The Assessment of Surgical Apgar Scores in Adult Patients with TB of the Spine Undergoing Major Spine Surgery.

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

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Declaration

I Kefilwe Boineelo Mogami 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.

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(Signature of candidate)

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Dedication

For my mother, Onalenna Mogami.

My rock and pillar of strength.

We did it Mommy!

Abstract

Background: Tuberculosis (TB) is an age old disease, dating back to the time of Hippocrates. In the spine, it most commonly affects the thoracic spine, followed by the thoracolumbar junction, lumbar spine and cervical spine. The management is largely medical, with surgery reserved for only the intractable and severe forms. Surgery is fraught with formidable complications, which has sparked an interest in a tool to predict those patients who are likely to do poorly, thus increase clinician vigilance.

Methodology: Our study aimed to assess the correlation of the surgical Apgar score as set out by Gawande *et al*. in patients undergoing surgery for TB of the spine. It is a retrospective study of patients' records who underwent surgery between 2010 and 2015 at Chris Hani Baragwanath (CHBAH) and Charlotte Maxeke Johannesburg Academic (CMJAH) Hospitals.

Results: We reviewed the records of 33 patients, and we found 15 patients with a score of 0-/= 4, 10 of them had complications, while five had none. Of the 10 patients with a score of 5-6, only two developed complications. Additionally, none of the eight patients with a score of 7-8 developed any complications. There was a statistically significant negative correlation between low Surgical Apgar Score (SAS) and the development of complications.

Conclusion: We concluded that in a subset of spine patients undergoing surgery for TB, a low SAS could be predictive for the development of complications. There was no correlation with the level of the spine affected, the patient's age or their underlying comorbidities.

Acknowledgements

I would like to acknowledge the following people, without whom this project would not have been successful;

Firstly, my supervisors, for their support and encouragement. Special mention for Dr LD Ramushu, who envisioned this project and chose me for it. Dr F Ukunda and A Akinjolire for their assistance. And Professors M Lukhele and MT Ramokgopa who was never too busy to assist.

My Fiance, Mahwi J Benjamin for your unwavering love and support.

To my family and friends, thank you for your patience, prayers and encouragement.

Tunde Ajidahun, for helping to make sense of it all.

And most importantly, God for giving me the strength and wisdom to get it done.

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Nomenclature

CT: Computer Tomography

DVT: Deep Vein Thrombosis

EBL: Estimated Blood Loss

ESR: Erythrocyte Sedimentation Rate

HR: Heart Rate

ICU: Intensive Care Unit

MAP: Mean Arterial Pressure

MRI: Magnetic Resonance Imaging

RVD: Retro-Viral Disease

PE: Pulmonary Embolism

SAS: Surgical Apgar Score

SIRS: Systemic Inflammatory Response Syndrome

TB: Tuberculosis

TRALI: Transfusion Related Acute Lung Injury

1 CHAPTER 1

1.1 Background and Literature Review

1.1.1 Background

Tuberculosis (TB) of the spine is an age-old disease, with a recorded history, which dates back to the time of Hippocrates, and possibly before (1). In most instances, the mycobacterium tuberculosis, the bacteria responsible for the disease spreads to its distant sites *via* the bloodstream, and usually from a pulmonary source. However, in some instances and particularly in TB of the spine, bacteria may be seeded from a contiguous lesion (2)(3). The thoracic and thoracolumbar spine are most commonly affected in TB. Disease occurring in multiple level, and at times with skip lesions is common, and the incidence is reported between 7% and 10% (4). Patients with spinal TB may present with a variety of symptoms, including focal back pain, radiculopathy and myelopathy. Patients may also have systemic symptoms of active TB, including cough, shortness of breath and fevers/chills (5).

Spinal TB often follows an indolent slowly progressive course. In endemic regions, the diagnosis is often made based on clinical presentation. However, there are imaging features that may be suggestive of the diagnosis of TB. A definitive diagnosis is made on the isolation of tuberculous Bacilli on biopsy sampling of the lesion (6)(7). Plain film radiography (X-ray) has a limited role in the diagnosis of TB, although there are salient features that can be diagnostic using this modality. Despite this, there needs to be extensive vertebral body destruction before these changes are visible on plain films, which decreases its sensitivity (3). A Computer Tomography (CT) scan will delineate bone destruction earlier than a radiograph but has poor sensitivity in assessing neural compression. A Magnetic Resonance Imaging (MRI) scan is a far more superior modality, allowing the evaluation of the entire spine for skip lesion, but also providing valuable information pertaining to neural compression. It also shows signs of vertebral destruction even before they become visible on plain images (2)(6)(7).

Serum testing can aid in the diagnosis of TB, although a majority of these tests are non-specific and may only be suggestive of infection. A relative lymphocytosis, low haemoglobin and a raised Erythrocyte Sedimentation Rate (ESR) are sometimes found in active tubercular disease (6). More specific tests such as Tuberculin Skin Testing and Interferon Gamma Release Assay allow for the evaluation of patients who have been exposed to the bacteria. Molecular diagnostic tests such as Polymerase chain reactions are also used more commonly now due to their increased reliability and rapidity. (8)These tests are more sensitive and specific than the above mentioned serum tests (2)(3). The definitive diagnosis is however, made on biopsy of the lesion. This also allows the doctor to exclude other potential mimickers of disease as well as to institute appropriate therapy (2)(7).

