

Airway assessment of diabetic patients at a central hospital

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

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Declaration

I, Storm Cara Moon 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 Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

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Abstract

Background: Diabetic patients have been shown to have a higher incidence of difficult laryngoscopy. The aim of this study was to assess the airways of diabetic patients at Charlotte Maxeke Johannesburg Academic Hospital using the El-Ganzouri risk index (EGRI) score.

Methods: A prospective, contextual, descriptive research design using consecutive convenience sampling was used. The study population consisted of patients presenting to the Diabetic Clinic. The EGRI score and the prayer sign were assessed on 189 patients. Patient characteristics, risk factors and diabetic control parameters were documented.

Results: Seven (3.7%) patients had an EGRI score of ≥ 4 and 3 (1.6%) had a positive prayer sign, indicating a potentially difficult laryngoscopy. A higher percentage of non-insulin-dependent diabetic patients (14.3%) had an EGRI score ≥ 4 , when compared to insulin-dependent diabetic patients (1.9%) ($p = 0.010$). Patients with an EGRI score ≥ 4 , had a significantly higher weight than those patients with an EGRI score < 4 ($p = 0.003$). Of the 7 patients with an EGRI score > 4 , 6 were classified as Mallampati class III. There was no significant difference between the annual average HbA1c ($p = 0.194$) and serum creatinine ($p = 0.972$) in patients with EGRI score < 4 versus ≥ 4 . There was no significant difference in EGRI score outcome when comparing categories: estimated glomerular filtration rate ($p = 0.356$), urine albumin-creatinine ratio (0.108), duration of diabetes ($p = 1.000$) and in annual average HbA1c ($p = 0.2375$) between the categories of duration of diabetes.

Conclusion: The majority of diabetic patients assessed in this study are not at risk for difficult laryngoscopy based on the EGRI. The variables mainly responsible for a high EGRI score in this population were weight and a Mallampati class III. No preoperative airway assessment has been shown to be 100% sensitive for a difficult airway. Further research needs to be conducted to ascertain if the findings of the EGRI in this population group translate into practice.

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Table of contents

Declaration	ii
Abstract	iii
Acknowledgements	iv
Table of contents	v
List of tables	vii
Abbreviations.....	viii
Statement.....	ix
Section 1: Review of the literature	1
1.1 Introduction	1
1.2 The difficult airway	1
1.3 Diabetes.....	2
1.3.1 Definition.....	2
1.3.2 Diagnosis of diabetes.....	3
1.3.3 Diabetic nephropathy	3
1.3.4 Management of diabetes	4
1.3.5 Epidemiology of diabetes.....	4
1.3.6 Risk factors for diabetes	6
1.3.7 Co-morbidities associated with diabetes.....	6
1.3.8 Airway concerns in diabetic patients	6
1.4 Airway assessment	8

1.4.1 The El-Ganzouri risk index scoring system	10
1.4.2 The prayer sign and palm print test.....	13
1.4.3 Preoperative airway assessments in diabetic patients.....	13
1.5 Summary.....	14
1.6 References.....	15
Section 2: Author's guidelines	23
Section 3: Draft article	29
Section 4: Proposal	46
4.1 References.....	59
4.2 Appendices	62
Section 5: Annexures	68
5.1 Ethics approval.....	68
5.2 Graduate studies approval	69
5.3 CEO Approval	70
5.4 Turnitin report.....	71

List of tables

Literature review

Table 1. EGRI..... 11

Table 2. Mallampati Classification (90) modified by Samsoon et al. (84) 12

Draft Article

Table I. Patient characteristics 35

Table II. Airway parameter indicating a potentially difficult airway..... 36

Table III. Patient risk factors and diabetic control parameters compared to EGRI
score outcome..... 37

Abbreviations

ACR	Albumin-creatinine ratio
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
eGFR	Estimated glomerular filtration rate
EGRI	El-Ganzouri multivariate risk index
HbA1c	Glycated haemoglobin A1c
MDRD	Modification of Diet in Renal Disease
SJS	Stiff joint syndrome

Statement

This Research Report consists of a literature review, draft article, study proposal and appendices. The study proposal is included for background reference and is not for examination.

The formatting of this Research Report complies with the University of the Witwatersrand's Style Guide for Theses, Dissertations and Research Reports. The formatting of the draft article is in keeping with the rest of the Research Report thus may not comply with the author guidelines of the Southern African Journal of Anaesthesia and Analgesia (SAJAA), the journal to which it is intended to be submitted.

Section 1: Review of the literature

1.1 Introduction

In this section, the literature regarding a difficult airway and various aspects of diabetes, with a focus on the diabetic airway, will be discussed. A discussion of preoperative airway assessments with special reference to the El-Ganzouri risk index (EGRI) score and the prayer sign will follow.

1.2 The difficult airway

An unanticipated difficult airway in anaesthesia may be a cause of major morbidity and mortality (1). Roth et al. (2) state that a difficult airway is hard to define as it involves availability of airway equipment, anatomical differences as well as differing levels of clinicians' experience. According to a report by the American Society of Anaesthesiologists Task Force on Management of the Difficult Airway (3), definitions of airway difficulties vary. The Task Force (3) defines a difficult airway as "a clinical situation in which a conventionally trained anaesthesiologist experiences difficulty with face mask ventilation of the upper airway, difficulty with tracheal intubation, or both," and a difficult laryngoscopy as not being able "to visualise any portion of the vocal cords after multiple attempts at conventional laryngoscopy" and difficult tracheal intubation as "tracheal intubation that requires multiple attempts, in the presence or absence of tracheal pathology".

Corso et al. (4) state that according to the Italian Difficult Airway Management Guidelines, difficult intubation is defined as "a manoeuvre performed with a correct head position and external laryngeal manipulation resulting in: (a) difficult laryngoscopy, defined as being characterised by the impossibility of obtaining a view of the vocal cords even after the best external laryngeal manipulation; (b) necessity of repeated attempts; (c) necessity of non-standard devices and/or procedures; (d) withdrawal and procedure re-planning".

Difficult tracheal intubation is responsible for 17% of airway injuries and leads to increased morbidity and mortality (5). Anaesthetists' major responsibility is maintaining airway patency to provide adequate oxygenation and ventilation, thereby preventing debilitating brain damage or death (6). It may be crucial to be

able to insert an endotracheal tube using a laryngoscope to avoid life threatening hypoxemia (7). Steadman et al. (8) stated that 17% of Closed Claims outcomes, such as brain death, were due to respiratory complications. These authors further stated that 27% of those respiratory complications were due to difficult intubation. Gupta et al. (5) describe respiratory events as the most common anaesthetic-related injuries, with difficult tracheal intubation amongst the top three causes. The authors further state that up to 28% of anaesthetic-related deaths are due to the inability to intubate. El-Ganzouri et al. (6) report a similar incidence of anaesthetic-related deaths being due to the inability to maintain a patent airway.

Tracheal intubation is necessary in numerous surgical procedures as well as in most critical care patients (9). The incidence of difficult tracheal intubation has been reported to be between 1.5 – 12% depending on the patient population (9-14). Sonavdekar and Nayak (15) report an incidence of 9 – 12%. According to Shiga et al. (16), the incidence of difficult laryngoscopy (which is part of the definition of difficult intubation) with a Macintosh blade is approximately 5.8%. Therefore, safe airway management is vital in anaesthesia.

Sonavdekar and Nayak (15) state that congenital diseases, arthritic conditions, acromegaly, as well as diabetes, are a few of the pathologies commonly associated with difficult intubation. This literature review will discuss issues relating to the airway of diabetic patients.

1.3 Diabetes

1.3.1 Definition

According to the American Diabetes Association (17), “diabetes is a group of metabolic diseases characterized by hyperglycaemia resulting from defects in insulin secretion, insulin action, or both”. The Society for Endocrinology, Metabolism and Diabetes of South Africa (18) defines diabetes mellitus as a disorder of metabolism. The Society describes that there are multiple pathogenic processes involved in diabetes and that major types of diabetes based on aetiology are type 1, type 2 and gestational diabetes (18). The Society further states that type 2 diabetes is the most common, with an incidence of between 90 – 95% of the disease spectrum (18). The aetiology of diabetes is multifactorial:

dysregulation in insulin secretion, insulin action or both lead to chronic hyperglycaemia and carbohydrate, fat and protein metabolism dysfunction (18).

1.3.2 Diagnosis of diabetes

Hyperglycaemia is determined by testing plasma glucose after fasting or after a glucose load, or by measuring the glycated haemoglobin A1c (HbA1c) (17). HbA1c is used as a marker of average glucose control over a 2 – 3 month duration (17). HbA1c is useful in the management of patients with diabetes and depicts adequacy of treatment as well as being a good predictor of both microvascular and macrovascular complications (17). The Society for Endocrinology, Metabolism and Diabetes of South Africa Type 2 Diabetes Guidelines Expert Committee (18) explains that the HbA1c value is influenced by all the glucose attached to circulating red blood cells, from oldest to youngest, at the time of testing and is indicative of the average blood glucose levels during the 120-day red blood cell cycle prior to testing (18). The society also explains that haemoglobinopathies and alterations in red blood cell turnover affect the red cell lifespan and therefore, in these circumstances, HbA1c may not be a true reflection of glycaemic levels (18). The American Diabetes Association (17) recommends that the target HbA1c amongst patients with diabetes should be < 7% (19). Inadequate glucose control was found in 90% of the South African population with diabetes (18). Ngassa Piotie et al. (20) found that 88% of their study population at a tertiary care clinic in South Africa had poor glycaemic control.

