cyst removal (see Figure 3.1).

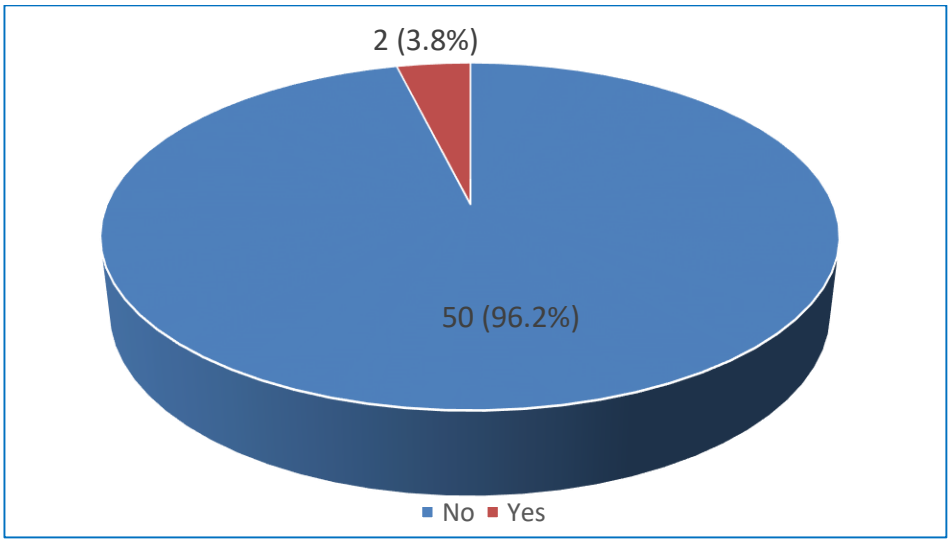



**Figure 3.1:** Previous history of the anterior neck surgery

Only 19 patients (36.5%) had comorbidities, majority of the patients did not have any comorbidity (see Figure 3.2). Some of the comorbidities identified were hypertension, diabetes, gout, hypertensive cardiac disease, previous pulmonary tuberculosis and polytrauma. Hypertension accounted for majority of the patients.

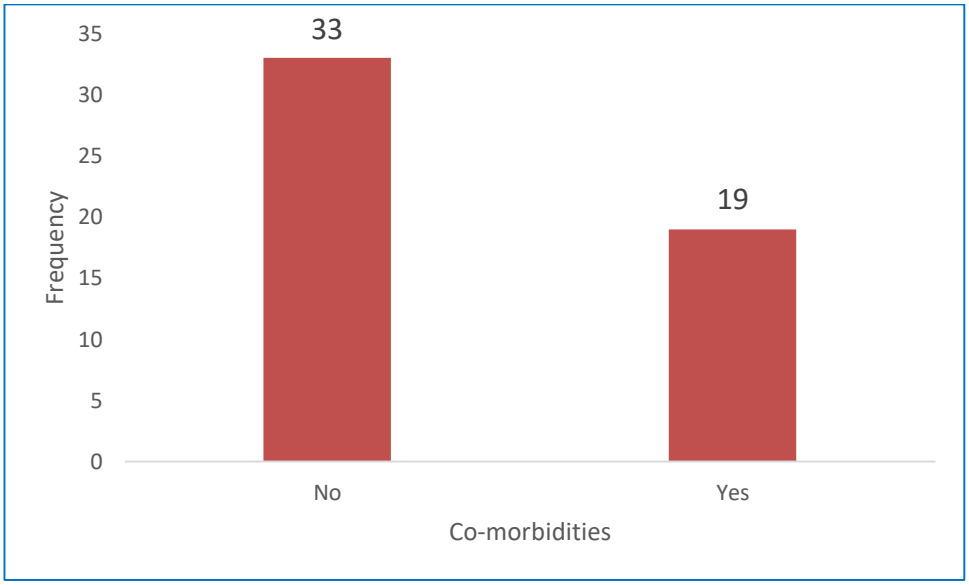



**Figure 3.2:** Co-morbidities found in the participants

Duration of surgery fell below 5 hours in the majority (98%) of the patients. The shortest duration was 65 minutes with longest duration being 320 minutes. Only one patient surgery lasted longer than 5 hours (see Figure 3.3). The mean operation time was 130 minutes, (SD = 53.4).

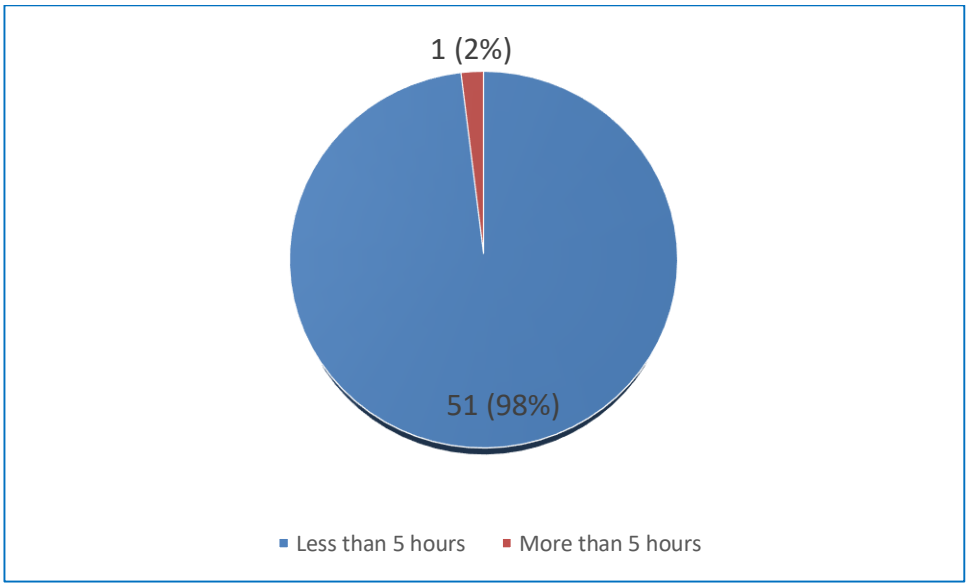



**Figure 3.3:** Duration of the surgery

Majority of the patients (49 patients out of 52 participants (94%)) in our study underwent only anterior cervical spine surgery. Only three patients had combined anterior and posterior cervical spine surgery. All three patients had staged procedures, i.e. anterior and posterior cervical spine and required two visits to the operating room.

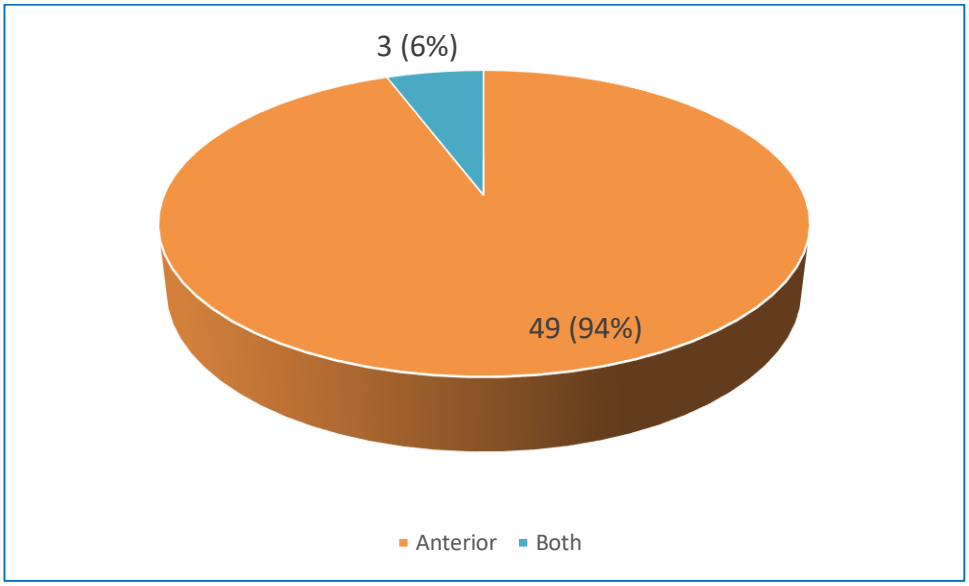



**Figure 3.4:** Approach used during the surgery

Figure 3.5 describes the number of levels fused per patient. Majority (96.2%) of the patients had less than 3 levels fused. Only two patients had 3 levels or more fused. One had 3 levels fused and the other had 4 levels fused.