Before the advent of anti-tuberculous therapy in the 1940s, the management of TB of the spine included bed-rest, improvement of nutritional status and in some cases posterior fusion to rest the disease focus locally. In 1944, Wilkinson revived an interest in active surgical intervention for TB of the spine (1). The methods of surgical treatment in TB of the spine include single or two stage surgical approaches (9). With the evolution of more complex surgical techniques and an aging population, these surgical procedures may result in increased perioperative risk. There are a number of potential and formidable intraoperative and postoperative complications associated with any surgical procedure. Operations for TB of the spine are no exception, fraught with multiple complications. These include neurological injuries, thoracic organ injury, gastrointestinal, thrombophlebitis leading to Deep venous thrombosis or Pulmonary embolism (DVT/PE) infection-local or systemic, bedsores and large vessel injures as some of the major ones (10) .

Careful preoperative surgical planning and patient care, improved surgical technique and postoperative patient management are thought to be the most important factors to minimise the complications. With this in mind, Gawande *et al.* sought to find a reliable score that surgical teams could calculate at the end of operative procedure to accurately grade conditions and chances of major complications and/or mortality in the early postoperative period. Inspired by the neonatal Apgar score initially introduced in 1953 by anaesthesiologist Virginia Apgar to rate the condition of a newborn immediately following delivery, Gawande *et al*. published a 10-point surgical Apgar score (SAS), which is easily calculated at the bedside based on three intraoperative variables, these being: estimated blood loss, lowest heart rate, and lowest mean arterial pressure (see Table 1.1) (9). This score was to be the basis of much research in a variety of surgical fields, because of its potential impact on postsurgical care.

Table 1.1: A 10 point surgical outcomes score (10)

	0 points	1 point	2 points	3 points	4 points
Estimated blood loss (mL)	> 1,000	601–1,000	101–600	≤ 100	—
Lowest mean arterial pressure (mmHg)	< 40	40–54	55–69	≥ 70	—
Lowest heart rate (beats/min)	> 85	76–85	66–75	56–65	≤ 55†

Surgical score = sum of the points for each category in the course of a procedure.
*Based on model 1 from cohort 1.
†Occurrence of pathologic bradyarrhythmia, including sinus arrest, atrioventricular block or dissociation, junctional or ventricular escape rhythms, and asystole also receive 0 pts for lowest heart rate.

1.1.2 Literature Review

SAS was originally developed in patients undergoing general and vascular surgery, and was later validated in different surgical specialties, including colorectal, urological and gynaecological surgery. This score has been shown to be a good tool that could be used for predicting the risk of major complications or death within 30 days of surgery; There is an inverse relationship between the score and presence of complications. With a high score the likelihood of complications is low, whereas a low score presents a higher likelihood of complications.(11). With increasing surgical complexities in orthopaedic surgeries and the increase in the aging population, it has now become even more important to have good perioperative management, in order to reduce complications.

In the orthopaedic field, two previous studies have evaluated the utility of the SAS in patients undergoing hip and knee arthroplasty, and another in those undergoing lower limb arthroplasty or femoral neck fracture treatment (12). Wuerz *et al*. concluded that for patients undergoing hip and knee arthroplasty, the score captures important intraoperative data regarding the risk of complications and contributes additional information to preoperative risk, however, on its own it is insufficient to provide comprehensive risk stratification for arthroplasties (13).

Arthroplasty patients undergoing surgery for femoral neck fractures represent a small subgroup of orthopaedic procedures, as such Urrutia *et al*. carried out a prospective study to evaluate the utility of the SAS in patients undergoing major and intermediate orthopaedic operations. From their study they concluded that the SAS does not predict 30 day major complications and death in patients undergoing general orthopaedic surgery, but it is useful in the subgroup of patients undergoing spine surgery (12).

In another study, Urrutia *et al*. suggested that cardiovascular disease may have more of an effect on the outcomes of patients undergoing limb surgery as compared to those undergoing spine surgery. In limb surgery, it seems complications are more dependent on patients' previous characteristics, as they often still undergo complications despite high SAS scores (10)(12). The effects on the cardiovascular system that often lead to low SAS scores in spine surgery are associated with intraoperative bleeding. The exposure of the spine, with stripping of muscle off bone, leaves exposed surfaces of muscle and bone that can bleed. Significant blood loss also results in greater fluid shifts, which can affect cardiac, pulmonary and renal status, or even, in the extreme example, lead to transfusion-related acute lung injury (TRALI) (11).