1.3.3 Diabetic nephropathy

Microvascular and macrovascular complications of diabetes include retinopathy, nephropathy and neuropathy (21). Zac-Varghese and Winocour (22) describe the definition of chronic kidney disease in a patient with diabetes as the presence of albuminuria, hypertension and worsening kidney function. The authors state that chronic kidney disease is diagnosed by an elevated urine albumin-creatinine ratio or a reduced estimated glomerular filtration rate or both together, on two occasions over a three month period (22). In developed and developing countries, diabetes is the leading cause of chronic kidney disease and end-stage renal disease (23). Proteinuria has been found in 32 – 57% of patients with a duration of diabetes of 5

– 10 years (24). According to the Kidney Disease: Improving Global Outcomes guidelines (25), urine albumin-creatinine ratio is abnormal if > 2.5 mg/mmol in males and > 3.5 mg/mmol in females and the ratio is graded as mild, moderate or severe, indicating the extent of protein in the urine. This has replaced the older classification of microalbuminuria and macroalbuminuria.

Screening for diabetic kidney disease includes measuring albumin in a spot urine sample (26, 27). The result of a spot urine sample is given as an albumin-creatinine ratio and if urine albumin tests are not available, a qualitative proteinuria test can be done using a dipstick (26). Albumin excretion may be normal in patients with a low rate of renal glomerular filtration. Renal glomerular filtration can be estimated using the Cockcroft-Gault equation which incorporates age, gender, body weight and serum creatinine (26). Of the 754 patients studied at Kalafong Hospital in Pretoria by Ngassa et al. (20), 17.3% had a decreased estimated glomerular filtration rate and 23% and 10.6% had microalbuminuria and macroalbuminuria, respectively. The authors estimate that 20 – 30% of diabetic patients will develop diabetic nephropathy and that 5 – 28% of diabetic patients have severe proteinuria (20). There is a lack of data on the incidence of proteinuria in type 2 diabetes (27). Most anaesthetic drugs are excreted by the kidneys and, therefore, diabetic nephropathy is of relevance to the anaesthetist (28).

1.3.4 Management of diabetes

Type 2 diabetes is primarily treated with the use of metformin and lifestyle modification and if glucose continues to remain uncontrolled, other oral hypoglycaemic agents and insulin may be added to the treatment regimen (29). Type 1 diabetic patients require injectable insulin therapy due to their absolute deficiency of insulin. Of the 360 type 2 diabetic patients studied in Riyadh, Saudi Arabia, by Abdulghani et al. (30), 23.1% were on insulin and oral hyperglycaemic agents, and 18.6% were on insulin alone.

1.3.5 Epidemiology of diabetes

Diabetes is a common disease that affects millions of people internationally (31). Cho et al. (32) estimate that in 2017, there were 451 million people (aged 18 – 99 years) living with diabetes worldwide. The authors further estimate that by 2045,

this number will increase to 693 million people (32). The increasing incidence is cause for concern (31). It is difficult to specifically state the incidence of type 1 and type 2 diabetes, as most studies do not report them separately (32). Globally, in 2015, approximately five million people between 20 – 79 years of age died of diabetes-related causes, making this a significant cause of mortality and morbidity (18, 33).

It is predicted that by 2040, the number of people living with diabetes in Africa will increase by 140%, this being the largest predicted increase in the world (18). Sub-Saharan Africa data has a peak prevalence rate at age 65 years and older (24). In adults, it is challenging to distinguish type 1 diabetes from insulin-dependent type 2 diabetes and latent autoimmune diabetes (34). Atun et al. (35) reported a 90% incidence of type 2 diabetes in sub-Saharan Africa. The prevalence of type 1 diabetes is reportedly low, however data detailing the epidemiology of type 1 diabetes in sub-Saharan Africa is scarce (24).

The International Diabetes Federation (18) estimated that there were 2.286 million adults with diabetes in South Africa between the ages of 20 – 79 years in 2015, a prevalence of 7% nationally. Baleta et al. (36) regarded this value as an “underestimation of the true burden”. Urbanisation and ageing are the main reasons for the increase in diabetes in developing areas, but it also appears that the incidence is increasing amongst people living in rural areas (18, 35). In South Africa, the prevalence of diabetes among black Africans and Whites is the lowest at about 8%, higher among Coloureds (13.4%) and the highest among Asian/Indians (30%) (37).

There is no consensus regarding the gender spread of diabetes. Cho et al. (32) reported estimates of diabetes among women to be 8.4% and men to be 8.9% of the world’s population. Kengne et al. (38) state that four studies have shown a higher prevalence of diabetes in women than in men and three studies concluded the opposite. Liang et al. (27) found 57.5% of their type 2 patients were male. Abdulghani et al. (30) studied 360 type 2 diabetic patients, of which 62.8% were females. Mbanya et al. (24) are of the opinion that gender has little effect on diabetes prevalence. In 2015, deaths due to diabetes in Africa were 1.7 times higher in women (18).

1.3.6 Risk factors for diabetes

The Society for Endocrinology, Metabolism and Diabetes of South Africa Type 2 Diabetes Guideline Expert Committee (18) states that risk factors for diabetes can be divided into modifiable and non-modifiable. The Society reports that amongst the South African population, non-modifiable risk factors include ageing, positive family history, Human Immunodeficiency Virus and AIDS, psycho-social factors as well as living in rural areas, the urban-rural differences and urbanisation (18). Modifiable risk factors include adiposity, decreased physical activity, stress, alcohol consumption and smoking. Obesity is the greatest modifiable risk factor for diabetes (18). The South African Medical Research Council (36) states that 61% of the population is overweight, obese or severely obese. The South African Health and Nutrition Examination Survey (37) of 25 000 people in 2012, reported two-thirds of women and a third of men were overweight or obese (37).

1.3.7 Co-morbidities associated with diabetes

Diabetic patients carry an increased risk of cardiac, peripheral arterial and cerebrovascular disease (18). Peer et al. (39) found an 8.4% incidence of cardiac disease amongst 160 diabetic patients in urban South Africa. The incidence of hypertension in South African patients with diabetes has been shown to be 83.3%, (39) and 61.4% in Saudi Arabian patients with diabetes (30). Long and Dagogo-Jack (21) and Liang et al. (27) report that the incidence of hypertension amongst diabetic patients is up to 75% in the United states and 55.4% in the United Kingdom, respectively. Hage et al. (40) explain that thyroid disease and diabetes are two of the most commonly encountered endocrine disorders and they frequently coexist and influence each other. The authors report that thyroid disease has an incidence of between 12.3 – 16% in diabetic patients (40). Diabetes and glucose control is more commonly being associated with HIV, possibly due to the natural history of HIV, co-morbidities and drug therapy (38).

1.3.8 Airway concerns in diabetic patients

The number of diabetic patients is increasing globally (36, 41). Diabetic patients are particularly vulnerable to airway difficulties (9, 15, 28, 42). It is noted that data relevant to the airway of diabetic patients in South Africa is limited. The incidence

of difficult laryngoscopy amongst patients with diabetes has been reported to be much higher than that of the general population. The incidence of difficult laryngoscopy in diabetic patients has been reported as 27 – 31% by Hashim and Thomas (43), 43% by Gondane et al. (44) and 30% (in type 1 diabetic patients) by Reissel et al. (45). Warner et al. (46) included 209 patients with diabetes in their study and concluded a lower rate (4.5%) of a difficult laryngoscopy. Patients with diabetes have an increased risk of perioperative complications according to Chauh et al. (47). Stevanovic et al. (48) reported that approximately 50% of diabetic patients present for surgery at some point in their lifetime, while the South African Surgical Outcomes Study (49) reported that 10.2% of the surgical population is diabetic.

Stevanovic et al. (48) are of the opinion that managing the airway of diabetic patients is perhaps the most complicated perioperative task, amongst this group of patients, for the anaesthetist. The authors define the co-morbid conditions that increase diabetic patients' risk of difficult intubation as obesity, increased neck circumference and decreased head and neck movement, damage to the musculoskeletal system, short sternomental distance and short thyromental distance (48). A large proportion of diabetic patients are obese, especially those with type 2 diabetes (50). Lavi et al. (51) concluded that patients with a higher body mass index are more likely to be at risk of a difficult intubation. Body mass index has been shown to be a weak yet significant predictor of difficult intubation (52, 53) and according to several studies (54-56), the difficulty of laryngoscopy increases with increasing weight. Predicting difficult laryngoscopy in obese patients can be improved according to Gonzalez et al. (57) if the following criteria are observed: history of obstructive sleep apnoea, high Mallampati score, increased age, male sex, short neck and buck teeth. A larger neck circumference is associated with increased occurrence of difficult intubation in obese and diabetic patients (58).

Hyperglycaemia in diabetes leads to glycosylation of joints, known as stiff joint syndrome (SJS), including cervical joints, which affect head and neck movement, making intubation difficult (28). The musculoskeletal system is altered by metabolic disturbance, specifically, hyperglycaemia, caused by uncontrolled

diabetes (48). SJS, also known as limited joint mobility syndrome or diabetic cheiroarthropathy, has an incidence of 8 – 50% in type 1 diabetic patients and has also been diagnosed in type 2 diabetic patients (59). It has an incidence of 25 – 45% in long standing diabetic patients (60, 61). Microangiopathy, non-familial short stature, tight waxy skin and limited joint mobility are signature features of this syndrome (62). Chang et al. (63) state that limited joint mobility is due to non-enzymatic glycosylation of collagen and its deposition in joints as well as its dysfunctional cross-linking. The small joints of the hands are mostly affected, but this condition can affect the spine as well (61, 62). The concern is that if the atlanto-occipital joint is involved, the lack of neck extension may render intubation impossible (45, 61). Failure to completely oppose the interphalangeal joints is suggestive that the patient has SJS (62). Age, insulin therapy and duration of diabetes are factors that affect SJS development (64, 65).

