The utility of base deficit and serum lactate as predictors of outcome in patients with intestinal obstruction at Kenyatta National Hospital

DR MURIUKI MEME
THE USE OF BASE DEFICIT AND SERUM LACTATE AS INDICATORS OF OUTCOME IN PATIENTS WITH INTESTINAL OBSTRUCTION AT KENYATTA NATIONAL HOSPITAL

A dissertation submitted in part fulfillment of the requirements for the award of the degree of Master of Medicine (General Surgery) of the University of Nairobi.

By
Dr. Muriuki Meme
MBCh.B (NRB)
H58/64193/2010
DECLARATION
I declare that this dissertation is my original work and has not been presented for the award of any degree at any other institution or university.

Signed………………………….. Date…………………………

Dr. Muriuki Meme
This dissertation has been submitted for examination with my approval as university supervisor.

SUPERVISORS

Dr. Dan Kipkemboi Kiptoon,
MBCh.B, M.MED (Gen Surg.),
Consultant Surgeon/Lecturer,
Department of Surgery,
University of Nairobi.
dkiptoon@gmail.com

Sign………………………………Date……………………………

Dr Daniel Kinyuru Ojuka
MBCh.B, MMED (Gen. Surgery)
Consultant Surgeon/Lecturer,
Department of Surgery,
University of Nairobi.
kinyuruojuka@gmail.com

Sign………………………………Date……………………………
DEPARTMENTAL APPROVAL

This dissertation has been presented at the Department of Surgery meeting and is hereby approved.

Sign........................................Date...........................................

Chairman,
Department of Surgery,
University of Nairobi.
DEDICATION
This work is dedicated to my wife Dr. Susan Adongo-Meme, my parents Dr. Margaret Nyirenda-Meme and the late Prof. Julius S. Meme
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ABSTRACT

Background
Intestinal Obstruction is a key cause of morbidity and mortality among all age groups. Diagnosis and treatment of intestinal obstruction is key in preventing adverse outcomes. Metabolic derangements as well as intestinal ischemia are common complications of intestinal obstruction. Base Deficit and serum lactate are markers of inadequate perfusion status. They have also been used to predict complications and mortality especially in trauma patients.

Objective
To assess utility of initial base deficit and serum lactate as predictive indicators of adverse outcomes in intestinal obstruction.

Methodology
This was a prospective descriptive study evaluating 54 patients, carried out in the general and paediatric surgical units, Kenyatta National Hospital, Nairobi Kenya. Consecutive patients aged 1 month and above, presenting with intestinal obstruction to the Kenyatta Nation Hospital Accident & Emergency (A&E) department were recruited. The patients’ demographic and clinical data were obtained using a structured questionnaire. Initial arterial blood gas and serum lactate results were compared against patient outcomes. Data was analysed using a level of significance P<0.05

Results
The average age of the patients was 27 (SD=23) years, with 74% of them being males. The most common presentations were abdominal distension (87%), vomiting (79.6%), constipation (44%) and pain (37%). The most common cause of intestinal obstruction were instususception (31.5%) and adhesions due to previous surgery (24%). Mortality was (16.7%) while morbidity was (12.9%). The prevalence of derangements of base deficit was 64.8% and of serum lactate 27.8% on admission. There was no significant relationship (P = 0.633) between base deficit and adverse outcome nor was there any statistical significance (P = 0.072) between serum lactate and adverse outcome in intestinal obstruction. There was no correlation between the initial base deficit, initial serum lactate levels and adverse outcome in patients with intestinal obstruction.

Conclusion
The initial base deficit and serum lactate levels did not have a bearing on the probability of developing adverse outcomes in patients admitted with a diagnosis of intestinal obstruction.
INTRODUCTION

Intestinal obstruction is a surgical emergency that accounts for approximately 8% of non-traumatic acute abdominal admissions to a surgical unit. Obstruction occurs when there is interruption in the normal flow of bowel contents and can be classified broadly as dynamic (mechanical) or adynamic (functional) which can be acute or chronic. Further classification systems of IO depend on the site/level, nature of obstruction and the duration of onset. Mechanical intestinal obstruction is a surgical emergency with comparatively high morbidity and mortality rates. The causes of IO vary significantly depending on geographical location.

Adhesions are the main cause of IO, it is frequently difficult to differentiate simple obstruction from strangulation. Sarr found that experienced clinicians were wrong over 50% of the time for preoperative diagnoses of no strangulation. Thus early recognition of intestinal strangulation is important to make a decision on the need for emergency surgery or non-surgical management. This ensures that health workers can make a timely decision on the need for surgical intervention to avoid mortality and ensure proper management of patients.

Metabolic derangements as well as intestinal ischemia are common complications of intestinal obstruction. In the event of excessive bowel dilation or strangulation, intestinal perfusion may be compromised leading to necrosis or perforation. Pathophysiological changes that occur during tissue hypoxia trigger other harmful effects that result in a poor outcome for the patient. The two most common markers in assessing resuscitation are base deficit (BD) and serum lactate. BD and serum lactate are markers of tissue hypoxia due to poor perfusion as they guide in resuscitative measures and predict outcomes. A notable base deficit has been a marker of mortality in many studies and elevated initial and 24-hour lactate levels have been shown to be significantly correlated with mortality.
LITERATURE REVIEW

Definition
Base Deficit is the amount of base (in mmol) needed to titrate a litre of whole arterial blood to the normal pH of 7.40 at partial pressure of carbon dioxide (PaCO₂) of 40 mmHg¹¹.

Metabolic acidosis is a low arterial pH (normal range 7.35-7.45) and a low serum bicarbonate concentration (normal range 22-28 meq/L).

Epidemiology
A study in Saudi Arabia found that intestinal obstruction accounted for at least 8% of non-traumatic acute abdominal admissions to a surgical unit¹. In Kenyatta National Hospital it accounts for 6.9% of admissions to the surgical unit¹⁴.

The main underlying cause of acute bowel obstruction in developed countries is postoperative adhesions accounting for approximately 60% of IO cases¹⁵,¹⁶.

In Africa and developing countries data on IO mortality rate is sparse or not documented, however studies have shown the mortality rate to range from 4.5% to 20%¹⁷,¹⁸.

A study by G.G. Musila in Kenyatta National Hospital found an overall mortality rate of 17.7%⁷. He also found that small bowel obstruction accounted for 65% of mechanical obstruction and large bowel obstruction accounted for 25%.

The commonest cause of small bowel obstruction was adhesions accounting for 36.7% followed by hernias at 20.7%⁷. Pankaj G. Jani found volvulus to be the commonest cause of intestinal obstruction in the elderly male¹⁹.

The most common complications were found to be dehydration at 15.4% and bowel gangrene 10.7%⁷.