Given the high risks associated with spine surgery, it is important to find an easy to use, easily reproducible and inexpensive tool that could guide postoperative care of spine patients undergoing surgery for TB. Based on their previous work, Urrutia *et al*., undertook another study to validate the utility of the SAS, this time focusing on the subgroup of spine patients undergoing major and intermediate surgeries (11). They found that patients who scored a SAS of 7 or less had an increased risk of complications in the postoperative period, and yet still those who scored 4 or less, had a 10-fold increase in their relative risk for complications compared to controls. They concluded that the SAS is a useful tool that allows patients undergoing spine surgery to be grouped according to their risk for complications (11).

A tool such as the SAS, which helps to identify at-risk postoperative patients, would allow clinicians to stratify patients according to their risk for major complications. This would be a very useful tool for intra and inter-departmental communication and hand over. Furthermore, in resource limited settings such as public health settings, this would allow equitable distribution of already scarce resources and increased vigilance of treating physicians. (8). To this effect, the current study aims to extend the work previously done by others to validate the utility of the SAS in yet another subgroup of orthopaedic patients, those undergoing surgery for TB of the spine.

1.1.3 Study Aim and Objectives

Our study aimed at assessing the SASs of adult patients with TB of the spine, undergoing surgery at Chris Hani Baragwanath Academic Hospital (CHBAH) and Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) from 2010 to 2015 and to correlate it with 30 day morbidity and mortality. The specific objectives of the study are outlined below:

1. To score the SAS of each patient according to their anaesthetic charts. The scores were aggregated into four subgroups (less or = 4, $5-6, 7-8, 9-10$), as was done in Gawande *et al.*'s original paper and subsequent papers assessing SAS (10)(11).
2. To assess major morbidity and mortality in the first 30 postoperative days. Major morbidity and mortality as defined by Gawande *et al*. (10) include: acute renal failure, bleeding requiring four Units red cell transfusion within 72 hours after operation, cardiac arrest requiring Cardio Pulmonary Resuscitation (CPR), coma for 24 hours or longer, deep venous thrombosis, septic shock, myocardial infarction, unplanned intubation, ventilator use for 48 hours or longer, pneumonia, pulmonary embolism, stroke, wound disruption, deep surgical site infection, sepsis, and systemic inflammatory response syndrome.
3. To correlate SASs with patient outcomes *i.e.* major morbidity and mortality in the first 30 postoperative days.
4. To assess if there were regional differences in outcomes depending on the location of the TB *i.e*. the thoracic spine may have poorer outcomes compared to the lumbar spine.

2 CHAPTER 2

2.1 Research Question

Is the SAS a reliable and accurate tool that can be used to predict 30 day major morbidity and mortality in patients undergoing spine surgery for TB of the spine?

2.2 Research Methodology

2.2.1 Research design

This was a retrospective study of patients who underwent spine surgery for TB of the spine from 2010 to 2015 at CMJAH and CHBAH.

Eligibility criteria

Inclusion Criteria

- Adult (≥ 18) patients with TB of the spine
- Those who have undergone spine surgery
- Anaesthetic chart indicating Estimated Blood Loss (EBL), lowest Mean Arterial Pressure (MAP) and lowest Heart Rate (HR)
- Intensive Care Unit (ICU) records including blood results
- In-patient admission booklet/chart

Exclusion criteria

- Incomplete data where parameters required to score patients are incomplete or where records cannot be found
- Extra spinal TB
- Patients managed non-operatively

2.3 Materials and methods

2.3.1 Sampling

A sample of convenience of all patient records eligible to participate in the study at CMJAH and CHBAH between 2010 and 2015 were reviewed for this study.

2.3.2 Data collection

The principal investigator (Dr Mogami) collected all the data for the study. We used theatre record books from the years 2010 to 2015 to identify all patients who had undergone TB spine surgery. We then retrieved their anaesthetic charts, ICU records as well as their inpatient records. The records were analysed to obtain a score for each patient (see Appendix A) and any record of the above stipulated morbidities or mortalities was documented on the data collection sheet (see Appendix A). Each patient was assigned a study number to maintain patient anonymity and only the principal investigator had access to the original patient data.

2.3.3 Data analysis

Data analysis was conducted using the IBM SPSS software 25 ®. Parametric and non-parametric tests were used to analyse the data depending on the normality of the continuous variables. The data analysis matrix for our study is outlined in Table 2.1 below. Inferential statistics were not conducted due to the small sample size (N=33) as well as to avoid type II error (14). Interquartile range was expressed as 25% − 75%. *P*-values < 0.05 were considered to be statistically significant.