Intubation difficulty amongst patients with diabetes is associated with a longer duration of disease burden. According to Sachin et al. (44), the incidence of difficult intubation was 66.7% among diabetic patients with more than 10 years of the disease. Nadal et al. (60) also found laryngoscopy to be difficult among those with greater than 10 years of the disease.

Multiple organ dysfunction caused by ongoing hyperglycaemia and proteinuria can be used as a marker of tissue damage, specifically diabetic nephropathy (66). If either proteinuria or high HbA1c results are present, then tissue damage, including the cervical spine, has likely occurred. This may be a cause for airway difficulty. It is imperative that a thorough preoperative assessment and focused airway examination is undertaken in diabetic patients in order for the anaesthetist to predict clinical concerns and prevent airway difficulties that may arise (48, 67-69).

1.4 Airway assessment

Identifying the patient with difficulties preoperatively will aid the anaesthetist in planning an approach for establishing an airway. If the airway is deemed to be difficult then a discussion should be had with the assistant anaesthetist about alternative management strategies. Expert advice can be called upon timeously and advanced difficult airway equipment can be made available in theatre. Several

guidelines exist to aid in managing a difficult airway (70, 71). Knudsen et al. (72) explain that various societies globally have developed guidelines to achieve safe airway management and that a preoperative airway assessment, necessary airway equipment and a plan to manage a failed airway are integral parts of these guidelines. The authors found that half of the 68 anaesthetic departments studied in Sweden had guidelines for managing a difficult airway and had a written patient information card for when a difficult airway was encountered, and yet had poor guidelines on preoperative assessments (72). In another European survey, half of the 174 respondent anaesthesiologists did not do a preoperative assessment on any of their patients (73).

A major focus of an anaesthetist's preoperative assessment should be the airway (48). The lack of preoperative records of airway assessment has been shown to be associated with a higher incidence of adverse airway events during anaesthesia (74). Predicting difficulties more accurately may reduce unnecessary airway interventions associated with false positive predictions (6).

An anaesthetist's skill and knowledge should not influence a preoperative airway assessment (75). The Fourth National Audit Project (76) showed that poor preoperative assessment may lead to an airway disaster. The preoperative airway assessment should be quick, simple to perform and easily reproducible (77). This assessment is merely a screening test expected to have low specificity yet high sensitivity to identify all cases of potential airway difficulty (2, 10, 78). Preoperative airway assessments are a guideline and should not be used as an absolute defining assessment (79). According to Stevanovic et al. (48), there is no single screening test that is an absolute predictor of difficult intubation. There are several tests, that if used together, will help enhance the likelihood of predicting a difficult intubation (48, 67). Shiga et al. (16) demonstrated that the sensitivity and specificity of individual tests are low. However, if used in combination, the sensitivity and specificity will significantly increase (16). The components for evaluation of a difficult airway include the following: bag mask ventilation, supraglottic airway insertion, tracheal intubation and the possibility of percutaneous emergency airway access (80). It is important for airway assessment tests to have a high positive predictive value so that fewer patients

are subjected to difficult airway procedures (81, 82). Tests currently being used to assess the airway have low sensitivity, low positive predictive value, significant false positives and average specificity (11, 12, 83, 84). Baker (80) is of the opinion that improved predictability of a difficult airway can be achieved by combining airway assessment tests. The Wilson Risk Sum Score (85), the Simplified Score (10) and the EGRI score (6) are examples of multivariate scoring systems.

1.4.1 The El-Ganzouri risk index scoring system

El-Ganzouri et al. (6) studied 10 507 patients who were assessed preoperatively using seven different criteria. These criteria were described as independent predictors of difficult laryngeal visualisation. These authors concluded that “improved risk stratification for difficulty with visualisation during rigid laryngoscopy (Grade IV) can be obtained by the use of a simplified preoperative multivariate airway risk index, with better accuracy compared to oropharyngeal (Mallampati) classification at both low and high risk levels” (6). The EGRI has been reported to be a superior airway assessment. Caldiroli and Cortellazzi (86) state that the EGRI has 91% accuracy with regard to difficult laryngoscopy. It has multiple strengths. It is a quick assessment, can be easily implemented and taught within a clinical setting and was validated amongst a large patient group (87). An EGRI score of ≥ 4 has greater sensitivity (64.5% versus 59.8%), specificity (93.8% versus 87.4%) and positive predictive value (9.8% versus 4.7%) for predicting difficult laryngeal visualisation when compared to the Mallampati class III (6).

The EGRI (6) comprises of seven airway variables: the extent of mouth opening (88), the thyromental distance (89), the Mallampati classification (90), the extent of head and neck movement (91), the ability to prognath (85), body weight (92) and a history of difficult intubation (93).

Table 1. EGRI

Airway assessment variable	Score
Mouth opening	
≥ 4 cm	0
< 4 cm	1
Thyromental distance	
> 6.5 cm	0
6.0 – 6.5 cm	1
< 6 cm	2
Mallampati Classification	
I	0
II	1
III	2
Head and neck movement	
> 90°	0
80° – 90°	1
< 80°	2
Ability to prognath	
Yes or edentulous	0
No	1
Body weight	
< 90 kg	0
90 – 110 kg	1
> 110 kg	2
History of difficult intubation	
Absent	0
Questionable	1
Definite	2

The normal mouth opening is 4.6 cm or more and is assessed to predict ease of insertion of a laryngoscope blade (15). Mouth opening is measured as the distance between the upper and lower incisors. It is categorised in the EGRI score as ≥ 4 cm or < 4 cm, with less than 4 cm being associated with a difficult airway. If the patient has no teeth the distance between the upper and lower gums is measured (6).

The thyromental distance is the measurement from the thyroid notch to the lower border of the mandible with the head fully extended. It is categorised in the EGRI

as > 6.5 cm, 6.0 – 6.5 cm, or < 6.0 cm (6). A short thyromental distance may indicate that head extension might be limited and that there is a small mandibular space (89, 94).

The Mallampati Classification is the assessment of the oropharyngeal structures. The patient is examined in a seated position and opens their mouth without phonation (6). Mallampati et al. (90) showed an association between the ability to view the oropharyngeal structures and the ability to view the laryngeal structures during direct laryngoscopy. If the base of the tongue is large and obstructs visualisation of the faucial pillars and soft palate, it is predicted that the direct view during laryngoscopy may be difficult. If all three structures (faucial pillars, soft palate and uvula) are visible then it is predicted that the larynx will be adequately visualised on direct laryngoscopy (90). Samsoon and Young (84) added a fourth class to the original three classes described by Mallampati (Table 1). These authors found that patients with class III and IV had difficult laryngoscopy. Class IV is not used in the EGRI due to the extreme interobserver variability (6). If class III (only soft palate is visible) or class IV (soft palate is not visible) is assessed by the examiner, then the maximum score of two is used (95).

Table 2. Mallampati Classification (90) modified by Samsoon et al. (84)

Class	Oropharyngeal view (90)
I	Faucial pillars, soft palate, and uvula (90)
II	Facial pillars and soft palate can be seen but the uvula is obstructed by the base of the tongue (90)
III	Only the soft palate can be seen (90)
IV	Hard palate only is seen (84)

Head and neck movement is measured with the patient's neck fully extended. The range of movement from full flexion to extension is categorised as > 90, 80 – 90, or < 80 degrees (6). The normal range of extension is 70 degrees and flexion is 80 – 90 degrees (96). Wilson et al. (85) suggested head and neck movement as a risk factor in predicting difficult intubation. Intubation requires oral, pharyngeal and laryngeal structures to be in a straight line, which is best achieved in the sniffing position (15).

If the patient can protrude the jaw forward and bring the lower incisors in front of the upper incisors the patient can prognath. If the patient has no teeth then the patient is graded as able to prognath (6). Wilson et al. (85) suggested jaw movement as a risk factor in predicting difficult intubation.

Body weight in the EGRI is categorised as < 90 kg, 90 – 110 kg, or > 110 kg (6, 92). Obesity is an independent risk factor for difficult intubation (57, 85, 97).

A history of difficult intubation is either absent, questionable or definite (6).

Previous difficult laryngoscopy on history is the single most important predictor of difficult laryngoscopy for future anaesthesia (6, 9).

1.4.2 The prayer sign and palm print test

The prayer sign and palm print test are two additional tests used to predict difficult airway and are specific to patients with diabetes as they indicate SJS (48).

Patients with diabetes that lack joint mobility in the small joints of the hands will not be able to oppose the palms and fingers in the position known as “the prayer sign” (62, 98). The prayer sign is examined by asking the patient to place his hands together as if praying and the gap between the fingers and palms is observed. If there is no gap the sign is negative, if there is a gap the sign is positive and laryngoscopy may be difficult (62). The prayer sign is a simple bedside test (98). The prayer sign should be used as a predictor of airway difficulty in conjunction with other airway assessments (43, 44, 62, 68). Reissell et al. (45) recommend that the degree of interphalangeal joint dysfunction can also be assessed by scoring the impression made by the ink palm print of the dominant hand.