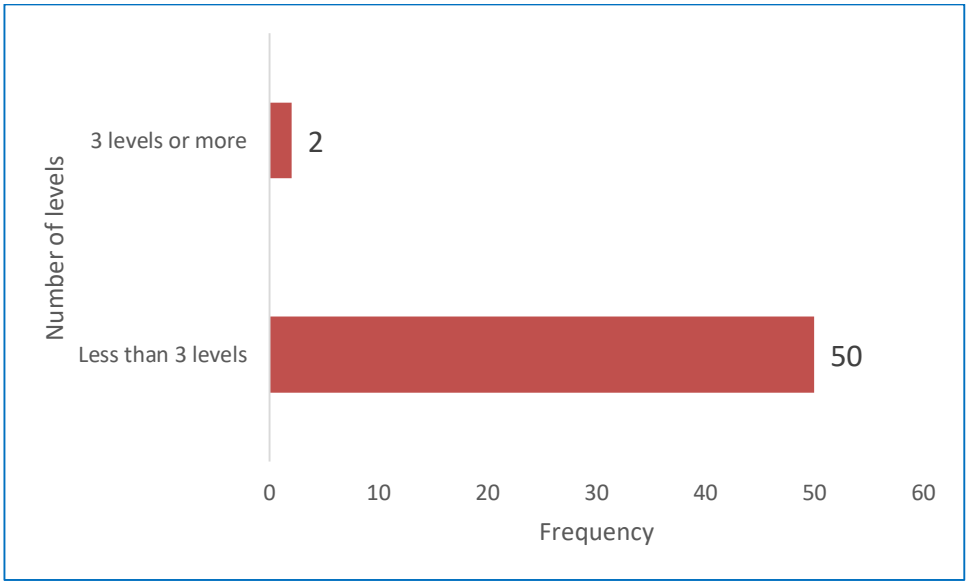



**Figure 3.5:** Number of levels fused during the surgery

Figure 3.6 depicts the intra-operative blood loss. Blood loss was less than 300 ml in 40 patients (77%) recruited in our study. The blood loss ranged between 80 ml (minimum) and 800 ml (maximum). The mean blood loss was 236 ml (SD = 190).

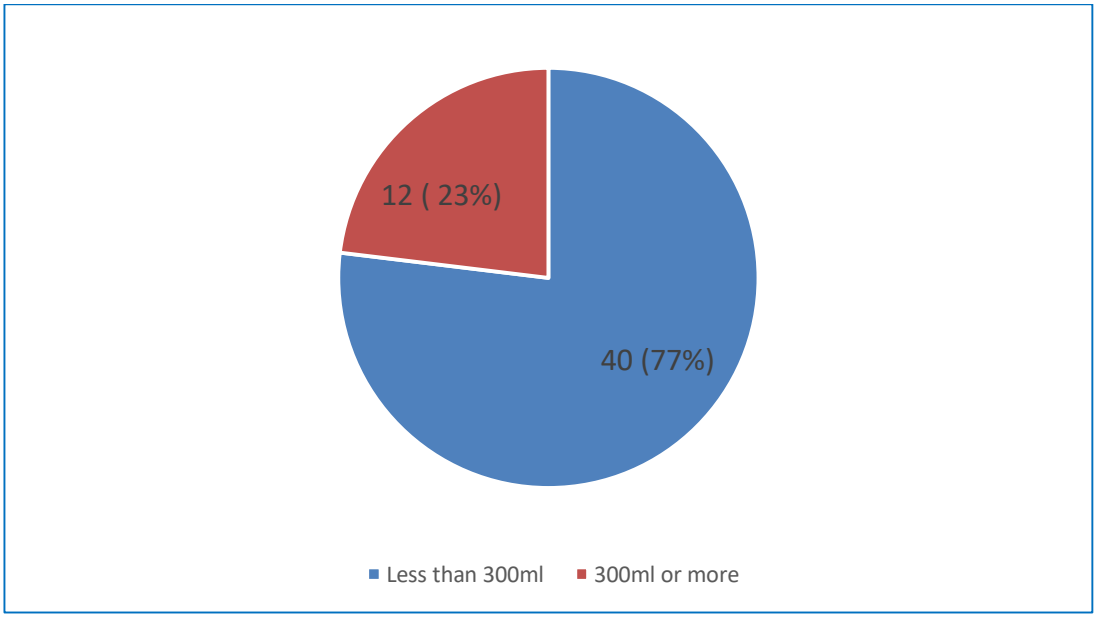



**Figure 3.6:** Estimated blood loss during the surgery

More than two thirds (73.1%) of the patients presented had neurology ranging from ASIA C, D and E. Only 14 patients (26.9%) in our study presented with severe neurology, i.e. ASIA A and B (see Figure 3.7).

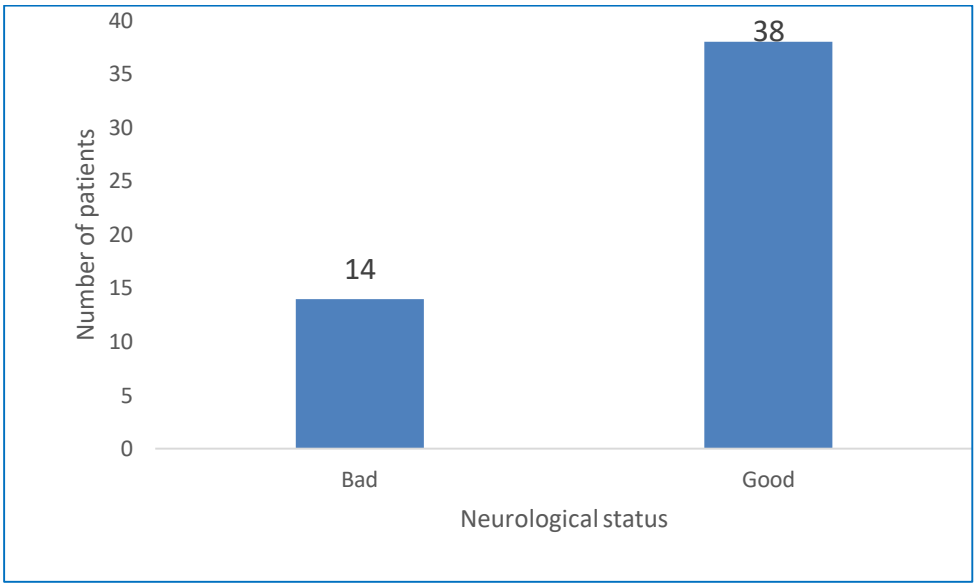



**Figure 3.7:** Neurological state of the patients

The pie chart below (see Figure 3.8) illustrates levels of spine fused in all the patients in the study. More than half of the patients (58%) had cervical spine fusion from C4 disc level and below, and more than a third (42%) of the patients had cervical spine fusion from C3 disc level and above.