Table 2.1: Data analysis matrix

Objectives	**Variables**	**Statistical test**
To determine the normality of the continuous	Age, estimated blood loss (EBL), lowest mean	Shapiro Wilk test was used. Variables with *p*-value < 0.05 were not normally distributed.

variables	arterial pressure, lowest heart rate and CD4 count	
To present the demographic characteristics of the participants	Age, gender, RVD status and CD4 count	**Categorical variables**: Descriptive statistics of frequency and percentage was used to summarise the categorical variables of gender and RVD status. **Continuous variables:** Descriptive statistics of mean and standard deviation was used to summarise the age and the CD4 count of the participants
To present the site of tuberculosis of the spine	Site of tuberculosis	**Categorical variables**: Descriptive statistics of frequency and percentage was used to summarise the site of tuberculosis.
To present the results of the clinical outcome measures	Estimated blood loss, Lowest mean arterial pressure, Lowest heart rate and total SAS	**Continuous variables:** Descriptive statistics of median and interquartile range was used to summarise the skewed variables (estimated blood loss and the lowest heart rate) and mean and standard deviation (SD) was used to summarise the normally distributed lowest mean arterial pressure of the participants. **Categorical variables**: Descriptive statistics of frequency and percentage was used to summarise the total SAS of the participants.
To present the complications associated with the surgical procedure	Complications and type of complications	**Categorical variables**: Descriptive statistics of frequency and percentage was used to summarise the complications associated with the surgical procedure of the participants.

2.5 Ethics Approval

Ethical approval was obtained from the Human Research Ethics Committee (HREC)(Medical), at the University of Witwatersrand. The clearance certificate number is **M160802** (see Appendix B). We also obtained hospital permission to conduct the study from both CHBAH and CMJAH CEO's offices (see Appendix C).

3 CHAPTER 3

3.1 Demographic characteristics of the participants

From our hospital records we identified 115 patients who could potentially participate in this study. Only the records of 51 of these patients could be found. In analysing the records, we found complete data captured for only 33 patients. Thus, a sum total of 33 patients met the criteria for inclusion in this study. Of the 33 patients, there were 11 males and 22 females with an average age of 42.39 (SD = 13.39). Twenty patients in the study were reported to be HIV positive, twelve were negative and one was unknown/not reported. The average CD4 count for those whose HIV status was known and was positive was 252.5 cells/mm^3 (see Table 3.1).

Table 3. 1: Demographic characteristics of the participants

Demographics (N = 33)	
Age, Mean (SD)	42.39 (13.39)
Gender, n (%)	
Male	11 (33.3)
Female	22 (66.7)
RVD, n (%)	
Positive	20 (60.6)
Negative	12 (36.4)
Unknown/not reported	1 (3)
CD4 count	252.5 (130.36)

3.2 Test for normality

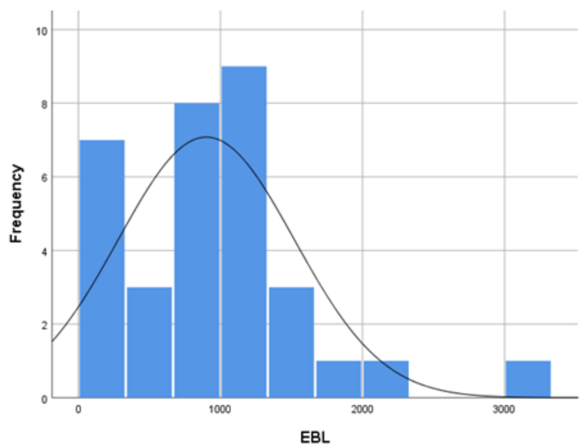
The test for normality was conducted with the continuous variables and the results show that estimated blood loss and lowest heart rate were not normally distributed, as the *p*-values were less than 0.05 (see Table 3.2).

Table 3. 2: Test for normality

	Shapiro-Wilk test		
Tests of Normality	**Statistic**	**df**	**Sig.**
Age	0.94	6	0.649
Estimated blood loss (EBL)	0.67	6	0.003*
Lowest mean arterial pressure	0.91	6	0.402
Lowest heart rate	0.65	6	0.002*
CD4	0.93	6	0.548

**p*-value < 0.05

The histogram below in Figure 3.1 shows the distribution curve of the estimated blood loss, which showed the data were not normally distributed.



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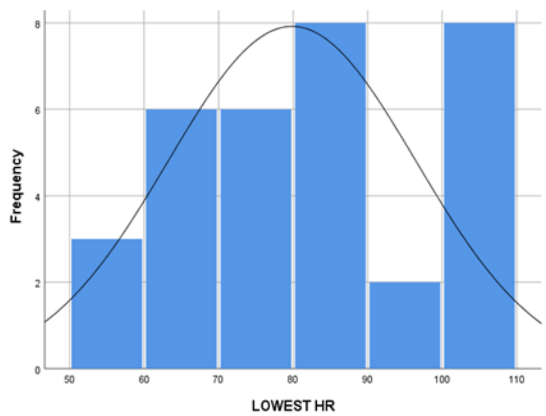

B

Figure 3. 1: Test for normality for estimated blood loss and lowest heart rate

3.3 Site of tuberculosis of the spine

The thoracic spine was the most common site of TB and the surgery procedure, 27 out of the total 33 patients had the procedure done in the thoracic spine as shown in Figure 3.2 below.