1.4.3 Preoperative airway assessments in diabetic patients

Kute et al. (99), Hashim and Thomas (43) and Gondane et al. (44) report that a difficult Mallampati class (III and IV) amongst diabetic patients has an incidence of 63.6%, 30%, and 68.3%, respectively. The authors further report that neck extension is limited (< 21 degrees) in 35.5%, 45% and 35% of diabetic patients, respectively and that the thyromental distance is < 6 cm in 16.4%, 28.3% and 16.7% of diabetic patients, respectively. Kute et al. (99) concluded that amongst patients with diabetes, 15.5% have restricted mouth opening (< 4 cm), 20.9% have

a body mass index > 30 kg/m² and 28% are unable to bite their upper lip (upper lip bite test class III). Kute et al. (99), Hashim and Thomas (43), Erden et al. (98) and Gondane et al. (44) state that the incidence of a positive prayer sign amongst patients with diabetes is 42.7%, 55%, 31.3%, and 40%, respectively.

1.5 Summary

There is limited research describing the airways of diabetic patients. Diabetes places a patient at risk of difficult intubation, therefore, it is critical to understand the risk factors these patients have and to red flag potentially difficult airways (48). This will allow the anaesthetist to construct a clear, succinct and individualised preoperative plan for future airway management in diabetic patients (48). A formal assessment is an essential component of an anaesthetic record chart. The lack of a formal airway assessment is problematic as the incidence of diabetes observed in the patient population undergoing anaesthesia is high. In order to better understand the perioperative risks imposed by patients with diabetes, the anaesthetist needs to take a detailed history, document the EGRI score and the prayer sign and note the HbA1c, estimated glomerular filtration rate and urine albumin-creatinine ratio results. The anaesthetist may then be able to use these clinical findings to formulate a concise management plan for a potentially difficult airway.

1.6 References

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1. Jun BC, Song SW, Park CS, Lee DH, Cho KJ, Cho JH. The analysis of maxillary sinus aeration according to aging process: volume assessment by 3-dimensional reconstruction by high-resolucional CT scanning. *Otolaryngol Head Neck Surg*. 2005 Mar;132(3):429-34.
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Section 3: Draft article

Airway assessment of diabetic patients at a central hospital

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Key words: Difficult airway assessment, diabetic airway, El-Ganzouri risk index, prayer sign, diabetic nephropathy

Abstract

Background: Diabetic patients have been shown to have a higher incidence of difficult laryngoscopy. The aim of this study was to assess the airways of diabetic patients at Charlotte Maxeke Johannesburg Academic Hospital using the El-Ganzouri risk index (EGRI) score.

Methods: A prospective, contextual, descriptive research design using consecutive convenience sampling was used. The study population consisted of patients presenting to the Diabetic Clinic. The EGRI score and the prayer sign were assessed on 189 patients. Patient characteristics, risk factors and diabetic control parameters were documented.

Results: Seven (3.7%) patients had an EGRI score of ≥ 4 and 3 (1.6%) had a positive prayer sign, indicating a potentially difficult laryngoscopy. A higher percentage of non-insulin-dependent diabetic patients (14.3%) had an EGRI score ≥ 4 , when compared to insulin-dependent diabetic patients (1.9%) ($p = 0.010$). Patients with an EGRI score ≥ 4 , had a significantly higher weight than those patients with an EGRI score < 4 ($p = 0.003$). Of the 7 patients with an EGRI score > 4 , 6 were classified as Mallampati class III. There was no significant difference between the annual average HbA1c ($p = 0.194$) and serum creatinine ($p = 0.972$) in patients with EGRI score < 4 versus ≥ 4 . There was no significant difference in EGRI score outcome when comparing categories: estimated glomerular filtration rate ($p = 0.356$), urine albumin-creatinine ratio (0.108), duration of diabetes ($p = 1.000$) and in annual average HbA1c ($p = 0.2375$) between the categories of duration of diabetes.

Conclusion: The majority of diabetic patients assessed in this study are not at risk for difficult laryngoscopy based on the EGRI. The variables mainly responsible for a high EGRI score in this population were weight and a Mallampati class III. No preoperative airway assessment has been shown to be 100% sensitive for a difficult airway. Further research needs to be conducted to ascertain if the findings of the EGRI in this population group translate into practice.

Introduction

Anaesthetists' major responsibility is maintaining airway patency to provide adequate oxygenation and ventilation, thereby preventing debilitating brain damage or death (1). In anaesthesia, an unanticipated difficult airway may be the cause of major morbidity and mortality (2). Roth et al. (3) state that a difficult airway is hard to define as it involves anatomical differences as well as differing levels of clinicians' experience and availability of airway equipment. Gupta et al. (4) state that difficult tracheal intubation is amongst the top three causes of anaesthetic related injury. Difficult tracheal intubation has an incidence of 1.5 – 12% depending on the patient population and the study (5-12).

Diabetic patients are particularly vulnerable to airway difficulties (9, 11, 13, 14). The incidence of difficult laryngoscopy in diabetic patients has been reported as varying between 18.7 – 43.3% (15-18). Stevanovic et al. (19) list the co-morbid conditions that increase diabetic patients' risk of difficult intubation as obesity, increased neck circumference, decreased head and neck movement, damage to the musculoskeletal system, short sternomental distance and short thyromental distance.

Hyperglycaemia caused by diabetes leads to glycosylation of joints, known as stiff joint syndrome (SJS), including cervical joints, which affect head and neck movement making intubation difficult (13). Multiple organ dysfunction is caused by ongoing hyperglycaemia (20). Glycated haemoglobin (HbA1c) (21), estimated glomerular filtration rate (eGFR) (22) and a urine albumin creatinine ratio (ACR) (23) provide insight into the extent of target organ damage caused by hyperglycaemia.

An airway assessment is a crucial part of the anaesthetist's preoperative examination (1). The preoperative airway assessment should be quick, simple to perform and easily reproducible (24). Preoperative airway assessments are a guideline and should not be used as an absolute defining assessment (25). There are several tests, that if used together, will help enhance the likelihood of predicting a difficult intubation (19, 26).

The El-Ganzouri risk index (EGRI) (1) is a multivariate scoring system which comprises seven airway assessment variables: a history of difficult intubation, the Mallampati classification, thyromental distance, the extent of mouth opening, head and neck movement, the ability to prognath and body weight. Each variable is assigned a weighted value dependent on their assumed degree of risk. These scores are added together to get an EGRI score. An EGRI score of ≥ 4 is predictive of a difficult laryngoscopy.

The prayer sign is a test used to predict a difficult airway in diabetic patients and it indicates SJS (19). A positive prayer sign is seen in patients with diabetes that lack joint mobility in the small joints of the hands and these patients will not be able to oppose the palms and fingers, which indicates generalised joint glycosylation (18, 27).

It is imperative that a thorough preoperative assessment and focused airway examination is undertaken in diabetic patients in order for the anaesthetist to construct an individualised preoperative plan for airway management (19, 28, 29). A large percentage (50%) of patients with diabetes present for surgery (19) and a lack of preoperative airway assessment records has been shown to be associated with a higher incidence of adverse airway events during anaesthesia (30). At Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) no formal preoperative airway assessment is documented, yet it has been shown to be an essential component of an anaesthetic record chart (31). In order to recognise the diabetic patients' perioperative risks, this study aimed to assess the airways of diabetic patients at CMJAH using the EGRI.

Methods

A prospective, contextual, descriptive research design was followed. Approval to conduct the study was obtained from the Human Research Ethics Committee (Medical) and other relevant authorities.

The study population consisted of patients with diabetes presenting to the Diabetic Clinic at CMJAH. Consecutive convenience sampling was used. In consultation with a biostatistician, a minimum sample size of 189 patients was calculated, with 10% precision, a significance level of 0.05 and a power of 0.80, using the Wald

test. This was based on previous studies (16, 27, 32) showing an average incidence of difficult intubation in diabetic patients of 30%. Patients were excluded if they had: obvious anatomical variation of the face, neck, palate or hands; cervical spine fractures or previous cervical spine surgery; rheumatoid arthritis, carpal tunnel syndrome or Dupuytren's contractures and if they did not give consent.

The Diabetic Clinic took place on Mondays and Thursdays. Consented patients were examined in a private room by one author (SM). The following information was requested from the patients: age, gender, co-morbid conditions, type and duration of diabetes, diabetic medication (insulin-dependent versus non-insulin-dependent) and a history of difficult intubation. Annual HbA1c values and the most recent serum creatinine with an eGFR calculated using the Modification of Diet in Renal Disease study equation (MDRD) (33), were obtained from the patients' files. The patients' urine samples were sent to the laboratory for an ACR. The EGRI score and prayer sign were assessed. The patients were weighed on a standardised scale and their mouth opening was measured using a tape measure. The Mallampati class was assessed during mouth opening. The thyromental distance was measured using a tape measure and the degree of head and neck movement was measured using a protractor. The ability to prognath was assessed. If a patient's airway was found to be potentially difficult according to the EGRI score outcome, the patient was informed verbally as well as given a written note and it was documented in their file.

Data were captured onto a Microsoft Excel spreadsheet and analysed in consultation with a biostatistician using Stata version 14.0 (StataCorp, USA). Categorical variables were described using frequencies and percentages. Continuous variables were described using means and standard deviations or medians and inter-quartile ranges, depending on the distribution of the data. The Mann-Whitney U test was used when comparing two groups and more than two groups were compared using the Kruskal-Wallis test. The Fisher's exact test was used to compare the EGRI score outcome (< 4 and ≥ 4) with categorical variables. A p-value of < 0.05 was considered statistically significant.

