# Indications for Emergency Thoracotomy in Penetrating Thoracic Trauma

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A Research Report submitted to the Faculty of Health Science, University of the Witwatersrand, in fulfilment of the requirements for the degree of Master of Medicine.

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## Declaration:

I, **Megan Lubout**, declare that this research report is my own, unaided work. It is being submitted for the degree of Master of Medicine at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

Signature of Candidate:

22nd day of July 2019 in Johannesburg

***This Research Report is written in the format for publication by the World Journal of Surgery. The word count excluding abstract, tables, figures, and references list is 2490 (i.e. not more than 2500 as requested by the journal)***

# Co-Authors declaration:

The postgraduate office,
Faculty of Health Sciences,
University of the Witwatersrand,

Dear Sir/Madam

**Co-authors declaration letter on Dr Lubout's contribution to her submissible MMed report**

This letter serves to confirm Dr Lubout's contribution to her submissible MMed report titled "**Indications for Emergency Thoracotomy in Penetrating Thoracic Trauma**". We the undersigned acknowledge Dr Lubout as the first author on this work and give permission for its submission for the degree of MMed at the University of the Witwatersrand. The candidate significantly contributed to updating the database, data analysis and interpretation, writing, revising and approval of the final submissible version of the paper.

Please give her the assistance she requires.

Yours sincerely,

Co-author 1: ____Pascaline Fru________________

Signature: ____________ Date: _07/08/2019____________

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# Abstract:

Background: Violent interpersonal acts account for a large proportion of unnatural deaths in South Africa. A significant proportion is due to penetrating thoracic trauma and the preventable haemorrhage it leads to. Current indications for emergency thoracotomy are unreliable. We propose the use of lactate, shock index (SI) and base deficit (BD) as a triage tool in patients with penetrating thoracic injuries to identify high-risk patients requiring surgical intervention in order to prevent treatment delays.

Methods: A review of the trauma registry of the Charlotte Maxeke Johannesburg Academic Hospital was carried out between March 2011 and March 2016. We collected 491 patients consisting of a non-operative group of 245 patients and an operative group of 246 patients. We compared lactate; SI and BD independently and within panels to ascertain which would best predict the need for operative intervention in these patients. Abnormal was defined as lactate ≥ 4 mmol/l, SI ≥ 08 and BD ≤ -4 mmol/l.

Results: Of the 491 patients, lactate (p <0.001), SI (p<0.001) and BD (p<0.001) differed significantly between operative and non-operative groups. Statistical significance was lost (p=0.34) once BD was analysed in combination with lactate and SI. Lactate alone was a strong predictor of intervention (AUC=0.814). The strongest predictor was a combined panel of lactate and SI (AUC=0.8308, p<0.001).

Conclusion: Lactate and SI in combination are useful as triage tools that could assist in decision making, as well as aid in predicting which patients are more likely to require surgical intervention and thus avoid unnecessary delay.

## Acknowledgements:

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# List of abbreviations:

| | |
|---|---|
| AIS | Abbreviated Injury Score |
| ATLS | Advanced Trauma Life Support |
| AUC | Area Under the Curve |
| BD | Base Deficit |
| ERT | Emergency Room Thoracotomy |
| GCS | Glasgow Coma Scale |
| GSW | Gunshot Wound |
| Hb | Haemoglobin |
| HR | Heart Rate |
| ICD | Intercostal Drain |
| RR | Respiratory Rate |
| ROC | Receiver Operating Characteristic |
| SI | Shock Index |
| SBP | Systolic Blood Pressure |

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## Introduction:

Traumatic injury is considered one of the most common causes of death and disability internationally [1]. Penetrating thoracic trauma is responsible for approximately half of all penetrating traumatic deaths [2]. Approximately 10-30% of thoracic trauma patients will require an immediate thoracotomy to control haemorrhage, while the remaining 70-90% can be managed non-operatively or with minimally invasive techniques such as insertion of an intercostal drain (ICD) [3-6]. Various controversies exist regarding operative intervention versus observation of these patients [4-7].

This study sought to investigate whether the use of biomarkers, specifically lactate levels of $\geq$ 4mmol/L and BD $\leq$ -4 mmol/L together with a SI of > 0.8 could predict the need for surgical intervention in penetrating thoracic trauma patients. These cut-off values were chosen after scrutiny of the literature [8-21]. Predicting surgical intervention early would decrease time to intervention and potentially prevent poor outcomes due to delays.

## Methods:

The study was a quantitative retrospective analysis of a prospectively collected database at the Trauma Unit at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), Johannesburg, South Africa. All patients presenting to the unit between March 2011 and March 2016 with penetrating thoracic injuries (including those who died before and after intervention) were included. Patients with minor non-abdominal injuries, defined as those with an abbreviated injury score (AIS) of $\leq$ 2 were also included.

Standard protocol in the unit dictates that all penetrating thoracic trauma be admitted to the resuscitation area. Demographic characteristics and vital signs including systolic blood pressure (SBP), pulse rate, respiratory rate (RR), Glasgow coma scale (GCS), and arterial blood gas analysis were recorded. These vital signs and blood samples were taken on arrival in the resuscitation area. From these, SI was calculated by dividing heart rate by SBP, BD and lactate were recorded. Patients with incomplete data, thoraco-abdominal injuries, air embolism, tracheobronchial injuries and cardiac tamponade were excluded. Sampling criteria is shown in Figure 1.

