NASOGASTRIC DECOMPRESSION VERSUS N0N- DECOMPRESSION AFTER ELECTIVE LAPAROTOMY AT KENYATTA NATIONAL HOSPITAL: A COMPARISON OF POST-OPERATIVE OUTCOMES

By

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DECLARATION

This dissertation is my original work and has not been published elsewhere or presented for award of degree in any other university.

Signed..... Date...6th December, 2012.

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DEDICATIONS

I would like to thank my supervisor Dr. Elly Nyaim for the encouragement and guidance he provided in this piece of work.

Appreciation to my family for standing with me in the entire period of doing this work, friends for the moral support and the university of Nairobi, department of surgery for the unwavering support without which this work wouldn't have been possible.

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ABBREVIATIONS

KNH	-	Kenyatta National Hospital
USA	-	United States of America
SPSS	-	Statistical package for social sciences
UON	-	University of Nairobi
NGT	-	Nasogastric tube
CXR	-	Chest X-ray
WCC	-	White blood cell count
GSW	-	General surgical wards
KNHERC	-	Kenyatta National Hospital Ethics and Review Committee
GIT	-	Gastrointestinal tract
df	-	degrees of freedom
CI-	-	Confidence interval

SUMMARY

Background

Prophylactic nasogastric decompression after elective laparotomy is being practiced at Kenyatta National Hospital. Available evidence suggests that complications like vomiting and anastomotic leakage cannot be prevented by using nasogastric tubes after elective open laparotomy. The use of nasogastric tubes is associated with increase duration of return of normal bowel function and pulmonary complications hence prolonging hospital stay. Furthermore it increases patient discomfort. Following the above findings, the use of prophylactic nasogastric tubes might not be necessary. Most studies done elsewhere in abdominal surgical centers with a high volume of patients as opposed to our general surgical units do not support its use. In a Study carried out in the neighbouring region among patients undergoing laparotomy, nasogastric decompression was not found to prevent occurrence of complications. There is need for a study to assess the local situation. This study is aimed at evaluating the differences in outcomes in decompressed versus non-decompressed groups after elective open laparotomy.

Objective

This prospective randomized clinical study sought to evaluate the difference in outcomes in non-decompressed versus decompressed groups after elective laparotomy.

Study design

A prospective randomized clinical study.

Setting

The general surgical, gynecological wards and theatres at Kenyatta National Hospital.

Patients and method

Eighty eight consecutive patients scheduled for elective laparotomy between 15th July and 15th October, 2011 who met the inclusion criteria (in section 3.3) were recruited.

Patients enrolled in this study were randomly assigned to one group in whom decompression was used and another in whom decompression was not used. Randomization was done using a computer generated table of random numbers. The randomization was provided by an independent computer consultant. The surgeon was informed of the group designation just before closure of the abdomen.

Results

Eighty eight consecutive patients who underwent elective laparotomy randomized into non-decompression and decompression groups were studied with 43(48.9%) and 45(51.1%) being males and females respectively. The age range was 14 to 86 years with a mean of 44.25 years. The commonest reason for laparotomy was closure of gut stomas (43.2%). The occurrence of complications (vomiting, pulmonary and anastomotic leakage) was slightly higher in the decompression group though it did not reach statistical significance. The decompression group stayed longer in the hospital as compared to the non-decompression group 8.67 and 5.19 days respectively with a p-value of 0.0004.

Conclusion

The use of nasogastric decompression after elective laparotomy did not reduce the occurrence of complications. Decompressed patients spent longer in the hospital postoperatively.

1.0 INTRODUCTION

Laparotomy is one of the most performed operative procedures in general surgery and gynecology[1] wards at KNH. Prophylactic nasogastric decompression after abdominal surgery is widely practised with the intention being to hasten the return of normal bowel function, increase patient comfort, prevent pulmonary complications and anastomotic leakage and hence shorten the hospital stay[2]. Some complications may have adverse effects. Leakage can lead to peritonitis which is life threatening[3]. The fear of such complications therefore prompts the surgeon to use prophylactic nasogastric decompression[3]. At Kenyatta National Hospital anecdotal evidence indicates that prophylactic decompression is empirically practised without clear guidance criteria having been inherited from old surgical practice which was not evidence based.