Pathophysiology
Progressive dilation of the intestine proximal to the site of blockage occurs, while distal to the blockage the bowel decompresses as luminal contents pass²⁰. Initially, the proximal dilated bowel is characterized by increased peristalsis due to stretch receptor stimulation leading to severe colicky abdominal pain²¹. The pain is mainly due to delta fibres and non-localised in nature²². This reflex activity diminishes until a total inhibition of intestinal motility ensues that has a protective action in preventing vascular damage from raised intraluminal pressure²¹. This occurs several hours from the time of onset of the obstruction.

The distension proximal to an obstruction is caused by two factors²¹:-

- Gas:- Proliferation of both aerobic and anaerobic organisms results in gas production mainly of nitrogen and hydrogen sulphide
- Fluid:- During obstruction, fluid builds up in the bowel wall and any excess is secreted into the lumen, whilst absorption from the gut is reduced

As much as 7-8 litres of fluid may be lost in intestinal obstruction due to sequestration and vomiting leading to dehydration and hypovolemia.
**Base deficit**

The normal reference range of base excess/deficit is between 2 and -2 mmol/L. A value lower than -2mmol/L is considered as base deficit. Base deficit (BD) as a marker of severity of injury is based on the fact that reduction in blood volume (via secretion of fluid into the lumen) and hypo-perfusion, result in diminished oxygen delivery hence the onset of anaerobic metabolism\(^{23}\). The resultant anaerobic respiration results in the accumulation of lactic acid creating a base deficit inorder to normalise the PH\(^{24}\). Base deficit has been found to correlate with the length of gangrenous bowel\(^{25}\) as it is an accurate measure of both the degree and the duration of inadequate perfusion\(^{26}\).

Base deficit has been a marker of mortality in a number of studies\(^{27,28}\). In some busy emergency centres may necessitate that certain hemodynamically stable patients experience some delay between diagnosis of injury and surgery. A study of patients that sustained trauma jkkh without head injury found that a base deficit of -8mmol/L was associated with 25% mortality in patients younger than 55 years\(^{26}\). In 1988, 209 trauma patients were studied and the degree of shock was categorised based on the initial BD: mild shock (-2 to -5mmol/L), moderate shock (-6 to -14mmol/L) and severe shock (> -15mmol/L). They found that initial base deficit was a useful guide in volume resuscitation of hypovolemic patients\(^{29}\). Base deficit stratification has been found to be superior to the current Advanced Trauma and Life Support classification of hypoperfusion in determining the presence of hypovolemic shock and in risk stratifying patients in need of early intervention\(^{30}\).

<table>
<thead>
<tr>
<th>Class 1</th>
<th>Class 2</th>
<th>Class 3</th>
<th>Class 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shock degree</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>Initial Base Deficit</td>
<td>≤ 2mmol/l</td>
<td>2-6mmol/l</td>
<td>6-10mmol/l</td>
</tr>
</tbody>
</table>

Factors that may confound the use of the BD in estimating hypo-perfusion are the administration of bicarbonate, hypothermia, heparin, alcohol and ketoacidosis. However, base deficit remains one of the most widely used tool in estimating oxygen debt because of its clinical relevance, accuracy, and availability\(^{31}\).

**Lactic acidosis**

Normal plasma lactate concentration range is 0.5 to 1.5 meq/L. Lactic acidosis is considered present if the plasma lactate level exceeds 4 to 5 meq/L. In excessive bowel dilation, vessels in the bowel wall become compromised and intraluminal perfusion is reduced\(^{32}\). Venous return is compromised prior to the arterial supply. Once arterial supply is impaired, hemorrhagic infarction occurs resulting to compromise of bowel wall viability and perforation\(^{33}\). A study in Uganda found that Serum lactate assay had a specificity of 53% and sensitivity of 66% for bowel ischemia in general and a higher specificity of 80% and sensitivity of 71% for irreversible bowel ischemia\(^{34}\). Lange and Jackel found that serum
lactate had a specificity of 42% and sensitivity of 100% as a marker of mesenteric ischaemia.\textsuperscript{35}

A retrospective study conducted on patients admitted to the Emergency Department (ED) with gastrointestinal trauma found that venous lactate drawn as part of initial laboratory studies was predictive of mortality and a lactate greater than 4 meq/L conferred a 6.4-fold increased odds of in-hospital mortality (94% specificity, $P < .001$).\textsuperscript{36}

**Type A lactic acidosis**

This is because of marked tissue hypoperfusion in shock (hypovolemia, sepsis or cardiac failure).\textsuperscript{37}

Due to reduced blood supply, anaerobic metabolism by intestinal enterocytes and myocytes leads to the formation of lactic acid via the conversion of pyruvate to lactate by lactate dehydrogenase,\textsuperscript{38} this reaction is catalyzed by lactate dehydrogenase and involves conversion of reduced nicotine adenine dinucleotide to oxidized nicotine adenine dinucleotide (NADH into NAD+, respectively).

15 to 20mmol/kg of lactic acid is produced daily via the glycolytic pathway or the deamination of alanine.\textsuperscript{39} Lactic acid is rapidly buffered by bicarbonate generating lactate. In the liver and kidney, lactate is metabolized back to pyruvate which is then converted to either carbon dioxide and water or glucose.

Lactate accumulation can be due to increased production or diminished lactate utilization.\textsuperscript{40} Three mechanisms can underlie excess lactate:

- Increased pyruvate production
- Retarded pyruvate conversion to carbon dioxide and water or to glucose
- Altered redox state within the cell in which pyruvate is converted to lactate

**Type B lactic acidosis**

Findings of systemic hypoperfusion are not apparent. This is seen in malignancy, diabetes mellitus and metformin, HIV infection, alcoholism.

The mechanisms involved are:

- Regional ischemia
- Toxin induced impairment of cellular metabolism

**History and clinical examination**

The most common symptoms are vomiting, abdominal distension, inability to pass flatus and colicky abdominal pain. Patients may or may not complain of obstipation since it takes 12 to 24 hours for the colon to empty after the onset of bowel obstruction.\textsuperscript{41,33} Patients who have undergone resection of the large bowel or other pelvic/abdominal surgery are prone to becoming obstructed.\textsuperscript{42,43}

Inspection should reveal degree of distension and presence of surgical scars. Auscultation may reveal high pitched or low-pitched bowel sounds. Upon light percussion, tenderness, guarding suggests the presence of peritonitis. Tympany is present due to air
filled loops of bowel. An abdominal mass may indicate tumor, volvulus or abscess. Rectal examination may reveal an empty rectal vault, a rectal mass which can be the cause of obstruction, blood may be found with intestinal neoplasm, ischemia and intussusception.

Management of intestinal obstruction
Intestinal decompression by nasogastric suction, intravenous replacement and maintenance of fluid and electrolyte balance are essential components of a management of all cases of intestinal obstruction.

Resuscitation
This is guided by Blood pressure, pulse rate, hourly urine output, hematocrit, Serum electrolytes, central venous pressure and serum lactate dehydrogenase and base deficit.