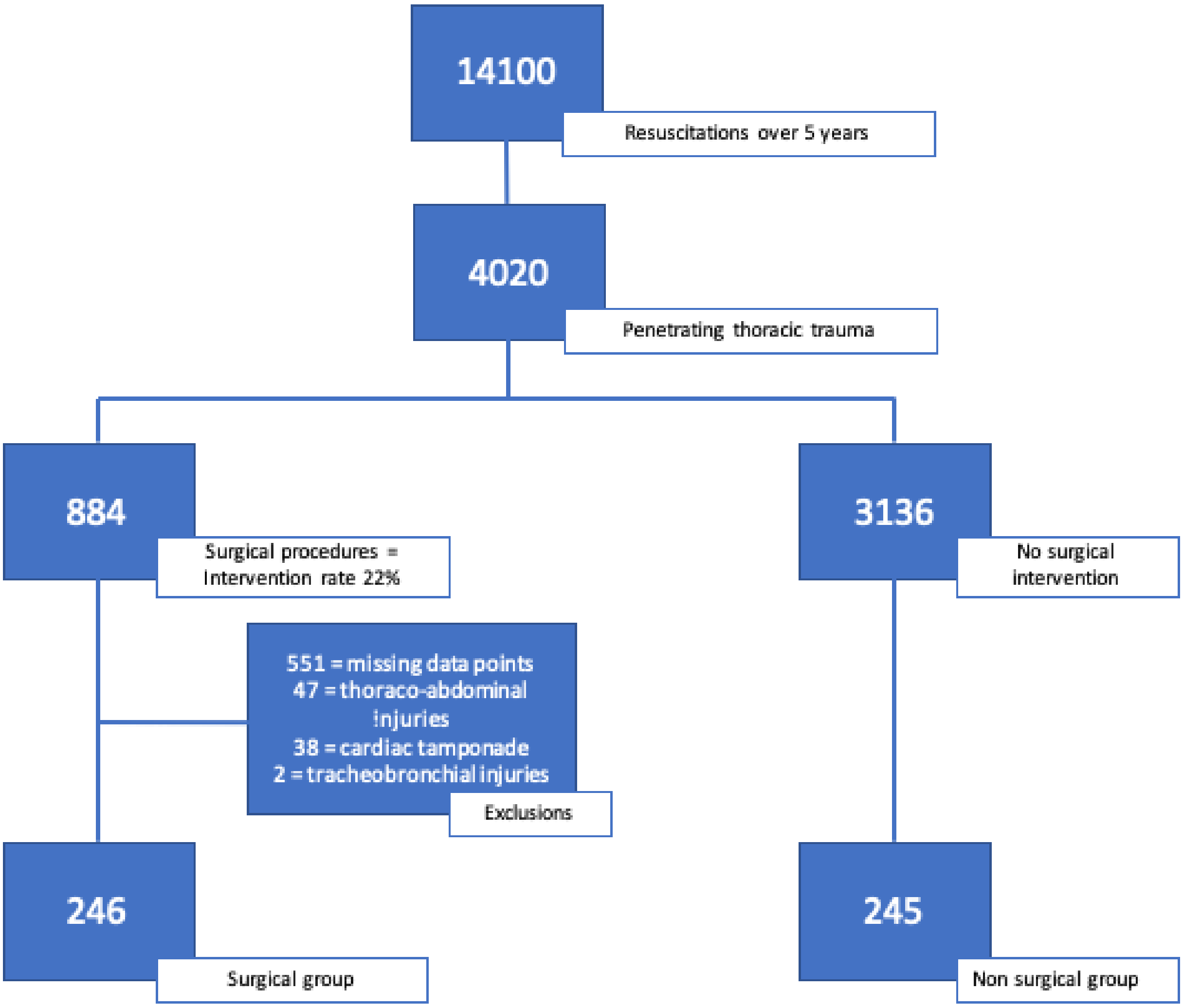


**Figure 1**: Sample size and exclusions
*Intervention rate = number of surgical procedures/penetrating thoracic trauma (proportion of patients presenting with penetrating thoracic trauma who required surgical intervention)*

The sample size of 491 patients consisted of 246 patients requiring an emergency operative intervention that met the inclusion criteria. 638 patients were excluded from the operative group due to missing data points or due to being classified as thoracoabdominal injuries, cardiac tamponade or tracheobronchial injuries. A non-operative group of 245 consecutive patients with penetrating thoracic injuries who met the inclusion criteria and were managed with conservative measures in the same time period as those who received an operative procedure was then collected. Collection was halted once a similar sample size to the operative group was reached.

Non-operative interventions included ICD insertion, suturing of wounds in the emergency department and observation with a repeat chest x-ray after six hours to rule out the development of a haemothorax or pneumothorax. Other parameters captured included; need for and type of surgical (including thoracotomy and sternotomy) and non-surgical intervention, time to surgical intervention from arrival at the unit, as well as clinical findings at the time of intervention and outcomes (discharge/death).

Statistical analysis:

An estimated sample size of 207 participants per group was calculated to be sufficient for a significance level (alpha) of 0.05 and power of 90% (ratio control vs experiment of 1), to show a 20% difference between the groups for a two-sample t-test. Therefore, this study was sufficiently powered.

The study variables (Appendix 2) were captured into a Microsoft Excel spreadsheet and imported into STATA Version 14.2 suit of analytics software. Descriptive statistics were conducted and the Shapiro-Wilk W test was performed to determine the normality of distribution of the data. Non-parametric Mann-Whitney U tests were performed, as appropriate, to determine differences in continuous variables between the groups (Table 1), and means (±SD) or medians and ranges reported. The Fishers' exact tests were conducted for analyses of categorical variables between the groups (Table 1) and the results are expressed as absolute and relative frequencies. Significance was set at 5%. Univariate and multivariate logistical regression analyses were conducted for prediction model building in Table 4 and only variables with a p values < 0.20 in the univariate analyses were included in multivariate model building.

The Hosmer-Lemeshow (HL) Test was applied to determine the goodness-of-fit of the combined marker panels in multivariate models, with the highest P value and lowest HL $chi^2$ indicating the best-fit model for this dataset. Receiver Operating Characteristic (ROC) curve analysis was conducted and the area under the curve (AUC) reported to determine the ability of the individual variables or combined variable panels to accurately predict surgical intervention.

## Results:

Table 1 shows demographic and biochemical data collected from both the non-intervention (n=245) and intervention group (n=246). The mean age of the study population was 29.1 years (15-64 years) with no significant age differences between the two groups. A marked male predominance was noted (468/491, 95.1%).

**Table 1. Demographic and biochemical parameters of intervention vs non-intervention trauma patients**

| Parameter | Participants (n=491) | Non-intervention (n=245) | Intervention (n=246) | P value* | Effect size (OR/Cohen's d) | 95% CI |
|---|---|---|---|---|---|---|
| Age, years | 29.1 (7.1) | 29.3 (7.7) | 28.8 (6.6) | 0.94 | *0.07* | *0.12 - 0.25* |
| Male gender, % | 95.1% | 93.1% | 97.6% | 0.02 | 0.34 | 0.12 – 0.91 |
| Male: Female | 19.6:1 | 13.4:1 | 40.0:1 | | | |
| RR (bpm) | 21.94 (7.24) | 21.0 (4.19) | 22.9 (9.34) | 0.005 | *-0.27* | *-0.45 – (-0.09)* |
| Cat: RR >20 | 53.7% | 50.4% | 57.0% | 0.149 | 1.30 | 0.89 - 1.90 |
| pH | 7.33 (0.10) | 7.36 (0.06) | 7.30 (0.11) | <0.0001 | *0.70* | *0.51 - 0.88* |
| Cat: pH <7.35 | 52.1% | 40.0% | 64.2% | <0.0001 | 2.69 | 1.84 - 3.95 |
| Hb (g/dL) | 12.31 (2.56) | 13.4 (2.28) | 11.4 (2.45) | <0.0001 | *0.85* | *0.65 - 1.04* |
| Cat: Hb < 8 | 5.5% | 1.0% | 9.5% | <0.0001 | 10.42 | 2.50 - 92.23 |
| GCS (Median/IQR) | 15 (15-15) | 15 (15-15) | 15 (14-15) | <0.0001 | *0.48* | *0.30 - 0.67* |
| Cat: GCS < 15 | 14.8% | 2.9% | 27.6% | <0.0001 | 12.72 | 5.60 - 33.61 |
| HR (bpm) | 91.14 (21.28) | 87.42 (17.68) | 94.69 (23.89) | <0.0001 | *-0.41* | *-0.59 – (-0.23)* |
| Cat: HR > 120 | 8.8% | 4.1% | 13.5% | <0.0001 | 3.68 | 1.71 - 8.55 |
| SBP (mmHg) | 121.67 (29.24) | 132.6 (23.0) | 109.55 (28.27) | <0.0001 | *0.95* | *0.77 - 1.14* |
| Cat: < 90 | 11.8% | 0.8% | 22.8% | <0.0001 | 35.8 | 9.21 - 305.3 |
| Lactate (mmol/L) | 3.88 (3.04) | 2.49 (1.46) | 5.39 (3.47) | <0.0001 | *-1.13* | *-1.32 – (-0.94)* |
| Cat: Lact >4 | 35.3% | 13.1% | 57.6% | <0.0001 | 9.05 | 5.65 - 14.64 |
| BD (mmol/L) | -5.65 (5.33) | -3.86 (3.51) | -7.85 (5.56) | <0.0001 | *0.86* | *0.67 - 1.04* |
| Cat: BD < -4 | 52.3% | 33.1% | 71.5% | <0.0001 | 5.09 | 3.41 - 7.62 |
| SI | 0.80 (0.33) | 0.68 (0.19) | 0.93 (0.38) | <0.0001 | *-0.89* | *-1.07 – (-0.70)* |
| Cat: SI > 0.8 | 38.9% | 23.7% | 54.3% | <0.0001 | 3.83 | 2.56 - 5.77 |
| ISS | 13.22 (5.51) | 9.68 (1.33) | 17.72 (5.52) | <0.0001 | *-2.13* | *-2.37 – (-1.90)* |