Despite the goals intended to be achieved by nasogastric decompression, its use may increase air swallowing resulting in gastric dilatation[4, 5]. It may also cause gastro-esophageal reflux hence predisposition to postoperative pneumonia[6] and thus prolongation of hospital stay[7].Cheathal et al found out that nasogastric decompression was associated with prolonged return of normal bowel function, increased incidence of pulmonary complications and fever[8]. It may also contribute to significant discomfort to the patient[9].

Since the current practice in fast track surgery favors non-decompression, prophylactic nasogastric decompression has become increasingly questioned[10]. This study aimed at evaluating the difference in outcomes in non-decompressed versus decompressed groups after elective laparotomy.

2.0 LITERATURE REVIEW

The idea of nasogastric decompression dates back to 1921 with the introduction of Levin`s tube[11]. The practice was popularized by Wangesteen and Paine[13] as a form of management of acute small bowel obstruction. It was popularized in the elective setup by Gerber[12].

The intention has been[2] to prevent nausea, vomiting and abdominal distension, and hastening return of normal bowel function, reducing the risk of pulmonary complications, reducing the incidences of anastomotic leaks with subsequent infection and reducing the duration of hospital stay. Clinical trials carried out so far indicate that these goals are not always met[2, 8] and therefore the practice has come under increased scrutiny and questioning.

A nasogastric tube itself has been shown to induce vomiting [14] and is associated with a number of complications such as nasopharyngeal soreness, otitis, sinusitis and esophagitis. Clevers et al observed that the return of normal bowel function is a self-regulatory mechanism[15]. Normal Small bowel motility returns within 12 hours, gastric activity after 24 hours and colonic activity after 2 to 4 days.

Patients have been observed to still vomit despite the use of nasogastric decompression. This has been attributed to factors such as advanced age, male gender, non-smoking and history of previous postoperative vomiting[16].

This challenges the very reason why decompression should be undertaken.Other measures such as omissions of nitrous oxide, propofol administration, intravenous hydration and reduction of opioids have been shown to reduce chances of post-operative vomiting[16].

In 1 out of 10 patients, nasogastric decompression does not prevent vomiting [8] .Some studies have demonstrated a moderate increase in vomiting[8] in patients who are not prophylactically decompressed.

The return of normal bowel function is faster[2] in non-decompressed group than the decompressed group. Nelson et al in a systematic review[2] concluded that nasogastric tube use did not hasten return of bowel function. Spinal and local neural reflexes, local and systemic mediators have been shown[18] to be responsible for postoperative ileus. Cheatham et al also reported significantly fewer days to oral intake[8] in the non-decompressed group compared to the decompressed group. With earlier return of normal bowel function[2, 8] in the non-decompressed group, earlier enteral feeding is feasible[20] and it has been found to have favorable outcomes in terms of recovery[9, 21, 22] after laparotomy.

There were no differences reported[19] between two groups with or without decompression in terms of morbidity, postoperative course or mortality after gastric surgery in a European study conducted in Italy (tertiary care centers) between 1st June, 2001 and 31st December, 2002. These findings have also been reported in studies done in Asian set up (Korea) [23, 24]. In spite of overwhelming evidence, many surgeons[3] are still using decompression in certain instances like multiple proximal anastomoses based on individual preferences and experiences.

Pulmonary complications are observed more in the decompression group[2, 7, 8] as compared to the non-decompression group. Nelson et al reported a slight decrease in pulmonary complications in the non-decompression group[2]. A meta-analysis by Cheatham et al in 1995 reported a significant decrease[8] in incidence of pulmonary complications in the non-decompression group. Among patients who developed pulmonary complications after non-thoracic operations perioperative nasogastric decompression was noted to be a major risk factor.