Results

Of the 192 patients approached at the Diabetic Clinic, 189 were enrolled in the study. Two patients declined to participate in the study and one patient was excluded for not meeting the inclusion criteria. The characteristics of the patients are shown in Table I. It was found that 2 (1.1%) patients had been newly diagnosed with diabetes at the time of the study and therefore had not been initiated on diabetic treatment. One hundred and four patients (55%) had two or more co-morbidities.

Table I. Patient characteristics

Characteristics	Mean (SD)	Range
Age	54 (16.1)	18 – 92
Weight (kg)	82.2 (18.6)	39.8 – 146
	Number	Percentage
Weight categories		
< 90	137	72.5
90 – 110	41	21.7
> 110	11	5.8
Sex		
Male	82	43.4
Female	107	56.6
Previous anaesthetic		
Yes	107	56.6
No	82	43.4
Type of diabetes		
Type 1	37	19.6
Type 2	152	80.4
Duration of diabetes		
< 5 years	52	27.5
5 – 10 years	104	55
> 10 years	33	17.5
Diabetic medications		
Insulin only	48	25.4
Insulin and metformin	113	59.8
Metformin only	19	10
Metformin and glimepiride	7	3.7
No agents	2	1.1
Co-morbidities		
Hypertension	125	66.1
Hyperlipidaemia	96	50.8
Hypothyroidism	21	11.1
Cardiac disease	14	7.4
Cancer	10	5.3
Pulmonary disease	10	5.3
Renal failure	7	3.7
Retroviral disease	5	2.6
Other	28	14.8

According to the EGRI, 7 (3.7%) patients had a score of ≥ 4 . The airway parameters indicating a potentially difficult airway, used in the EGRI, are shown in Table II. Three (1.6%) patients had a positive prayer sign. Of the patients with an EGRI score of ≥ 4 , only 1 (14.3%) patient had a positive prayer sign.

Table II. Airway parameter indicating a potentially difficult airway

Airway parameter	Patients	
	Number	Percentage
Mouth opening < 4cm	1	0.5
Thyromental distance 6.0 – 6.5 cm	2	1.1
Thyromental distance < 6 cm	5	2.6
Mallampati class II	86	45.5
Mallampati class III	56	29.6
Head and neck movement < 80°	1	0.5
Unable to prognath	5	2.6
Weight 90 – 110 kg	41	21.7
Weight > 110 kg	11	5.8
History of difficult intubation questionable	6	0.03
History of difficult intubation definite	0	0

There was no significant difference in annual average HbA1c between the categories of duration of diabetes ($p = 0.2375$). Various other patient risk factors and diabetic control parameters were compared with the EGRI score outcome as shown in Table III. Of the 3 (1.6%) patients with a positive prayer sign, only 1 (33.3%) had a severely increased urine ACR (33.4 mg/mmol) indicating severe proteinuria. The other 2 (66.7%) patients had a normal to mildly increased urine ACR (0.7 mg/mmol).

Table III. Patient risk factors and diabetic control parameters compared to EGRI score outcome

Risk Factor or control parameter	EGRI score < 4 Median (IQR)	EGRI score ≥ 4 Median (IQR)	p-value
Annual HbA1c average (%) (n = 188, range 5.2 – 16.2)	8.5 (7.3 – 9.8)	7.1 (6.3 – 9.8)	0.194
Serum creatinine (mmol/l) (n = 185, range 43 – 508)	81 (66 – 101)	85.5 (67 – 99)	0.972
Weight (kg) (n =189, range 39.8 – 146)	81.6 (70.8 – 91.2)	112 (81.1 – 145.3)	0.003
	n (%)	n (%)	p-value
Type of diabetes			
Type 1	37 (100)	0	0.349
Type 2	145 (95.4)	7 (4.6)	
Duration of diabetes			
< 5 years	50 (96.2)	2 (3.8)	1.000
5 – 10 years	100 (96.2)	4 (3.8)	
> 10 years	32 (97)	1 (3)	
Insulin use			
Insulin-dependent	158 (98.1)	3 (1.9)	0.010
Non-insulin-dependent	24 (85.7)	4 (14.3)	
Urine ACR (mg/mmol)			
Normal to mildly increased: < 3	116 (96.7)	4 (3.3)	0.108
Moderately increased 3 – 30	52 (98.1)	1 (1.9)	
Severely increased > 30	10 (83.3)	2 (16.7)	
eGFR (MDRD) (ml/minute/1.73m²)			
> 60 ml/minute/1.73m2	126 (97.7)	3 (2.3)	0.356
≤ 60 ml/minute/1.73m2	49 (94.2)	3 (5.8)	
Mild-moderately decreased 45 – 60	34 (65.4)		
Moderate-severely decreased 30 – 44	12 (23.1)		
Severely decrease 15 – 29	4 (7.7)		
Kidney failure < 15	2 (3.8)		

Discussion

Safe airway management in anaesthesia is vital. Knudsen et al. (31) explain that various societies globally have developed guidelines to achieve safe airway management and that a preoperative airway assessment is an integral part of these guidelines. The Fourth National Audit Project (34) showed that poor preoperative assessment may lead to catastrophic airway complications. As previously mentioned the preoperative airway assessment should be quick, simple to perform and easily reproducible (24). Baker (35) is of the opinion that improved predictability of a difficult airway can be achieved by combining airway assessment tests. Caldiroli and Cortellazzi (36) state that the EGRI has 91% accuracy with regard to difficult laryngoscopy and has multiple strengths. It is a quick assessment, can be easily implemented and taught within a clinical setting and was validated amongst a large patient group (37). Therefore, this study used the EGRI to assess the airways of 189 patients with diabetes in an outpatient setting at CMJAH.

As highlighted in the introduction, diabetic patients are particularly vulnerable to airway difficulties (9, 11, 13, 14). Stevanovic et al. (19) are of the opinion, that for the anaesthetist, managing the airway perioperatively in diabetic patients, is perhaps the most complicated task. It is imperative that a thorough preoperative assessment and focused airway examination is undertaken in diabetic patients in order for the anaesthetist to predict clinical concerns and prevent airway difficulties that may arise (19, 26, 28, 29).

In our study, 3.7% of patients with diabetes had a potentially difficult laryngoscopy as predicted by an EGRI score of ≥ 4 . This finding was unexpectedly low compared to previous studies done in patients with diabetes that showed higher rates of difficult laryngoscopy ranging between 18.7 – 43.3% (15-18). Only one retrospective study (38) found a similar incidence (4.5%) of difficult laryngoscopy in diabetic patients. Several factors may have contributed to the lower incidence of potentially difficult laryngoscopy. Firstly, previous studies reported an actual difficult laryngoscopy, whereas our study reported a potentially difficult laryngoscopy assessed at the Diabetic Clinic. Secondly, our study used a multivariate test, where the others used single variate tests. Thirdly, the majority of

our study sample had a duration of diabetes < 10 years (82.5%) and a body weight < 90kgs (74%). Lastly, the majority of patients in our study showed a relatively preserved microvascular renal function, evidenced by an eGFR of > 60 ml/minute/1.73m² (72%) and an ACR < 3 mg/mmol (65.2%).

Patients in our study had an average annual HbA1c of 8.5%, with 84% of patients having an HbA1c > 7% indicating poor control. Ngassa Piotie et al. (39) similarly found that 88% of their study sample at a tertiary care clinic in South Africa had poorly controlled diabetes. In our study, there was no statistically significant difference when comparing the HbA1c value to the EGRI outcome.

The main risk factors contributing to a high EGRI score in our study were weight and a Mallampati class III. In keeping with studies (19, 40-42) which stated that obesity increases intubation difficulty, our study found that 5 of the 7 (71.4%) patients with a predicted difficult airway, had a body weight > 110 kg. Our study found that body weight is a statistically significant contributor to a higher EGRI score. However, using the body mass index, which incorporates height, may be more accurate when predicting difficult intubation using multivariate indices (43). Our study concluded that 56 (29.6%) patients with diabetes had a Mallampati class III, which is consistent with Hashim and Thomas (15) that concluded 30% of patients with diabetes have a Mallampati class III and above, yet these authors found no statistically significant association between Mallampati classification and difficult laryngoscopy. In our study, 6 of the 7 patients with an EGRI score ≥ 4, had a Mallampati class III.

The prayer sign is another preoperative airway assessment used to predict difficult airway in diabetic patients and is a simple bedside test (18). Reissel et al. (16) attributed the difficulty of intubation in diabetic patients to the glycosylation of cervical joints (as part of SJS) which affect head and neck movement, making intubation difficult. A positive prayer sign indicates the presence of this syndrome, as it first starts to affect the small joints of the hands. A positive prayer sign was found in 1.6% of patients in our study, of which one of these patients had an EGRI score ≥ 4. Our study reported a far lower incidence of positive prayer sign compared to Erden et al. (18), who reported an incidence of 31.25%. These

authors showed no significant association between a positive prayer sign and difficult laryngoscopy.

Of note, one patient with a positive prayer sign had type 1 diabetes, consistent with Stevanovic et al. (19), who state that SJS is seen in 8 – 50% of patients with type 1 diabetes. This patient also had limited head and neck movement and > 10 years of diabetes, which are two factors associated with SJS (13, 44, 45).

Therefore, the prayer sign may be a useful screening tool for SJS. As a preoperative assessment the prayer sign should be used as a predictor of airway difficulty in conjunction with other airway assessments (15, 17, 27, 28).