Mann-Whitney test for continuous variables, Fisher's exact test for categorical variables. Continuous variables are expressed as mean ± SD, unless specified otherwise. Categorical variables are expressed as relative frequencies. *Abbreviations*: BD: Base deficit, Cat: categorical variable, GCS: Glasgow coma scale, Hb: haemoglobin, HR: heart rate, NS: not significant, RR: respiratory rate, SBP: systolic blood pressure, SI: Shock index, ISS: injury severity score

Despite significant differences in the mean SBP and heart rate (HR) values between the intervention and non-intervention groups (110 mmHg vs. 133 mmHg and 95 bpm vs. 87 bpm, respectively), these levels still fell within what is considered the "normal" range for these vital signs [3]. Moreover, these parameters were well above the cut-off levels where vital signs alone would prompt immediate surgical intervention according to current guidelines, i.e. SBP < 90mmHg and HR > 120 bpm [3]. This finding supports existing evidence that vital signs alone are not reliable indicators of shock or need for surgical intervention in penetrating trauma [8-9,22].

Statistically significant differences between the non-intervention and intervention group were also noted for GCS, haemoglobin, lactate, BD, pH and SI (p-values <0.0001; Table 1). Furthermore, when these parameters were categorised according to internationally recognized cut-off values in trauma patients, significant differences between the groups remained very strong, as noted by scrutinizing the effect size.

When the types of penetrating injuries sustained were further classified into stab or gunshot wounds, the majority of traumatic thoracic injuries encountered were found to be as a result of stab wounds, a trend found in both groups (Table 2). However, the intervention group had a significantly higher proportion of gunshot wounds (20.8%) compared to the non-intervention group (6.9%), most likely due to the higher kinetic energy transfer involved with GSW causing more significant injury [12, 23].

**Table 2. Type of injury**

| **Type of injury** | **Non-intervention (%)** | **Intervention (%)** | **Total (%)** |
|---|---|---|---|
| GSW (n=68) | 17 (6.9) | 51 (20.8) | 68 (13.8) |
| Stab (n=242) | 228 (93.1) | 194 (79.2) | 422 (86.1) |
| **Total** | 245 | 245* | 490 |

*1 missing data point. *Abbreviations*: GSW: gunshot wound.

The surgical intervention rate was 22% yearly, which is similar to international averages of approximately 10 - 30% [6, 22]. Table 3 outlines the surgical interventions undergone by the study participants in the intervention group.

**Table 3: Type of operative intervention:**

| **Operative Intervention** | | **Number (n=246)** |
|---|---|---|
| Sternotomy | | 87(35%) |
| Pericardial window | | 21 (8.5%) |
| Negative | 6 | |
| Positive (converted to sternotomy) | 15 | |
| Thoracotomy | | 115(47%) |
| Right | 22 | |
| Left | 35 | |
| Side not specified | 40 | |
| ERT | 15 | |
| Clamshell | 3 | |
| Subclavian artery exploration | | 4 (1.5%) |
| Would exploration | | 6 (2.5%) |
| Neck exploration | | 2 (1%) |
| Axillary artery exploration | | 2 (1%) |
| Unspecified operative intervention | | 9 (3.5%) |

*Abbreviations*: ERT – emergency room thoracotomy

Sternotomies, including those patients with positive pericardial windows (n=102, 42%) and thoracotomies (n=97, 40%) formed the bulk of the procedures performed. Patients who underwent pericardial window were subdivided into those with a positive window who went on to have a sternotomy and a negative pericardial window who did not.

Of the 246 patients who underwent an operative intervention, 159 (65%) were operated within two hours of presentation, 61 (25%) within two to four hours, 11 (4%) within four to six hours, 13 (5%) more than six hours after presentation and two (1%) patients had no recorded time to intervention.

A logistical regression analyses (summarised in Table 4) was performed to further establish which parameters would be more reliable when predicting the need for surgical intervention in penetrating thoracic trauma.

**Table 4: Logistical regression analyses of univariate and multivariate panels**

| Parameter | AUC | Odds ratio | OR 95% CI | P Value |
|---|---|---|---|---|
| Lactate | 0.814 | 1.89 | 1.66 – 2.16 | <0.0001 |
| BD | 0.741 | 0.82 | 0.78 – 0.86 | <0.0001 |
| SI | 0.730 | 32.5 | 13.9 – 76.0 | <0.0001 |
| GCS | 0.623 | 12.7 | 5.7 – 28.5 | <0.0001 |
| pH | 0.621 | 2.69 | 1.87 – 3.88 | <0.0001 |
| HR | 0.542 | 3.68 | 1.77 – 7.64 | <0.001 |
| Hb | 0.542 | 10.4 | 2.4 – 44.9 | <0.0001 |
| ***Combined panels:*** | | | | |
| **Lactate-BD-SI** | **0.833** | | | **<0.0001** |
| Lactate | | 1.67 | 1.42 – 1.94 | <0.0001 |
| BD | | 0.97 | 0.92 – 1.03 | 0.34 |
| SI | | 7.36 | 2.87 – 18.8 | <0.0001 |
| Constant | | 0.031 | 0.014 – 0.068 | <0.0001 |
| **Lactate-BD** | **0.815** | | | **<0.0001** |
| Lactate | | 1.81 | 1.55 – 2.10 | <0.0001 |
| BD | | 0.96 | 0.91 – 1.02 | 0.23 |
| Constant | | 0.107 | 0.067 – 0.170 | <0.0001 |
| **BD-SI** | **0.784** | | | **<0.0001** |
| BD | | 0.86 | 0.82 – 0.91 | <0.0001 |
| SI | | 17.2 | 6.9 – 42.4 | <0.0001 |
| Constant | | 0.050 | 0.025 – 0.103 | <0.0001 |
| **Lactate-SI** | **0.831** | | | **<0.0001** |
| Lactate | | 1.73 | 1.51 – 1.98 | <0.0001 |
| SI | | 7.45 | 2.92 – 19.0 | <0.0001 |
| Constant | | 0.031 | 0.015 – 0.068 | <0.0001 |