The length of hospital stay has been shown to be longer in patients who undergo decompression[10, 25, 26]. A study conducted in Mulago Hospital Uganda on routine versus selective nasogastric suction after elective laparotomy reported slightly longer hospital stay for patients who had routine nasogastric suction[10].Zeeshan et al in their assessment of the role of routine nasogastric decompression[25] after intestinal anastomosis noted that routine nasogastric decompression was associated with longer hospital stay (11 days versus 8 days). Nadim et al in their justification of non-decompression after elective closure of gut stomas[26] and bilioenteric anastomosis also reported a longer hospital stay in the decompression group.

The above studies show that non- decompression is associated with fewer complications as compared to routine nasogastric decompression. At KNH, the practice needed to be re-evaluated to establish whether decompression was really necessary given that a number of studies done elsewhere have not demonstrated more benefits as compared to non-decompression.

2.1 Study Justification

Studies done elsewhere had shown that routine prophylactic nasogastric decompression after elective laparotomy did not prevent occurrence of complications[2, 7, 8, 10, 25].

These studies had found non-decompression to be associated with better outcomes in terms of complications and hospital stay than decompression.

Decompression was associated with several risks[2, 7, 8, 25, 10] including significant sodium losses, sore throat, nose bleeding, nausea, vomiting, cough, pneumonia, atelectasis, aspiration, fever, delay in return of normal bowel function and longer hospital stay. Following closure of stomas, it had been associated with abdominal distension[26]. In some studies non-decompression had been associated with a moderate increase in vomiting[8, 9] (5% of patients).

The incidence of anastomotic leakage had been found to be similar in both groups of patients[2, 17].

In our set-up, there is no standard protocol on the use of nasogastric decompression after elective laparotomy.

This study sought to evaluate whether prophylactic decompression after elective laparotomy was necessary.

2.2 Study Question

Is there a difference in outcomes in non-decompression versus decompression groups after elective laparotomy?

2.3 Study Objectives

2.3.1 Primary objective

To evaluate the differences in outcomes in nasogastric non-decompressed versus decompressed groups after elective laparotomy.

2.3.2 Secondary objectives

i) To determine occurrence of vomiting in non-decompressed versus decompressed groups.

ii) To determine occurrence of anastomotic leaks in non-decompressed versus decompressed groups.

iii) To determine occurrence of pulmonary complications in non-decompressed versus decompressed groups.

iv) To determine length of hospital stay in non-decompressed and decompressed groups.

3.0 RESEARCH METHODOLOGY

3.1 Study Population

This study was conducted among all patients aged 13 years and above who underwent elective laparotomy between 15th July and 15th October, 2011 at KNH general surgical and gynecological wards who met the inclusion criteria below.

3.2 Study Design

A prospective randomized clinical study. There were two treatment arms in the study: with non-decompression group (one) arm and decompression group (two) arm.

3.3 Sample Size

It was calculated using the formula highlighted below [27];

$$N = \frac{2[(a+b)^2 \sigma^2]}{(\mu_1 - \mu_2)^2}$$

Where N= sample size in each of the groups

(μ_1= population mean in decompression group)

(μ_2= population mean in the non-decompression group)

($\mu_1 - \mu_2$= clinically significant difference to be detected)

(σ^2= population variance)= Standard deviation= 25

a= conventional multiplier for alpha (probability for type I error) = 1.96

b= conventional multiplier for beta (probability for type II error) = 0.842

Therefore the estimated sample size per group= $2[(1.96 +0.842)^2 \times 25^2] / 15^2$

=43.6 which was rounded off to 44 patients per group

Therefore 88 patients were randomized into 44 decompressed and 44 non-decompressed groups.

Patients

Inclusion Criteria

(i) Patients 13 years and above who were scheduled for elective laparotomy.

(ii) Patients who gave a written consent (next of kin for those under 18 years).

Exclusion Criteria

(i) Impaired level of consciousness.

