SERUM POTASSIUM AND SODIUM DERANGEMENT IN BOWEL PREPARATION WITH POLYETHYLENE GLYCOL (PEGLEC) PRIOR TO ELECTIVE COLORECTAL SURGERY AT KENYATTA NATIONAL HOSPITAL

Dissertation Submitted In Part Fulfillment Of The Requirements Of The University Of Nairobi For Award Of The Degree Of Masters In Medicine In General Surgery (M.Med. General Surgery).

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H58/71012/09

Signature........................................................          Date............................................

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Signature........................................................          Date............................................
DECLARATION

I hereby certify that this study is my original work and has not been presented for dissertation at any other university.

DR. PHILEMON K. TOO

Signature: .................................... Date......................................
ACKNOWLEDGEMENT

I thank God the Almighty for the good health and sustenance that he has benevolently provided till this present day.

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Finally, my heartfelt appreciation to all the patients who volunteered to take part in this study, without whom this study would not have been possible.

Thank you all and God bless you.
DEDICATION

This dissertation is dedicated to my dear wife Betty for being very supportive and loving. She ensured that I never walk alone.
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<tr>
<td>B</td>
<td>Beta Value</td>
</tr>
<tr>
<td>ERC-</td>
<td>Ethics And Research Committee</td>
</tr>
<tr>
<td>K⁺-</td>
<td>Potassium Ions</td>
</tr>
<tr>
<td>Kg-</td>
<td>Kilogram</td>
</tr>
<tr>
<td>KNH-</td>
<td>Kenyatta National Hospital</td>
</tr>
<tr>
<td>MBP-</td>
<td>Mechanical Bowel Preparation</td>
</tr>
<tr>
<td>Min-</td>
<td>Minutes</td>
</tr>
<tr>
<td>Mls-</td>
<td>Milliliters</td>
</tr>
<tr>
<td>Mmoll/L-</td>
<td>Millimoles Per Litre</td>
</tr>
<tr>
<td>N-</td>
<td>Number</td>
</tr>
<tr>
<td>Na⁺-</td>
<td>Sodium Ions</td>
</tr>
<tr>
<td>OSP-</td>
<td>Oral Sodium Phosphate</td>
</tr>
<tr>
<td>PEGLEC-</td>
<td>Polyethylene Glycol With Electrolytes</td>
</tr>
<tr>
<td>Pts-</td>
<td>Patients</td>
</tr>
<tr>
<td>SD-</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td>SPSS-</td>
<td>Statistical Package For Social Science</td>
</tr>
<tr>
<td>TIG-</td>
<td>Total Irrigation Of The Gut</td>
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<td>UON-</td>
<td>University Of Nairobi</td>
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DEFINITIONS

- Mechanical bowel preparation (MBP) – purging the bowel of faecal material
- Hypokalaemia – serum potassium less than 3.5 mmol/L (1)
- Hyperkalaemia- serum potassium less than 5.0 mmol/L
- Hyponatraemia- serum sodium less than 135 mmol/L (1)
- Hypernatraemia- serum sodium more than 145 mmol/L
- Elderly- ≥ 65 years of age
SUMMARY

Background: Polyethylene Glycol With electrolytes (PEGLEC) is a commonly used oral preparation for mechanical bowel preparation prior to colorectal surgery at KNH. Its use has seen bowel preparation started one day prior to surgery as opposed to the traditional 3-5 days regimen. However it is not known whether the use of PEGLEC solution in our setup has any effect on the serum level of sodium and potassium which is critical in any gastrointestinal surgery. This study therefore seeks to assess for any derangement in the serum level of potassium and sodium following bowel preparation with PEGLEC.

Objective: To determine serum potassium and sodium derangements in bowel preparation using PEGLEC solution prior to elective colorectal surgery.

Study Design: This is a prospective descriptive cross-sectional study.

Setting: KNH surgical wards

Patients and methods: Thirty six (36) consecutive patients who were scheduled to undergo elective colorectal surgery and requiring mechanical bowel preparation were recruited after fulfilling the inclusion criteria. Serum potassium and sodium levels before and after bowel preparations with PEGLEC solution administration were analyzed. The data were collected by the principle investigator with the help of research assistant using structured questionnaire. The data were then analyzed using SPSS 17.0 and the results presented using tables, charts and graphs.

Main outcome measure: Changes in the serum level of sodium and potassium after mechanical bowel preparation.

Results: A total of 36 patients were recruited. Out of this, 67% were male and 33% were female. Fourteen percent (14%) and 2.8% developed hyponatraemia and hypokalaemia respectively. The hyponatraemia was statistically significant (p value 0.001) while the hypokalaemia was insignificant (p value 0.084). Most patients who
developed hyponatraemia were aged above 50 years (60.40 ± 12.58 years). There was a positive correlation between development of hyponatraemia and age (p value 0.037). None of the patients developed hypokalaemia nor hyponatraemia.

Conclusions: Prevalence of hyponatraemia and hypokalaemia in MBP with PEGLEC at KNH is 14% and 2.8% respectively. Hyponatraemia is likely to develop after the age of 50 years in bowel cleansing with PEGLEC. It’s therefore not necessary to repeat serum electrolytes in patients aged below 50 years after MBP.
INTRODUCTION

Mechanical bowel preparation (MBP) prior to elective colorectal surgery procedures remains a routine at Kenyatta National Hospital. Methods of bowel preparation have evolved from the traditional approach of dietary restriction and enemas, which although effective, are time-consuming and uncomfortable.

The support for MBP dates back to 20th century, when the high rates of infection related complications associated with abdominal surgery prompted surgeons to employ special diets and the use of laxative to evacuate gastrointestinal tract before surgery (2). Though the benefit of mechanical bowel preparations before colorectal surgery remains contested (3), anecdotal evidence shows that it is widely practiced at KNH. A 2003 survey of practicing colorectal surgeons in America revealed that 99% of respondents continue to employ MBP, though 10% did question its role in elective surgery (4). The practice appears to have long been accepted and ingrained among American colorectal surgeons.

The widely accepted rationale behind mechanical bowel preparation includes the evacuation of stool thus allowing easy visualization of luminal surface and improves intra-operative bowel handling; reduction in fecal flora, which is believed to translate into lower risk of infection and post anastomotic complications. The colon harbors more than 400 bacterial species with a total of \(10^8\) to \(10^{12}\) organisms per gram of stool. This represents one third of faecal dry weight (5). Uncontrolled contact of faeces with the peritoneum usually leads to life threatening peritonitis.

Bowel preparation though practiced routinely is said to be unpleasant to the patient and is associated with various complications such as dehydration, nausea, vomiting, mucosal lesions, hypokalaemia and other electrolytes disturbances (6). Most of these complications are seen irrespective of the bowel-cleansing procedure and regimen used (7). Since the introduction of polyethylene glycol in 1980, its use has widely been accepted. Anecdotal evidence shows that PEGLEC solution appears to be the regimen of choice for most surgeons at KNH. Whereas the traditional regimens and methods
require 3 to 5 days, it has been shown that PEGLEC solution is effective if instituted 20 hours prior to surgery\(^\text{(8)}\). The prolonged periods of diet restriction is therefore avoided.

The effect of polyethylene glycol on electrolyte balance is critical. Electrolytes abnormalities have been reported especially in the elderly patients (≥ 65 years of age) after polyethylene glycol use with an incidence of 9.6% hypokalaemia\(^\text{(9)}\). Significant electrolytes derangement has also been reported in children with potassium and chloride being affected\(^\text{(10)}\).