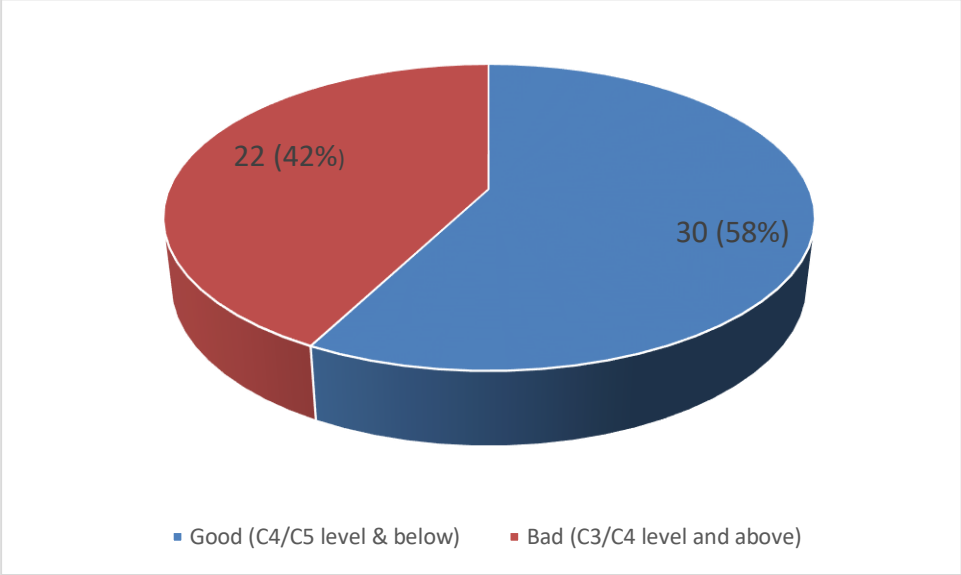



**Figure 3.8:** Level of the spine fused

### 3.1.3 Outcome measures

Table 3.2 summarises the outcome measures in our study. The main primary outcome measures were the incidence of re-intubation, tracheostomy and death in our patient's population. The secondary outcome measures included number of days spend in ICU post-operatively, time to extubation after surgery. Time to extubation is recorded as either immediately post-operatively (i.e. while the patient is still in the operating room), or beyond post-operative period (i.e. once the patient is discharged from operating room and is admitted in ICU). The incidence of re-intubation and tracheostomy were 7.69% and 1.92%, respectively. Overall, post-operative airway complication rate was 9.61%. Mortality rate was found to be 13.46%. Majority of the patients (61.54%) spend only one day (overnight) in ICU, and 67.3% of the patients were extubated immediately post-operatively.

### 3.1.4 Anaesthesia time

The mean anaesthesia time was found to be 228 minutes (SD = 78.9) in our study.

**Table 3.2:** Outcomes measures

| | Frequency | Percentage |
|---|---|---|
| Number of days in ICU | | |
| 1 | 32 | 61.54 |
| 2 – 4 | 16 | 30.77 |
| 5 or more | 4 | 7.69 |
| Re-intubation in ICU | | |
| No | 48 | 92.31 |
| Yes | 4 | 7.69 |
| Tracheostomy in ICU | | |
| No | 51 | 98.08 |
| Yes | 1 | 1.92 |
| Death in ICU | | |
| No | 45 | 86.54 |
| Yes | 7 | 13.46 |
| Time to extubation | | |
| Immediate post-operative time | 35 | 67.3 |
| Beyond post-operative time | 17 | 32.7 |

Table 3.3 summarise the indication for surgery and related age groups. Majority of patients who were operated because of trauma were under the age of 40 years (24 patients out of 52 participants). All patients who were operated for degenerative disease were all above the age of 40 years. Two patients who were operated because of tumour were all above the age of 40

years. Three patients had surgery because of infection, one patient was above the age of 40 years and two were below the age of 40 years.

**Table 3.3:** Indication for surgery *versus* Age

| | **Age group** | |
|---|---|---|
| **Indication** | Less than 40 years | 40 years and older |
| Degenerative disease | 0 | 9 |
| Infection | 2 | 1 |
| Trauma | 24 | 14 |
| Tumour | 0 | 2 |
| **Total** | **26** | **26** |

### 3.2 Inferential statistics

Inferential statistics were carried out using Student's t-test, Pearson's Chi-square test and logistic regression analysis. Logistic regression analysis was used to assess association between outcome (re-intubation) and the risk factors (previous neck surgery, comorbidities, operation time, surgical approach, number of levels exposed, blood loss, neurological state of patient and level fused) (see Table 3.4). Student's t-test was used to assess association between outcome (re-intubation) and anaesthesia time (see Table 3.5).

**Table 3.4:** Re-intubation *versus* Risk factors

| | **Odds ratio** | ***p*-value** | **95% Confidence Interval** |
|---|---|---|---|
| Previous neck surgery | | | |
| No | 1 | | |
| Yes | 2.1 | 0.655 | 0.09 – 50.04 |
| Comorbidities | | | |
| No | 1 | | |
| Yes | 0.56 | 0.622 | 0.05 – 5.75 |
| Operation time | | | |
| Less than 5 hours | 1 | | |
| More than 5 hours | 41.6 | 0.031 | 1.4 – 1220.31 |
| Approach | | | |
| Anterior | 1 | | |
| Both | 7.7 | 0.135 | 0.53 – 110.65 |
| Number of levels | | | |
| Less than 3 levels | 1 | | |
| 3 levels or more | 2.1 | 0.655 | 0.09 – 50.04 |
| Blood loss | | | |
| Less than 300 ml | 1 | | |
| 300 ml or more | 3.8 | 0.208 | 0.47 – 30.42 |
| Neurological state of patients | | | |

| | | | |
|---|---|---|---|
| Bad (A, B) | 1 | | |
| Good (C, D, E) | 0.33 | 0.297 | 0.04 – 2.63 |
| Level fused | | | |
| Good (C4/C5 level and below ) | 1 | | |
| Bad (C3/C4 level and above) | 0.4 | 0.477 | 0.4 – 4.42 |

**Table 3.5:** Re-intubation *versus* Anaesthesia time

| | Re-intubation | | |
|---|---|---|---|
| | No<br>Mean (SD) | Yes<br>Mean (SD) | *p*-value |
| Anaesthesia time (minutes) | 220.8 (75.0) | 315 (83.4) | 0.020 |

Operation time and anaesthesia time were the two risk factors associated with increased risk of re-intubation. The patients who spent more than 5 hours during operation were 41.6 times more likely to be re-intubated compared to those who spent less than 5 hours during operation (OR = 41.6, 95% CI = 1.4 – 1220.31, *p*-value = 0.031). The patients who were re-intubated had longer mean anaesthesia time compared to those who were not re-intubated 315 minutes *versus* 220.8, *p*-value 0.020. The other risk factors did not show any statistically significant association with increased risk of re-intubation.

Logistic regression analysis was used to assess association between outcome (tracheostomy) and the risk factors (previous neck surgery, comorbidities, operation time, surgical approach, number of levels exposed, blood loss, neurological state of patient and level fused) (see Table 3.6 below). Student's test was used to assess association between outcome (tracheostomy) and anaesthesia time.

**Table 3.6:** Tracheostomy *versus* Risk factors

| | **Odds ratio** | ***p*-value** | **95% Confidence Interval** |
|---|---|---|---|
| Previous neck surgery | | | |
| No | 1 | | |
| Yes | 6.6 | 0.283 | 0.21 – 206.57 |
| Comorbidities | | | |
| No | 1 | | |
| Yes | 0.56 | 0.723 | 0.02 – 14.32 |
| Operation time | | | |
| Less than 5 hours | 1 | | |
| More than 5 hours | 11.2 | 0.187 | 0.31 – 40622 |
| Approach | | | |
| Anterior | 1 | | |
| Both | 4.62 | 0.375 | 0.16 – 135.59 |
| Number of levels | | | |
| Less than 3 levels | 1 | | |
| 3 levels or more | 6.6 | 0.283 | 0.21 – 206.57 |
| Blood loss | | | |
| Less than 300ml | 1 | | |
| 300ml or more | 1.1 | 0.975 | 0.04 – 27.53 |
| Neurological state of patients | | | |

| | | | |
|---|---|---|---|
| Bad (A, B) | 1 | | |
| Good (C, D, E) | 0.12 | 0.197 | 0.01 – 3.05 |
| Level fused | | | |
| Good (C4/C5 level and below) | 1 | | |
| Bad (C3/C4 level and above) | 0.44 | 0.617 | 0.02 – 11.24 |

As shown in Table 3.6, none of the risk factors showed any statistically significant association with increased risk of tracheostomy.

Logistic regression analysis was used to assess association between outcome (death in ICU) and the risk factors (previous neck surgery, comorbidities, operation time, surgical approach, number of levels exposed, blood loss, neurological state of patient and level fused) (see Table 3.7 below). Student's t-test was used to assess association between outcome (death in ICU) and anaesthesia time (see Table 3.8).