Non operative
This supportive treatment is essential and may suffice alone in some cases like partial adhesive bowel obstruction. This includes:

- intravenous fluids
- nasogastric suction
- intestinal rest

This type of management should be attempted for only 3-5 days.

Although appropriate management of adhesive obstruction is controversial, a substantial number of patients ranging from 30% to 70%, can safely be treated non-operatively. Non-operative management requires that bowel strangulation be ruled out. Patients with strangulated obstruction have a higher mortality rate than patients with simple obstruction relieved in 24 hours.

Operative
Surgical treatment is offered to patients with continuous abdominal pain, fever, tachycardia, leukocytosis, metabolic acidosis, complete obstruction, peritonitis or those who develop these signs and symptoms during the course of non-operative treatment.

The aims of surgical treatment are:

- Decompress obstructed bowel
- Correct the cause
- Maintain intestinal continuity

A critical point of surgical treatment is the assessment of bowel viability to decide on the need for intestinal resection. A useful approach involves wrapping questionably viable bowel in warm saline-soaked gauze for about 15 minutes. Return on motility, normal color and mesenteric pulses indicates bowel viability. An alternative method involves IV injection of fluorescein with subsequent illumination of bowel with fluorescent light, patchy fluorescence or non-fluorescence indicates non-viable bowel.
Bowel anastomosis is done once the intestines are found viable, tension free, and devoid of peritoneal soiling. Otherwise stoma formation of the bowel ends is a safer option.

**Adverse outcomes**

Unless managed promptly, high morbidity and mortality is associated with intestinal obstruction.

Adverse outcomes include:

- dehydration,
- electrolyte imbalance,
- bowel gangrene,
- peritonitis,
- sepsis
- death.

In busy hospital emergency departments limited operating rooms may necessitate delay in haemodynamicaly stable patients between diagnosis and surgery. Studies have shown the usefulness of using Base Deficit and Serum Lactate to identify those patients who have the most severe injuries or who are at greatest risk for haemodynamic instability

**JUSTIFICATION OF THE STUDY**

Mechanical intestinal obstruction is a surgical emergency with comparatively high mortality rates of 17.7%

Studies have demonstrated the use of base deficit and serum lactate as indicators of severity of metabolic derangements, tissue hypoxia and in the prediction of outcome in critically ill patients.

Determination of these parameters can be used as rapid and accurate methods in assessment of outcome and they could serve as additional diagnostic tools to improve clinical decision-making. There are no local studies to evaluate the outcome predictive value of the two parameters in patients with intestinal obstruction.

This study sought to demonstrate the use of serum lactate and base deficit levels as indicators of severity of morbidity in patients with mechanical intestinal obstruction.

**STUDY QUESTION**

Can base deficit and serum lactate be used to predict outcomes of patients with intestinal obstruction in KNH
NULL HYPOTHESIS
Base deficit and serum lactate levels are not associated with the outcome of intestinal obstruction.

OBJECTIVES OF THE STUDY

Broad objective
To determine the utility of initial base deficit and serum lactate in predicting outcome of patients with intestinal obstruction in KNH

Specific Objectives
1. Determine the prevalence of base deficit and serum lactate derangements on admission in patients with intestinal obstruction
2. Determine the relation between base deficit and adverse outcome in intestinal obstruction
3. Determine the relation between serum lactate and adverse outcome in intestinal obstruction

MATERIALS AND METHODS

Setting: The study was carried out in the A&E, surgical operating rooms and the surgical Wards at KNH

Study population: Patients who were 1 month old and above, admitted to the paediatric and general surgical wards diagnosed with intestinal obstruction will be recruited into the study. Informed consent was sought from the recruited patients or their next of kin.

Duration of the Study: Five months (5)

Study Design: A Prospective observational Study

Sampling Method and Sample size Determination:
The sample size was calculated using the Cochran formula given by:

\[ n_0 = \frac{Z^2pq}{e^2} \]

Where
\[ n_0 \] is the initial sample size
\[ p \] is the expected proportion (In KNH, mortality due to intestinal obstruction accounts for 17.7% )
\[ q \] is 1 – \[ p \]
\[ e \] is the level of precision (5% for this study)
\[ Z \] is the abscissa of the normal distribution under level of precision (1.96)
Therefore the initial sample size will be:

\[ n_0 = \frac{1.96^2 \times 0.177 \times (1-0.177)}{0.05^2} = 224 \]

On average there are approximately 150 cases of intestinal obstruction at KNH per annum. Therefore during the study period (5 months) there would be approximately 63 such cases. Since the total population is finite and less than 10000, the final sample size was obtained by using the finite population correction factor given by

\[ n = \frac{n_0}{1 + \frac{n_0 - 1}{N}} \]

Where

- \( n_0 \) is the initial sample size
- \( n \) is the final sample size
- \( N \) is the total population

\[ n = \frac{224}{1 + \frac{224 - 1}{63}} = 50 \]

Thus for the purpose of this study the researcher utilized 5 cases inclusive of 10% attrition.

During the study period, a consecutive list of patients presenting features of intestinal obstruction will be maintained from which it will form the study sampling frame on a rolling basis. Systematic sampling will be used to sample respondents whereby every second patient in the consecutive sampling frame will be recruited to participate on the study on consent.

**Inclusion Criteria**

Patients who presented with features of intestinal obstruction (based on history and physical signs) were 1 month and above and gave informed consent (or from next of kin for patients unable to consent).

**Exclusion Criteria**

Patients who declined to give consent

Patients with diabetic ketoacidosis (history of diabetes and random blood sugar)

Renal failure (history of renal disease and renal function test)

Hepatic failure (history of liver disease and liver function test)

Patients with intestinal congenital malformation

**Data Collection:**

A research assistant (Clinical Officer who have successfully completed their rotations in Surgery) was employed to assist in data collection in pre-designed questionnaires.
Patients who had intestinal obstruction were recruited after informed consent. Demographic information (age, sex) was collected for enrolled patients as well as medical histories and clinical data: blood pressure, pulse rate, presence or absence of signs of peritonitis.

**Quality assurance:**
Serum lactate and arterial blood samples were taken for all patients suspected to have intestinal obstruction upon admission to A&E in the following manner:

**Pre-analytical**
- Serum lactate and blood gas analysis was ordered via request form
- An arterial blood sample was collected from either the radial or femoral artery
- A heparinised syringe was labeled with the patients identification
- The sample was obtained using a needle and syringe to puncture the artery. The syringe was pre-heparinized and handled to minimize air exposure that would alter the blood gas values
- 1-2ml of arterial blood was collected
- A safety syringe with a needle cover that allows the syringe to be capped before transport, without manually recapping was used
- The puncture site was bandaged after collection
- A container with crushed ice was used for transportation of the sample to the laboratory

**Analytical**
- samples were sent for blood gas analysis using the blood gas analyzer (Siemens RapidPoint 500) in the ICU laboratory at KNH.