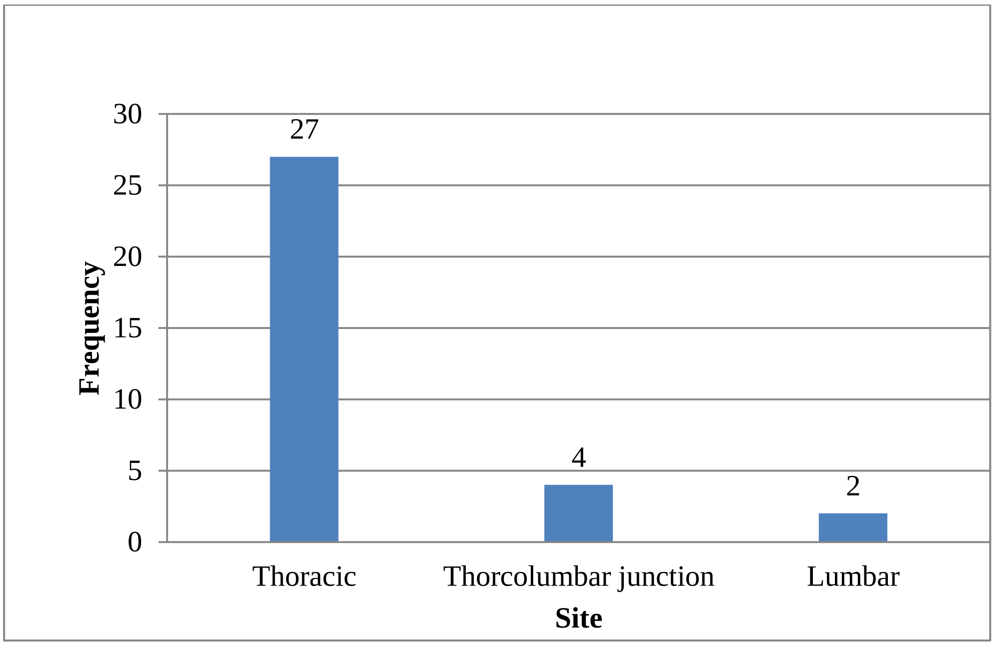

Figure 3. 2: Site of tuberculosis

3.4 Clinical outcome measures

Of the individual variables of the SAS, the median EBL was found to be 800, whereas the average for the lowest mean arterial pressure was 67.42 and lowest heart rate was 80 (see Table 3.3).

Table 3. 3: Clinical outcome measures

Outcomes	Median	IQR	Mean	SD
Estimated blood loss	800	425-1175	-	-
Lowest mean arterial pressure	-	-	67.42	9.66
Lowest heart rate	80	65-97.5		

3.5 Total SAS

The scores were analysed categorically as was done in Gawande *et al.*'s original paper, which divided the patient groups as those who scored 0-/= 4, 5 − 6, 7 − 8, 9 − 10 (see Table 3.4).

Table 3. 4: Total SAS

Total SAS (N = 33)	n	%
0 − 4	15	45.5
5 − 6	10	30.3
7 − 8	8	24.2
9 − 10	0	0

As shown in Table 3.4 above, the majority of patients (15) scored 4 or less, while 10 patients scored 5 − 6, eight patients scored 7 − 8, while none scored 9 − 10.

Table 3.5 shows that the patients with high risk total SASs were older (44.13 ± 15.32 years) than those considered as low and moderate risk. The estimated blood loss and lowest heart rate was higher in patients considered as high risk compared to those considered as low and moderate risk.

Table 3. 5: Mean difference between the outcome and total SAS

	Low risk	**Moderate risk**	**High risk**
Age, Mean (SD)	42.13 (14.42)	40 (9.96)	44.13 (15.32)
Estimated blood loss volume, Median (Interquartile range)	275 (70-700)	750 (300-1000)	1150 (800-1500)
Lowest mean arterial pressure, Mean (SD)	62.88 (3.18)	72.90 (9.88)	66.20 (10.51)
Lowest heart rate, Median (Interquartile range)	60 (55-63.75)	75 (68.75-85)	100 (82-100)

3.6 Complications

In the group analysed, 21 patients were reported to have no complications while 12 had complications in the first 30 postoperative days. The complications that were noted were those listed by Gawande *et al*. (8). The majority of the complications were related to blood loss and the requirement for massive transfusion in eight patients, one patient had pneumonia, one had acute kidney injury while two had a Systemic Inflammatory Response Syndrome (SIRS) response (see Figure 3.3). In analysing the correlation of the score with the presence of complications, we found that of the 15 patients with a score of 0-/= 4, 10 of them had complications, while five had none. Of the 10 patients with a score of 5 – 6 only two developed complications. Additionally, none of the eight patients with a score of 7 − 8 developed any complications (see Table 3.6).