**Table 3.7:** Death in ICU *versus* Risk factors

| | **Odds ratio** | ***p*-value** | **95% Confidence Interval** |
|---|---|---|---|
| Previous neck surgery | | | |
| No | 1 | | |
| Yes | 1.2 | 0.926 | 0.05 – 26.63 |
| Comorbidities | | | |
| No | 1 | | |
| Yes | 0.66 | 0.646 | 0.11 – 3.78 |
| Operation time | | | |

| | | | |
|---|---|---|---|
| Less than 5 hours | 1 | | |
| More than 5 hours | 21 | 0.071 | 0.77 – 571.90 |
| Anaesthesia time | | | |
| Anterior | 1 | | |
| Both | 3.6 | 0.326 | 0.28 – 45.80 |
| Number of levels | | | |
| Less than 3 levels | 1 | | |
| 3 levels or more | 1.2 | 0.926 | 0.06 – 26.63 |
| Blood loss | | | |
| Less than 300 ml | 1 | | |
| 300 ml or more | 1.3 | 0.712 | 0.24 – 8.34 |
| Neurological state of patients | | | |
| Bad (A, B) | 1 | | |
| Good (C, D, E) | 0.1 | 0.012 | 0.02 – 0.60 |
| Level fused | | | |
| Good (C4/C5 level and below) | 1 | | |
| Bad (C3/C4 level and above) | 1.0 | 0.975 | 0.21 – 5.13 |

**Table 3.8:** Death in ICU *versus* Anaesthesia time

| | Death | | |
|---|---|---|---|
| | No<br>Mean (SD) | Yes<br>Mean (SD) | *p*-value |
| Anaesthesia time (minutes) | 220.8 (74.3) | 274.3 (98.0) | 0.096 |

Neurological state of patients was the only risk factor associated with death in ICU. The patients with good neurological state were 90% less likely to die in ICU compared to those with bad neurological state (OR = 0.1, 95% CI = 0.02 – 0.60, *p*-value = 0.012).

Chi-squared test was used to assess association between outcome (days in ICU) and the risk factors (previous neck surgery, comorbidities, operation time, surgical approach, number of levels exposed, blood loss, neurological state of the patient and level fused) (see Table 3.9 below). ANOVA was used to assess association between outcome (days in ICU) and anaesthesia time (see Table 3.10).

**Table 3.9:** Days in ICU *versus* Risk factors

| | Days in ICU | | | |
|---|---|---|---|---|
| | 1-day<br>*n* (%) | 2 – 4 days<br>*n* (%) | 5 or more days<br>*n* (%) | *p*-value |
| Previous neck surgery | | | | |
| No | 31 (96.9) | 15 (93.8) | 4 (100.0) | 1.000 |
| Yes | 1 (3.1) | 1 (6.3) | 0 (0.0) | |
| Comorbidities | | | | |
| No | 20 (62.5) | 11 (68.8) | 2 (50.0) | 0.745 |

| | | | | |
|---|---|---|---|---|
| Yes | 12 (37.5) | 5 (31.3) | 2 (50.0) | |
| Operation time | | | | |
| Less than 5 hours | 32 (100.0) | 16 (100.0) | 3 (75.0) | 0.077 |
| More than 5 hours | 0 (0.0) | 0 (0.0) | 1 (25.0) | |
| Approach | | | | |
| Anterior | 31 (96.9) | 15 (93.8) | 3 (75.0) | 0.243 |
| Both | 1 (3.1) | 1 (6.25) | 1 (25.0) | |
| Number of levels | | | | |
| Less than 3 levels | 32 (100.0) | 14 (87.5) | 4 (100.0) | 0.143 |
| 3 levels or more | 0 (0.0) | 2 (12.5) | 0 (0.0) | |
| Blood loss | | | | |
| Less than 300 ml | 29 (90.6) | 8 (50.0) | 3 (75.0) | 0.006 |
| 300 ml or more | 3 (9.4) | 8 (50.0) | 1 (25.0) | |
| Neurological state of patients | | | | |
| Bad (A, B) | 3 (9.4) | 9 (56.3) | 2 (50.0) | 0.001 |
| Good (C, D, E) | 29 (90.6) | 7 (43.8) | 2 (50.0) | |
| Level fused | | | | |
| Good (C4/C5 level and above) | 16 (50.0) | 10 (62.5) | 4 (100.0) | 0.181 |
| Bad (C3/C4 level and below) | 16 (50.0) | 6 (37.5) | 0 (0.0) | |

**Table 3.10:** Days in ICU *versus* Anaesthesia time

| | Days in ICU | | | |
|---|---|---|---|---|
| | 1-day Mean (SD) | 2 – 4 days Mean (SD) | 5 or more days Mean (SD) | *p*-value |
| Anaesthesia time (minutes) | 204 (56.3) | 271.6 (84.0) | 246.3 (145.6) | 0.138 |

As shown in Table 3.9, blood loss and neurological state of patients were the two risk factors that were statistically associated with increased number of days spent in ICU. The other risk factors did not show any statistically significant association with increased number of days spent in ICU.

Logistic regression analysis was used to assess association between outcome (time to extubate) and the risk factors (previous neck surgery, comorbidities, operation time, surgical approach, number of levels exposed, blood loss, neurological state of patient and level fused) (see Table 3.11 below). Student's t-test was used to assess association between outcome (time to extubate) and anaesthesia time (see 3.12).

**Table 3.11:** Time to extubate *versus* Risk factors

| | **Odds ratio** | ***p*-value** | **95% Confidence Interval** |
|---|---|---|---|
| Previous neck surgery | | | |
| No | 1 | | |
| Yes | 0.38 | 0.543 | 0.02 – 8.42 |
| Comorbidities | | | |
| No | 1 | | |

| | | | |
|---|---|---|---|
| Yes | 0.63 | 0.459 | 0.18 – 2.17 |
| Operation time | | | |
| Less than 5 hours | 1 | | |
| More than 5 hours | 6.5 | 0.261 | 0.25 – 167.04 |
| Approach | | | |
| Anterior | 1 | | |
| Both | 1.04 | 0.981 | 0.09 – 12.24 |
| Number of levels | | | |
| Less than 3 levels | 1 | | |
| 3 levels or more | 11.5 | 0.123 | 0.52 – 252.79 |
| Blood loss | | | |
| Less than 300 ml | 1 | | |
| 300 ml or more | 4.2 | 0.038 | 1.09 – 16.24 |
| Neurological state of patients | | | |
| Good (C, D, E) | 1 | | |
| Bad (A, B) | 6.8 | 0.005 | 1.76 - 25.85 |
| Level fused | | | |
| Good (C4/C5 level and below) | 1 | | |
| Bad (C3/C4 level and above) | 0.29 | 0.063 | 1.07 |

**Table 3.12:** Time to extubate *versus* Anaesthesia time

| | Time to extubate | | |
|---|---|---|---|
| | Immediate post-op Mean (SD) | Beyond post-op/never Mean (SD) | *p*-value |
| Anaesthesia time (minutes) | 213.8 (53.1) | 257.4 (100.1) | 0.061 |

Blood loss and neurological state of patients were the two risk factors associated with increased time to extubate (i.e. delayed extubation). The patients who had blood loss of 300 ml or more were 4.2 times more likely to be extubated beyond the immediate post-operative period (i.e. extubated in the ICU) compared to those with blood loss less than 300 ml (OR = 4.2, 95% CI = 1.09 – 16.24, *p*-value = 0.038). The patients with bad or poor neurological state were 6.8 times more likely to be extubated beyond the immediate post-operative period (i.e. extubated in the ICU) compared to those with good neurological state (OR = 6.8, 95% CI = 1.76 – 25.85, *p*-value = 0.005).

### 3.3 Further analysis after re-categorising neurological state

The neurological state was further re-categorised into bad, fair and good neurological state as depicted in Table 3.13, to assess if bad neurology was the significant independent risk factor to the clinical outcome measures. Majority of the patients in our study had good neurology (i.e. ASIA D and E) which accounted for 55.8% of the patients. Only 26% had bad neurology (i.e. ASIA A and B) and fair neurology (i.e. ASIA C) accounted for minority of the patients (17.3 %).

**Table 3.13:** New neurological categories

| **Neurology** | **ASIA score** | **Frequency (%)** |
|---|---|---|
| Bad | A, B | 14 (26.9) |
| Fair | C | 9 (17.3) |
| Good | D, E | 29 (55.8) |

Statistical analysis was performed after this re-classification of the neurological state and the findings are summarised in the Tables 3.14 – 3.18.