Various studies have assessed the general safety of PEGLEC though the effect on serum biochemistry was not documented\(^\text{(11)}\). There are no local studies to show the effect of PEGLEC on serum biochemistry. This study therefore seeks to establish whether there is any derangement in the serum level of sodium and potassium following bowel preparation using PEGLEC at KNH.
LITERATURE REVIEW

Mechanical bowel preparation (MBP) before carrying out elective colorectal surgery has remained a practice over the years. Early observational studies and long-standing clinical experience have shown that removal of faecal matter from the bowel lumen prior to surgery has been associated with decreased patient morbidity and mortality (12). MBP is considered necessary in preventing post-operative infectious complications after colorectal surgery (13). Important related infectious complications include wound infection, peritonitis, intra-abdominal abscess formation and anastomotic leakage.

Since the early 20th century when MBP has been in practice, a number of cleansing methods and regimens have been used. The practice became routine and accepted among surgeons in the 1970s. The methods employed then ranged from dietary restriction with cathartics to enemas to large volume of saline or mannitol irrigation via a nasogastric tube (14). The dynamism seen in the methods employed is based on the patient tolerability, safety and the ease of preparations. Polyethylene glycol based solutions, commonly used today, were introduced in 1980 as a superior alternative to previous regimens, with improved patients tolerance and less time required for preparation prior to surgery (15).

Davis et al. developed polyethylene glycol electrolyte lavage solution (PEGLEC) which came into use for the first time in 1980 (15). Polyethylene glycol is a high molecular weight inert molecule that is commonly combined with electrolytes (sodium sulfate, sodium chloride, potassium chloride, and sodium bicarbonate) to form the ante grade bowel cleansing solution. Due to the osmotic properties of this solution, there is little absorption or secretion of electrolytes or water, though small amounts of polyethylene glycol have been detected in the urine of healthy patients and higher levels in the urine of patients with inflammatory bowel disease (16). However cases of PEGLEC aspiration has resulted into immediate lung oedema raising the issue that its osmotic potential could be higher than would be predicted by its molecular weight (17).

PEGLEC, like the other whole gut irrigation solutions, has been associated with various adverse effects. These include nausea, vomiting, abdominal fullness, and bloating in up
to 50% of the patients \(^{(18)}\). DiPalma et al. in a study, colonic cleansing for diagnostic and surgical procedures using PEGLEC, reported adverse effects including the disagreeable taste, nausea, vomiting, abdominal fullness, and rare cases of hypothermia, obstruction-perforation and lavage induced pill mal-absorption. Electrolyte-metabolic abnormalities and cardiac arrhythmias were also reported \(^{(19)}\). Aspiration, bleeding reactivation, gastric (Mallory-Weiss) tear, and perforation in toxic colitis have been discussed in various studies as potential problems related to PEGLEC solution \(^{(20)}\).

Due to its isotonic nature, PEGLEC solution must be consumed in large amount of fluid (2L to 4L depending on the regimen applied) than hypertonic preparations. The 4L volume of the standard preparation has caused problems with compliance. Up to 38% of patients in some studies have trouble ingesting the whole amount of fluids \(^{(21)}\). To solve this problem, split-dose regimens and reduced-volume regiments have been developed \(^{(22)}\).

Electrolyte disturbance related to PEGLEC solution consist of dysnatraemia (Hyponatraemia and hypernatraemia) \(^{(23)}\) as well as hypokalaemia and hypomagnesaemia \(^{(24)}\). Dysnatraemia is believed to occur as a result of salt loss caused by diarrhea, vomiting, and inadequate or excessive water intake during the cleansing procedure. Turnage et al using an isotope dilution technique assessed that plasma volume increases in an average of 5.9% following ingestion of polyethylene glycol \(^{(25)}\).

Elderly patients with reduced thirst and/or diminished renal handling of water are especially prone to develop electrolytes disturbance \(^{(26)}\). A retrospective chart review by Ho and colleagues \(^{(27)}\) found a 9.6% incidence of hypokalaemia (<3.0 mmol/l) in elderly hospitalized patients. Of these, 2.7% were notably hypokalaemic before the cleansing procedure \(^{(27)}\). Seinela et al in 2003 did a prospective study involving seventy two elderly patient on bowel preparation for colonoscopy and they concurred that there is a general decrease in the level of serum potassium and sodium \(^{(28)}\).

Donahue et al carried out a study in 1994 on the effect of PEGLEC electrolyte solution on serum electrolytes and hydration status in children. They evaluated 48 children aged less than two years who received PEGLEC for bowel preparation. Serum electrolytes
were measured before and after PEGLEC administration. They found a shift in electrolytes which was statistically significant, with a decrease in potassium and chloride \(^{(10)}\). However, in 2002, Dharmendra et al did not find any significant serum electrolyte imbalance in their study \(^{(8)}\). They evaluated 26 female patients aged 1 month to 12 months with anorectal malformation who were scheduled to undergo primary corrective surgery without the cover of proximal diverting colostomy. PEGLEC was administered through nasogastric tube at a rate of 3ml/kg/hr until a clear effluent was obtained. Serum sodium and potassium levels were then analyzed on the morning of surgery which showed no significant derangement.

Shandip et al \(^{(29)}\) in their study in 2007 compared the safety of pure sodium chloride (household common salt), PEGLEC and Ringer’s lactate in total gut irrigation in pediatric patients. They assessed 126 children with mean age of 3 years. Fifty five patients were assessed after PEGLEC use. They found that PEGLEC was associated with significant decrease in serum sodium in comparison with the other two groups whereas household common salt solution was associated with significant decrease in serum potassium. However none of these derangements were clinically significant.

A case of acute pancreatitis associated with PEGLEC ingestion has been reported \(^{(17)}\). Pancreaticoduodenal reflux was postulated as the cause. They theorized that increased intraluminal pressure may promote and facilitate reflux of activated enzymes and bile into the pancreatic duct. A study by Dahgreen \(^{(30)}\) in dogs showed that when intraluminal duodenal pressure exceeds pancreatic ductal secretion pressure from threefold to nine fold, acute pancreatitis may develop. The disturbance in electrolyte balance does occur due to third spacing of fluids. This however may not be an immediate finding. A direct toxic effect of the PEGLEC solution on the pancreas or its electrolyte component is less likely \(^{(16)}\).
STUDY QUESTION

Does PEGLEC affect the serum level of potassium and sodium when used in bowel preparation prior to elective colorectal surgery at Kenyatta National Hospital?

NULL HYPOTHESIS

There is no statistically significant change in the serum level of potassium and sodium following bowel preparation with PEGLEC prior to colorectal surgery.
STUDY JUSTIFICATION

It is not known whether use of PEGLEC solution in bowel preparation prior to elective colorectal surgery would lead to electrolytes derangement in our setup. Anecdotal evidence shows that PEGLEC solution use in bowel preparation remains one of the MBP regimens used by surgeons at KNH. While there are numerous internationally done studies on effect of PEGLEC on electrolyte balance, there is a varied conclusion. Most of these studies have been done on Caucasians outside Africa, and while it has been customary to extrapolate and generalize these results to other populations, the danger of placing inferences cannot be ignored. This is in view of such factors as genetics, environmental peculiarities, variability in pattern and response to medication.

During literature review, it was noted that most studies were retrospective. As such, patients who had significant electrolytes abnormalities after use of PEGLEC could have had their surgery postponed until corrected and would not have been included in the analysis.

There is no published Kenyan or regional study on the effect of PEGLEC on serum sodium and potassium. The dearth of information on the subject necessitated this study.

It is hoped that the findings from this study will give a guide in the pre-operative fluid and electrolyte management in elective colorectal surgery. This will include deciding on whether to continue having a repeat of the electrolyte analysis on the day of surgery for patients having bowel preparations. With increased patient load in our facility, there is a shift to outpatient surgery. This therefore means it will be better for bowel preparations to be done as an outpatient procedure. With reduced number of admission days, the cost of hospitalization will be minimized. This therefore calls for a safe outpatient MBP regimen.
OBJECTIVES

Broad Objective:

To determine whether there is serum potassium and sodium derangements in bowel preparation using PEGLEC solution prior to elective colorectal surgery.