**Post-analytical**
- The results were printed from the RapidPoint 500 printer
- Results were attached to the investigation request form
- Data was entered into the questionnaire

**Data Analysis:**
Data was recorded in MS Excel (version 2013) data sheets that were protected from access by unauthorized persons. Hard copy back-up copies were securely locked. The dependent variable was serum lactate and base deficit. Subdivision of data was according to age, sex, presence/absence of peritonitis, presence or absence of fever,.. Laboratory levels were given as mean values followed by the 95 percent confidence interval. Correlations between outcome of intestinal obstruction and levels of base deficit/serum lactate were computed using two sample t-test or Mann Whitney U test . All results were reported with 95% confidence interval. p-values less than 0.05 were considered statistically significant. Statistical analysis was performed using SPSS (version 20) software
ETHICAL CONSIDERATIONS

- Ethical approval was sought from:
  - The University of Nairobi, Department of Surgery and the
  - KNH-UON Ethics and Research Committee.
- Informed consent was obtained by the principle investigator from all the participants or their guardians before being enrolled into the study. Participants did not incur any extra costs and were free to withdraw from the study at any time. The information collected was treated with utmost confidentiality and no patient names was included in the questionnaire or any publications arising from the study.
- Findings from this study will be disseminated to the stakeholders and shared with the hospital staff in form of Continuous Medical Education.
STUDY TIME FRAME

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BUDGET

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<td>30,000</td>
</tr>
<tr>
<td>Stationery</td>
<td>15,000</td>
</tr>
<tr>
<td>Contingencies</td>
<td>20,000</td>
</tr>
<tr>
<td>Research fee</td>
<td>2,500</td>
</tr>
<tr>
<td>Research assistant</td>
<td>30,000</td>
</tr>
<tr>
<td>Printing and binding</td>
<td>15,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>112,500</strong></td>
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The study was funded by the principal investigator.
RESULTS
The aim of this study was to determine the utility of initial base deficit and serum lactate in predicting outcome of patients with intestinal obstruction in KNH. The study cohort consisted of 54 patients.

Age
The mean age of the patients was 27 (±23) within the range of 0.3 to 82 years as shown in Figure 1 below.

Figure 1. Age distribution
Sex

There were 40 (74%) male patients and 14 (26%) female patients giving a male to female ratio of 3:1.

Figure 2. Male to Female Ratio

Table 1. Symptoms

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Count</th>
<th>Percent (N=54)</th>
<th>Percent (N=153)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal distension</td>
<td>47</td>
<td>87.0%</td>
<td>30.7%</td>
</tr>
<tr>
<td>Nausea/ vomiting</td>
<td>43</td>
<td>79.6%</td>
<td>28.1%</td>
</tr>
<tr>
<td>Constipation</td>
<td>24</td>
<td>44.4%</td>
<td>15.7%</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>20</td>
<td>37.0%</td>
<td>13.1%</td>
</tr>
<tr>
<td>Bloody stool</td>
<td>14</td>
<td>25.9%</td>
<td>9.2%</td>
</tr>
<tr>
<td>Mucoid stool</td>
<td>3</td>
<td>5.6%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Back pain</td>
<td>1</td>
<td>1.9%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Breathing difficulty</td>
<td>1</td>
<td>1.9%</td>
<td>0.7%</td>
</tr>
</tbody>
</table>
Majority (29.6%) had previous abdominal surgery. More information on relevant past medical history is as shown in Table 2.

**Table 2. Relevant past medical history**

<table>
<thead>
<tr>
<th>Relevant past medical history</th>
<th>Count</th>
<th>Percent (N=54)</th>
<th>Percent (N=26)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous abdominal surgery</td>
<td>16</td>
<td>29.6%</td>
<td>61.5%</td>
</tr>
<tr>
<td>Neoplasm</td>
<td>3</td>
<td>5.6%</td>
<td>11.5%</td>
</tr>
<tr>
<td>Hernia</td>
<td>4</td>
<td>7.4%</td>
<td>15.4%</td>
</tr>
<tr>
<td>Radiation</td>
<td>1</td>
<td>1.9%</td>
<td>3.8%</td>
</tr>
<tr>
<td>Chest thoracostomy tube</td>
<td>2</td>
<td>3.7%</td>
<td>7.7%</td>
</tr>
</tbody>
</table>

**Physical findings**

Majority patients had abdominal distension (83.3%), bowel sounds diminished (55.6%), tachycardia (51.9%) and dehydration (51.9%). Other physical findings were as indicated in Table 3 below.

**Table 3. Physical findings**

<table>
<thead>
<tr>
<th>Physical findings</th>
<th>Count</th>
<th>Percent (N=54)</th>
<th>Percent (N=212)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal distension</td>
<td>45</td>
<td>83.3%</td>
<td>21.2%</td>
</tr>
<tr>
<td>Bowel sounds diminished</td>
<td>30</td>
<td>55.6%</td>
<td>14.2%</td>
</tr>
<tr>
<td>Tachycardia</td>
<td>28</td>
<td>51.9%</td>
<td>13.2%</td>
</tr>
<tr>
<td>Dehydration</td>
<td>28</td>
<td>51.9%</td>
<td>13.2%</td>
</tr>
<tr>
<td>Abdominal tenderness</td>
<td>26</td>
<td>48.1%</td>
<td>12.3%</td>
</tr>
<tr>
<td>Bowel sounds high pitched</td>
<td>16</td>
<td>29.6%</td>
<td>7.5%</td>
</tr>
<tr>
<td>Fever</td>
<td>11</td>
<td>20.4%</td>
<td>5.2%</td>
</tr>
<tr>
<td>Abdominal scars</td>
<td>9</td>
<td>16.7%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Evidence of hernias</td>
<td>6</td>
<td>11.1%</td>
<td>2.8%</td>
</tr>
<tr>
<td>Abdominal masses</td>
<td>5</td>
<td>9.3%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Visible peristalsis</td>
<td>4</td>
<td>7.4%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Hypotension</td>
<td>3</td>
<td>5.6%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Abdominal CT Scan- Chest Hernia</td>
<td>1</td>
<td>1.9%</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

**Types of obstruction**

Mechanical small bowel was the major type of obstruction and others as indicated in Table 4 below.

**Table 4. Types of obstruction**

<table>
<thead>
<tr>
<th>Type of obstruction</th>
<th>Frequency</th>
<th>Percent (N=54)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical small bowel</td>
<td>40</td>
<td>74%</td>
</tr>
<tr>
<td>Mechanical large bowel</td>
<td>12</td>
<td>22.2%</td>
</tr>
<tr>
<td>Functional bowel obstruction</td>
<td>2</td>
<td>3.7%</td>
</tr>
</tbody>
</table>
**Treatment**

Treatment was mainly operative (74.1%) Table 5 below.