**Table 3.14:** Re-intubation in ICU *versus* neurological status

| | **Odds ratio** | ***p*-value** | **95% Confidence Interval** |
|---|---|---|---|
| Neurological state of patient | | | |
| Good (D, E) | 1 | | |
| Fair (C) | 3.5 | 0.394 | 0.20 – 62.41 |
| Bad (A, B) | 4.7 | 0.226 | 0.39 – 56.51 |

Neurological state did not show any statistically significant association with re-intubation in ICU.

**Table 3.15:** Tracheostomy in ICU *versus* Neurological status

| | **Odds ratio** | ***p*-value** | **95% Confidence Interval** |
|---|---|---|---|
| Neurological state of patient | | | |
| Good (D, E) | 1 | | |
| Fair (C) | 3.1 | 0.578 | 0.06 – 167.44 |
| Bad (A, B) | 6.6 | 0.259 | 0.25 – 171.58 |

Neurological state did not show any statistically significant association with tracheostomy in ICU.

**Table 3.16:** Death in ICU v*ersus* Neurological status

| | **Odds ratio** | ***p*-value** | **95% Confidence Interval** |
|---|---|---|---|
| Neurological state of patient | | | |
| Good (D, E) | 1 | | |
| Fair (C) | 3.5 | 0.394 | 0.19 – 62.41 |
| Bad (A, B) | 15.6 | 0.018 | 1.60 – 151.26 |

Patients with bad neurological state were about 16 times more likely to die in ICU compared to patients with good neurological state (OR = 15.6, 95% CI = 1.60 – 151.26, *p*-value = 0.018).

**Table 3.17:** Number of days in ICU *versus* Neurological status

| | Days in ICU | | | |
|---|---|---|---|---|
| | 1-day *n* (%) | 2 – 4 days *n* (%) | 5 days or more *n* (%) | *p*-value |
| Neurological state of patient | | | | |
| Good (D, E) | 23 (71.9) | 4 (25.0) | 2 (50.0) | 0.002 |
| Fair (C) | 6 (18.8) | 3 (18.8) | 0 (0.0) | |
| Bad (A, B) | 3 (9.3) | 9 (56.2) | 2 (50.0) | |

Neurological state of patients showed statistical significant association with increased number of days spent in ICU, majority of the patients (23/32, 71.9%) who spent one day in ICU were patients with good neurological state.

**Table 3.18:** Time to extubate *versus* Neurological status

| | **Odds ratio** | ***p*-value** | **95% Confidence Interval** |
|---|---|---|---|
| Neurological state of patient | | | |
| Good (D, E) | 1 | | |
| Fair (C) | 1.10 | 0.922 | 0.18 – 6.69 |
| Bad (A, B) | 6.9 | 0.007 | 1.68 – 28.41 |

The patients with bad neurological state were about seven times more likely to be extubated beyond the immediate post-operative period (i.e. extubated in the ICU) compared to those with good neurological state (OR = 6.9, 95% CI = 1.68 – 28.41, *p*-value = 0.007).

# CHAPTER 4

# 4. DISCUSSION

### 4.1 Socio-demographic characteristics of patients

Our study found that, there were more males than females. Males accounted for 75% of the patients and only 25% of the patients were females. This was explained by the fact that trauma cases accounted for just under 50% of the surgeries performed (24 out of 52 participants (46%)). Cervical spine trauma is more common in males than females. These findings in our study were consistent with most of the data in the literature. Ter Haar *et al.* (2011) found in their series that, from 88 patients that had spinal cord injury (SCI), 77 (87%) were male and 11 (13%) were females.[55] Govender *et al.* (2000) treated 196 patients with fracture of the odontoid process of which 163 were men.[56] Our study did not assess the rate of airway complications amongst different sex groups. However, Sagi *et al.* (2002) found that the incidence of airway complication in male patients was 7.1% and for female patients it was 4.9%, however the difference was not statistically significant.[35]

### 4.2 Race

Black race group accounted for the majority in our study, with the white population being the second highest race group. This can be explained by the fact that, our hospital (CMJAH) is a public (government) facility and therefore caters for the majority in the society, i.e. black population.

### 4.3 Age of the patients

Median age of the patients in our study was 30.5 years (IQR = 23.5). Majority of the patients recruited in our study were operated because of traumatic cervical spine fractures. These patients accounted for 46% of the study population, hence, the lower median age. Cervical spine trauma occurs commonly is young patients as a results of high-energy mechanism (e.g. motor vehicle accident, diving and falls from height), and this is consistent with the literature.

Du Toit *et al.* (2008) reported the average age of 33.3 years in their series of patients with bifacet dislocation of the cervical spine.[57] Sagi *et al.* (2002 ) and Kim *et al.* (2017) both reported higher mean ages in the series of patients, 47 years and 51.56 years (non-protocol group) 52.56 years (protocol group), respectively, and this is explained by the fact that majority of patients in their series were operated as the result of degenerative disease which occurs commonly in elderly population.[35,32]

### 4.4 Risk Factors

#### 4.4.1 Previous neck surgery

Majority of the patients in our study did not have any history of previous anterior neck surgery. Only two patients (i.e. 3.8%) reported history of previous neck surgery. These is because the median age of our study was low. Majority of the patients were healthy young patients with traumatic cervical spine injury. Our results are similar to what Kim *et al.* (2017) reported in their study, where they found the incidence of previous anterior neck surgery of 2.55% and 3.8% in the non-protocol and protocol group respectively.[32]

#### 4.4.2 Comorbidities

The comorbidities were found in 36.5% of the population in our study. These finding can be explained by the fact that 26 patients out of 52 participants were below the age of 40 years and comorbid diseases are not common in this population group. Sagi *et al.* (2002) in their study reported that the incidence of medical comorbidities that may present with respiratory difficulty was 29% for group 1 and 26% for group 2, however for those patients requiring intubation, it was zero.[35]

#### 4.4.3 Operation time, Number of levels operated and Approaches (Anterior or Both)

The findings in our study was that overwhelming majority of the patients in our study had their surgery done less than 5 hours. Majority of the patients were done by two senior spine surgeons in the department and had one or two level surgery (96.2%) and only single anterior approach (94.2%). Fusion of 3 or more levels, and through the combined approaches (anterior and posterior approaches) were not commonly done, hence the general short mean operation time

(mean = 130 minutes, SD = 53.4). The shorter mean operation time was directly related to the fact that most patients in our study had one or two level surgery and only single approach.

### 4.4.4 Neurological state

Majority of the patients (73.1%) were diagnosed with good neurological state (ASIA C, D, E), and severe neurology accounted for 26.9% of the cases. The variability in the neurological status was due to the large spectrum of diagnostic indications of surgery. All patients above the age of 18 years who had anterior cervical spine surgery or combined were included regardless of the diagnostic indications.

### 4.4.5 Level fused

Sagi *et al.* (2002) found that if the highest level exposed was C4 or higher, there was a statistically significant increase in the incidence of an airway complication and re-intubation, and the incidence of patients who had C4 level exposed or higher in their study was 37% in Group 1 and 67% in Groups 2 and 2b.[35] The findings in our study was that fusion levels at C3/C4 level and above occurred in 42.3% of our cases. These findings are different to that of Kim *et al.* (2017), who reported the incidence of operation level above C3/C4 level of 11.27% and 12.93% in their non-protocol and protocol group, respectively.[32]

### 4.4.6 Anaesthetic time

Phan *et al*. (2017) concluded that prolonged anaesthesia duration is associated with increased odd of complication, venous thromboembolism, increased length of stay and return to the operating room.[60] The mean anaesthetic time in our study was 228 minutes (SD = 78.9). The short mean anaesthetic time is due to the fact that majority of the patients in the study had one or two level surgery and only single approach. The mean anaesthetic time is directly related to the mean operation time. The shorter the mean operation time the shorter the anaesthetic time.

### 4.5 Outcome measures

#### 4.5.1 Number of days in ICU

Majority of the patients in our study spend only one day in ICU (i.e. overnight), this accounted for 61.54% of the patients. Those that spend between 2 – 4 days only contributed 30.77% and only 7.69% of the patients spend 5 days or more in ICU. The decision to keep the patients either intubated or extubated post-operatively was solely dependent on the anaesthetic consultant's discretion doing the list on that day. The anaesthetic practice in our health institution for all the patients undergoing anterior cervical spine surgery is that the ICU bed must be available prior to surgery. Majority of the patients were extubated immediately post-operatively (67.3%) before being admitted in ICU for airway monitoring and 61.54% spend only one day in ICU.