There was no definite history of difficult intubation among any diabetic patient enrolled in this study. However, six patients did self-report a questionable history of difficult intubation, of which two had an EGRI score ≥ 4 . Detsky et al. (9), highlight that the “strongest risk factor for difficult intubation is a prior history of difficult intubation”. The lack of an appropriate warning card displaying this history for anaesthetists for future surgeries is concerning.

This study must be read against certain limitations. This study was done contextually at CMJAH and therefore, may not necessarily be a true reflection of the national or international diabetic population. The EGRI score uses the patient's weight instead of body mass index. Body mass index takes height into account which is a more accurate indicator of body habitus. Only the weight of the patient in this study was recorded. The EGRI score identifies patients with a potentially difficult laryngoscopy and not those with potentially difficult bag mask ventilation, intubation and surgical airway.

Conclusion

The majority of diabetic patients assessed in this study are not at risk for difficult laryngoscopy based on the EGRI. The variables mainly responsible for a high EGRI score in this population were weight and a Mallampati class III. There was no significant difference between the annual average HbA1c and serum creatinine in patients with EGRI score < 4 versus ≥ 4 . There was no significant difference in EGRI score outcome when comparing categories: eGFR, urine ACR, duration of

diabetes and in annual average HbA1c between the categories of duration of diabetes.

Preoperative airway assessments should be used as a guide. No preoperative airway assessment has been shown to be 100% sensitive for a difficult airway. Further research needs to be conducted to ascertain how the low incidence of difficult laryngoscopy among diabetic patients found using the EGRI preoperatively compares to the incidence of difficult laryngoscopy when managing these patients' airways intraoperatively.

Conflict of interest

The authors declare that we have no financial or personal relationships, which may have inappropriately influenced us in writing this paper.

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Section 4: Proposal

Airway assessment of diabetic patients at a central hospital

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1. Introduction and problem statement

Difficult tracheal intubation is responsible for 17% of airway injuries and leads to increased morbidity and mortality (1). Difficult tracheal intubation has an incidence of 1.5 – 13% depending on the patient population (2-5). An anaesthetist's major responsibility is maintaining airway patency (6). Anaesthetists are required to provide adequate oxygenation and ventilation to prevent debilitating brain damage or death (6). Steadman et al. (7) reported that 17% of Closed Claims outcomes, such as brain death, were due to respiratory complications. They further stated that 27% of those respiratory complications were due to difficult intubation. Gupta et al. (1) describe respiratory events as the most common anaesthetic-related injuries, with difficult tracheal intubation amongst the top three causes. El-Ganzouri et al. (6) also report a similar incidence of one third of anaesthetic related deaths being due to the inability to maintain a patent airway. Gupta et al. (1) further state that up to 28% of anaesthetic related deaths are due to the inability to intubate.

According to the report by the American Society of Anaesthesiologists Task Force on Management of the Difficult Airway (8), definitions of airway difficulties vary in the literature. The American Society of Anaesthesiologists (8) defines a difficult airway in their guidelines as “a clinical situation in which a conventionally trained anaesthesiologist experiences difficulty with face mask ventilation of the upper airway, difficulty with tracheal intubation, or both”. The authors further describe difficult laryngoscopy as “not being able to visualise any portion of the vocal cords after multiple attempts at conventional laryngoscopy” and that difficult tracheal intubation is “tracheal intubation that requires multiple attempts, in the presence or absence of tracheal pathology”.

Safe airway management is vital in anaesthesia. Identifying the patient with a potentially difficult airway will aid the anaesthetist in planning an approach to establishing an airway and may reduce unnecessary airway interventions associated with false positive predictions (6). Congenital diseases, arthritic (rheumatoid arthritis) conditions, acromegaly, as well as diabetes are a few of the pathologies commonly associated with difficult intubation (9, 10). The incidence of difficult laryngoscopy in diabetic patients has been reported as 27 – 31% (11-13)

and 43% (12). The number of patients with diabetes is increasing globally (14-16). Furthermore, approximately 50% of these patients present for surgery at some point in their lifetime (17). Diabetic patients have an increased risk of perioperative complications, the difficult airway being of relevance to this study (18). Associated factors specific to the difficult airway in diabetic patients include obesity, increased neck circumference and decreased head and neck movement. Hyperglycaemia leads to glycosylation of the joints, known as stiff joint syndrome, including cervical joints, which affects head and neck movement making intubation difficult. Therefore it is imperative that a thorough preoperative assessment is undertaken in diabetic patients (18). A major focus of this assessment should be the airway (6, 17).

The preoperative airway assessment should be quick, easy to perform and easily reproducible (19). Numerous preoperative airway assessments exist. These include a history of difficult intubation (9), the Mallampati classification (20), thyromental distance (1) and the Wilson score (21). The El-Ganzouri multivariate airway risk index (EGRI) (6) has been shown to be a superior airway assessment. An EGRI score of ≥ 4 has a greater sensitivity (64.5% vs 59.8%), specificity (93.8% vs 87.4%) and positive predictive value (9.8% vs 4.7%) for predicting difficult laryngeal visualisation compared to the Mallampati class III (6). The index includes seven aspects all known to predict difficult airway independently: mouth opening, thyromental distance, Mallampati classification, head and neck movement, ability to prognath, body weight and history of difficult intubation (6). The Mallampati Classification used in the El-Ganzouri index is the original Classification described by Mallampati et al (20). It was decided by El-Ganzouri et al. (6) that the fourth oropharyngeal view described by Samsoon et al. (22) and used in the modified Mallampati classification would be left out due to the high interobserver variability associated with this view. If class III (only soft palate is visible) or class IV (soft palate is not visible) is assessed by the examiner, then the maximum score of 2 is used (23). The Prayer sign is another preoperative airway assessment that has been shown to predict a difficult airway in diabetic patients but it is recommended that it is used in conjunction with other airway assessments (12, 13, 24, 25). The Prayer sign is an easy bedside test (26). The Prayer sign is positive in patients with limited joint mobility in the small joints of the hands (26).

Limited joint mobility occurs due to non-enzymatic glycosylation of the collagen as a result of prolonged hyperglycaemia (27). The small joints of the hands are mostly affected, but this condition can affect the spine as well (28). The concern is that if the atlanto-occipital joint is affected, the lack of neck extension may make intubation impossible (28). Limited joint mobility is present in 25 – 50% of diabetic patients and is more common in those patients on insulin and those with a longer duration of diabetes (27). Microvascular and macrovascular complications like nephropathy are more prevalent in these patients (27). Diabetic nephropathy is defined as proteinuria > 0.5g/24 hours (29). Screening for diabetic nephropathy includes measuring albumin in a spot urine sample (29). The result of a spot urine sample can be given as an albumin-to-creatinine ratio (29). If urine albumin tests are not available, a qualitative proteinuria test can be done using a dipstick. Albumin excretion may be normal in patients with a low glomerular filtration rate, therefore it should also be measured. It can be predicted with the Cockcroft-Gault equation using age, sex, body size and serum creatinine (29).

The Society for Endocrinology, Metabolism and Diabetes of South Africa states that there is a lack of data describing the epidemiology of diabetes in Africa (30). South Africa lacks data describing the airways of diabetic patients. According to the Society, urbanisation and aging in our country are driving the rise in prevalence of diabetes, which is bound to add huge economic and resource strain (30). This will lead to an increased number of diabetic patients presenting for surgery.

There is currently no formal multivariate preoperative airway assessment as part of the anaesthetic chart at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). The profile of airway concerns in diabetic patients at CMJAH is not known. It would be of value to conduct a study to describe the airways of diabetic patients in order to better understand these patients' risk factors and to red flag potentially difficult airways (17).

2. Aim

The aim of this study is to assess the airways of diabetic patients at CMJAH using the El-Ganzouri multivariate risk index score.

3. Objectives

The primary objectives of this study are to:

- assess the airway using the El-Ganzouri multivariate risk index score
- document the incidence of potentially difficult airways.

The secondary objectives of this study are to:

- document the incidence of a positive prayer sign
- document the incidence of albuminuria according to the Kidney Disease Improving Global Outcomes (KDIGO) classification
- document serum creatinine and estimated glomerular filtration rate
- document the incidence of a positive prayer sign in patients with an El-Ganzouri risk index score of ≥ 4
- compare the El-Ganzouri multivariate risk index score outcome ≥ 4 and < 4 of non-insulin dependent diabetic patients versus insulin dependent diabetic patients
- compare the annual average haemoglobin A1c results between those with an El-Ganzouri risk index score ≥ 4 and < 4
- document the presence of microalbuminuria according to the KDIGO classification in patients with a positive prayer sign
- compare the El-Ganzouri multivariate risk index score outcome ≥ 4 and < 4 of the urine albumin-creatinine ratio categories
- compare the El-Ganzouri risk index score outcome ≥ 4 and < 4 between the estimated glomerular filtration rate categories
- compare the El-Ganzouri risk index score outcome ≥ 4 or < 4 between the duration of diabetes categories
- compare the body weight between those with an El-Ganzouri risk index score ≥ 4 and < 4
- compare the serum creatinine between those with an El-Ganzouri risk index score ≥ 4 and < 4

- compare the annual average haemoglobin A1c results between the duration of diabetes categories.

4. Research assumptions

The following definitions will be used in the study.

Adult: is a person 18-years and older.

El-Ganzouri multivariate airway risk index: is a preoperative airway assessment developed by El-Ganzouri et al (6). It comprises seven variables: mouth opening, thyromental distance, the Mallampati classification, head and neck movement, the degree of prognathism, body weight and previous history of difficult intubation (6). These variables are individually assessed and scored. A total score of ≥ 4 correlates with difficult laryngeal visualisation during rigid laryngoscopy after induction of general anaesthesia (6).