**Table 5. Treatment**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Count</th>
<th>Percent (N=54)</th>
<th>Percent (N=88)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative</td>
<td>40</td>
<td>74.1%</td>
<td>45.5%</td>
</tr>
<tr>
<td>Non-operative</td>
<td>14</td>
<td>25.9%</td>
<td>15.9%</td>
</tr>
</tbody>
</table>

The most common intraoperative diagnosis was intussusception (31.5%), seen mainly in the under five year population. Adhesion bands (24%) was the second most common seen mainly in the adult population >13yrs.

**Table 6. Type of intra-operative diagnosis**

<table>
<thead>
<tr>
<th>Type of intra-operative diagnosis</th>
<th>Frequency</th>
<th>Percent (N=54)</th>
<th>Percent (N=40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intussusception</td>
<td>17</td>
<td>31.5%</td>
<td>51.5%</td>
</tr>
<tr>
<td>Adhesions</td>
<td>13</td>
<td>24%</td>
<td>32.5%</td>
</tr>
<tr>
<td>Sigmoid volvulus</td>
<td>2</td>
<td>3.7%</td>
<td>6.1%</td>
</tr>
<tr>
<td>Small bowel perforation</td>
<td>2</td>
<td>3.7%</td>
<td>6.1%</td>
</tr>
<tr>
<td>Strangulated hernia</td>
<td>2</td>
<td>3.7%</td>
<td>6.1%</td>
</tr>
<tr>
<td>Diaphragmatic hernia</td>
<td>1</td>
<td>1.9%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Large bowel tumour</td>
<td>1</td>
<td>1.9%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Gastric cancer</td>
<td>1</td>
<td>1.9%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Obstructed inguinal hernia</td>
<td>1</td>
<td>1.9%</td>
<td>3.0%</td>
</tr>
</tbody>
</table>

**Outcome**

The main outcome was recovery (66.7%).

**Table 7. Outcome**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Frequency</th>
<th>Percent (N=54)</th>
<th>Percent (N=52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recovery</td>
<td>36</td>
<td>66.7%</td>
<td>69.2%</td>
</tr>
<tr>
<td>Death</td>
<td>9</td>
<td>16.7%</td>
<td>17.3%</td>
</tr>
<tr>
<td>Recovery after complications</td>
<td>7</td>
<td>13.0%</td>
<td>13.5%</td>
</tr>
</tbody>
</table>

**Complication**

Death was the most common complication (16.7%)

**Table 8 Complication**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Frequency</th>
<th>Percent (N=54)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>9</td>
<td>16.7%</td>
</tr>
<tr>
<td>Wound sepsis</td>
<td>3</td>
<td>5.5%</td>
</tr>
<tr>
<td>Peritonitis</td>
<td>2</td>
<td>3.7%</td>
</tr>
<tr>
<td>Bowel ischaemia</td>
<td>2</td>
<td>3.7%</td>
</tr>
</tbody>
</table>
Mortality vs duration of symptoms
This shows a significant association between duration of symptoms and mortality. There is an increase in mortality rate compared to increase in duration of symptoms.

Table 9 Mortality vs duration of symptoms

<table>
<thead>
<tr>
<th>Days of symptoms</th>
<th>Mortality</th>
<th>No mortality</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2</td>
<td>20(100%)</td>
<td></td>
<td>20</td>
</tr>
<tr>
<td>3-4</td>
<td>4(33%)</td>
<td>12(67%)</td>
<td>16</td>
</tr>
<tr>
<td>&gt;5</td>
<td>5(38%)</td>
<td>13(62%)</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>45</td>
<td>54</td>
</tr>
</tbody>
</table>

Hospital stay
Majority of patients (55.5%) were discharged within 7 days in Table 10 below.

Table 10 Hospital stay

<table>
<thead>
<tr>
<th>DAYS</th>
<th>NUMBER(n=54)</th>
<th>PERCENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-7</td>
<td>30</td>
<td>55.5</td>
</tr>
<tr>
<td>8-14</td>
<td>21</td>
<td>38.8</td>
</tr>
<tr>
<td>15-21</td>
<td>5</td>
<td>9.2</td>
</tr>
<tr>
<td>&gt;21</td>
<td>8</td>
<td>14.8</td>
</tr>
</tbody>
</table>

The mean duration of hospital stay was 13.4 (±16.1) days within the range of 2 to 86 days as shown in Figure 7 below.
Distribution of Base deficit and Serum lactate

Base deficit had a mean of -4.406(±6.78) and distributed as indicated below in Figure 3.

![Distribution of Base deficit](image)

Serum lactate had a mean of 1.86(±1.033) and distributed as indicated below in Figure 5.

![Distribution of Serum lactate](image)
Figure 5. Distribution of Serum lactate

Prevalence
The prevalence of derangements of base deficit was 64.8% and of serum lactate 27.8% on admission in patients with intestinal obstruction.

Relationship
Base deficit
There was no significant relationship (p-value=0.633) between base deficit and adverse outcome in intestinal obstruction. There was no difference between the means of patients with and without adverse outcomes, -8.438 and -7.314 respectively as indicated by box plot in Figure 6 below.
Figure 6. Base deficit by occurrence of adverse effects

Odds ratio between base deficit and occurrence of adverse effects was 0.225 however not significant (p-value=0.178).

Table 8 gives more details.

Table 8. Base deficit by occurrence of adverse effects

<table>
<thead>
<tr>
<th>Base deficit</th>
<th>Presence of adverse outcome</th>
<th>Total</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Absent</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>Deranged</td>
<td>27</td>
<td>15</td>
<td>42</td>
</tr>
<tr>
<td>Normal</td>
<td>8</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Total</td>
<td>35</td>
<td>16</td>
<td>51</td>
</tr>
</tbody>
</table>

Serum lactate

There was no significant relationship (Mann-Whitney U test p-value=0.072) between serum lactate and adverse outcome in intestinal obstruction. There was no difference between the means of patients with and without adverse outcomes, 3.49 and 2.76 respectively as indicated by box plot in Figure 7 below.
Odds ratio between Serum lactate and occurrence of adverse effects was 0.25 and significant (p-value=0.034). This implied that those with deranged serum lactate were 0.75 times more likely to have adverse effects as compared to those with normal. Table 9 gives more details.

**Table 9. Serum lactate by occurrence of adverse effects**

<table>
<thead>
<tr>
<th>Serum lactate</th>
<th>Presence of adverse outcome</th>
<th>Total</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Absent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deranged</td>
<td>7</td>
<td>8</td>
<td>15</td>
</tr>
<tr>
<td>Normal</td>
<td>28</td>
<td>8</td>
<td>36</td>
</tr>
<tr>
<td>Total</td>
<td>35</td>
<td>16</td>
<td>51</td>
</tr>
</tbody>
</table>
DISCUSSION
Intestinal obstruction remains a frequently encountered problem in abdominal surgery and a common surgical emergency, contributing to admissions to hospital emergency surgical departments. This study attempts to determine the utility of initial base deficit and serum lactate in predicting outcome of patients with intestinal obstruction.