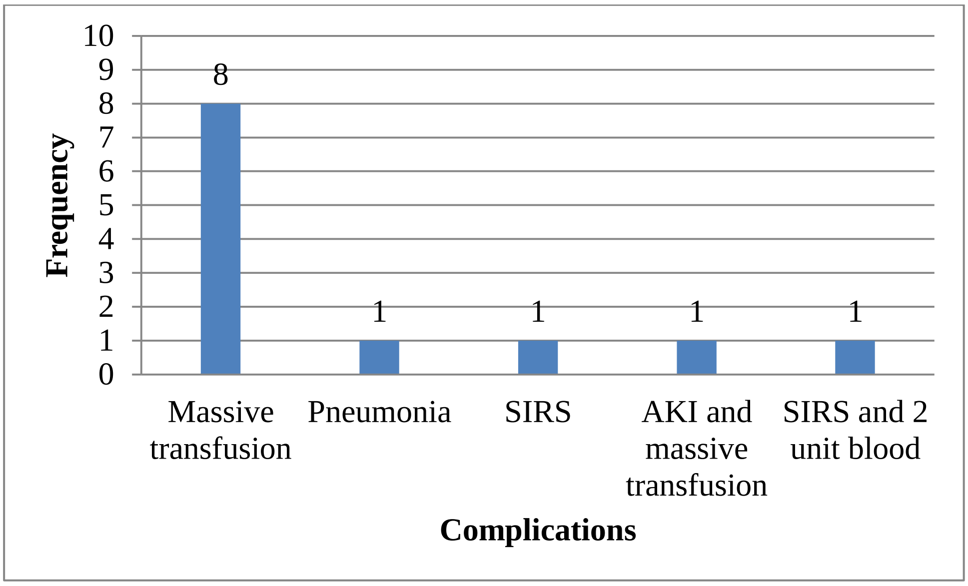

Figure 3. 3: Type and frequency of the complications (n = 12)

Table 3. 6: Complications

Complications (N = 33)	**n**	**%**
No complications	21	63.6
With complications	12	36.4

Figure 3.4 below shows a stratification of patients according to their SAS scores. Patients were then assessed for the presence and/or absence of complications. Patients with SAS of 4 or less were stratified as high risk due to their higher likelihood of having complications. Conversely, those with high scores were less likely to develop complications, as evidenced by the absence of complications in patients with a score of 7 or more.

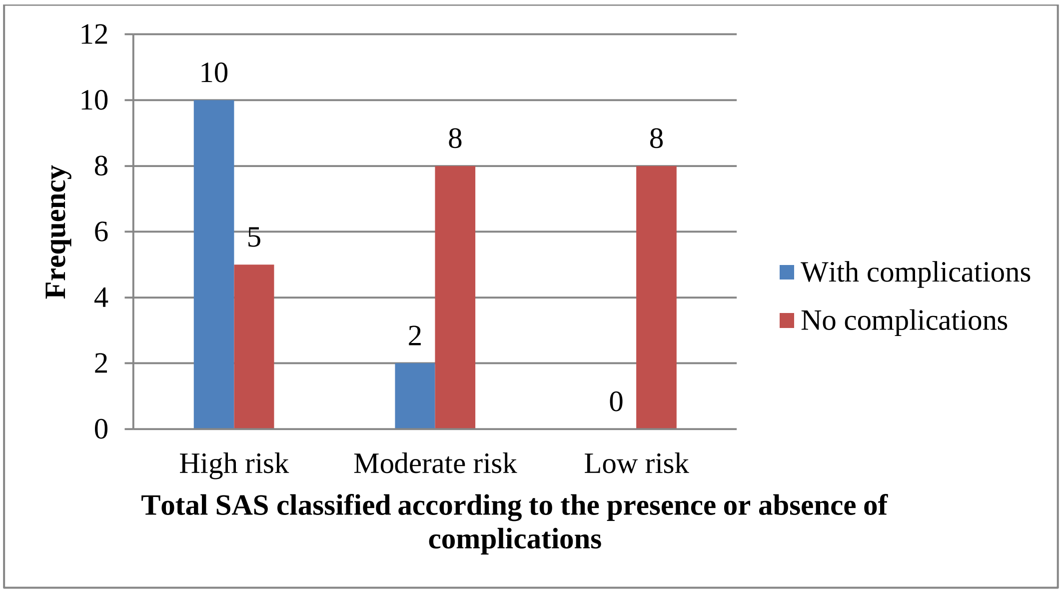

Figure 3.4: Total SAS classified according to the presence or absence of complications

3.7 Difference between patients with complications and those without

Table 3.7 below presents the results of the clinical and demographic outcome measures in patients with complications and those without.

Table 3. 7: Difference between patients with complications and those without

	With complications (n = 12)	No complications (n = 21)
Age	40.5 (15.79)	43.38 (12.10)
Estimated blood loss volume	1175 (850-1575)	700 (300-1000)
Lowest mean arterial pressure	65.83 (10.68)	68.33 (9.17)
Lowest heart rate	92.50 (80.50 – 103.75)	70 (60-85)

As shown in Table 3.7, the patients with complications (43.38 ± 12.10 years) were younger than those without (40.5 ± 15.79 years). However, this difference was not statistically significant (p>0.05). Estimated blood loss was higher in patients with complications (1175, IQR: 850 − 1575) than in those without (700, IQR: 300 − 1000).