Mouth opening: is measured as the distance between the upper and lower incisors. It is categorised as > 4 cm or ≤ 4 cm. If the patient has no teeth the distance between the upper and lower gums is measured (6).

Thyromental distance: is from the thyroid notch to the lower border of the mandibular mentum with the head fully extended. It is categorised as > 6.5 cm, $6.0 - 6.5$ cm, or < 6.0 cm (6).

The Mallampati classification (20): is the assessment of the oropharyngeal structures done with the patient in a sitting position without phonation (6). The classification distinguishes the following three classes:

Class Oropharyngeal view

I Faucial pillars, soft palate, and uvula

II Facial pillars and soft palate can be seen but the uvula is obstructed by the base of the tongue

III Only the soft palate can be seen (20).

Samsoon et al. (22) added a fourth class where the soft palate is not visible. If the soft palate is not visible a total of 2 is scored on the EGRI.

Head and neck movement: is measured in degrees when the patient's neck is fully extended. The range of movement from full flexion to extension is categorised as $> 90^\circ$, $80^\circ - 90^\circ$, or $< 80^\circ$ (6).

Ability to prognath: is the ability to protrude the jaw forward and bring the lower incisors in front of the upper incisors. If the patient has no teeth then the patient is graded as able to prognath (6).

Body weight: is categorised as $< 90\text{kg}$, $90 - 110\text{kg}$, or $> 110\text{kg}$ (6, 31).

A history of difficult intubation: will be documented as either absent, questionable or definite (6).

Prayer Sign: The patient is asked to place his hands together as if praying and the gap between the fingers and palms is observed. If there is no gap the sign is negative, if there is a gap the sign is positive (32).

5. Demarcation of study field

The study will be conducted in the Diabetic Clinic at CMJAH, a 1200-bed central hospital. The clinic manages approximately 80 patients a day, twice a week and approximately 10 000 patients per annum.

6. Ethical considerations

Approval to conduct the study will be obtained from the Human Research Ethics Committee (Medical) and the Graduate Studies Committee of the University of the Witwatersrand. Permission to conduct the study will be obtained from the Chief Medical Officer of CMJAH (Appendix 1) and the Head of the Diabetic Clinic at CMJAH (Appendix 1).

Patients at the Diabetic Clinic will be approached and the study will be explained to them and they will be invited to take part. If they agree, they will be given an

information letter (Appendix 2) and be asked to sign a consent form (Appendix 3). Measures will be taken to ensure the patient's place in the queue will be kept.

Patient data anonymity will be protected as no identifying information will be recorded on the data collection sheet. A list of patient name, study number and hospital number will be generated and this will be filed separately. Confidentiality will be ensured as only the researcher and supervisors will have access to the raw data. The raw data will be kept in a locked cupboard and later stored securely on a password protected Microsoft Excel spreadsheet for six years after completion of study.

If a patient is assessed as having a potentially difficult airway, the patient will be informed verbally and in writing and a note will be made in their file.

Study will be conducted according to the principles of the Declaration of Helsinki (33) and the South African Guidelines for Good Clinical Practice (34).

7. Data collection

7.1 Research design

A prospective, contextual, descriptive research design will be followed in this study.

A prospective study according to Brink et al. (35) is defined as: a study in which “data about a presumed cause are first collected and then the effect or outcome is measured”. This study is prospective as data will be collected first and then the outcome will be measured.

In a contextual study, a specific group of individuals in a specific environment is analysed. This is described as a “small-scale world” (36). This study is contextual as it is assessing diabetic patients at CMJAH.

A descriptive design study portrays the variables of the study as they are naturally found. The occurrence of these variables are specific to the sample studied. The relationship between the variables is also described but no causality is inferred (37). This study will describe diabetic airways at the Diabetic Clinic at CMJAH.

7.2 Study population

The study population consists of all the diabetic patients presenting to Diabetic Clinic at CMJAH.

7.3 Study sample

Sample method

In this study consecutive convenience sampling will be used. According to Endacott and Botti (38) convenience sampling is “the use of the most readily accessible individuals or units in a study” and consecutive sampling is “a version of convenience sampling where every available individual or event within an accessible population is chosen.” According to the authors this is the best choice of non-random sampling.

Sample size

The sample size was determined in consultation with a biostatistician using Stata version 14.0. The Wald test calculated a minimum sample size of 189 patients. This was based on previous studies showing a prevalence of difficult intubation in diabetic patients of 30% with a precision of 10%. A significance level of 0.05 and power of 0.80 was used in the calculation.

Inclusion and exclusion criteria

The inclusion criteria for this study are:

- adult patients
- patients presenting at the Diabetic Clinic at CMJAH
- patients who consent to take part in the study.

The exclusion criteria in this study are patients who have:

- obvious anatomical variation of the face, neck, palate or hands
- cervical spine fractures and previous cervical spine surgery
- rheumatoid arthritis, carpal tunnel syndrome, Dupuytren’s contracture.

7.4 Collection of data

After receiving approval from Ethics and the Graduate Studies Committee, data will be collected at the Diabetic Clinic at CMJAH. Diabetic Clinic takes place on a Monday and Thursday and approximately 80 patients are seen at the clinic on each of these days. Data collection will continue until the estimated sample size has been reached. The study will be explained to the patients and they will be invited to participate. Those who agree will receive an information letter (Appendix 3) and they will be asked to sign a consent form (Appendix 4). The patient will be taken to a private examination room and measures will be taken to keep their position in the queue. A history and airway examination will be performed on the patient. On history, the following information will be requested: the age of the patient, gender, co-morbid conditions, type and duration of diabetes, diabetic medication (insulin dependent vs non-insulin dependent) and previous anaesthetic history, particularly a history of difficult intubations. Glycated haemoglobin A1c (HbA1c) results from the previous year and the most recent serum creatinine with estimated glomerular filtration rate will be documented from the patient's file. The researcher will collect a urine sample which will be sent to the laboratory for a microalbumin-to-creatinine ratio. On examination, the EGRI score and Prayer Sign will be assessed. The patient will be weighed using a standardised scale and then will be asked to open their mouth to measure mouth opening using a standardised tape measure and to assess their Mallampati Score. They then will be asked to extend their head and neck to measure thyromental distance using a standardised tape measure and head and neck movement using a protractor. They then will be asked to bring the lower incisors in front of the upper incisors to assess ability to prognath.

The information obtained will be recorded on a data collection sheet (Appendix 5). If a patient is assessed as a potentially difficult airway, the patient will be informed verbally and in writing and a note will be made in their file.

8. Data analysis

Data will be captured onto a Microsoft Excel spreadsheet and analysed in consultation with a biostatistician. Descriptive and inferential statistics will be used to analyse the data. Categorical variables will be described using frequencies and percentages. Continuous variables will be described using means and standard deviations or medians and inter-quartile ranges, depending on the distribution of the data.

Chi-square or Fisher's Exact test will be used to compare the El-Ganzouri multivariate risk index score of non-insulin dependent diabetic patients versus insulin dependent diabetic patients. Independent t-tests or the Mann-Whitney tests will be used to compare the duration of diabetes of those with an El-Ganzouri risk index score ≥ 4 versus < 4 . The correlation of the yearly average HbA1c result and the El-Ganzouri risk index score outcome as well as the correlation of the presence of microalbuminuria with the El-Ganzouri risk index score outcome and the correlation of the glomerular filtration rate with the El-Ganzouri risk index score outcome will be done using Spearmans correlation coefficients. ROC curves will be done. A p-value of < 0.05 will be considered statistically significant.

Significance of the study

The Society for Endocrinology, Metabolism and Diabetes of South Africa states that there is a lack of data describing diabetic airways (30). The rise in prevalence of diabetic patients in South Africa means that the number of diabetic patients presenting for surgery will increase (14, 15). This will demand increased resources from the health care system. Due to the incidence of airway difficulty in diabetic patients, diabetic patients presenting for surgery may require special airway interventions in order to prevent adverse outcomes such as hypoxia and brain death (12).

CMJAH is a central hospital with large referral drainage areas. It is important to better understand the patient population in order to optimise usage of resources (1).

In order to avoid unnecessary use of resources, an appropriate preoperative plan for these patients should be made (6). The anaesthetist should assess these high

risk patients preoperatively (12). This study's results will describe diabetic patients' airways at CMJAH and will document the incidence of potentially difficult airways. The outcome of the study will aid the anaesthetist in understanding any possible airway problems with this population group. This will allow the anaesthetist to consolidate a concise preoperative plan for future airway management for patients presenting for surgery (12).

9. Validity and reliability of the study

Validity of a study means ensuring that the measured variables reflect the true variables and reliability means the results are repeatable, consistent and dependable (39).

Steps taken to ensure the validity and reliability of this study include:

- using an appropriate study design
- a sample size that was determined in consultation with a biostatistician
- a single researcher assessing airways
- the same protractor, tape measure and scale will be used for all the patients
- analysing data with the assistance of a biostatistician.

10. Potential limitations of the study

The study describes airway variables in diabetic patients contextually at CMJAH. This information may not necessarily be a true reflection of the national or international population with diabetes.

The EGRI score uses patient's weight and not body mass index. Body mass index takes height into account which would be more accurate.

11. Project outline

Activity	Sept 2018 - Jan 2019	Feb 2019	Mar - May 2019	June - July 2019	Aug 2019	Sept 2019
Proposal						
Proposal submission						
Ethics & Post Grad approval						
National Health Research Committee						
Data collection						
Data analysis						
Draft article						
Submission						

12. Financial plan

The Department of Anaesthesiology will bear the cost of printing and paper for the proposal, ethics and post graduate approvals. The protractor, tape measure and scale will be for the researcher's cost.