The mean age of the patients was 27 (±23) within the range of 0.3 to 82 years. Compared to the 7th decade in Greece. Ashad Malik found a mean age of 43 (13), though in his study the age range was 13-74 years.

In this study, 40(74%) patients were male while 14(26%) were female with a male to female ratio of 3:1. This compares to a local study where the ratio was 3:1. Another study looking at 229 patients found 74% were males and 26% were females.

The most common symptoms included abdominal distension (87%) and nausea/vomiting (79.6%) constipation (44%). Perea et al studied patients with adhesive small bowel obstruction and found that the presenting symptoms were vomiting (77%), colicky abdominal pain (68%), absence of passage of flatus and/or feces (52%).

Majority of the cases had had previous abdominal surgery (29.6%). This is comparable to Feval et al who noted that patients with previous abdominal/pelvic surgery were more prone to intestinal obstruction.

The most common physical findings were abdominal distension (83.3%), bowel sounds diminished (55.6%), tachycardia (51.9%). Markogionnakis found distention to be the most common physical finding (79%) of the cases at presentation. This is due to the large volumes of fluid lost through vomiting and sequestration into the lumen of the obstructed bowel. Patients were adequately stabilised preoperatively.

Mechanical small bowel was the major type of obstruction (66.7%). Mechanical large bowel obstruction accounted for (22.2%) while functional obstruction (3.7%). Other studies found small bowel obstruction ranging from 65% to 93%.

The mode of treatment was mainly operative (74.1%), the rest of the patients. The most common intraoperative diagnosis was intussusception (31.5%), seen mainly in the under five year population. Adhesion bands (24%) was the second most common seen mainly in the adult population >13yrs. Non-operative treatment was seen in 26% of the patients who also had previous history of abdominal/pelvic surgery. This is in line with other studies that observed a substantial number of patients with adhesive obstruction, ranging from 30% to 70%, can safely be treated non-operatively.

Most patients recovered (66.7%), those that recovered with complications were 13%. Mortality was 16.7% similar to mortality rates of 17% observed by the hospital records department. Other studies observed mortality rates ranging from 4.5% to 20%.
was a significant association between duration of symptoms and morality. Early diagnosis and immediate treatment is of the essence in order to reduce morbidity and mortality.

Majority of the patients (55.5%) were discharged within 7 days. The mean duration of hospital stay was 13.4 days. Ooko in a study of 445 patients looking at pattern of adult intestinal obstruction in Tenwek Hospital noted a mean hospital stay of 4.1 days. Musila noted 68.1% of patients treated for intestinal obstruction were discharged within 7 days.

There was no significant relationship between base deficit and adverse outcomes in intestinal obstruction. This is contrary to Takeuchi et al when performing clinical studies of strangulating small bowel obstruction found base deficit correlated with the length of gangrenous bowel. Base deficit has also been found to be a sensitive measure of both the degree and the duration of inadequate perfusion. In 1995, Banon studied 40 patients with operative truncal injuries admitted at the Cook County Trauma Unit, Chicago and determined base deficit was a good marker of mortality.

There was no significant relationship between serum lactate and adverse outcomes in intestinal obstruction. This is contrary to a study in Uganda that found Serum lactate assay had a sensitivity of 66% and specificity of 53% for bowel ischemia in general and a higher sensitivity of 71% and specificity of 80% for irreversible bowel ischemia. Lange and Jackel noted that serum lactate had a sensitivity of 100% and specificity of 42% as a marker of mesenteric ischaemia. Sarr et al evaluated preoperative diagnostic parameters for the determination of the presence or absence of intestinal strangulation in 51 patients with intestinal obstruction. They noted that no preoperative clinical parameter, including leukocytosis, or acidosis, or a combination of the same proved to be sensitive, specific, and predictive for strangulation.

**LIMITATION**

This was a single centre study, with few subjects. A longer multicentre study may be required in order to get results that could be generalized in our context.
CONCLUSION
The commonly affected age group is <5 yrs with males more affected than females. Abdominal distension, constipation/obstipation and nausea vomiting are the most common presentations with the main cause of intestinal obstruction being intussusception in under five years age group and adhesions in adult population. Operative management is more common than non-operative management however, the mortality rate was higher in patients who presented late. This study found that initial base deficit and serum lactate levels did not have a bearing on probability of developing adverse outcomes in patients with intestinal obstruction.

RECOMMENDATION
A high index of suspicion is necessary in the diagnosis of intestinal obstruction inorder to initiate prompt treatment. This will reduce the duration of symptoms as well as lower mortality. Further studies with more centres, that captures duration of symptoms and monitors base deficit and serum lactate for 24 hour duration for normalisation may be necessary in order to identify accurate early predictors of mortality and morbidity in these patients.

REFERENCES


34. Kintu-Luwaga R, Galukande M, Owori FN. Serum lactate and phosphate as biomarkers


APPENDIX I: DATA COLLECTION WORKSHEET

DATE _______________________________________________________

STUDY NUMBER  ______________________________________________

PATIENT NUMBER  _____________________________________________

AGE ____              SEX__________

RESIDENCE __________________________________________________

CONTACT NO. _________________________________________________

1. Symptoms
   1.1. Nausea/vomiting  
   1.2. Abdominal Distension  
   1.3. Constipation  
   1.4. Others (specify)...............  

2. Relevant Past Medical History
   2.1. Previous Abdominal Surgery  
   2.2. Hernia  
   2.3. Neoplasms  
   2.4. Inflammatory Masses  
   2.5. Radiation  
   2.6. Others (specify)...............  

3. Physical findings
   3.1. Tachycardia  
   3.2. Hypotension  
   3.3. Dehydration  
   3.4. Fever  
   3.5. Abdominal Distension  

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3.6. Abdominal Tenderness
3.7. Abdominal Scars
3.8. Evidence of hernias
3.9. Visible Peristalsis
3.10. Bowel sounds high pitched
3.11. Bowel sounds Diminished
3.12. Abdominal masses
3.13. Others (specify)

4. Investigation
4.1. Serum sodium mmol/L (135-145)
4.2. Serum potassium mmol/L (3.5-5.0)
4.3. Serum bilirubin mmol/L (0-2.5)
4.4. Serum glucose mmol/L (3.5-8.3)
4.5. Base Deficit mmol/L (2.0-(-)2.0)
4.6. Serum lactate mmol/L (0.5-2.22)
4.7. Others (specify).............