3.8 Difference between patients with RVD positive and negative

Table 3.8 below presents the results of the clinical and demographic outcome measures in RVD positive and negative patients.

Table 3. 8: Difference between patients with RVD positive and negative

	RVD positive (n = 20)	**RVD negative (n = 12)**
Age, Mean (SD)	37.33 (9.33)	44.20 (14.14)
Estimated blood loss volume, Median (IQR)	700 (337.5-1112.5)	950 (550-1162.5)
Lowest mean arterial pressure, Mean (SD)	65.67 (11.05)	68.35 (9.12)
Lowest heart rate, Median (IQR)	80 (67.50-85)	78.50(61.25-100)

3.9 Difference between the sites of TB

Table 3.9 below presents the results of the clinical and demographic outcome measures specific to the location (site) of TB.

Table 3. 9: Difference between the sites of TB

	Thoracic	**Lumbar**	**TL junction**
Age, Mean (SD)	42.88 (12.63)	25 (5.66)	41.75 (12.87)
Estimated blood loss volume, Median (IQR)	800 (450-1200)	1530 (0)	950 (750-1000)
Lowest mean arterial pressure, Mean (SD)	67.08 (9.40)	61 (1.41)	72.25 (13.99)
Lowest heart rate, Median (IQR)	82 (70-100)	70 (14.14)	62.5(55-92.50)

There was no significant difference in the average age, estimated blood loss volume, lowest arterial pressure and lowest heart rate ($p > 0.05$) between the sites of TB as shown in Table 3.9.

4 CHAPTER 4

4.1 Discussion

South Africa carries a very high burden of TB, contributing significantly to the world burden of disease. The country is estimated to be one of the six countries contributing to 60% of the burden of TB in the world (15). This disease affects patients at all ages, however in our study population, there was an average age of 42 years. This highlights the significance of the disease burden and its affectation of a young active population. The World Health Organisation (WHO) South African estimates for 2017 cited that in patients older than 14, the majority of patients affected were males (16). This is in contrast to the data we found in our study, where the majority were females. We do however acknowledge that the low sample size may have a significant impact on the numbers we found in our study.

The presence of HIV and TB co-infection is a well-documented phenomenon (16)(17). The global literature suggests that the high resurgence of TB is related to the upsurge of HIV infection (8). We investigated if this co-infection actually influenced the SAS among our study participants and thus outcomes of the surgery and there was no correlation. Amongst those patients whose status was known in this study, which was 32 patients, the majority were HIV positive. As discussed in previous sections of this study, the SAS relies on parameters based on haemodynamic parameters, which may explain why neither HIV, nor comorbidities for that matter, were associated with poorer outcomes.

The TB epidemic has resulted in major consequences, where patients often have severe debilitating deformity and neurology. In some instances, the disease results in mortality. While the management is largely medical, there are instances where surgical intervention is required in a specific subset of patients. The indications for surgery in TB of the spine include obtaining a biopsy for diagnosis, for abscesses causing neurology, where there is instability of the spine and/or failed medical treatment (5). TB spine surgery is fraught with complications, largely due to the type of approach and the severe muscle stripping which can result in significant blood loss.

Our study showed that the lower the SAS the more likely a patient was to have complications. This was particularly more so in patients who had scores of 4 or less. There was a statistically significant association between SAS and presence of morbidity in the early postoperative period. Of all the parameters, the estimated blood loss (EBL) and heart rate (HR) seemed to have a more significant correlation. If we consider that spine surgery, particularly for TB involves a high risk of blood loss, it then follows that a score based on parameters that is made up of haemodynamic parameters would show such an association. This observation is in contra-distinction to that made in previous literature on the SAS and the general orthopaedic procedures, where often complications were secondary to pre-existing comorbidities rather than blood loss at the operation (12)(13) as opposed to Urrutia *et al*.'s study (11), who looked only at a subset of spine patients and found that indeed in this subset of patients, low scores correlated with morbidity.

In our analysis, and certainly that made in previous literature (10)(11), the lower the SAS the more likely a patient was to have complications in the postoperative period. Studies have shown that patients with a score of 7 or less tend to do poorly, whereas if they scored 4 or less they did even worse (18)(19). This same finding was reproduced in our study, where we found that patients with a score of 4 or less had the highest risk of complications. There however has been some conflicting findings in other studies where they investigated the utility of SAS in a subset of neurosurgical, spinal metastasis and general orthopaedics patients (12)(20)(21). In these studies, no correlation was found between the SAS and postoperative complications. This conflicting finding may be due to a number of factors including patient heterogeneity and varying study designs and methodology.