Specific objectives:

1. To determine the magnitude of potassium and sodium derangement in bowel preparation using PEGLEC solution prior to colorectal surgery.

2. To identify possible associated factors leading to serum potassium and sodium derangements.
MATERIAL AND METHODS

Study Design

This was a prospective descriptive cross-sectional study.

Study Location

The study was conducted at Kenyatta National Hospital surgical wards (paediatric surgery, general surgical and gynaecological wards).

KNH is a metropolitan tertiary, referral and teaching hospital situated at Upper Hill area on Hospital Road about five kilometers from Nairobi city centre. It is one of the two main referral hospitals in Kenya. It also serves the greater part of East and Central Africa.

The main surgical units at KNH are situated at the fourth, fifth and sixth floors of the tower block. The units are further subdivided into the various sub-specialties. Paediatrics, cardiothoracic and plastic surgery occupy the fourth floor while general surgery and orthopaedic surgery are on the fifth and sixth floors respectively. Gynaecology wards on the other hand occupy the first floor. Close surveillance was also carried out in the other non surgical wards for satellite cases.

Study Population

All patients admitted at KNH and are scheduled to undergo elective colorectal surgical procedure and require prior bowel preparation.

Study Duration

The data were collected between June 2012 and September 2012.
Inclusion criteria

1. All patients admitted at KNH and are scheduled to undergo elective colorectal surgery and require prior bowel preparation.
2. Patients who will give informed consent
3. Patients with serum potassium and sodium levels within normal range prior to bowel preparation.

Exclusion criteria

1. Patient or patient’s next of kin refusal to give consent.
2. Patients with deranged serum potassium and sodium levels within 24 hours prior to bowel preparation.
3. Patient already diagnosed with renal disease.
4. Patients known to have history of congestive heart failure.
Sampling.

All eligible patients admitted at KNH were enrolled in the study until the required sample size of thirty six (36) patients was obtained.

Sample size

The following formula described by Fischer (31) was used to calculate the sample size. This was chosen because the study is a cross-sectional study with the objective aimed at getting proportions.

\[ n = Z^2_{(1-\alpha/2)} \times P(1-P) \]

\[ d^2 \]

Where;

\( n \) = sample size to be determined

\( Z^2_{(1-\alpha/2)} \) - is the standard error of the mean corresponding to a 95% confidence interval and the corresponding value from a t-table is 1.96.

\( P \) = is the expected prevalence of the event to occur. In this study, since there is no regional published study, we shall use 7% as the estimated prevalence of potassium derangements in surgical patients at KNH (32). Therefore our \( P \) will be 0.07.

\( d \) = is the target margin of error which will be 5% (0.05).

\[ n = 1.96^2 \times 0.07 \times (1 - 0.07) \]

\[ 0.05^2 \]
Thus $n = 100$.

At KNH, it was estimated that about 14 cases of colorectal surgical procedures requiring prior bowel preparation were carried out per month. This translated to 56 cases in four months. Since the population to be studied was less than 10,000, a second formula was used incorporating the sample size obtained above.

The following formula was applied according to Mugenda O et al (33):

$$nf = \frac{n}{1 + \frac{n}{N}}$$

$$= \frac{100}{1 + \frac{100}{56}}$$

$$= 35.898$$

Hence the calculated minimum number of patients required for the study was estimated at 36.
Data Collection

(a) Patient recruitment

The principle investigator with the help of research assistant contacted on a daily basis the already sensitized senior house officers (SHOs), medical officer intern, clinical officers and the nurses working in the various surgical units for information on patients scheduled for colorectal surgical procedure. Patients who required bowel preparation prior to surgery were recruited into the study after they fulfilled the set inclusion criteria.

(b) Specimen collection, storage and analysis

Blood specimen (approximately 2mls) for analysis of serum potassium and sodium levels was collected before commencement of bowel cleansing and repeated on the day of surgery. The PEGLEC solution was administered at least 20 hours prior to surgery. For purposes of uniformity, the blood samples were collected at around 10a.m. one day prior to surgery and repeated at around 7.30 a.m. on the day of surgery. Polyethylene glycol electrolyte solution were prepared and administered as per the attached instructions (see appendix III) within 30 minutes from the time of first blood sample collection. Sachets of PEGLEC powder were provided for the patients who did not have their own at the time of recruitment. All the participants or their caretakers were provided with written instruction on the steps taken in bowel preparation.

Collected blood specimens were then kept at room temperature till separation of serum was done. Each specimen was centrifuged and analyzed within one hour of collection at the KNH renal laboratory. Haemolysed samples were discarded and another specimen taken within thirty minutes. Potassium and sodium were analyzed using the AVL 9180 electrolytes analyzer based on potential difference in their specific ion selective electrodes and a reference in serum containing either sodium or potassium. The analyzer based at the renal unit, KNH, was utilized in this study. Obtained serum was stored temporarily at 4°C in case the machine was engaged in analyzing other specimens.
© Quality Control

Procedure of specimen collection, transportation and preparation were adhered to strictly as outlined above to minimize pre-analytical source of error. The laboratory team was requested to routinely carry out calibration of the analyzer according to the manufacturer’s specifications. Further, the investigator took every sixth specimen to ICU laboratory for comparison of results.

(d) Data to be collected

The data collected included patient demographic data, diagnosis and procedure to be performed. Serum potassium and sodium levels before and after bowel preparations were also collected and tabulated accordingly. Any clinically significant derangements in sodium or potassium level were communicated to the relevant clinicians for necessary intervention. The type and volume of fluids given to the patient during the MBP were recorded accordingly. Any adverse effects noted in the process such as vomiting were also documented. Necessary interventions to mitigate this adverse effect were instituted.

(e) Management of electrolytes imbalance (if it occurs).

Patients who develop electrolytes imbalance in bowel preparation with PEGLEC were managed according to the protocol available in that particular surgical unit. The principle investigator liaised with the primary doctor in the patient management. The interventions taken were documented in the data collection sheet.
Data Analysis And Presentation

Data was collected using structured questionnaire. The data collected was then entered and cleaned in Microsoft excel 2007. Data analysis was performed using Statistical Package for Social Sciences version 17.0 (SPSS statistical 17.0).

Continuous variables such as age were summarized using mean or median. Paired t-test was used to compare the serum potassium and sodium levels before and after bowel preparation and chi-squared analysis for demographic data. Multiple logistic regressions was used in the multivariate analysis to determine if there were any predictive factors such as age, gender, coexisting disease or use of drugs for patients who develop deranged serum potassium and sodium levels. A p value < 0.05 was considered significant.

Results were then presented in the form of tables, charts and graphs.
STUDY LIMITATION

1. Occasional breakdown of electrolytes analyzer or lack of reagents.

2. Challenge in enforcing instructions given regarding PEGLEC administration.

3. Possibility of having undiagnosed co-morbid condition which has significant effect to electrolyte balance. Previous medical records were invaluable in most cases.

The above challenges were minimal and hopefully had no impact on the outcome of this study. There were two days during the study period when reagents in the laboratory were unavailable. The specimens were therefore managed as stated above till new reagents were availed.

Preparations and administration of PEGLEC was done with minimal supervision. Patients and guardians co-operation was quite encouraging.
ETHICAL CONSIDERATIONS

Approval to conduct the study was sought from the department of surgery, University of Nairobi and Kenyatta National Hospital Ethics and Research committee. Approval was granted vide number P227/04/2012. Data collection commence immediately this approval was granted.

Participants or their next of kin in this study were required to give a written informed consent. Patients who declined to give consent after all their concerns were addressed were subsequently excluded. They were however assured that their management at the hospital was not going to be compromised. All information obtained shall be treated with utmost confidentiality. All participants were allocated a study serial number linking them to their bio-database accessible only to the principle investigator.