#### 4.5.2 Time to extubation

The minimum time for airway complication post extubation has always been subject of discussion in the literature. Controversy exist over the minimum period before extubation that is considered reasonable and safe. Palumbo *et al.* (2013) said in his paper that the practice of many spine surgeons is to maintain intubation overnight and consider removal of the endotracheal tube (ETT) on the morning of the first post-operative day within 12 to 18 hours of the surgical end time.[58] However, Emery *et al*. (1991) and Sagi *et al.* (2002) reported the average time to development of airway complications after anterior cervical spine surgery to range from 23 to 37 hours.[33,35] Based on the data Kim *et al.* (2017) recommended to consider airway protection further beyond until this time.[32] However, 67.3% of the patients in our study were extubated immediately post-operatively without any adverse outcome.

#### 4.5.3 Re-intubation and tracheostomy in ICU

Post-operative airway complications requiring unplanned re-intubation or tracheostomy are rare, but catastrophic complications can ensue if inappropriately managed.[35] The literature reports airway complications associated with anterior cervical spine surgery to range from 1.7% to 6.1%.[32] Emery *et al*. (1991) in his study reported re-intubation rate of 5.2% in seven patients undergoing cervical multilevel corpectomy for myelopathy.[33] Manninen *et al.* (2007*)*

reported acute post-operative airway obstruction requiring intubation in 1.2% of patients undergoing cervical spine procedure.[34] Despite this low complication rate in the literature, the anaesthetic practice in our health institution is for every patient to be admitted in ICU after anterior cervical spine surgery. Risk factors associated with airway complication are well documented in the literature and therefore patients should be stratified according to their risk profile. Kim *et al.* (2017) showed that implementing an extubation protocol based on the risk factors of the patients significantly reduced post-operative airway complications.[32] The rate of re-intubation and tracheostomy in our study was 7.69% and 1.92%, respectively. The re-intubation rate was slightly higher than what is reported in the literature by Emery and Manninen. The overall post-operative airway complication in our study was 9.61%. The slightly higher post-operative airway complication rate in our study was because we included ASIA A and B (i.e. patients with severe neurological deficit), and cervical trauma patients who are already at risk of this complications. Patients with severe neurological deficit are prone to pulmonary dysfunction as they have weak cough reflex secondary to respiratory muscle weakness. The rate of post-operative airway complication in our study is still low to warrant that all patients be admitted in ICU, particularly in our resource-constrained environment. We recognise the fact that the complication associated with anterior cervical spine surgery can be catastrophic as documented in the literature. We suggest that the patients that are high risk should be identified and be managed differently from those with the low risk or no risk factors. As Kim *et al.* (2017) showed in his study, we believe that our slightly higher overall post-operative airway complication rate can be reduced even further if a management protocol/algorithm is derived.

### 4.5.4 Death in ICU

Mortality rate in our study was high compared to what has been reported in the literature. Seven patients from 52 participants died, these accounted for overall mortality rate of 13.46%. Kim *et al.* (2017) reported only 0.36% mortality rate in their study, however patients with severe neurological deficit (ASIA A and B) were excluded.[32] The high mortality rate is attributed to the fact that we did not exclude patients based on their neurological status as discussed before, and traumatic cervical spine injury population were included. Patients with severe neurological deficit and traumatic cervical spine injury are already at risk of airway complications and death

due to their inability to breathe spontaneously and pre-operative soft tissue swelling, respectively. The other reason for high mortality rate in patients with traumatic cervical spine injury is high association with other life threatening injuries. Mechanism of injury for cervical spine injury is because of high energy, and nearly 50% of patients have other significant skeletal or visceral injuries.[59]

### 4.6 Indications for surgery *versus* Age

Most of the patients that were operated in our study was as the results of trauma, 24 out of 52 participants, which contributed 46% of all the patients. These high number of trauma cases, explains the slightly high post-operative airway complication rate and high mortality rate found in our study. As stated previously the cervical spine trauma has high association with cervical spinal cord injury and subsequent neurological deficit, severe cervical soft tissue injury and other life threatening injuries.

### 4.7 Inferential statistics

#### 4.7.1 Risk factors against the outcome measures

The risk factors for development of post-operative airway complications has been well documented in the literature. Although the incidence of this complication is low, the outcome may be catastrophic if inappropriately managed. Therefore, we need to identify those patients who are at risk of developing this complication. Kim *et al*. (2017) based on the previous studies identified the risk factors and developed what they called Asian Extubation Protocol (AEP) to determine the time to extubation in complicated cases and subsequently reduced the incidence of post-operative airway complication.[32]

##### 4.7.1.1 Re-intubation *versus* the risk factors

Duration of surgery and anaesthetic time in our study were the two risk factors associated with increased risk of re-intubation post-operatively. The operation time of more than 5 hours significantly increased the likelihood for re-intubation post-operatively in our study (OR = 41.6, 95% CI = 1.4 – 1220.31. *p*-value = 0.031). Kim *et al*. (2017) found that longer operative

time was a significant risk factor to post-operative airway complication (*p*-value = 0.045).[32] Prolonged operation time increases the risk of local trauma and subsequent soft tissue swelling due to the longer periods of soft tissue retraction. Sagi *et al.* (2017) also reported that operative time of longer than 5 hours was statistically related to increased risk of re-intubation (*p*-value = 0.0143).[35] Other significant risk factors that has been reported in the literature that are associated with the increased risk of intubation includes blood loss greater than 300 ml, cervical spine exposure at C4 and above.[35]

Prolonged anaesthesia time was found to be a significant risk factor to re-intubation post-operatively in our study (*p*-value = 0.020). These findings are consistent with study by Phan *et al.* (2017) who reported after univariate analysis that increased anaesthetic time was significantly associated with pulmonary complications (*p*-value < 0.0001).[60] However, they did not provide the reason for this association. Emery *et al.* (1991) also concluded that the anaesthetic time was significantly associated with post-operative airway complication, however all patients in his series had multilevel corpectomies, all had at least four vertebral bodies exposed and average anaesthetic time was 5 hours.[33] The airway complication associated with anaesthetic time is related to the prolonged operative time and subsequent local trauma and post-operative prevertebral soft tissue swelling. The spinal cord injury was not statistically related to increased risk of re-intubation (*p*-value = 0.0994, respectively) as reported by Sagi *et al*. (2002).[35] This results were consistent with our study that found the neurological deficit was not associated with increased risk of re-intubation (OR = 0.33, 95% CI = 0.04 – 2.63, *P*-value = 0.297). Medical comorbidity did not show any statistical significant association with increased risk of re-intubation (OR = 0.56, 95% CI = 0.05 – 5.75, *P*-value = 0.622). These was consistent with study by Sagi *et al.* (2002) who found zero incidence of medical comorbidities in patients requiring re-intubation.[35] The other risk factors were not significantly associated with re-intubation as reported in other studies.

#### 4.7.1.2 Tracheostomy *versus* risk factors

None of the risk factors in our study showed any significant association with increased risk of tracheostomy post anterior cervical spine surgery. Kim *et al.* (2017) reported the incidence of tracheostomy of 0.36% and 0% in the non-protocol group and protocol group respectively, however there was no statistical significant difference between the two group (*p*-value = 1.000).[32] Sagi *et al.* (2002) also showed no statistical significant difference in post-operative

airway complication between the patients with spinal cord injury and those without spinal cord injury (*p*-value = 0.3327).[35] He reported that only three patients in the spinal cord injury group required re-intubation, but did not mentioned anyone who needed tracheostomy.