We know that the risks associated with TB spine surgery are often associated with the level of the vertebrae operated on and the approach used, where some risks are inherent to the anatomical structures in the surgical field. We thus reviewed our patients to assess if there were any variations in the SAS as related to the anatomical area of the TB and if this affected outcomes. The majority of patients had thoracic spine TB, which is to be expected and in keeping with general disease distribution. TB spine tends to follow pulmonary TB, and in fact some patients are first diagnosed with pulmonary TB when they present with spine symptoms. There is also haematogenous spread of the bacilli *via* the Batson plexus, making the thoracic spine a common area for the inoculation of this pathogen (5). In relation to the SAS though, there was no statistically significant association between the site of TB and the presence of complications. However, with the majority of patients having had mainly thoracic spine TB, this may have skewed the results.

The complications we assessed were in keeping with those described by Gawande *et al*. in their landmark paper and are listed in the methodology section of this report. The majority of our patients did not have any complications. However, amongst those who did, massive transfusion seemed to be the most common complication noted. This is hardly surprising and follows on from the previous discussion of major blood loss being common in TB spine surgery. While the findings of our study support those by Urrutia *et al*., where they investigated the SAS in general spine patients, we do acknowledge that our study may have limitations, which may be due to the small sample size, as well as the retrospective nature of the study.

4.2 Recommendations

Based on the results obtained from this study, the following recommendations are made:

1. Further follow up studies in this area, in a prospective manner to reduce the risk of data loss. This will involve the liaison of all relevant stakeholders such as the theatre nursing staff, ward staff, treating doctors and anaesthetists.

2. Increased vigilance in the perioperative management of TB spine patients, including preoperative optimisation of patients, recording of Apgar scores and appropriate dispensation based on scores.
3. Patients with TB spine to be treated according to the merits of their disease. Our study shows no difference in outcomes when age, site of TB or HIV co-infection were considered.

4.3 Limitations

This study was limited by data availability and the high loss to follow up. Of the 115 patients who could have potentially been included in the study, only 33 had complete records. Furthermore, the identification of potentially eligible patients through theatre surgical registers was made difficult by inaccurate data capturing. In some instances, names or surnames were misspelled, hospital numbers incorrectly entered, or operations incompletely filled out. This made tracing patient records difficult. Once this was overcome, certain documents such as anaesthetic charts or inpatient booklets were missing or incompletely filled out leading to patient exclusion. This data loss resulted in a high number of patients who were lost to follow up. As a consequence, this study had an attrition rate of over 200%, that lowering the accuracy of the findings, as well as making the results not generalisable to the general population.

5 CHAPTER 5

5.1 Conclusion

In conclusion, for the subset of TB spine patients who underwent major surgery, there is an association between low SAS and the presence of complications in the early postoperative period. There, however, is no correlation with the level of the spine affected or the patient's age. The scores of 7 or less were found to be predictive of complications, but those of 4 or less seem to be even more so. The SAS is thus an important hand over tool and can assist in the allocation of valuable resources such as ICU beds. It also would increase clinician vigilance when dealing with this subset of patients.

APPENDICES

Appendix A

DATA COLLECTION SHEET

DEMOGRAPHICS

STUDY NUMBER	
AGE	
GENDER	
LOCATION OF TB	

SAS

PARAMETERS	0	1	2	3	4
EBL					
LOWEST MAP					
LOWEST HR					
TOTAL SAS					

DOCUMENTED COMPLICATIONS ACCORDING TO PATIENT RECORDS

COMMENTS

Appendix B

Ethics Clearance Certificate

R14/49 Dr kefilwe Boineelo Mogami

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160802

NAME: (Principal Investigator) Dr kefilwe Boineelo Mogami

DEPARTMENT: Orthopaedic Surgery
Chris Hani Baragwanath Acaedemic Hospital
Charlotte Maxeke Johannesburg Academic Hospital

PROJECT TITLE: The Assessment of Surgical Apgar Scores in Adult Patients with TB of the Spine undergoing Major Spine Surgery

DATE CONSIDERED: 26/08/2016

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Dr Dimakatjo Ramashu and Prof Mkhululi Lukhele

APPROVED BY: Professor P Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 07/10/2016

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

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 301, Third floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in August and will therefore be due in the month of August each year.

Principal Investigator Signature

Date 27/10/16

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix C

Hospital Permission Letters

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

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

Dear Dr Kefilwe B Mogami

STUDY TITLE: The Assessment of Surgical Apgar Scores in Adult Patients with TB Spine undergoing major surgery.

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

Supported/~~not supported~~

Dr M.I. Mofokeng
Clinical Director
DATE: 1/08/2016

Approved/not approved

Ms G. Bogoshi
Chief Executive Officer
Date: 2.8.2016

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 1 Aug 2016

TITLE OF PROJECT: The assessment of surgical Apgar scores in adult patients with TB spine undergoing major surgery

UNIVERSITY: Witwatersrand

Principal Investigator: KB Mogami

Department: Orthopaedic Surgery

Supervisor (If relevant): LD Ramushu, M Lukhele

Permission Head Department (where research conducted): Yes

Date of start of proposed study: 1 Aug 2016
Date of completion of data collection: Dec 2018

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Human Research Ethics Committee of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

....
Recommended
(On behalf of the MAC)
Date: 01 August 2016

....
Approved/Not Approved
Hospital Management
Date: 05 08 16

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