5. Type of obstruction
5.1. Mechanical small bowel obstruction
5.2. Mechanical large bowel obstruction
5.3. Function obstruction

6. Treatment
6.1. Non-operative
6.2. Operative
6.3. Intra-operative diagnosis

7. Outcome
7.1. Recovery
7.2. recovery after complications
7.3. death
7.4. Duration of hospital stay
APPENDIX II: INFORMED CONSENT FORM

STUDY TOPIC: the use of serum lactate and base deficit in the diagnosis of morbidity in intestinal obstruction at KNH

This informed consent form is for patients who have intestinal obstruction and are undergoing treatment at KNH. I am inviting you to participate in this research on a voluntary basis.

Principal Investigator: Dr. Muriuki Meme

Institution: University of Nairobi, School of Medicine, Department of Surgery.

This Informed Consent Form has three parts:

1) Information Sheet (to share information about the research with you).
2) Certificate of Consent (for signatures if you agree to take part).
3) Statement by the researcher/person taking consent.

You will be given a copy of the full informed consent form.

PART I: Information Sheet

Introduction

My name is Dr. Muriuki Meme, a post graduate student in General Surgery at the University of Nairobi. I am carrying out a research to determine the use of serum lactate and Base deficit in the diagnosis of significant morbidity in patients with intestinal obstruction at KNH.

Purpose of the research

Intestinal obstruction is a cause of morbidity and mortality in Kenya today. Diagnosis of intestinal obstruction may require a very high index of suspicion. This is because the physical signs are sometimes masked by the neurological status of the patient. The current modalities for the investigation of intestinal obstruction include abdominal x-ray, contrast studies and CT scan. All this modalities have their own limitations hence the need to study other ways to complement them.

I am going to give you information and invite you to be a participant in this research. There may be some words that you do not understand or that you may need clarification. Please ask me to stop as we go through the information and I will explain or clarify.

Type of Research Intervention

This research will involve physical examination of your body, your serum lactate and arterial blood gas analysis, examination of your imaging results and post- operative medical records with your doctor’s permission [or their representative] to obtain the intra-operative
findings. If you are discharged shortly after admission or from A&E, you will receive a phone call 5 days later to find out how you are doing.

**Voluntary participation/right to refuse or withdraw**

It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this hospital will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this hospital for your condition. You have a right to refuse or withdraw your participation in this study at any point.

**Confidentiality**

The information obtained will be treated with confidentiality and only be available to the principal investigator and the study team. Your name will not be used. Any information about you will have a number on it instead of your name. We will not be sharing the identity of those participating in this research.

**Sharing the results**

The knowledge that we get from this study will be shared with the policy makers in the Ministry of Health, KNH and doctors through publications and conferences. Confidential information will not be shared.

**Risks**

There is no direct risk resulting from your participation in the study.

**Cost and compensation**

There will be no extra cost incurred for participating in this study nor is there compensation offered. However your time will be required to participate in the interview.

This proposal has been reviewed and approved by UoN/KNH Ethics Committee, which is a Committee whose task is to make sure that research participants are protected from harm.

**PART II: Certificate of Consent**

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.
Print Name of Participant _______________________________________________
Signature of Participant ________________________________________________
Date _____________________________________

If Illiterate :
I have witnessed the accurate reading of the consent form to the potential participant, and
the individual has had the opportunity to ask questions. I confirm that the individual has
given consent freely.

Print Name of witness
__________________________________________ Thumb print of participant

Signature of witness
__________________________________________

Date _____________________________________

Who to contact
If you wish to ask any questions later, you may contact:

1. Principal Researcher:
   Dr Muriuki Meme
   Department of Surgery, School of Medicine, University of Nairobi
   P.O. Box 19676 KNH, Nairobi 00202.
   Mobile no. 0722267135
   Email: - Muriukimeme@gmail.com

2. University of Nairobi Supervisors:
   • Dr. Dan Kipkembo Kiptoon,
     MBCh.B, M.MED (Gen Surg.),
     Consultant Surgeon/Lecturer,
     Department of Surgery, School of Medicine, University of Nairobi
If you have any ethical concerns, you may contact:

- Secretary,
  KNH/UoN-ERC,
  P.O. Box 20723 KNH, Nairobi 00202
  Tel +254-020-2726300-9 Ext 44355

Email: KNHplan@Ken.Healthnet.org

**PART III: Statement by the researcher**

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands that the following will be done:

- Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment.
- All information given will be treated with confidentiality.
- The results of this study might be published to facilitate treatment and diagnosis of prostate cancer.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.
B. SWAHILI

Fomu ya idhini

utafiti kuumua thamani ya base déficit na serum lactate katika menejimenti kwa wagonja waliolazwa kwajili ya matumbo kufungana katika kitengo cha upasuaji hospitali kuu ya taifa ya Kenyatta

Sehemu ya kwanza – Maelezo ya Daktari mtafiti.

Mimi ni Dkt Muriuki Meme, kutoka shule ya Elimu ya Afya idara ya upasuaji Chuo Kikuu cha Nairobi (University of Nairobi). Mimi nataka kufanya utafiti kuumua thamani ya base déficit na serum lactate katika menejimenti kwa wagonja waliolazwa kwajili ya matumbo kufungana katika kitengo cha upasuaji hospitali kuu ya taifa ya Kenyatta.


Sehemu ya pili: Idhini ya mgonjwa

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Mimi......................... kutoka..........................nimekubali kushiriki katika utafiti huu unaofanywa na Daktari Muriuki Meme kutokana na hali ambayo nimeelezwa na sio kwa malipo ama shurutisho lolote.

Jina la mshiriki...........................................
Sahihi....................................................... 
Tarehe....................................................... 

Kushoto thumb magazeti ya mshiriki iwapo 

hawawezi saini

Unaweza kuuliza maswali yeote kuhusu utafiti huu na ukiridhika tafadhali ijaze fomu ya idhini liiyopo hapa chini. Unaweza pia kuuliza swali lolote baadaye kwa kupiga simu ya mtafiti mkuu ama mkuu wa idara ya upasuaji katika chuo kikuu cha Nairobi ama walimu wasimamizi wa utafiti ukitumia nambari za simu zifuatazo;

- Mtafiti: Muriuki Meme, 
  Idara ya Upasuaji ya Shule ya Afya – Chuo kikuu cha Nairobi, 
  Sanduku la Posta 2678  KNH Nairobi 00202. 
  Nambari ya simu: 0722267135

- Walimu wakuu wa Chuo kikuu cha Nairobi:

- Dr. Dan Kipkemboi Kiptoon, 
  MBCh.B, M.MED (Gen Surg.),
Consultant Surgeon/Lecturer,
Department of Surgery, School of Medicine, University of Nairobi
P.O. Box 19676 KNH, Nairobi 00202.

Tel:- 0202726300

• Dr Daniel Kinyuru Ojuka
MBCh.B, MMED (Gen. Surgery), FCS (ECSA)
Consultant Surgeon/Lecturer,
Department of Surgery, School of Medicine, University of Nairobi
P.O. Box 19676 KNH, Nairobi 00202.