Item	Number	Cost	Total
Printing	2000	R1/page	R2000
Binding	4	R200	R800
Protractor	1	R20	R20
Tape measure	1	R20	R20
Scale	1	R500	R500
Grand Total			R3340

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4.2 Appendices

Appendix 1: Letter to the CEO of CMJAH

21 January 2019
Dr Storm Moon
Department of Anaesthesiology
University of the Witwatersrand
Storm.cara@gmail.com

Dear Chief Executive Officer,

I am a registrar in the Department of Anaesthesiology. I am conducting a study as part of my Master of Medicine in Anaesthesiology titled: Airway assessment of diabetic patients at a central hospital.

I hereby request permission to conduct research at the diabetic clinic at CMJAH between January 2019 and May 2019. The length of time may be extended if the minimum number of participants have not been recruited during these three months.

The study will include patients at the Diabetic Clinic at Charlotte Maxeke Johannesburg Academic Hospital. I will be describing diabetic airways using the El-Ganzouri multivariate risk index score and the Prayer Sign. I will be taking a history and examining their airway. Their place in the clinic queue will not be compromised. If a patient's airway is assessed as potentially difficult, they will be informed verbally and in writing and a note will be made in their file.

The study has received Ethics and Postgraduate approval. Please see the attached approval letters. I have submitted my protocol to the National Health Research Database. Please see attached conformation letter.

The study will not result in any additional cost to the hospital.

Please do not hesitate to contact me for further information. I have attached the proposal.

With kind regards
Yours sincerely
Dr Storm Moon

Mobile number: 0824354861

Appendix 2: Letter to the Acting Head of Department at CMJAH

25 September 2018
Dr Storm Moon
Department of Anaesthesiology
University of the Witwatersrand
Storm.cara@gmail.com

Dear Prof Mahomed,

I am a registrar in the Department of Anaesthesiology. I am conducting a study as part of my Masters of Medicine in Anaesthesiology titled: Airway assessment of diabetic patients at a central hospital.

I hereby request permission to conduct research at the diabetic clinic at CMJAH between March 2019 and May 2019. The length of time may be extended if the minimum number of participants have not been recruited during these three months.

The study will include patients at the Diabetic Clinic at Charlotte Maxeke Johannesburg Academic Hospital. I will be describing diabetic airways using the El-Ganzouri multivariate risk index score and the Prayer Sign. I will be taking a history and examining their airway. Their place in the clinic queue will not be compromised. If a patient's airway is assessed as potentially difficult, a note will be made in their file.

The study will receive Ethics and Postgraduate approval before the start of data collection.

The study will not result in any additional cost to the hospital.

Please do not hesitate to contact me for further information. I have attached the proposal.

With kind regards

Yours sincerely

Dr Storm Moon

Mobile number: 0824354861

Supported by:

Acting Head of Medicine:

Prof Mahomed

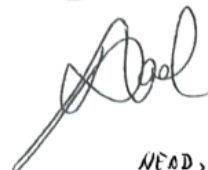
Head of School of Clinical Medicine:

Prof Wing

SOCT





19 
PROF F.J. RAAL
FCP(SA), PhD 1 OCT 2018
HEAD, DIVISION of ENDOCRINOLOGY

Appendix 3: Information letter

Dear Patient

Hello, my name is Storm, I am a doctor training to be a specialist anaesthetist. As part of my training I need to do research. This letter is an invitation to you to partake in my M Med research study titled: Airway assessment of diabetic patients at a central hospital. An anaesthetist is a doctor that puts a patient to sleep for an operation or procedure. They care for the patient throughout the duration of the operation or procedure. In order to put a patient to sleep the anaesthetist needs to help the patient to breathe. In order to do this the anaesthetist may need to place a tube in the throat. Placing this tube in diabetic patients can sometimes be difficult. The benefit of my study will help to find these difficulties and therefore help the anaesthetist to make any necessary preparations to deal with these difficulties before an operation or procedure. There is no risk to take part in this study. If I find that it may be difficult to place a pipe in your throat, I will tell you and give you a letter. I will also write it in your clinic file.

It is entirely your decision to be in the study. You can also withdraw from the study at any time. If you do not want to take part, you will still receive the same treatment. There is no payment to take part in this study. If you agree to take part in the study, you will be asked to sign a consent form. I will ask your medical history and examine you. I will weigh you, ask you to open your mouth so I can look at the back of your throat and ask you to put your hands together as if you are praying. This will take place in a private examination room while you are waiting for your clinic appointment, will take about 15 minutes and you will not lose your place in the queue.

All your information will be kept anonymous and confidential. Only my supervisors and I have access to your information. The Human Research Ethics Committee (HREC)(Medical) (Number xxxx) and the Graduate Studies Committee of the University of the Witwatersrand have given me permission to do this study. By signing your name on the consent form, it means that you agree that you will participate in the study. You will be given a copy of this letter to keep.

Any questions or concerns regarding this study can be directed to the following people:

- Professor C Penny (chairperson of the HREC): (011) 717 2301 Clement.Penny@wits.ac.za
- Zanele Ndlovu (HREC administrator): (011)717 2700 Zanele.Ndlovu@wits.ac.za
- Rhulani Mukansi (HREC administrator): (011) 717 1234 Rhulani.Mukansi@wits.ac.za
- Storm Moon (researcher): 0824354861 storm.cara@gmail.com

Thank for your time

Dr Storm Moon

October 2018

Appendix 4: Consent form

Consent to participate in the research study:

I _____, have been informed and understand the study.
I consent to participate in the study. I have read and understand the information sheet. All my questions have been answered. I understand that my identity will be protected and concealed at all times. I understand that participation in the study will not cause me harm. I know that I may withdraw from the study at any time, without prejudice towards myself.

Name of participant

Signature of participant

Date

Name of researcher

Signature of researcher

Date

Appendix 5: Data collection sheet

Date:			
Study Number:			
History			
Age (years)			
Sex	Female		Male
Co-morbid conditions	Hypertension		Heart disease
	Osteoarthritis		COPD
	Renal Failure		Psychiatric disorder
	Hyperlipidaemia		If other, specify:
Type diabetes	Type 1	Type 2	If other, specify:
DOD	<5yrs	5-10yrs	>10yrs
Diabetic medication	Metformin		Insulin
	Glimepiride		
	Pioglitazone		
	If other, specify:		
HbA1c results from the past year			
Urine microalbumin-to-creatinine ratio	Low		High
The most recent Serum Creatinine			
The most recent estimated glomerular filtration rate			
Previous anaesthetic	Yes		No
Difficult intubation previously	Absent	Questionable	Definite

Examination				
El-Ganzouri Risk Index Score				
Measured variable			Exact measurement	Score
Mouth opening				
≥4cm (0)	<4cm (1)			
Thyromental distance				
>6,5cm (0)	6.0 – 6.5cm (1)	<6cm (2)		
Mallampati Classification				
I (0)	II (1)	III (2)		
Head and neck movement				
>90 degrees (0)	80° – 90° (1)	<80° (2)		
Ability to prognath				
Yes or edentulous (0)	no (1)			
Body weight				
<90kg (0)	90 – 110kg (1)	>110kg (2)		
History of difficult intubation				
absent (0)	questionable (1)	definite (2)		
Prayer Sign	Positive		Negative	

Section 5: Annexures

5.1 Ethics approval



R14/49 Dr Storm Cara Moon et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M181048

NAME: Dr Storm Cara Moon et al
(Principal Investigator)
DEPARTMENT: Anaesthesiology
The Diabetic Clinic at CMJAH

PROJECT TITLE: Airway assessment of diabetic patients at a central hospital

DATE CONSIDERED: 26/10/2018

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Helen Perrie

APPROVED BY: 
Dr CB Penny, Chairperson, HREC (Medical)

DATE OF APPROVAL: 16/01/2019

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 the 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 **October** and will therefore be due in the month of **October** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____

Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

5.2 Graduate studies approval



Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

Dr SC Moon
127 Linden Street
Unit 80 The Trails
Sandown
2196
South Africa

04 January 2019
Person No: 0701499D
PAG

Dear Dr Storm Moon

Master of Medicine in Anaesthesia: Approval of Title

We have pleasure in advising that your proposal entitled *Airway assessment of diabetic patients at a central hospital* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

A handwritten signature in black ink, appearing to read "S. Benn", with a horizontal line underneath.

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

5.3 CEO Approval



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
15th January 2019

GP_201901_023

Dear Dr. Strom Cara Moon et al

STUDY TITLE: Airway Assessment of Diabetic Patients at a Central 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. Mofokeng
Clinical Director

DATE: 21/01/2019

Approved/not approved



Ms. G. Bogoshi
Chief Executive Officer
Date: 28.01.2019

5.4 Turnitin report



20th November, 2019

The Chairperson
Graduate Studies Committee
Faculty of Health Sciences
University of the Witwatersrand

Dear Madam,

Re: M Med: **Airway assessment of diabetic patients at a central hospital**

Dr Storm Moon, student number: 0701499D, has submitted her research report to Turnitin which revealed a similarity index of 13%. These similarities appear not to be plagiarism but mainly the use of common terminology and phrases specific to the topic of the research.

Yours sincerely,

A handwritten signature in black ink that reads 'HCPERRIE'.

Helen Perrie
Supervisor

ORIGINALITY REPORT

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Publication

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"Minutes of the 44th Genral Assembly of the