(ii) Minimal access surgery (laparoscopic).

(iii) Refusal of consent.

3.4 Sampling Method

All eligible patients were counseled and recruited into the study. At first contact patients were subjected to randomization. Age, gender, diagnosis and type of procedure were noted.

Patients and method

The principal investigator and research assistants who were postgraduate students/residents in surgery and obstetrics and gynecology recruited patients in the general surgical and gynecological wards who met the inclusion criteria. Consent for participation in the study was sought from the patients after pre-consent counseling. Consultant surgeons and gynecologists were sensitized and recruited into the study before the operations. laparotomy was done as per the indication. French gauge 14 to 18 (as per age of patient) was inserted before closure of the abdomen for those in the decompression group. Patients were reviewed in the immediate postoperative period and daily till discharge. During the study; vomiting, pulmonary complications (based on radiologist`s report of chest radiograph for those patients with respiratory symptoms), anastomotic leak (if intestinal contents were observed from surgical site or on development of peritonitis) and the hospital stay were recorded. Patients were monitored closely for need for surgical intervention, nasogastric tube insertion or re-insertion. Based on clinical findings patients were not denied the appropriate service if the need arose. The patients were discharged when they did not have any complication after the nasogastric tube had been removed (decompression group) and were feeding and opening bowels normally. The time when the decision to discharge was made was recorded.

Personnel

Consultant surgeons and gynecologists and senior residents in their final year participated in the study.

Standard laparotomy incisions were made and intra-abdominal surgeries were performed as per the indication. Surgical incisions were closed depending on the type using the same technique.

3.5 Data Collection and Analysis

Data was collected by the principal investigator and trained co-investigators (surgical and gynecological residents in their part II) using pre-designed data collection sheets.

Data collected included:

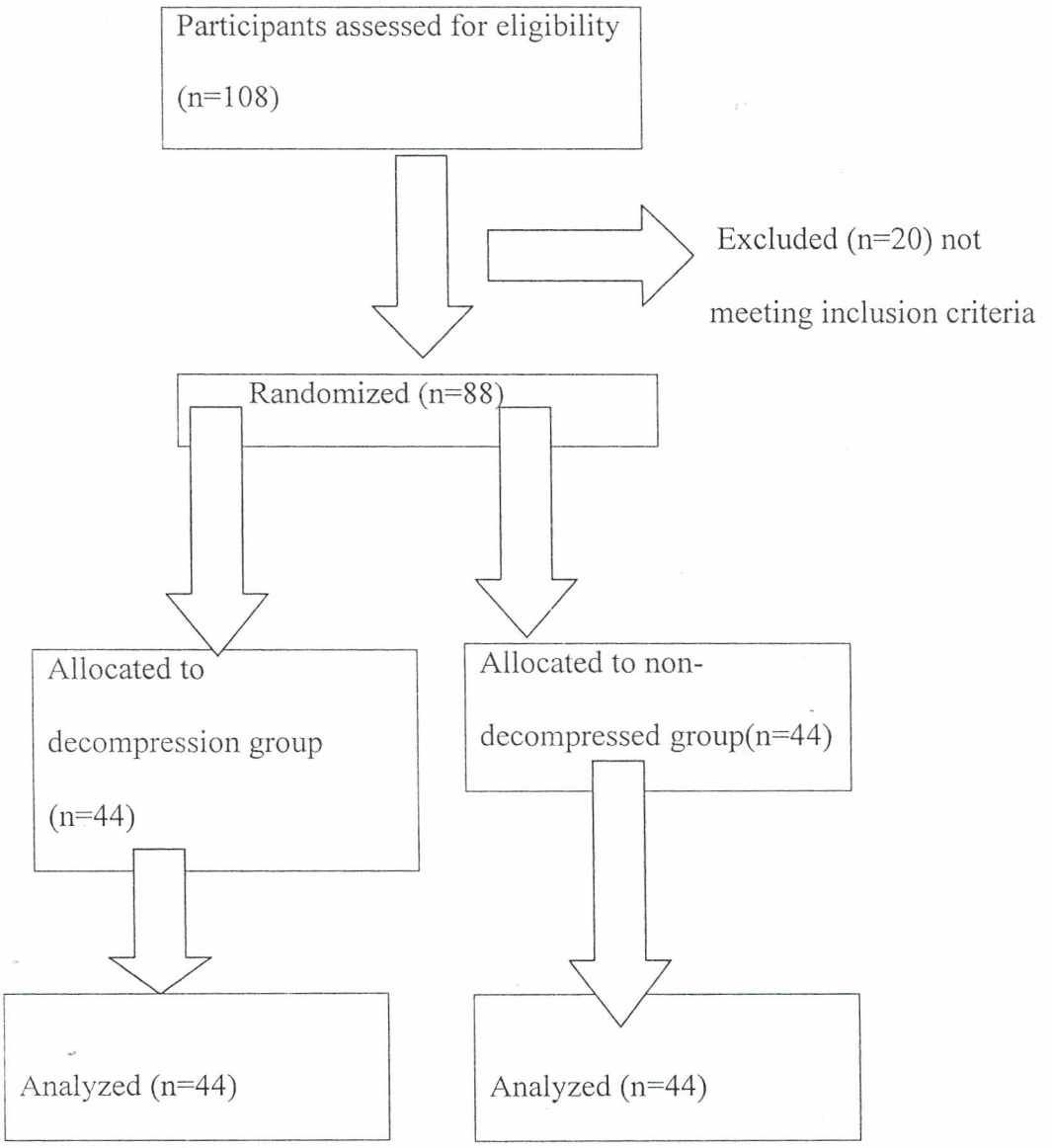
- Age and gender
- Diagnosis
- Type of procedure
- Presence of vomiting, pulmonary complications, anastomotic leak and length of hospital stay.