In this study PEGLEC brand was used specifically for uniformity purposes and considerations were also made based on its ease of availability. I declare that there was no vested interest whatsoever in the particular brand used in this study. I further declare that there was no assistance in anyway by the company or other affiliated bodies towards this study. Anecdotal evidence has shown that PEGLEC is the most common brand used at KNH.

FUNDING

This study was solely funded by the principle investigator.
RESULTS

A total of thirty six patients who required bowel preparations prior to colorectal surgery were recruited. Thirty one percent (11 patients) of the patients were drawn from the paediatrics surgical unit while the rest from adult general surgical and gynaecological wards.

DEMOGRAPHICS OF THE PATIENTS

SEX:

Out of the 36 patients recruited, 24 were males and 12 were females. This gave a male to female ratio of 1:2.

Table 1: Gender Distribution of the Patients.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
<td>Male</td>
<td>24</td>
<td>66.7%</td>
</tr>
<tr>
<td>Female</td>
<td>12</td>
<td>33.3%</td>
</tr>
</tbody>
</table>
Figure 1: Gender Distribution of the Patients.

AGE:

The age range was between 1.5 to 80 years with a mean of 33 years (SD= 24.37 and skewness= 0.155). Most patients were between 0 – 10 years accounting for 30.6% while the least proportion was in the age group 11- 20 years (2.8%).
Table 2: Distribution of Patients by Age-Group.

<table>
<thead>
<tr>
<th>Age Group in Years</th>
<th>Frequency</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>0-10</td>
<td>11</td>
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<td>41-50</td>
<td>4</td>
<td>11.1</td>
</tr>
<tr>
<td>51-60</td>
<td>6</td>
<td>16.7</td>
</tr>
<tr>
<td>61-70</td>
<td>3</td>
<td>8.3</td>
</tr>
<tr>
<td>71-80</td>
<td>2</td>
<td>5.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>36</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>
Figure 2: Distribution of Patients by Age Group.
INDICATIONS FOR THE COLORECTAL SURGERY

Colorectal carcinoma was the commonest condition (31%) followed by Hirschsprung disease (14%). Thirty three percent of the patients had previously been operated on and were admitted for closure of colostomy.

Table 3: Colorectal conditions (n= 36).

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal carcinoma</td>
<td>11</td>
<td>31</td>
</tr>
<tr>
<td>Hirschsprung disease</td>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td>Colorectal injuries</td>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td>Anorectal malformation</td>
<td>4</td>
<td>11</td>
</tr>
<tr>
<td>Haemorrhoids</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Obstructive uropathy</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Fecal incontinence</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Urinary incontinence</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>
Enterocutaneous fistula | 1 | 3
Rectal prolapsed | 1 | 3

|       | 36 | 100% |

Majority of the patients (73%) who presented with colorectal carcinoma were aged above fifty years while all patients with hirschsprung disease were less than five years of age.

**PROCEDURES (OPERATIONS)**

Colostomy stoma closure (33%) and colectomy (14%) were the most common procedures.

**Table 4**: Procedure carried out (n=36).

<table>
<thead>
<tr>
<th>Type of procedure</th>
<th>Frequency(pts)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colostomy closure</td>
<td>12</td>
<td>33.3</td>
</tr>
<tr>
<td>Colectomy</td>
<td>5</td>
<td>13.8</td>
</tr>
<tr>
<td>Abdomino-perineal resection</td>
<td>4</td>
<td>11.1</td>
</tr>
<tr>
<td>Anterior resection</td>
<td>3</td>
<td>8.3</td>
</tr>
<tr>
<td>Procedure</td>
<td>Count</td>
<td>Percentage</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>-------</td>
<td>------------</td>
</tr>
<tr>
<td>Urinary diversion</td>
<td>3</td>
<td>8.3</td>
</tr>
<tr>
<td>Hemorrhoids</td>
<td>2</td>
<td>5.6</td>
</tr>
<tr>
<td>Anoplasty</td>
<td>2</td>
<td>5.6</td>
</tr>
<tr>
<td>Pull-through</td>
<td>2</td>
<td>5.6</td>
</tr>
<tr>
<td>Rectal biopsy</td>
<td>1</td>
<td>2.8</td>
</tr>
<tr>
<td>Rectopexy</td>
<td>1</td>
<td>2.8</td>
</tr>
<tr>
<td>Repair of enterocutaneous fistula</td>
<td>1</td>
<td>2.8</td>
</tr>
<tr>
<td><strong>36 (pts)</strong></td>
<td><strong>36</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

**PATIENT BURDEN AT KNH**

More than half (58%) of the patients had their operation postponed previously. This was due to lack of bed space in the surgical wards (95%).

**VOLUME OF PEGLEC ADMINISTERED**
Out of the 36 patients in the study, eleven (30.5%) were in the paediatrics age group (<12 years). The average effective volume of PEGLEC required among this age group was 16.36 millilitres (approximately 16 mls) per kilogram body weight in one hour (SD 5.91). The minimum and maximum rates were 9.3 mls/kg/hr and 30 mls/kg/hr respectively.

**Table 5(a):** Rate of PEGLEC administration children.

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Weight (kg)</th>
<th>Volume Admin (mls)</th>
<th>Duration (Hours)</th>
<th>Administration Rate (ml/kg/hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>27</td>
<td>800</td>
<td>2</td>
<td>14.8</td>
</tr>
<tr>
<td>4</td>
<td>16</td>
<td>460</td>
<td>2</td>
<td>14.4</td>
</tr>
<tr>
<td>2.5</td>
<td>14</td>
<td>480</td>
<td>2</td>
<td>17.1</td>
</tr>
<tr>
<td>3</td>
<td>13</td>
<td>520</td>
<td>4</td>
<td>10.0</td>
</tr>
<tr>
<td>4</td>
<td>15</td>
<td>420</td>
<td>3</td>
<td>9.3</td>
</tr>
<tr>
<td>3.5</td>
<td>15</td>
<td>900</td>
<td>2</td>
<td>30.0</td>
</tr>
<tr>
<td>1.5</td>
<td>12</td>
<td>300</td>
<td>2</td>
<td>12.5</td>
</tr>
<tr>
<td>2</td>
<td>10</td>
<td>520</td>
<td>3</td>
<td>17.3</td>
</tr>
<tr>
<td>3</td>
<td>14</td>
<td>800</td>
<td>3</td>
<td>19.0</td>
</tr>
<tr>
<td>2.5</td>
<td>13</td>
<td>520</td>
<td>3</td>
<td>13.3</td>
</tr>
<tr>
<td>5</td>
<td>15</td>
<td>1000</td>
<td>3</td>
<td>22.2</td>
</tr>
</tbody>
</table>

**16.36**
Table 5(b): Rate of PEGEC administration (Children)

<table>
<thead>
<tr>
<th>Volume (Mililiters)</th>
<th>N</th>
<th>Min</th>
<th>Max</th>
<th>Median</th>
<th>Mean</th>
<th>Std Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>11</td>
<td>9.3</td>
<td>30</td>
<td>16.355</td>
<td>14.80</td>
<td>5.911</td>
</tr>
</tbody>
</table>

Among the adults, the average effective volume of PEGLEC solution consumed was 2266 milliliters (SD= 324.268). More than half (52%) of the adults consumed between 2L and 2.4L.

Table 6(a): Volume of PEGLEC consumed (Adults).

<table>
<thead>
<tr>
<th>Volume (Mililiters)</th>
<th>N</th>
<th>Min</th>
<th>Max</th>
<th>Median</th>
<th>Mean</th>
<th>Std Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>25</td>
<td>1800</td>
<td>3000</td>
<td>2200</td>
<td>2266</td>
<td>324.268</td>
</tr>
</tbody>
</table>
Table 6(b): Volume of PEGLEC consumed (Adults).