#### 4.7.1.3 Death in ICU *versus* risk factors

Neurological state of the patients was the only risk factor that was associated with increased risk of death in ICU. The patients with good neurological state were 90% less likely to die in ICU compared to those with severe neurological deficit (OR = 0.1, 95% CI = 0.02 – 0.60, *P*-value = 0.012). These findings suggest that good neurological state is protective for those patients undergoing anterior cervical spine surgery. Nogoshi *et al*. reported one patient who died amongst nine patients who required re-intubation, however analysis of the associated risk factors was not done.[61] Kim *et al.* (2017) also reported only one patient (0.36%) who died in their series without analysing the associated significant factors.[32] Prolonged anaesthesia time did not show any statistical significant association with increased risk of death. These finding was similar to what Phan *et al*. (2017) reported in their study.[60]

#### 4.7.1.4. Days spend in ICU and Time to extubation *versus* Risk factors

Our study found that, patients with intra-operative blood loss of more than 300 ml, and those patients with bad neurological state pre-operatively, had statistical significant association with increased time to extubation, and as a result increased number of days spent in ICU. Sagi *et al*. (2002) also found an association between increased blood loss (> 300 ml) and airway complication and re-intubation, however they concluded that post-operative airway complication is related to the extent of surgical dissection rather than blood loss *per se*.[35] The delayed extubation and subsequent increased number of days spent in ICU in patients with bad neurological state is because of inability to breath spontaneously due to weak respiratory muscle and phrenic nerve dysfunction. Our results are not different from that of Kwon *et al.* (2006) who found that delayed extubation was significantly related to the total operative time, volume of crystalloid replacement and intra-operative blood transfused.[62]

### 4.8 Re-categorising Neurological State

Neurology status was further re-classified to assess its association with the outcome measures. Bad neurological state showed strong association with increased risk of mortality (OR = 15.6,

95% CI = 1.60-151.26, *p*-value = 0.018), delayed extubation (OR = 6.9, 95% CI = 1.68, *p*-value = 0.007) and increased number of days spent in ICU (*p*-value = 0.002), and these findings were statistically significant.

### 4.9 Summary of the results

The study included 52 patients; all patients were admitted in ICU/HCA post-operatively. Majority of these patients (67.3%) were extubated immediately post-operatively, and 61.54% spend only one day in ICU/HCA (overnight) and our re-intubation and tracheostomy rate was 7.79% and 1.92%, respectively. Mortality rate in our study was 13.46%. Overall, post-operative airway complication rate was 9.61%, slightly higher than what is reported in the literature. Risk factors that contributed to the airway complications and mortality are operation time, anaesthetic time, poor neurological status, increased blood loss.

Neurological status was further re-classified to assess its association with the outcomes. Bad neurological status was significantly associated with increased mortality, extubation only beyond the immediate post-operative time, and subsequent increased number of days spent in ICU.

### 4.10 Study limitations

The limitations in our study was its retrospective nature and was performed in a single health institution. However, its strength was the long observation time of 10-year duration.

### 4.11 Recommendations

We recommend further multicentre, prospective studies with large sample size. Spinal cord injury is reported in some studies as the confounding factor especially in trauma patients. We also believe that severe spinal cord injury and cervical spine trauma were confounding factors in our study. We therefore recommend that trauma patients and those with severe neurological deficit should be classified into separate categories for airway management in prospective studies.

# CHAPTER 5

# 5. CONCLUSION

Anterior cervical spine surgery is the one of the commonest procedures done for many cervical spine pathologies with excellent and predictable outcomes. It has lower complication rates compared to posterior approach. Despite the satisfactory outcomes associated with anterior cervical spine surgery, there are potential rare complications that can ensue. The reported post-operative airway complication rates after isolated anterior cervical spine surgery are 1.7% to 6.1%. Risk factors associated with post-operative airway complication are well documented in the literature, and these include medical comorbidities, prolonged operation time, neurological deficit, increased blood loss, operation involving C3 – C4 level and above, exposure of more than three levels, etc.

Because of the lower complication rates reported in the literature, and the potential catastrophic event that can occur after this procedure, e.g. death and hypoxic brain damage, patients should be stratified pre-operatively according to their risk profile and management/treatment of the airway post-operatively should be individualised. This is particularly important in resource-constrained environment like ours to ensure safety of the patient while saving the cost of treatment. Standardised post-operative airway management algorithm/protocol is essential based on the risk profile of the patient.

The aim of our study was to review the appropriateness of the practice of post-operative airway management in patients who underwent cervical spine surgery, and to determine the risk factors, airway complication and the mortality rate in our population. The overall airway complication rate and mortality rate was low in our study at 9.61% and 13.4%, respectively. Majority of the patients in our study were extubated immediately post-operatively (67.3%) and most of them (61.4%) spent only one day in ICU (i.e. overnight).

The risk factors in our population that showed statistically significant association with this outcome measures were increased operation time, anaesthetic time, increased intra-operative blood loss, and poor neurological status.

Due to these findings in our study and our constrained resource environment, (i.e. both human, infrastructure and financial resources) as well as long waiting surgical list and expensive ICU

facilities, we conclude that the current practice of post-operative airway management is inappropriate, not all patients undergoing anterior cervical surgery require admission in ICU post-operatively. Our study has shown that majority had excellent outcome, and these is consistent with the literature, that patients with no risk or low risk factors are less likely to develop airway complications post-operatively. Stratification according to the risk profile of the patient should be performed and management of airway post-operatively should be individualised, and evidence based logical stepwise decision-making process based on the protocol/algorithm should be followed.

We therefore suggest that patients with no risk or low risk factors can be admitted in the general ward post-operatively, if they are closely monitored in an area well equipped for monitoring vital signs and any clinical deterioration. Based on the findings in our study and risk factors that have been reported in the literature we suggest/recommend the following management algorithm to be implemented in our health institution to manage the airway after isolated anterior cervical spine surgery or combined anterior and posterior cervical spine surgery (see Appendices F1 and F2 for suggested post-operative airway management protocol/algorithm).

# Appendices

**APPENDIX A:** DATA COLLECTION SHEET (PRE-OPERATIVE DATA)

| STUDY NUMBER | AGE | SEX | GENDER | RACE | INDICATIONS FOR SURGERY | BMI | PREVIOUS NECK SURGERY | COMORBIDITIES |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

**APPENDIX B:** DATA COLLECTION SHEET (INTRA-OPERATIVE DATA)

| STUDY NUMBER | OPERATIVE TIME | ANAESTHESIA TIME | APPROACH USED | NUMBER OF LEVELS EXPOSED | ESTIMATED BLOOD LOSS | BLOOD TRANSFUSION | TIME TO EXTUBATION |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

**APPENDIX C:** DATA COLLECTION SHEET (POST-OPERATIVE DATA)

| PATIENT NUMBER | RE-INTUBATION | TRACHEOSTOMY | NUMBER OF DAYS IN ICU | DEATH | DISCHARGE HOME |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

**APPENDIX D:** HUMAN RESEARCH ETHICS CLEARANCE CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Dr SM Tlhabane

## HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
## CLEARANCE CERTIFICATE NO. M181135

| | |
|---|---|
| **NAME:** (Principal Investigator) | Dr SM Tlhabane |
| **DEPARTMENT:** | School of Clinical Medicine<br>Department of Surgery<br>Division of Orthopaedic Surgery<br>Charlotte Maxeke Johannesburg Academic Hospital |
| **PROJECT TITLE:** | Postoperative airway management of cervical spine surgery at Charlotte Maxeke Johannesburg Academic Hospital |
| **DATE CONSIDERED:** | 30/11/2018 |
| **DECISION:** | Approved unconditionally |
| **CONDITIONS:** | |
| **SUPERVISOR:** | Drs S Khan and M Jingo |
| **APPROVED BY:** | Dr CB Penny, Chairperson, HREC (Medical) |
| **DATE OF APPROVAL:** | 01/02/2019 |

**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 on 3rd floor, Phillip V Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/We fully understand the conditions under which I am/we are authorised 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 to the Committee. I agree to submit a yearly progress report. When a funder requires annual re-certification, the application date will be one year after the date of the meeting when the study was initially reviewed. In this case, the study was initially reviewed in November and will therefore reports and re-certification will be due early in the month of November each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

03/02/2019
Date

**PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES**

**APPENDIX E:** CHIEF EXECUTIVE OFFICER (CEO) LETTER

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

**CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL**

Enquiries:
Ms. N. Mzila
Office of the Clinical Director
Tell: (011): 488-4812
Email: Nolwazi.Mzila@gauteng.gov.za
23 May 2019

GP_201902_011

Dear Dr. S. M. Tlhabane

**STUDY TITLE: Post-Operative Airway Management of Cervical Spine Surgery at Charlotte Maxeke Johannesburg Academic Hospital**

Permission is granted for you to conduct the above recruitment activities as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic Hospital will not anyway incur or inherit costs as result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the HOD and Unit Manager or sister in charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