To maintain confidentiality no name of the study participants was recorded. Data was entered using Microsoft Excel©.

These were coded and analyzed using the SPSS software version 17©. The descriptive analysis of sample characteristics was presented in the form of tables. Differences between the two groups were analyzed with chi-square test and student t-test. Results were expressed as mean $\pm$ SD.

Chi-squared test was performed for presence of vomiting, anastomotic leak, pulmonary complications. Student t –test was performed for age and duration of hospital stay.

Figure 3.1: Chart on Participants



3.6 Results

These are the findings of the study which recruited a total of 88 patients, who had undergone elective laparotomy at KNH general surgical and gynecology wards between 15th July and 15th October, 2011. There were two arms; decompression (n = 44) and non-decompression (n = 44).

Demographic and clinical characteristics

The analysis of the demographic characteristics of the patients showed that the two groups did not differ significantly in terms of their baseline characteristics.

The comparisons between study groups for differences in patient characteristics are presented below.

3.6 Age

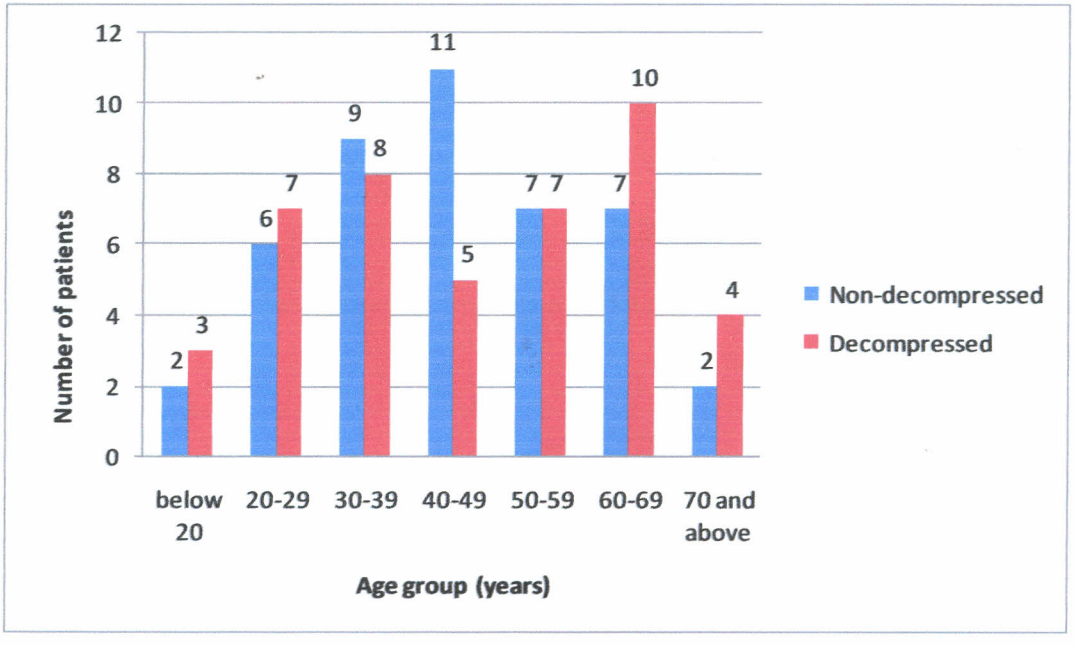
Overall, the average age of patients in the study was 44.25 years (SD 17.18). The age range was between 14 and 86 years. Table 3.1 below shows that there were no significant differences in the age of patients in the decompression and non-decompression groups (t-test, p = 0.57). The mean age of patients in the decompression group was 45.3 years compared to an average age of 43.14 years among patients in the non-decompression group.

Table 3.1: T-test comparison of the average age of decompressed and non-decompressed groups

	Number of patients	Average (SD) age in years	95% CI	t-test p value
Group				
Non-decompressed	44	43.14 (16.04)	38.08 to 48.21	
NGT decompression	44	45.30 (18.33)	39.66 to 50.94	0.57

The distribution of patients in the different age categories showed that the youngest (below 20) and oldest (70 and above) age groups had the least number of patients in both non-decompressed and decompressed groups (Figure 3.2). Most age group had comparable number of patients in the two groups except 40-49 year olds.

Figure 3.2: percent distribution of patient age according to treatment group



3.7 Gender

There were a total of 43 (48.9%) male and 45 (51.1%) females in the study as shown in Figure 3.3 below.

Figure 3.3: Gender distribution of patients in non-decompressed and decompressed groups