<table>
<thead>
<tr>
<th>Volume (mls)</th>
<th>Frequency (pts)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1600-1800</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>1801-2000</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>2001-2200</td>
<td>7</td>
<td>28</td>
</tr>
<tr>
<td>2201-2400</td>
<td>6</td>
<td>24</td>
</tr>
<tr>
<td>2401-2600</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>2601-2800</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>2801-3000</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

|              |                 | 100%           |

Figure 3: Volume of PEGLEC consumed (Adults).
DURATION OF PEGLEC ADMINISTRATION

Seventy percent of the patients took between 2 and 3 hours to consume a given volume of the prepared PEGLEC solution. On average it took 2.92 hours (SD= 0.554).

Table 7(a): Duration of PEGLEC administration statistics.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Min</th>
<th>Max</th>
<th>Median</th>
<th>Mean</th>
<th>Std Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration (Hours)</td>
<td>36</td>
<td>2</td>
<td>4</td>
<td>3.0</td>
<td>2.92</td>
<td>0.554</td>
</tr>
</tbody>
</table>

![Volume Percentage (%)](chart.png)
Table 7(b): Duration of PEGLEC administration

<table>
<thead>
<tr>
<th>Duration (minutes)</th>
<th>Frequency (pts)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>60-120</td>
<td>7</td>
<td>19.4</td>
</tr>
<tr>
<td>121-180</td>
<td>25</td>
<td>69.5</td>
</tr>
<tr>
<td>181-240</td>
<td>4</td>
<td>11.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>

Figure 4: Duration of PEGLEC administration.
FLUID MANAGEMENT

After administration of PEGLEC solution, hydration of patients was maintained by fluid administration either orally or via intravenous route depending on their tolerance. Fluids given were either plain water, especially for those who tolerated oral intake, normal saline, 5% dextrose or hartmann’s solution. The primary doctor prescribed the type and amount of fluid given.

The average amount of hydration fluids given was 564mls and 1416mls for children and adults respectively.

**Figure 5:** Average amount of fluids given in milliliters.
POTASSIUM ANALYSIS

Out of the 36 patients’ serum analyzed, only one patient developed hypokalaemia (serum potassium level <3.5mmol/L). This translated to a prevalence of 2.8%. This was a 68 year old male admitted for abdomino-perineal resection of rectal tumor. He did not have any co-morbid condition. The mean serum potassium levels before and after MBP was 4.16 (SD 0.287) and 4.02 (SD 0.237) respectively.

Table 8: Potassium Levels statistics
<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>K⁺ Before</td>
<td>36</td>
<td>3.71</td>
<td>4.80</td>
<td>4.1619</td>
<td>0.28720</td>
</tr>
<tr>
<td>K⁺ After</td>
<td>36</td>
<td>3.32</td>
<td>4.50</td>
<td>4.0156</td>
<td>0.23719</td>
</tr>
<tr>
<td>Valid N</td>
<td>36</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 6: Prevalence of Hypokalaemia**

When potassium serum levels before and after bowel preparation with PEGLEC were compared, it was found to be statistically significant (p value < 0.0001)[Table 10(a)].
**Table 9(a):** p-value for comparison between serum potassium before and after MBP

<table>
<thead>
<tr>
<th>Paired Differences</th>
<th>95% Confidence Interval of the Difference</th>
<th>P-value</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>Std. Deviation</td>
<td>Std. Error Mean</td>
<td>Lower</td>
</tr>
<tr>
<td>0.14639</td>
<td>0.11579</td>
<td>0.01930</td>
<td>0.10721</td>
</tr>
</tbody>
</table>

There was no clinical significance (p value 0.084) when the patient who developed hypokalaemia was compared to those who had normal serum potassium [Table 10(b)].

**Table 9(b):** p-value for comparison between those who developed hypokalaemia and the ones who had normal serum potassium.

<table>
<thead>
<tr>
<th>N= Total No. Patients</th>
<th>Hypokalaemia K⁺ &lt; 3.5 mmol/L</th>
<th>Normal serum K⁺ Level</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>36</td>
<td>1</td>
<td>35</td>
<td>0.084</td>
</tr>
</tbody>
</table>

Since only one patient developed hypokalaemia, it was not possible to carry out multivariate analysis to determine its correlation with other depended variables (Age, sex, weight and volume of PEGLE solution administered).

None of the patients developed hyperkalaemia.
SODIUM ANALYSIS

The mean serum levels of sodium before and after MBP were 139.39 (SD 2.02) mmol/L and 137.58 (SD 2.62) mmol/L respectively. Fourteen (14%) of the patients developed hyponatremia. Out of this, 80% were males while the rest were females. Sixty percent (60%) were patients above 60 years of age. The mean age was 60.4 ± 12.58 years.

Table 10: Sodium Levels Statistics.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na⁺ Before</td>
<td>36</td>
<td>135.0</td>
<td>144.0</td>
<td>139.39</td>
<td>2.0171</td>
</tr>
<tr>
<td>Na⁺ After</td>
<td>36</td>
<td>132.0</td>
<td>142.0</td>
<td>137.58</td>
<td>2.6181</td>
</tr>
<tr>
<td>Valid N</td>
<td>36</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 7: Prevalence of Hyponatraemia.
The changes in the serum levels of sodium after bowel cleansing was statistically significant (change $1.82 \pm 1.91$ mmol/L; $p$ value 0.0001).

**Table 11(a):** $p$-value for comparison between serum sodium before and after MBP

<table>
<thead>
<tr>
<th>Paired Differences</th>
<th>95% Confidence Interval of the Difference</th>
<th>$P$-value Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>Std. Deviation</td>
<td>Std. Error Mean</td>
</tr>
<tr>
<td>1.8167</td>
<td>1.9095</td>
<td>0.3182</td>
</tr>
</tbody>
</table>

None of the patients who developed hyponatraemia showed any clinical signs and symptom. The occurrence of hyponatraemia was statistical significant ($p$ value 0.001) when patients who developed hyponatraemia were compared to those who had normal serum sodium level. However, none of the five patients who had hyponatraemia showed any clinical signs and symptoms.

There was no patient who developed hypernatraemia.
Table 11(b): p-value for comparison between those who developed hyponatraemia and the ones who had normal serum sodium.

<table>
<thead>
<tr>
<th>N= Total No. Patients</th>
<th>Hypokalaemia Na⁺ &lt; 135.5 mmol/L</th>
<th>Normal serum Na⁺ Level</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>36</td>
<td>5</td>
<td>31</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Hyponatraemia was corrected with hartmanns’ solution in all the five patients. The amount of fluid required was calculated and administered by the primary doctor.

MULTIVARIATE ANALYSIS: CORRELATION BETWEEN THE VARIOUS VARIABLES AND THE DEVELOPMENT HYPONATRAEMIA.

When a multivariate logistic regression was run, age was the only independent variable associated with an increased risk of developing hyponatraemia (p value 0.037). Sex (p value 0.225), weight of the patient (p value 0.135) and the volume of PEGLEC solution (p value 0.149) administered had no statistically significant predictive value.
Table 12: Multivariate Analysis; hyponatraemia.

<table>
<thead>
<tr>
<th></th>
<th>Unstandardized Coefficients</th>
<th>Standardized Coefficients</th>
<th>95.0% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>Std. Error</td>
<td>Beta</td>
</tr>
<tr>
<td>(Constant)</td>
<td>1.888</td>
<td>0.218</td>
<td>-</td>
</tr>
<tr>
<td>SEX</td>
<td>0.145</td>
<td>0.117</td>
<td>0.198</td>
</tr>
<tr>
<td>AGE</td>
<td>-0.008</td>
<td>0.004</td>
<td>-0.574</td>
</tr>
<tr>
<td>Weight of pt</td>
<td>0.012</td>
<td>0.008</td>
<td>0.793</td>
</tr>
<tr>
<td>PEGLEC volume</td>
<td>0.000</td>
<td>0.000</td>
<td>-0.701</td>
</tr>
</tbody>
</table>

a. Dependent Variable: Sodium Derangement

SIDE EFFECTS OF PEGLEC ADMINISTRATION

Two patients (5.6%) had one episode of vomiting at the initiation of PELEC solution intake. This was seen in young adult patients aged 18 and 24 years. The patients attributed this to the blunt taste of the PEGLEC solution. This however did not recur and the patients continued with the consumption of the solution till the desired effects were achieved. There were no other side effects reported.