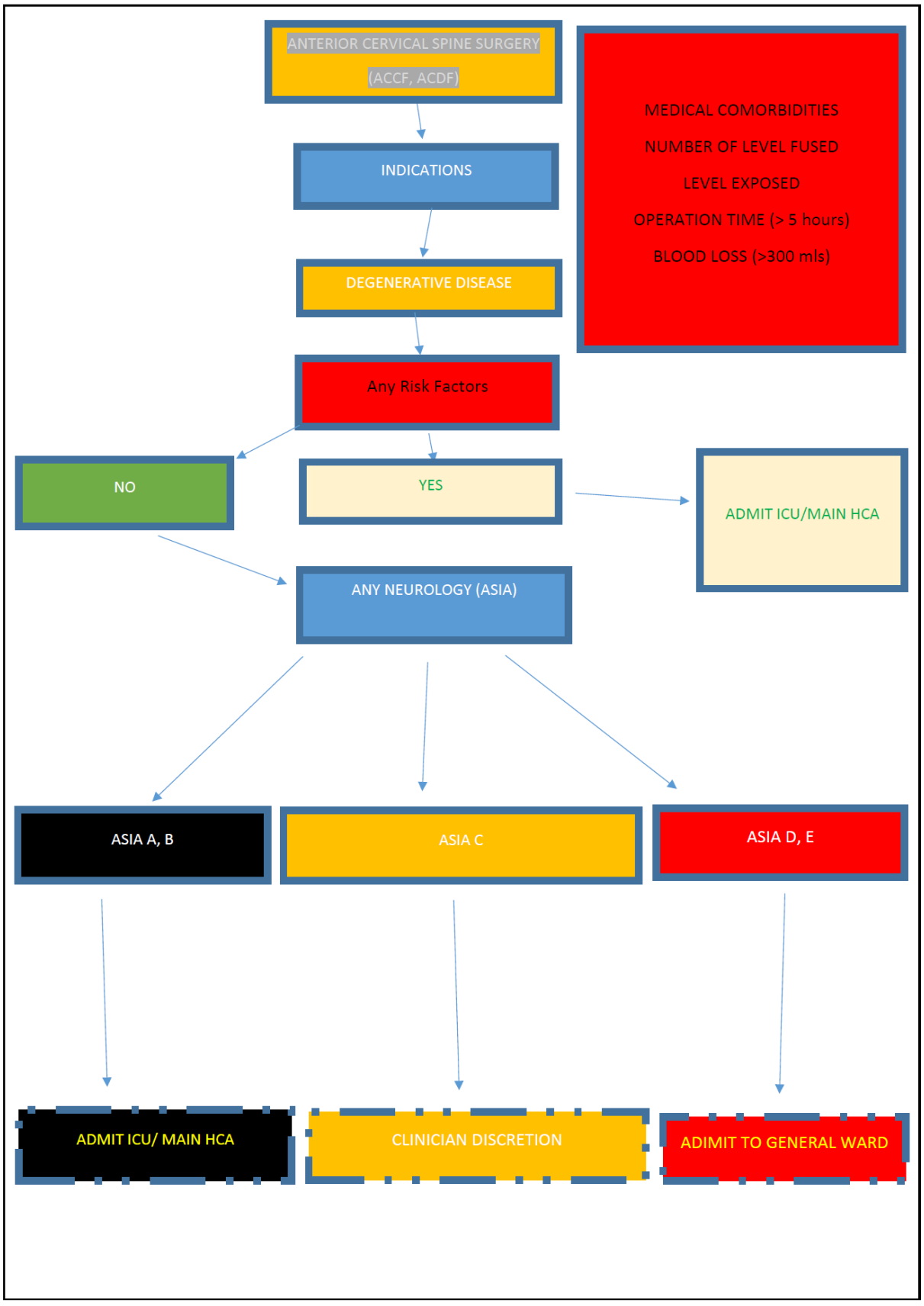
Supported / ~~not supported~~

Dr. M.I. Mothokeng
Clinical Director
DATE: 24/05/2019

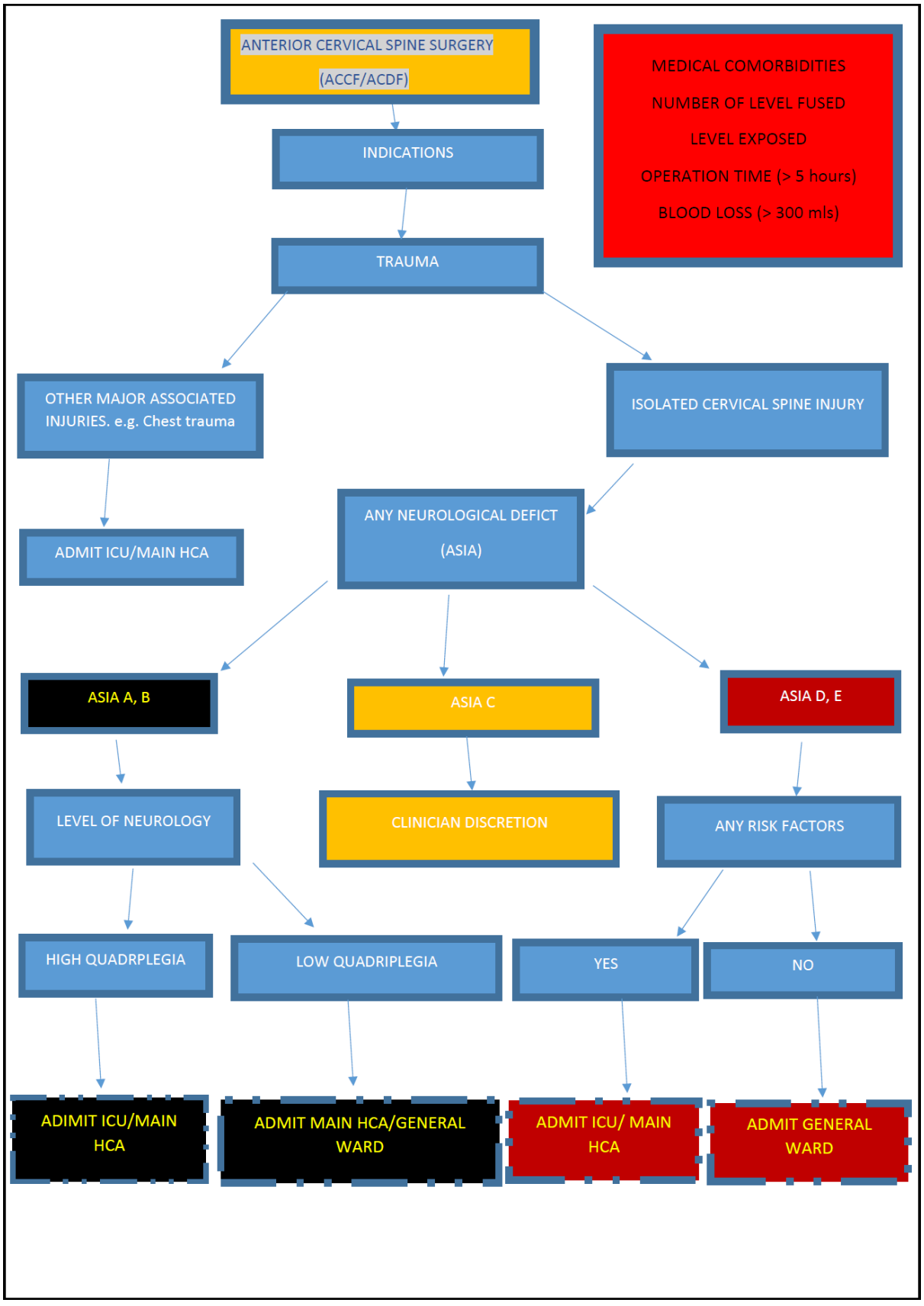
Approved/not approved

Ms. G. Bogoshi
Chief Executive Officer
Date: 24.05.2019

**APPENDIX F1:** MANAGEMENT PROTOCOL – ALGORITHM OF DEGENERATIVE DISEASE



**APPENDIX F2:** MANAGEMENT PROTOCOL – ALGORITHM OF CERVICAL SPINE TRAUMA



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