*Multivariate regression was used to combine parameters identified in univariate analyses and the hosmer lemeshow test was used to select the best combination model/panel. The odds ratio indicates the weight. Abbreviations*: BD: Base deficit, GCS: Glasgow coma scale, Hb: haemoglobin, HR: heart rate, RR: respiratory rate, SBP: systolic blood pressure, SI: Shock index.

In line with the literature, haemoglobin and GCS were unreliable as early predictors of surgical intervention (Table 4) when the AUC are compared [3-7, 22-25]. BD, Lactate and SI showed the strongest statistical significance individually, with good AUC's and good fitting of the data, between the groups. Lactate was the only parameter to achieve an AUC of >0.8 and the best goodness-of-fit according to the Hosmer-Lemeshow test (AUC = 0.814; HL $chi^2 = 5.98$, $p = 0.65$).

Lactate, BD and SI were then grouped in different combinations to ascertain which panel would best predict operative intervention using multivariate logistic regression (Table 4, Figure 2). When BD was grouped with lactate and SI or lactate alone its statistical significance within the panel deteriorated significantly (p=0.34 and 0.23, respectively).

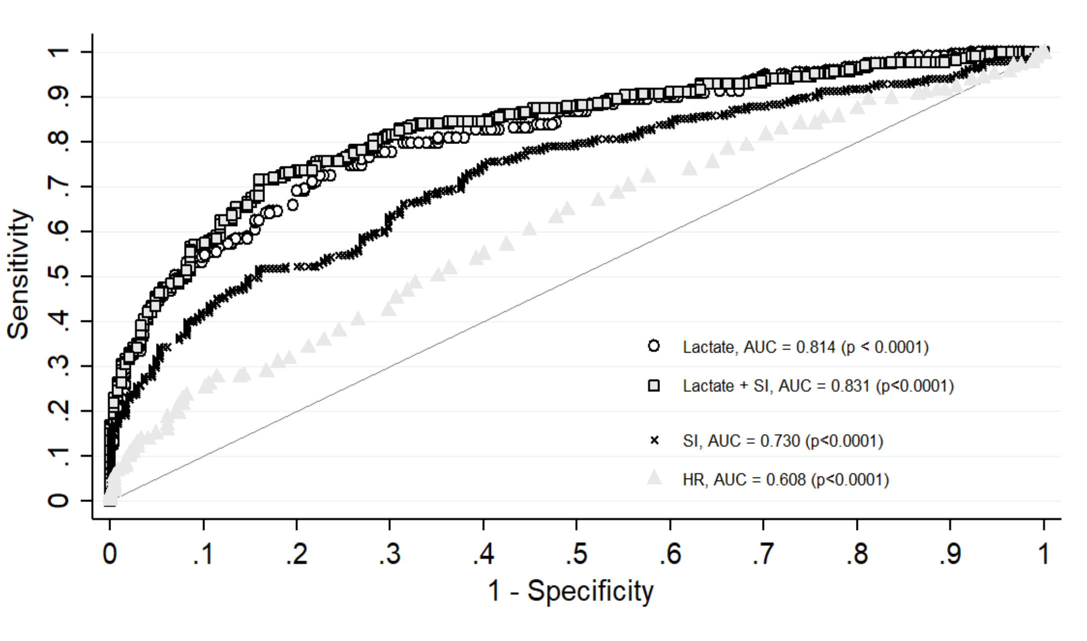


**Figure 2**. ROC curve for lactate and SI individually and in combined multivariate panels as predictors of surgical intervention

Although the panel of Lactate-BD-SI achieved the highest AUC of 0.833, the Hosmer-Lemeshow test showed it was a relatively poor fit to the data (HL $chi^2$ = 7.55, p = 0.48). Furthermore, when BD was combined with SI alone the AUC dropped below 0.8. With BD excluded, the Lactate-SI panel was found to be the most reliable combination of parameters for the prediction of operative intervention (AUC = 0.831; HL $chi^2$ = 5.91, p = 0.66) with a sensitivity of 68.8%, a specificity of 84.1%, a positive predictive value of 80.9% and a negative predictive value of 72.37%. Overall, correctly classifying 76.5% of patients.

The constant of error is 0.031. Thus, we estimate the following model: 0.031 + 1.73 (Lactate) + 7.45 (SI), where the odds ratio indicates how variables were weighed. Therefore, from Table 4 and the equation shown in Figure 3, assuming the other markers in the panel remained constant, the effect of the odds (of operative intervention) of a 1-unit increase in lactate is 1.73, meaning the odds off having an operative intervention increase by 73%.

The effect of the odds of a 1-unit increase in SI is 7.45, meaning the odds of an operative intervention are approximately seven times more likely. As a 1-unit increase in SI is clinically highly unlikely, this translates to the equivalent of a 22% increase in the odds of operative intervention for a 0.1 unit increase in SI as shown in Figure 3.

| | |
|---|---|
| Estimate probability of operative intervention = | $\dfrac{e^{\ln(0.031)+[\ln(1.73)*\text{lactate}]+[\ln(7.45)*\text{SI}]}}{1+e^{\ln(0.031)+[\ln(1.73)*\text{lactate}]+[\ln(7.45)*\text{SI}]}}$ |
| *p-hat* = | $\dfrac{e^{-3.458+[0.5475*\text{lactate}]+[2.008*\text{SI}]}}{1+e^{-3.458+[0.5475*\text{lactate}]+[2.008*\text{SI}]}}$ |
| For Lactate of 4 and SI of 0.8: | |
| *p-hat* = | $\dfrac{e^{-3.458+[0.5475*4]+[2.008*0.8]}}{1+e^{-3.458+[0.5475*4]+[2.008*0.8]}}$ |
| *p-hat* = | $\dfrac{1.402}{2.402}$ |
| *p-hat* = | 0.584 |
| *Odds ratio* = | $\dfrac{0.584}{1-0.584}$ |
| = | **1.40** |
| For Lactate of 4 and SI of 0.9: | |
| *p-hat* = | $\dfrac{e^{-3.458+[0.5475*4]+[2.008*0.9]}}{1+e^{-3.458+[0.5475*4]+[2.008*0.9]}}$ |
| *p-hat* = | $\dfrac{1.714}{2.714}$ |
| *p-hat* = | 0.631 |
| *Odds ratio* = | $\dfrac{0.631}{1-0.631}$ |
| = | **1.71** |
| Odds ratio for a **0.1 unit increase in SI** = | $\dfrac{1.71}{1.40}$ |
| = | **1.22** |