DISCUSSION
Methods of bowel preparation have evolved from the traditional approach of dietary restriction and enemas to more effective osmotic agents such as PEGLEC and oral sodium phosphate (OSP). PEGLEC was developed by David et al. at the Baylor University when they substituted non-absorbable sodium sulfate in place of sodium chloride in the balanced electrolyte lavage solution. They also added polyethylene glycol for osmotic effect (15).

Current preoperative preparation for patients undergoing colorectal surgery at KNH involves both administration of systemic antibiotics and mechanical bowel preparation (MBP). Keighley et al in their study found that this combination was the most effective form of prophylaxis against wound sepsis and also appears to be associated with a low incidence of anastomotic dehiscence (34). Factors thought to contribute to anastomotic dehiscence include, among others, colonic tension, peritoneal sepsis, faecal soiling and the degree of faecal loading. There is no standard protocol on MBP being followed at KNH. The use of a one day PEGLEC preparation or the traditional five days regimen depends on the surgeon preference.

Studies carried out on the safety profile of the various MBP methods have reported various adverse effects. These ranged from disturbance in sleep, fecal incontinence to derangement in serum electrolytes (38). PEGLEC, like all other whole gut irrigation formulation, has been associated with various adverse effects such as nausea, vomiting and abdominal fullness (18). Effect of PEGLEC on serum electrolytes in patients at KNH is critical considering its wide use.

Out of a total of 43 patients reviewed during the study period, thirty six patients were included in the study. Twenty four (67%) were males and twelve (33%) were females. Their ages ranged from 1.5 years to 80 years with a mean age of 33 ± 24.37 years. Majority of the patients (30.6%) were in the 0 to 10 years cluster. The commonest surgical diagnoses were colorectal carcinoma (31%), hirschsprung’s disease (14%) and colorectal injuries (14%) [Table 2]. Closure of colostomy stoma (33.3%), colectomy
(13.8%) and abdomino-perineal resection of colorectal tumors (11.1%) were the most common procures undertaken [Table 3].

The mean weight change recorded after MBP was $0.064 \pm 0.0071$ which was not statistically significant ($p$ value 0.122). More than 50% of the patient recorded no change in their weights. This correlates well with a study by Ackland et al which found no significant weight change ($0.17$ [95% CI: -0.2-2.2 kg]; $p= 0.26$) after bowel preparation for patients to undergo sigmoidoscopy (35).

The high patient burden at KNH is reflected well by the number of surgeries being rescheduled due to lack of bed space in the surgical units. In this study, 58% of the patient reported that their scheduled surgery was postponed previously. Lack of bed space (95%) was given as the main reason for the deferment. This precludes inpatient bowel preparation except for the most immobile or infirm patients. To address the pressure on the hospital beds, minimizing bed occupancy before surgery is a feasible option. Getting a safe MBP regimen that can be used as an outpatient preparation will definitely change this scenario.

Previously, large volumes of PEGLEC solution, approximately 4 liters, were required for effective bowel preparation. This adversely affected patients’ compliance and tolerance, thus negating on the desired outcomes. However, Poon et al in a study in 2001 found that a 2L volume of PEGLEC was as effective (Endoscopists satisfaction mean score ± SD: 3.01 ± 2.09) and well tolerated by the patients (36).

The average volume of PEGLEC solution that was consumed among adults in this study was $2266 \pm 324.27$ milliliters. In children, the rate of administration was $16.36 \pm 5.91$ mls/kg/hr which is less than the manufacturer’s recommendation (30 mls/kg/hr). The volumes administered were well tolerated by the patients. It is however important that in future, a further study be carried out to assess the surgeons’ satisfaction on how well the bowel is prepared with these small volumes of PEGLEC solution.
In this study, the duration of time taken by patients to consume the prescribed volume of PEGLEC solution ranged from 2 to 3 hours (mean time duration $2.92 \pm 0.554$ hours). This duration, however, did not have any significant impact in the development of hyponatraemia ($T$ statistics $1.069$, $p$ value $0.293$).

Disturbances in electrolyte balance were noted in this study. The prevalence of hypokalaemia was $2.8\%$. The changes in the serum level of potassium after MBP was statistically significant ($p$ value $0.0001$). Only one patient had serum potassium level below $3.5$ mmol/L. This was however not clinically significant ($p$ value $0.084$). No patient in this study had hyperkalaemia.

The prevalence of hyponatraemia was $14\%$. There was a statistically significant change in the serum level of sodium after MBP ($1.82 \pm 1.90$ mmol/L, $p$ value $0.0001$). Five patients had serum sodium level below $135.0$ mmol/L. This was clinically significant ($p$ value $0.001$) when compared to those who had normal serum sodium levels. Shandip et al in their study in 2007 also found a significant decrease in serum sodium level after MBP with PEGLEC $^{29}$.

There was a positive correlation between development of hyponatraemia and age ($p$ value $0.037$). The mean age of patients who developed hyponatraemia was $60.40 \pm 12.58$ years. This findings were in keeping with what Seinela et al in 2003 found $^{28}$. It is therefore critical that patients with advancing (above 50 years in this study) are closely monitored during the MBP for possible development of hyponatraemia. Other factors such as sex ($p$ value $0.225$), weight of the patient ($p$ value $0.135$) and volume of PEGLEC solution administered ($p$ value $0.149$) did not have any positive correlation with the development of hyponatraemia. This is corroborated by a study by Hymann et al $^{37}$.

Hyponatraemia is associated with excess water retention during bowel preparation $^{38, 39}$. Schroppel et al in 2001 reported two deaths from severe hyponatraemia in patients with end stage renal disease after MBP with PEGLEC, and which also resulted in
hyponatraemic seizures in patients who had normal renal function \(^{40}\). The non osmotic release of antidiuretic hormone, possibly as a result of nausea and stress, likely impairs the ability to excrete free water \(^{41}\). Fluid management after PEGLEC administration is critical.

The principles of fluid management were be adhered to. These were in three fold; give maintenance volume, which averages 1.5 litres/24 hours in a 70kg adult or 1.2 mls/kg/hr, replace the ongoing losses and replace deficits. In a study done at Kenyatta National Hospital in 2003, there was a significant association between dehydration and electrolyte imbalance in patients with intestinal obstruction \(^{42}\).

Hydration of patients was maintained by fluid administration either orally or via intravenous route depending on their tolerance. All the paediatric patients had fluids administered via intravenous route. The adults on the other hand were on oral fluids. The average amount of hydration fluids given was 564mls and 1416mls for children and adults respectively. It was however difficult to enforce completion of prescribed amount of fluids especially in patients taking orally.

A single episode of vomiting reported in two patients may not have been severe enough to contribute to the electrolytes imbalance. The serum levels of potassium and sodium after MBP in these patients were within the normal range. The patients associated the nausea they developed with the blunt taste of the PEGLEC solution. This can possibly be avoided by use of flavored PEGLEC brands available in the market.

There was no mortality reported in this study. Apart from severe hyponatraemia reported in other studies as a cause of death, cases of acute pancreatitis have been reported \(^{17}\). Patients with significant chronic kidney insufficiency may on rare occasions experience a significant increase in the plasma volume after PEGLEC administration and decompensated heart failure may ensue.

**CONCLUSIONS**
The prevalence of hypokalaemia and hyponatraemia after MBP with PEGLEC solution was 2.8% and 14% respectively. Hyponatraemia was both statistically and clinically significant in this study. However with a larger patient sample, these findings may change.