Tel:- 0202726300

• Katibu wa utafiti, Hospitali kuu ya Kenyatta na Chuo kikuu cha Nairobi. Sanduku la
Posta 20723 KNH, Nairobi 00202.
Nambari ya simu 726300-9.

Sehemu ya tatu – Dhibitisho la mtafiti
Hii nikuidhinisha ya kwamba nimemueleza mshiriki kwenye utafiti kuhusu utafiti huu na pia
nimempa naafasi yakuuliza maswali. Nimemueleza yafuatayo;

• Kwamba kushiriki ni kwa hiari yako mwenye bila malipo.

• Kusiriki hakutasababisha madhara ama kuhatarisha maisha kamwe.

• Unaweza kujiondoa kutoka kwa utafiti huu wakati wote bila kuhatarisha matibabu
unayoyapata katika hospital kuu ya Kenyatta.

• Habari ambazo utapeana hazita tangazwa hadharani bila ruhusa kutoka kwako
(mshiriki) na pia kutoka kwa mdhamini mkuu wa utafiti wa hospital kuu ya Kenyatta
na chuo kikuu cha matibabu.

Jina la Mtafiti .........................................................

Sahihi...............................................................................

Tarehe...............................................................................

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APPENDIX III : ASSENT

‘The utility of base deficit and serum lactate as indicators of outcome in patients with intestinal obstruction at Kenyatta National Hospital’

Assent Form for children 12 years to 17 years

STUDY TOPIC: the use of serum lactate and base deficit in the diagnosis of morbidity in intestinal obstruction at KNH

This assent form is for patients who have intestinal obstruction and are undergoing treatment at KNH. If you would like, you can participate in this study.

Principal Investigator: Dr. Muriuki Meme

Institution: University of Nairobi, School of Medicine, Department of Surgery.

This Assent Form has three parts:

1) Information Sheet (to share information about the research with you).
2) Certificate of Assent (for signatures if you agree to take part).
3) Statement by the researcher/person taking consent.

You will be given a copy of the full Assent form.

PART I: Information Sheet

Introduction

My name is Dr. Muriuki Meme, a post graduate student in General Surgery at the University of Nairobi. I am carrying out a study to determine the use of serum lactate and Base deficit in the diagnosis of significant morbidity in patients with intestinal obstruction at KNH.

Purpose of the research

I am doing a study about ‘The utility of base deficit and serum lactate as indicators of outcome in patients with intestinal obstruction at Kenyatta National Hospital’. This may help us improve our outcomes and hence change our patient care, if any improvement on our part, is necessary.

Type of Research Intervention

This research will involve physical examination of your body, your serum lactate and arterial blood gas analysis, examination of your imaging results and post-operative medical records with your doctor’s permission [or their representative] to obtain the intra-operative findings. If you are discharged shortly after admission or from A&E, you will receive a phone call 5 days later to find out how you are doing.
Voluntary participation/right to refuse or withdraw

If you decide you want to participate in my study, you will be asked some personal questions and required to go through a questionnaire with me or my research assistant.

Your parents or guardian have to say it’s OK for you to be in the study. After they decide, you get to choose if you want to do it too. If you don’t want to be in the study, you will not get into any trouble. You can stop being in the study at any time.

Confidentiality

Other people will not know if you are participating in this study. Your answers and your progress will be kept private. When I tell other people about my research, I will not use your name, so no one can tell who I am talking about.

Sharing the results

The knowledge that we get from this study will be shared with the policy makers in the Ministry of Health, KNH and doctors through publications and conferences. Confidential information will not be shared.

Risks

There are no risks involved in this study.

Cost and compensation

You will not incur any extra costs for participating in this study.

This proposal has been reviewed and approved by UoN/KNH Ethics Committee, which is a Committee whose task is to make sure that research participants are protected from harm.

PART II: Certificate of Assent

Sign this form only if you:

- have understood what you will be doing for this study,
- have had all your questions answered,
- have talked to your parent(s)/legal guardian about this project, and
- agree to take part in this research

_______________________________________________________________________

Your Signature  Name  Date
Name of Parent(s) or Legal Guardian(s)

Who to contact

If you wish to ask any questions later, you may contact:

1. Principal Researcher:
   Dr Muriuki Meme

Mobile no. 0722267135

PART III: Statement by the researcher

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands that the following will be done:

- Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment.
- All information given will be treated with confidentiality.
- The results of this study might be published to facilitate treatment and diagnosis of prostate cancer.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Assent Form has been provided to the participant.

Name of researcher/person taking Assent

Signature of researcher/person taking Assent

Date

______________________

______________________
B. SWAHIILI

Fomu ya idhini

utafiti kuanua thamani ya base déficit na serum lactate katika menejimenti kwa wagonja waliolazwa kwajili ya matumbo kufungana katika kitengo cha upasuaji hospitali kuu ya taifa ya Kenyatta

Sehemu ya kwanza – Maelezo ya Daktari mtafiti.

Mimi ni Dkt Muriuki Meme, kutoka shule ya Elimu ya Afya idara ya upasuaji Chuo Kikuu cha Nairobi (University of Nairobi). Mimi nataka kufanya utafiti kuamua thamani ya base déficit na serum lactate katika menejimenti kwa wagonja waliolazwa kwajili ya matumbo kufungana katika kitengo cha upasuaji hospitali kuu ya taifa ya Kenyatta.


Utafiti huu utawasaidia madaktari kuelewa matokeo na kusuluhisha shida katika hospitali kuu ya Kenyatta. Kuhusika kwako kwenye utafiti huu hauna malipo yeyote ila ni kwa hiari yako mwenye na pia unaweza kujiondoa kwa hivyo. Habari yote ambayo yatajibiwa kwa fomu ya mgonjwa ya idhini ya mgonjwa

Sehemu ya pili: Idhini ya mgonjwa

Mimi................................. kutoka.............................. nimekubali kushiriki katika utafiti huu unaofanywa na Daktari Muriuki Meme kutokana na hali ambayo nimeelezwa na sio kwa malipo ama shurutisho lolote.
Sehemu ya tatu – Dhibitisho la mtafiti

Hii nikuidhinisha kwamba nimemueleza mshiriki kwenye utafiti kuhusu utafiti huu na pia nimempa nafasi yakuuliza maswali. Nimemueleza yafuatayo;

- Kwamba kushiriki ni kwa hiari yako mwenyewe bila malipo.
- Kushiriki hakutasababisha madhara ama kuhatarisha maisha kamwe.
- Unaweza kujiondoa kutoka kwa utafiti huu wakati wowote bila kuhatarisha matibabu unayopata katika hospital kuu ya Kenyatta.
- Habari ambazo utapeana hazita tangazwa hadharani bila ruhusa kutoka kwako (mshiriki) na pia kutoka kwa mdhamini mkuu wa utafiti wa hospital kuu ya Kenyatta na chuo kikuu cha matibabu.

Jina la Mtafiti ...........................................

Sahihi..........................................................

Tarehe.........................................................