**Figure 3**. Logistic regression equations for the Lactate-SI panel in predicting the odds of operative intervention. *Abbreviations: ln = natural log; SI= Shock index*

**Table 5.** Combined panel with cut-offs

| Parameter | Sensitivity (%) | Specificity (%) | NPV (%) | PPV (%) | Odds ratio | OR 95% CI | P Value |
|---|---|---|---|---|---|---|---|
| *Lactate-SI* | ***57.50*** | ***86.94*** | ***67.62*** | ***81.18*** | ***8.12*** | | ***<0.0001*** |
| **Lactate ≥4** | | | | | 6.96 | 4.34 – 11.2 | <0.0001 |
| **SI ≤0.8** | | | | | 2.11 | 1.36 – 3.28 | <0.001 |
| *Lactate-BD-SI* | ***67.08*** | ***80.41*** | ***71.38*** | ***77.03*** | | | ***<0.0001*** |
| **Lactate ≥4** | | | | | 4.89 | 2.95 - 8.08 | <0.0001 |
| **BD ≤ 4** | | | | | 2.46 | 1.57 - 3.83 | <0.0001 |
| **SI ≥ 0.8** | | | | | 1.83 | 1.17 - 2.89 | <0.01 |
| *Lactate-BD* | ***57.61*** | ***86.94*** | ***67.41*** | ***81.40*** | | | ***<0.0001*** |
| **Lactate ≥4** | | | | | 5.87 | 3.61- 9.53 | <0.0001 |
| **BD ≤4** | | | | | 2.70 | 1.75 – 4.18 | <0.0001 |
| *BD-SI* | ***71.60*** | ***66.94*** | ***70.39*** | ***68.24*** | | | ***<0.0001*** |
| **BD ≤4** | | | | | 3.98 | 2.67 – 5.95 | <0.0001 |
| **SI ≥ 0.8** | | | | | 2.67 | 1.76 – 4.04 | <0.0001 |

*Abbreviations: NPV=negative predictive value, PPV= Positive predictive value, SI= Shock index*

When specific cut-off values of lactate ≥ 4mmol/L and SI ≥ 0.8 were introduced a sensitivity and specificity of 57.50% and 86.94% respectively and positive and negative predictive values of 81.18% and 67.62% respectively were calculated, correctly classifying 72.4% of patients.

By scrutinising the ROC analysis cut-off values of lactate >3.2 and SI of > 1.1 (sensitivity = 75.0%, specificity = 76.7% negative predictive value =75.81, positive predictive value =75.9%) provided the highest overall predicative value of operative intervention and in combination correctly identify 75.88% of patients requiring surgery.

**Table 6: Combinations of variables with proposed cut off values**

| Combination: | Lactate 4 and SI 0.8: | Lactate 3.2 and SI 0.8 | Lactate 3.2 and SI 1.1 |
|---|---|---|---|
| **Sensitivity** | 57.50 | 71.25 | 75.0 |
| **Specificity** | 86.94 | 77.96 | 76.7 |
| **Correctly classified** | 72.37 | 74.64 | 75.88 |

*Abbreviations: SI=Shock Index*

Even so, using clinical judgement and previously prescribed indications 65% of patients underwent surgical intervention within the first two hours of presentation. The use of the above cut-off values which are easily at hand and available within minutes would have increased the identification of patients for surgical intervention in this study group.

## Discussion:

Listed below are the current Indications for thoracotomy as stated by Advanced Trauma Life Support (ATLS) ®: [3]

- Haemodynamic instability after penetrating thoracic trauma (systolic blood pressure <90 mmHg, pulse >120 bpm, non-responder to volume repletion).
- Initial blood loss of ≥ 1 500 mL on insertion of an ICD.
- Output of >500 mL of blood within the first hour post insertion of an ICD.
- On-going blood loss – indicated by continuous drainage of > 200 mL of blood per hour for four hours.
- Tracheobronchial disruption.
- Cardiac tamponade.
- Air embolism.

The premise of the above indications are based on observations made during the Vietnam War in the early 1970's [4-6]. Findings showed that risk of death increases linearly with total chest haemorrhage after thoracic injury and that mortality was three times higher with an output of >1500 mL of blood compared to that of 500 mL of blood [6]. Early performance of an emergency thoracotomy resulted in decrease in mortality [4-6,22].

Considering the many controversies regarding operative intervention versus observation of patients who have sustained penetrating thoracic trauma, hard and fast rules as stated above for intra-pleural drainage as an indication for thoracotomy are unreliable [4-6]. Factors influencing drainage include, but are not limited to blocked, kinked or clotted drains. Furthermore, abnormal vital signs signifying haemodynamic instability are late indicators of shock [22-26].

Much of the earlier literature surrounding the use of biomarkers in trauma focuses on their use to predict non-discriminatory end points such as death, admission to ICU or the need for massive transfusion [11,13,15-19].

Based on knowledge from studies published regarding lactate and BD use as a reliable predictor of poor outcome in ICU and after massive blood transfusion we believe that with this knowledge and that of the pathogenesis of arterial lactate accumulation it makes these biomarkers good indicators of haemorrhage and therefore need for surgical intervention. The same logic is applied to Shock index and thus we consider this a priori knowledge used to derive the models for regression analysis used above to further test this hypothesis.

Although several studies [8-18] have analysed the use of biomarkers such as lactate and BD as predictive tools for identifying high-risk trauma patients and diagnosing occult shock, only a few refer to the use of lactate and BD in decision-making regarding operative intervention. [8, 18, 20].

Caputo et al. in 2013 noted no difference in vital signs and BD between operative and non-operative trauma patients but a significant difference in lactate levels [8]. Patients with elevated lactate were more likely to require operative intervention [8]. In a study consisting of patients with blunt and penetrating thoracic trauma, Parsikia et el (2014) reported that lactate was a better predicator of operative intervention than vital signs with a p= 0.033 and AUC of 0.608 [27]. Caputo et el (2015) evaluated serum lactate, anion gap and base deficit's predictive value for massive transfusion and operative intervention [10]. Lactate and BD were comparable for the prediction of surgical intervention with an AUC of 0.62 and 0.67 respectively [10]. As with their 2013 study, the study group included trauma patients with blunt and penetrating injury to multiple body regions including the chest and abdomen [10].

Our study supports the above studies with regards to the use of lactate as a tool to assist in decision making with regards to the prediction of need for operative intervention in penetrating thoracic trauma. It provides compelling evidence as to its predictive value, which is improved further when combined with shock index.