Hyponatraemia was more significant in patients above fifty years of age. There was a positive correlation between age and development of hyponatraemia. This therefore calls for a closer monitoring of these patients during bowel cleansing. Elderly patients are likely to present with other co-morbid conditions which will impact on serum levels of electrolytes. It is clear from this study and other literature that fluid management during MBP is paramount.

Since nausea and vomiting was associated with the blunt taste of PEGLEC solution, use of flavored preparations would be ideal.

It was noted that when patients or guardians are given clear instructions on preparation and administration of PEGLEC, minimal supervision is required.

There was no positive correlation between the resultant derangement in serum sodium levels with the patient’s gender, weight and the volume of PEGLEC solution given. This conclusion is however underpowered given the type of study and the sample size used.

The implication for clinical practice of this study, with the foregoing situation, is that there is not enough strength of evidence at present to recommend a change in practice. There is a need for further higher powered trials to try to answer this question definitively. The only way that this may be achieved is by multi-centre controlled trials where it is easier to recruit a large number of patients.

**RECOMMENDATIONS**
1. Close monitoring and strict fluid management should be observed in patients above fifty years since they are prone to developing electrolytes derangements.

2. There is no need for repeat analysis of serum potassium and sodium after MBP especially in patients aged below 50 years. It is also not cost effective.

3. Use of flavored PEGLEC preparations is recommended. It is associated with better patient compliance and tolerance.

4. There is need for a further large controlled, multicenter study to establish the correlation between any electrolytes derangement that may occur and the various depended variables (age, sex, weight and fluids given).

REFERENCES


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38. **Frizelle FA, Colls BM:** Hyponatremia and seizures after bowel preparation: report of three cases. *Dis Colon Rectum* 48:393–396, 2005


42. **Musila G.** Acquired intestinal obstruction in adult patients as seen at Kenyatta National hospital. 2003. MMed Deissertation, University of Nairobi.

**APPENDICES:**

**APPENDIX I: DATA COLLECTION SHEET**

Study number ........................................ Hospital Number .....................
Date of recruitment……………………..

1) Patient’s personal detail:
   a) Sex
      ☐ Male
      ☐ Female
   b) Age……………………
   c) Date of admission ……………………..
   d) Ward admitted ………………………
   e) Weight( in kg)
      i) Before bowel preparation ………………
      ii) Day of surgery ………………………

2) Diagnosis:
   ☐ Anorectal malformation
   ☐ Cancer of the colon or rectum
   ☐ Obstructive uropathy
   ☐ Colorectal injuries
Closure of colostomy

Faecal incontinence

Rectal prolapsed

Others (specify)

3) Procedure to be carried out:

Colectomy
Pull-through
Urinary diversion
Rectopexy
Anterior resection
Abdominoperineal resection
Others (specify)

4) Surgical History
a) Any gastrointestinal or hepatobiliary surgery within the last one week?
   - YES
   - NO
b) Was this surgery postponed previously ……… YES/ NO
c) If yes in (b) above, what was the reason given:
   - Lack of bed space
   - Inadequate bowel preparation
   - Electrolytes derangement
   - Presence of active infection
   - Others (specify)

5) Polyethylene glycol administration
a) Volume of PEGLEC solution ……………………mls.
b) Time commenced (administration) …………………
c) Duration of administration ………………………
d) Method of administration:
   □ With nasogastric tube
   □ Without nasogastric tube
6) Fluid administration(from commencement of Peglec):
   □ Yes □ NO
   a) Route of administration
      □ Per oral
      □ Intravenous
   b) Type of fluid
      □ Plain water
      □ Normal saline
      □ Hartman’s solution
      □ 5% Dextrose
      □ Others (specify) ………………………………….
   c) Volume given ……………….. mls.
7) Serum potassium level
   a) Before the start of PEGLEC ………………mmol/L
   b) Day of surgery ………………………………… mmol/L
8) Serum sodium level
   a) Before the start of PEGLEC …………………mmol/L
   b) Day of surgery ………………………………… mmol/L
9) Correction of deranged potassium concentration
   a) Potassium supplementation
      Duration in hours ……………
      Amount in millimoles ……………
   b) Elimination of excess potassium
Duration in hours ……………………

Method used:

☐ Calcium gluconate  ☐ Insulin
☐ B₂ agonist  ☐ Hemodialysis
☐ Peritoneal dialysis

10) Correction of deranged sodium concentration

a) Sodium supplementation

Type of fluid given

☐ Hartmann’s solution
☐ Hypertonic normal saline solution
☐ Others(specify) …………………

Volume given …………………………mls.

b) Elimination of excess sodium

Duration in hours ……………………

Method

☐ Half-strength normal saline
☐ 5% dextrose
☐ Others(specify) …………………

Volume given ………………………… mls.

11) Any vomiting reported……………… Yes/ ☐  No ☐

Frequency …………………

12) Any co-morbidity ………………… Yes/ ☐  No ☐

Specify …………………

APPENDIX II: (a) CONSENT FORM

ADULT CONSENT FORM

Study Number…………………… Hospital Number ………………………

CONSENT EXPLANATION
I am Dr Philemon Too, a postgraduate student at the University of Nairobi currently undertaking masters programme in General Surgery. As part of my coursework I shall be carrying out a research entitled “serum potassium and sodium derangement in bowel preparation with polyethylene glycol (PEGLEC) prior to colorectal surgery at 53enyatta national hospital”. The aim of my study is to determine whether bowel preparation with PEGLEC has any effect on serum electrolytes which are critical in surgery.

This study has been approved by the Department of Surgery University of Nairobi and the Kenyatta National Hospital Ethics Committee vide approval number P227/04/2012. Your involvement in this study will be highly appreciated but is not a pre-condition for you to receive due care while in this hospital. Any information will be treated with utmost confidentiality i.e. no information will be divulged to people other than those directly involved in your care.

Blood samples (about 2mls) will be taken from you before and after bowel preparation with PEGLEC. There is no monetary or material gain for your participation in this study. Patients with similar conditions like you will here after benefit immensely from the findings of this study. However, you stand to benefit from the fact that if any abnormality/ problem is detected, your primary doctor will immediately be informed to optimize your care.

You have a right to decline recruitment in this study and this will not deny you access to all necessary medical attention that is required by you. You can terminate your participation in the study at anytime you wish. I wish you quick recovery.

Please sign in the spaces provided below as a sign of your willingness to participate in the study.

CONSENT FORM.

Having fully understood the above explanation, I have voluntarily agreed to be enrolled in this study.

Patient's/ Guardian's sign: __________________________ Date: ________________
I have explained to the patient/guardian the nature of the study, risks and benefits.

Investigator’s sign………………………………. Date…………………….

For any enquiries about the study, please contact:
Dr Philemon Too (Principle Investigator) Dr Ashford Sankar Parantai (Research assistant)
Mobile Number: 0722831158 Mobile Number: 0722175064
Email: toopkdr@yahoo.com Email: sankar58@yahoo.com

OR

The Chairman, KNH Ethics and Research Committee, on Tel 020-2726300 Ext. 44355.

PAEDIATRICS CONSENT FORM

Study Number………………………. Hospital Number ……………………………

CONSENT EXPLANATION
I am Dr Philemon Too, a postgraduate student at the University of Nairobi currently undertaking masters’ programme in General Surgery. As part of my coursework I shall be carrying out a research entitled “serum potassium and sodium derangement in bowel preparation with polyethylene glycol (PEGLEC) prior to colorectal surgery at Kenyatta national hospital”. The aim of my study is to determine whether bowel preparation with PEGLEC has any effect on serum electrolytes which are critical in surgery.

This study has been approved by the Department of Surgery University of Nairobi and the Kenyatta National Hospital Ethics Committee vides approval number P227/04/2012. Your child involvement in this study will be highly appreciated but is not a pre-condition for him/her to receive due care while in this hospital. All information will be treated with utmost confidentiality i.e. no information will be divulged to people other than those directly involved in your care.