Despite reported reliability issues from lactate and BD as predictive tools in the diagnosis of shock resulting from alcohol consumption [21, 28-30], the study showed statistically significant difference between the non-intervention group and the intervention group with both lactate and BD individually ($p<0.001$).

While lactate proved to be a strong parameter both alone and in combination with SI, the same could not be said for BD.  Given that up to 66% of our trauma population are under the influence of alcohol on presentation, the possibility, of alcohol influencing reliability cannot be ruled out [31].

## Limitations:

Considering that this was a retrospective study, there are limitations such as selection bias and the fact that the value of the data relies upon the accuracy of its collection in the past. Additionally, the single centre may not be illustrative of the more general population.

Furthermore, the study only included penetrating thoracic trauma and therefore no inferences can be made for blunt trauma or trauma involving other body regions. The choice of lactate, BS and SI with their respective cut off values were considered a priori, based on objective thought and reasoning based on the relevant literature though this leaves room for conjecture. Development and validation samples could have been used to test the validity of the derived models and confirm their suitability.

## Future Studies:

Future studies could include a similarly structured prospective study to ascertain the reliability of lactate and shock index as risk stratifying in penetrating thoracic trauma. Furthermore, the development of an algorithm to assist in decision making for patients with penetrating thoracic trauma would be useful and could be developed with the assistance of a prospective study to possibly include variables such as E-FAST, lactate and shock index. Biomarker comparison for patients who sustain penetrating versus blunt thoracic trauma as well as trauma to different body cavities can be done.

With no consensus regarding the effect of alcohol on lactate and whether this influences its reliability as a triage tool, further investigation into the effect of alcohol on blood gas parameters, such as lactate and BD, is needed [31].

## Conclusion:

This study highlights the usefulness of lactate and SI as a triage tool in patients with penetrating thoracic trauma. Although strict universal cut-off values of lactate and SI do not identify those patients requiring surgical intervention with 100% certainty, they improve the accuracy in identifying those patients at higher risk in a timely manner.

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**Appendices:**

**Approved protocol**

# Indications for Emergency Thoracotomy in Penetrating Thoracic Trauma.

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## 1. INTRODUCTION

Traumatic injury is among the top causes of death and disability worldwide (1). Approximately 5.8 million people die yearly as a result of traumatic injuries (1). Thus, trauma accounts for, on average, 10% of all worldwide deaths on a yearly basis (1).

Importantly, it is the leading cause of death in those aged younger than 45. As this is the age group that is most productive within a country's economy, it stands to reason that trauma therefore leads to a substantial economic burden due to loss of a large proportion of a nation's work force (1).

This economic burden falls disproportionately on low and middle-income countries; the global burden of injury is thus inversely proportional to income (1,2). By eliminating these inequalities it could potentially equate to the saviour of roughly two million lives per year (1,2).

The national injury mortality surveillance system (NIMMS) is used in South Africa to monitor death and disability within our society (3). Statistics published by NIMMS are in keeping with those published worldwide and support the statements made regarding burden of disease in low and middle-income countries (1,3).

In 2008 NIMMS reported 31177 non-natural deaths countrywide (3). Included in this figure, violence was reported as the leading cause of death (3). Categorising this further, the leading external causes of death were sharp object related, followed closely by firearm related injuries (3). These causes made up 13.6% and 10,8% respectively of the total countrywide non-natural mortalities (3).

In Gauteng alone there were 10502 non-natural deaths reported in 2011 of which violence accounted for 30.5% of these deaths (4). Again, sharp object and firearm related injuries were the leading cause of death (4). Notably, the age group most affected by violent death was 15 – 60 year olds, with the peak age of 20 – 29, supporting global statistics (1,3,4).

Penetrating thoracic trauma is responsible for approximately half of all penetrating traumatic deaths (5). Most penetrating thoracic injures can be managed non-operatively or with minimally invasive techniques such as the insertion of an intercostal drain (ICD), but approximately 10-15% of these patients will require an immediate thoracotomy (5).

**Indications for thoracotomy as stated by Advanced Trauma Life Support (ATLS) ®:** (6)

- Haemodynamic instability after penetrating thoracic trauma (systolic blood pressure <90mmHg, pulse >120bpm, non-responder to volume repletion).
- Initial blood loss of ≥ 1500ml on insertion of an ICD.
- >500ml output within the first hour post insertion of an ICD.
- On-going blood loss – indicated by continuous drainage of > 200ml of blood per hour for four hours.
- Tracheobronchial disruption.
- Cardiac tamponade.
- Air embolism.

The premise of the above indications is based on observations made during the Vietnam War in the early 1970’s (7-9). There are many controversies regarding operative intervention versus observation of patients who have sustained penetrating thoracic trauma. There are a wide variety of indications for emergency thoracotomy over a diverse selection of clinical scenarios (10).

Hard and fast rules for intra-pleural drainage as an indication for thoracotomy is not useful and is felt to be unreliable (11,12).

The definitive treatment of haemorrhagic shock is to stop the bleeding. There is therefore a need for a reliable, accurate, fast, accessible and cost effective method to ascertain the necessity for emergency thoracotomy in isolated penetrating thoracic trauma on admission. Such a method would not only assist in life-saving decision making but would also save time and money. In this study, biomarkers such as lactate and base excess will be used in conjunction with shock index (SI) and systolic blood pressure to predict the need for emergency thoracotomy and triage patients accordingly.

## 2. LITERATURE REVIEW

The relevant literature was reviewed by access to Google scholar, Scopus, PubMed, Clinical Key and the Cochrane Database. Medical Subject Headings (MESH) terms included: Indications, emergency thoracotomy, penetrating thoracic trauma, biomarkers, Lactate, base excess and operative intervention.

The landmark studies upon which current ATLS ® protocols are based were done in the early 1970's and included, most notably, those published by McNamara *et al*. (1970) and Kish *et al.* (1976) (7-9). Their conclusions were based on data analyses and observations made during the Vietnam War (7-9). These studies showed that early performance of an emergency thoracotomy produced a decrease in mortality in the context of penetrating thoracic trauma (7-9). McNamara *et al*. (1970) was the first published work in which the cut off values of >1500ml of blood on insertion of an intercostal drain and 500ml of blood within the first hour were used as indicators of the need for emergency thoracotomy (7,9).

Subsequent studies attempted to validate the indications put forward by these initial studies and from this work the current ATLS ® protocols for the indications for thoracotomy were constructed. The above studies were summarised by Karmy-Jones *et al*. (2001) when the group began a critical appraisal of the current indications for emergency thoracotomy in penetrating thoracic trauma (9). Findings included the conclusions that risk of death increases linearly with total chest haemorrhage after thoracic injury and that mortality is three times higher with an output of >1500ml of blood compared to that of 500ml of blood (9).

Mortality was found to be related to absolute volume of blood loss, emphasising the importance of not being distracted by the concept of monitoring hourly intrapleural drain output (9). The results of the study supported the concept that in the absence of shock or specific diagnosis, increasing blood loss coupled with prolonged delay to operative intervention is associated with an increased morbidity and mortality (9).

In 2002 Demetriades *et al*. looked at the validity of the current indications for emergency thoracotomy (10). Patient selection and controversies regarding indications for operation versus observation were cited as reasons for delayed intervention (10). Volumes of intrapleural drainage quoted as critical points for thoracotomy are not reliable indicators of the magnitude of the effect that the trauma had had on the patient's cardiovascular system (10). The decision to operate should be based on haemodynamic condition rather than unreliable indicators such as intrapleural drainage (10).

Hunt *et al*. (2006) further supported haemodynamic condition as an indication for thoracotomy in 2005 with their review of emergency thoracotomy for thoracic trauma (13). Survival rates correlated directly with the patient's physiological status based on simple vital signs such as systolic blood pressure (SBP) and pulse rate in the pre-hospital and hospital setting (13).

The question of when to perform a thoracotomy was controversial and needed to be clarified due to a wide assortment of indications for emergency thoracotomy over a varied selection of clinical scenarios (13). They were of the opinion that protocols for emergency thoracotomy would result in an improvement in survival rates (13).

Bastos *et al*. (2008) pointed out that there is the potential for rapid decompensation and demise due to unrecognised intrathoracic injury (12). There is significant room for clinical judgement with regards to timing of operative intervention and that blood loss alone measured from an ICD is not an absolute indication for thoracotomy (11, 12).

Clark *et al.* (2011), Beattie *et al.* (2014) and Hunt *et al*. (2006) all highlighted the unreliability of intrapleural ICD output as an indication for emergency thoracotomy, citing the possibility of blocked, kinked, clotted or poorly positioned drains and observer error as reasons (11, 13, 14). In all three studies haemodynamic instability was mentioned as the most reliable indication for the requirement of an emergency thoracotomy (11, 13, 14).

It is clear that intrapleural output, as an indication for thoracotomy is an unreliable parameter. Many authors indicated that the values used i.e., volume of drainage and time lapsed, in current guidelines are arbitrary cut-off points that do not take into account issues such as time lapsed since injury or the patient’s physiological reserve to withstand haemorrhage. It is clear that most authors were of the opinion that haemodynamic instability is a far more reliable indication for emergency.

Approximately 90% of deaths that were attributed to haemorrhage in all types of trauma are potentially survivable (15). Abnormal vital signs are late indicators of shock (15). There is growing interest in the use of lactate, base excess and pH measurements as a means to evaluate, triage and monitor trauma patients and thus eliminating repeated cycles of resuscitation and hypoperfusion which leads to the activation of a systemic inflammatory response and inevitable multi organ failure and death (15).

For patients in septic shock, high initial lactate and poor lactate clearance is a strong predicator of mortality as it is a reliable marker of tissue perfusion, even in the presence of a normal blood pressure (15). The same should theoretically be true during haemorrhagic shock (15).

Biomarkers as indicators of prognosis, although recently garnering interest, was first proposed in a published work by Weil *et al*. in 1970 (16). This early study showed lactate to be a reliable indicator of cumulative oxygen debt and a good prognosticator of survival during shocked states (16).

Multiple studies have been carried out between 2010 and 2015 with regards to the use of biomarkers such as lactate and base excess as a predictive tool for identifying high-risk trauma patients. Of importance are those published by Caputo *et al.* in three separate studies in 2013,2014 and 2015, Choi *et al.* (2012), Guyette *et al.* (2015), Remick *et al*. (2012) and Kruse *et al.* (2011) (17-23). All of the above studies agreed that the current methods of relying on vital signs (SBP and pulse) to diagnose shock are grossly inadequate and that missed occult shock in patients with normal vital signs leads to avoidable mortalities (17-23). Lactate was found to be superior in predicating mortality when compared to vital signs and even a single lactate measurement was able to predict adverse outcome (17-23).

Much of the literature surrounding the use of biomarkers in trauma focuses on their use to predict non-discriminatory end points such as death, admission to ICU or the need for massive transfusion (20, 22, 24-28).

Recently, there has been more of an interest in the use of biomarkers such as lactate and base excess as triage tools able to diagnose occult shock in trauma patients (15, 17, 23, 29, 30). A few such as Caputo *et al*. (2013,2014) in two separate studies and Remick *et al*. (2012) have pointed out that by triaging trauma patients correctly with the help of biomarkers allows for definitive management strategies such as more rapid operative intervention to be foreseen and implemented (17, 18, 19, 20).

Considering that, one needs to take into account that the predicative value of biomarkers such as base excess and lactate may be influenced by other factors, i.e. alcohol intoxication, liver disease, strenuous exercise and certain antiretroviral drugs (31). Multiple articles have focused on the fact that alcohol skews the relationship between lactate, base deficit and outcome in intoxicated trauma patients, resetting the threshold of values considered to be of significance. Despite these limitations, these studies concluded that base excess and lactate were still reliable indicators of major injury and that alcohol did not eliminate their prognostic value (32-35).

Absolute levels of serum lactate are not currently indicators for urgent surgery. It is proposed that the use of biomarkers (lactate and base deficit) will assist in deciding whether a patient requires an emergency thoracotomy or not. Their predictive value may be improved even further by coupling them with parameters that consider the biological state of the injured patient, i.e. systolic blood pressure and shock index (SI).

The traditional cut off value for systolic blood pressure of <90 mmHg notates the level at which life threatening haemorrhagic shock is present, these values indicate mortality rates of 40% or more. In fact Seamon *et al*. (2010) reported that a single, isolated hypotensive blood pressure measurement of <105 mmHg was associated with severe injuries and could predict the need for immediate operative intervention and intensive care admission in trauma patients (36).

Shock index is defined as heart rate divided by systolic blood pressure. It is an accurate diagnostic measure that is more useful than hypotension and tachycardia in isolation and is valuable in predicting critical bleeding which leads to post traumatic haemorrhagic shock (37). It is a readily available tool and can easily be implemented not only on arrival in the emergency unit but during pre-hospital assessment as well (37).

In summary, patients presenting with major intrathoracic haemorrhage after penetrating injury may be at a disadvantage when urgent life-saving surgery is delayed by relying on inaccurate parameters during the decision making process that leads to operative intervention. It is therefore proposed that well-known and commonly used parameters of shock/major haemorrhage available almost immediately on presentation in the emergency room, may more accurately predict the need for emergency thoracotomy.

# 3. AIM

To prove that commonly used parameters such as base excess, lactate, SI and systolic blood pressure are able to predict the need for emergency thoracotomy in penetrating thoracic trauma.

# 4. STUDY OBJECTIVES

## 4.1 Primary objectives

To investigate whether early decision making using Biomarkers, i.e. lactate >4 and base excess < -4, shock index >0.8 and systolic blood pressure <90mmHg decreases time to operative intervention and improves the predictive rate for urgent operative intervention in patients with isolated penetrating chest trauma and major intra-thoracic haemorrhage, compared to the traditional parameters listed in the current ATLS guidelines.