Blood samples (about 2mls) will be taken from your child before and after bowel preparation with PEGLEC. There is no monetary or material gain for his/her participation in this study. Patients with similar conditions like his/her will here after benefit immensely from the findings of this study. However, your child stands to benefit from the fact that if any abnormality/ problem are detected, your child primary doctor will immediately be informed to optimize his/her care.

You have a right to decline recruitment of your child in this study and this will not deny him/her access to all necessary medical attention that is required. You can terminate your child participation in the study at anytime you wish. I wish your child quick recovery.

Please sign in the spaces provided below as a sign of your willingness to participate in the study.

**CONSENT FORM.**

Having fully understood the above explanation, I have voluntarily agreed to have my child enrolled in this study.

Parent’s/ Guardian’s sign…………………………………… Date……………………
I have explained to the parent/guardian the nature of the study, risks and benefits.

Investigator’s sign........................................ Date.................................

For any enquiries about the study, please contact:

Dr Philemon Too (Principle Investigator)
Mobile Number: 0722831158
Email: toopkdr@yahoo.com

Dr Ashford Sankar Parantai (Research assistant)
Mobile Number: 0722175064
Email: sankar58@yahoo.com
OR

The Chairman, KNH Ethics and Research Committee, on Tel 020-2726300 Ext. 44355.

APPENDIX II: (b) FOMU YA KIBALI

FOMU YA WATU WAZIMA

Nambari Ya Utafiti............................ Nambari Ya Hospitali ....................... 

MAELEZO

Mimi ni Dr Philemon Too, mwanafunzi wa upazuaji katika Chuo Kikuu cha Nairobi. Ninafanya utafiti unayoitwa “serum potassium and sodium derangement in bowel preparation with polyethylene glycol (PEGLEC) prior to colorectal surgery at kenyatta national hospital”. Nitapima kiasi ya madini yanayokuwa katika damu yako ili nione kama yanabadilika baada ya matumisi ya dawa PEGLEC. Nikipata kipimo kisichostahili, nitamjulisha daktari wako haraka iwesekanavyo ili marekebisho yafanywe.


Tia sahihi kwenye nafasi uliyoachiwa hapa chini kwa ishara kwamba umeelewa na umekubali kushirikishwa katika utafiti huu kwa hiari.

**FOMU YA KIBALI**

Baada ya maelezo kuhusu utafiti huu, mimi nimekubali kusajiliwa katika zoezi hili.

Mgonjwa ama Anayemtunza……………………………..Tarehe……………………………..

Ninakili kwamba nimemueleza mgonjwa au mtunzi wake yote yanayohusu utafiti huu.

Mtafiti…………………………………………….. Tarehe……………………………..

Dr philemon Too.(Mtafiti mkuu) Nambari ya rununu: 0722831158

Ukiwa na maswali yoyote kuhusu utafiti, wasiliana na:

Mwenye kiti, kitengo cha utafiti katika Chuo kikuu cha Nairobi na Hospitali ya Kenyatta Katika nambari ya simu: 020- 2726300 Ext 44355.
FOMU YA WATOTO

Nambari Ya Utafiti………………………. Nambari Ya Hospitali ……………………

MAELEZO

Mimi ni Dr Philemon Too, mwanafunzi wa upazuaji katika Chuo Kikuu cha Nairobi. Ninafanya utafiti unayoitwa “serum potassium and sodium derangement in bowel preparation with polyethylene glycol (PEGLEC) prior to colorectal surgery at kenyatta national hospital”. Nitapima kiasi ya madini yanayokuwa katika damu ya motto wako ili nione kama yanabadilika baada ya matumisi ya dawa PEGLEC. Nikipata kipimo kisichostahili, nitamjulisha daktari wake haraka iwesekanavyo ili marekebisho yafanywe.


Tia sahihi kwenye na watu wengine chini kama ishara kwamba umeelewa na umekubali kushirikishwa kwa mtoto wako katika utafiti huu.
FOMU YA KIBALI

Baada ya maelezo kuhusu utafiti huu, mimi nimekubali kusajiliwa katika zoezi hili.

Mzazi ama Anayemtunza……………………………………Tarehe…………………………

Ninakili kwamba nimemueleza mgonjwa au mtunzi wake yote yanayohusu utafiti huu.

Mtafiti…………………………………… Tarehe……………………………………

Dr philemon Too.(Mtafiti mkuu) Nambari ya rununu: 0722831158

Ukiwa na maswali yoyote kuhusu utafiti, wasiliana na:

Mwenye kiti, kitengo cha utafiti katika Chuo kikuu cha Nairobi na Hospitali ya Kenyatta
Katika nambari ya simu: 020- 2726300 Ext 44355.
APPENDIX III: PEGLEC INSTRUCTIONS

How to prepare:

1. Take a clean 2 litres container and empty the entire pack of PEGLEC (137.15g) into it. Take note that for proper reconstitution of PEGLEC solution it is essential that the entire pack is emptied without leaving any quantity of powder in the pack.

2. Pour 1 litre of water into the container and shake vigorously to dissolve PEGLEC completely.

3. Pour one more litre of water into the container to make this solution into 2 litres and then shake the container 3-4 times.

4. Now the PEGLEC solution is ready for drinking.

How to Drink:

1. Shake the solution well and pour it into a cup (approx 200ml).

2. Drink 200ml (one cup) at a time every 10 to 15 minutes so as to consume 1 litre of solution (five cups) in a maximum of 1 hour's duration.

3. For children who are unable to drink from a cup, administer through a nasogastric tube at a predetermined starting rate of 30 ml/kg/h.
4. Normally the first bowel movement may occur after about one hour from the start of drinking.

5. Continue drinking the remaining PEGLEC solution even after the start of the bowel movement (in the same manner as shown in step 2 and 3 above). The bowel movement occurs several times (5-8 times). During the administration of the remaining solution, you may however stop drinking when the stool changes into water-like (colourless or yellowish) and without any solid matter which is an indication of lavage being completed.
APPENDIX IV: ELECTROLYTES REFERENCE RANGE

- Normal ranges of electrolytes:
  - Potassium - 3.5 to 5.0 millimoles/litre (mmol/L)
  - Sodium - 135 to 145 millimoles/litre (mmol/L)

- Composition of PEGLEC powder satchet:
  - Sodium (Na⁺) - 125 mmol/L
  - Potassium (K⁺) - 10 mmol/L
  - Calcium (Ca²⁺) - 1 mol/L
  - Polyethylene glycol - 18 mmol/L
  - Chloride (Cl⁻) - 35 mmol/L
  - Sulphate (SO₄²⁻) - 80 mmol/L
  - Bicarbonate (HCO₃⁻) - 20 mmol/L
Dear Dr. Too

Research proposal: “Serum potassium and Sodium Derangement in Bowel preparation with Polyethylene Glycol (PEGLEC) prior to elective colorectal surgery at Kenyatta National Hospital” (P227/04/2012)

This is to inform you that the KNH/UoN-Ethics & Research Committee (ERC) has reviewed and approved your above revised research proposal. The approval periods are 11th July 2012 to 10th July 2013.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.

b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.

c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.

d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.

e) Submission of a request for renewal of approval at least 50 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).

f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.

g) Submission of an executive summary report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website [www.uonbi.ac.ke/activities/KNHUoN](http://www.uonbi.ac.ke/activities/KNHUoN)

“Protect to Discover”
Yours sincerely

[Signature]

PROF. A.N. GUANTAI
SECRETARY, KNH/UON-ERC

c.c.
The Deputy Director CS, KNH
The Principal, College of Health Sciences, UoN
The Dean, School of Medicine, UoN
The Chairman, Dept. of Surgery, UoN
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Supervisor: Dr. J.M. Ndungu, Dept. of Surgery, UoN

"Protect to Discover"