## 4.2 Secondary objectives:

To ascertain whether such decision-making may obviate the need for time consuming investigations such as contrast CT scans.

# 5. METHODOLOGY

**5.1. Design**: Quantitative retrospective analysis of a prospectively collected database in the form of a trauma registry.

**5.2. Site of study**: Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). Trauma Unit.

**5.3. Study population**: All patients presenting to the CMJAH Trauma Unit from January 2007 to June 2010 with isolated penetrating thoracic trauma (This sample size may be expanded upon as noted in 5.4). The study population will be divided into those subjected to emergency thoracotomy after penetrating thoracic trauma and those not subjected to emergency thoracotomy after significant penetrating thoracic trauma. (Abbreviated injury scale [AIS] > 2)

**5.4. Sampling**: A database collected by D Surridge from the trauma registry at CMJAH encompassing data from January 2007 to June 2010 will be used with permission. This database will be expanded upon from the trauma registry kept by the trauma unit at CMJAH. A sample size of 235 patients, of which 160 are already available, will be needed for a confidence level of 95% and a 5% margin of error.

**5.5. Inclusion criteria:** All patients with isolated penetrating thoracic trauma (including those who die before and after intervention) and minor non-abdominal injuries will qualify for inclusion within the study. Minor defined as AIS ≤ 2.

**5.6. Exclusion criteria:** Incomplete data, thoraco-abdominal injuries, air embolism, tracheobronchial injuries, cardiac tamponade and minor isolated thoracic injuries (AIS 1-2).

**5.7. Data Collection:** Excel Database as noted above in 5.4 containing the following variables.

| | |
|---|---|
| Date of presentation to the Trauma Unit | Trauma registry number |
| Hospital number | Sex and age |
| Type of injury sustained (Stab, Gunshot, bottle) | Vital signs on scene – SBP, Pulse, GCS, Respiratory rate, revised trauma score |
| Vital signs and GCS on arrival in the trauma Unit - SBP, Pulse, GCS, Respiratory rate, Revised trauma score | Blood gas analysis (including base excess and lactate) on arrival in Casualty |
| AIS and injury severity score | Volume of colloid, crystalloid, blood products And inotropic support requirements |
| Intercostal drain insertion (Yes/no) | Findings of and time to special investigations (CXR, FAST, CT) e.g. occult haemothorax |
| Operative intervention<br>• Nil<br>• Suturing<br>• Thoracotomy | Outcomes:<br>• Survival/death at 30 days<br>• ICU days<br>• Ventilated days |

## 6. Data Analysis

Multiple discriminant analysis and logistic regression will be applied to the collected data. These techniques are appropriate when the dependant variables are non-metric and the independent variables are metric in nature. Sensitivity, specificity and negative predictive value will also be assessed. The help of a statistician will be required.

## 7. Ethics

Ethics approval will be sought from the University of the Witwatersrand Human Research Ethics Committee (HERC)

## 8. Timeline

**Table 1: Study timeline**

| PROCESS | JAN | FEB | MAR | APR | MAY | JUN | JUL | AUG | SEP | OCT |
|---|---|---|---|---|---|---|---|---|---|---|
| Preparing protocol | x | x | x | | | | | | | |
| Protocol deadline | | | 16/03/16 | | | | | | | |
| Protocol assessment | | | | 13/04/16 | | | | | | |
| Ethics application | | | 31/03/16 | | | | | | | |
| Collecting data | | | | | Research block | | | | | |
| Data analysis | | | | | | | x | x | x | |
| Write up - report | | | | | | | | x | x | |
| Report submission | | | | | | | | | | x |
| Write up - paper | | | | | | | | | | x |

## 9. Cost

No expected costs for the University or Hospital.

## 10. LIMITATIONS:

Retrospective study i.e. others are relied upon for accurate record keeping. The potential for bias is higher with retrospective studies. Selection bias will be avoided by using a clearly defined study population that are at risk of requiring an emergency thoracotomy, i.e. patients presenting with penetrating thoracic trauma.

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**Data Sheet:**

# DATA COLLECTION SHEET

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| DATE | | | STUDY NUMBER | | | | | |
| | | | SEX | M | F | AGE | | |
| TYPE OF INJURY | GSW | STAB | BOTTLE | OTHER | SPECIFY | | | |
| VITAL SIGNS | SCENE | | | | | | | |
| | | GCS | SBP | HR | RR | SHOCK INDEX | | |
| | 163 | | | | | | | |
| SCENE | | | | | | | | |
| | RTS | ISS | AIS | TRISS | | | | |
| 163 | | | | | | | | |
| BLOOD GAS 1 | PH | | LACT | | BE | | | |
| BLOOD GAS 2 | PH | | LACT | | BE | | | |
| CRYSTALOID | Y | N | COLLOID | Y | N | BLOOD PRODUCTS | Y | N |
| VOLUME | | VOLUME | | RCC | | FFP | | PLT |
| INOTROPES | Y | N | TYPE | | NO. OF DAYS | | | |
| ICD | Y | N | OPERATIVE INTERVENTION | Y | N | SPECIFY: | | |
| IF THOROCOTOMY DONE: | <2HRS | 2-4HRS | 4-6HRS | >6HRS | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| SPECIAL INVESTIGATIONS | CXR | Y | N | FAST | Y | N | CT | Y | N |
| FINDINGS | | | | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| MAJOR PRE-MORBID DISEASE | | | | Y | | N | |
| COMPLICATIONS | Y | N | SPECIFY | | | | |
| OUTCOMES | SURVIVAL | Y | N | NO. OF ICU DAYS | | | |
| TPN DAYS | | VENT DAYS | | | RRT DAYS | | |

**Turn it in report:**

By Pascaline Fru
Submission date: 07-Aug-2019 11:45AM (UTC+0200)
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Word count: 3670
Character count: 20373

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## Ethics clearance certificate

R14/49 Dr Megan Lubout

**HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)**

**CLEARANCE CERTIFICATE NO. M160463**

| | |
|---|---|
| **NAME:** (Principal Investigator) | Dr Megan Lubout |
| **DEPARTMENT:** | Surgery<br>Charlotte Maxeke Johannesburg Academic Hospital |
| **PROJECT TITLE:** | Indications for Thoracotomy in Penetrating Thoracic Trauma |
| **DATE CONSIDERED:** | 06/05/2016 |
| **DECISION:** | Approved unconditionally |
| **CONDITIONS:** | |
| **SUPERVISOR:** | Jaqcues Goosen |
| **APPROVED BY:** | Professor P. Cleaton-Jones, Chairperson, HREC (Medical) |
| **DATE OF APPROVAL:** | 04/07/2016 |

**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 10004,10th floor, Senate House/2nd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated,from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. 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 review in April and will therefore be due in the month of April each year.

Principal Investigator Signature ________ Date ________

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