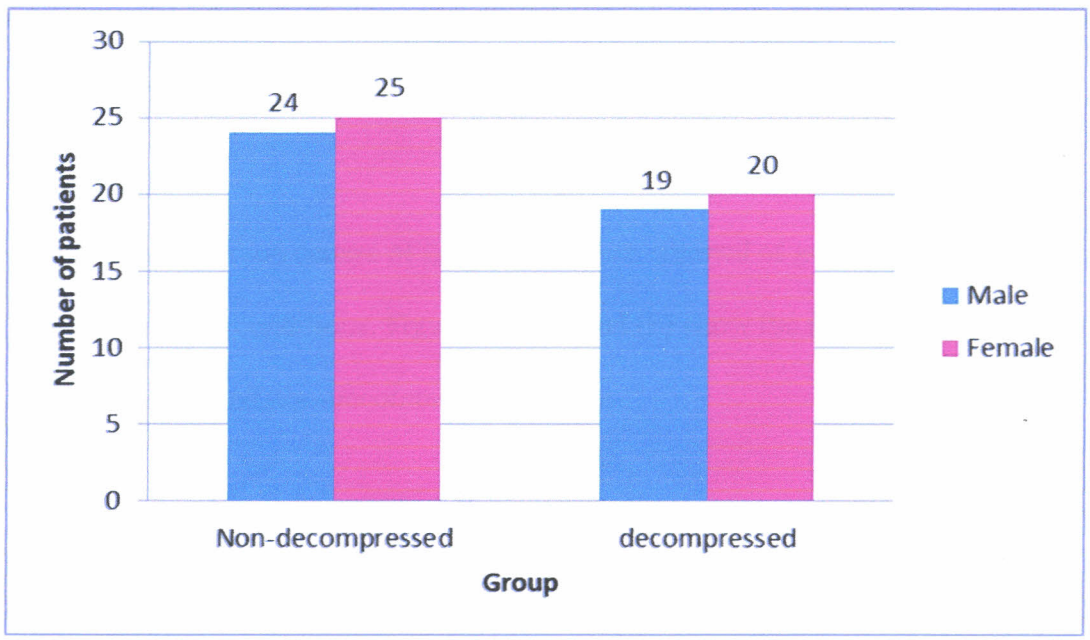


Table 3.2 shows the findings of the chi square test comparing distribution of male and female patients in the two treatment groups. Male and female patients were similarly distributed across the two study groups (chi= 1.14, df, =1, p = 0.286). Males constituted 43.2% (n = 19) of the patients in the non-decompression group and 54.5% (n = 24) of patients in the decompression group.

Table 3.2: Gender of patients in non-decompressed and decompressed groups

	Patients' gender			
	Male, n (%)	Female, n (%)	Chi square	P value
Group				
Non-decompressed	19 (43.2)	25 (56.8)		
NGT decompression	24 (54.6)	20 (45.4)	1.137	0.286

3.8 Diagnosis

Overall, the common causes of laparotomy were reversal of gut stomas, adhesions, GIT tumors and gynecologic conditions. Figures 3.4 (a) and (b) show the reasons for laparotomy in the decompression and non-decompression groups.

Figure 3.4 (a): Reasons for laparotomy in the decompressed group

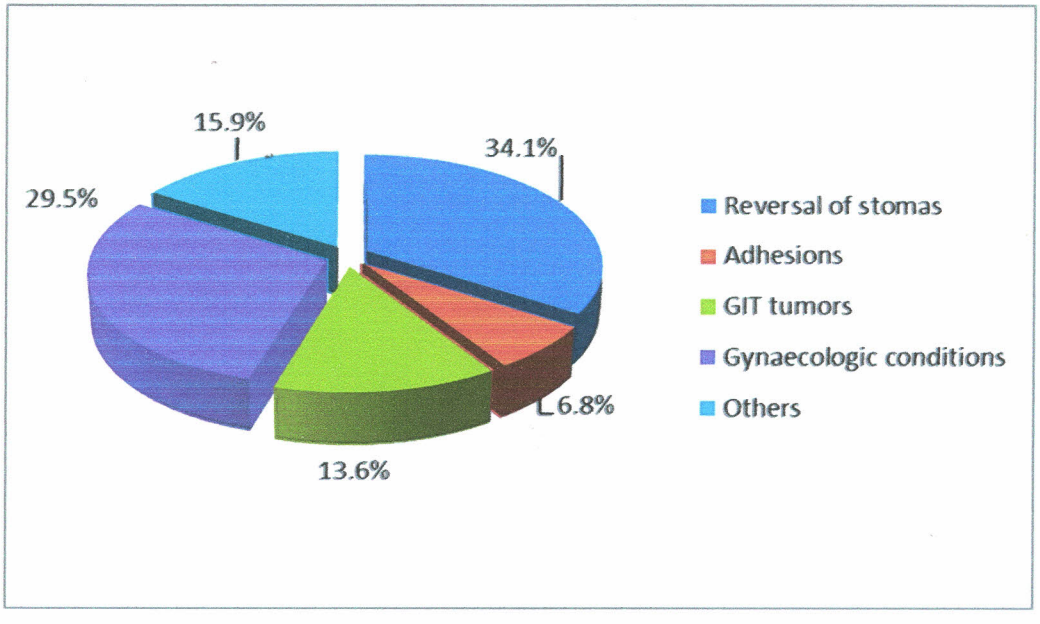
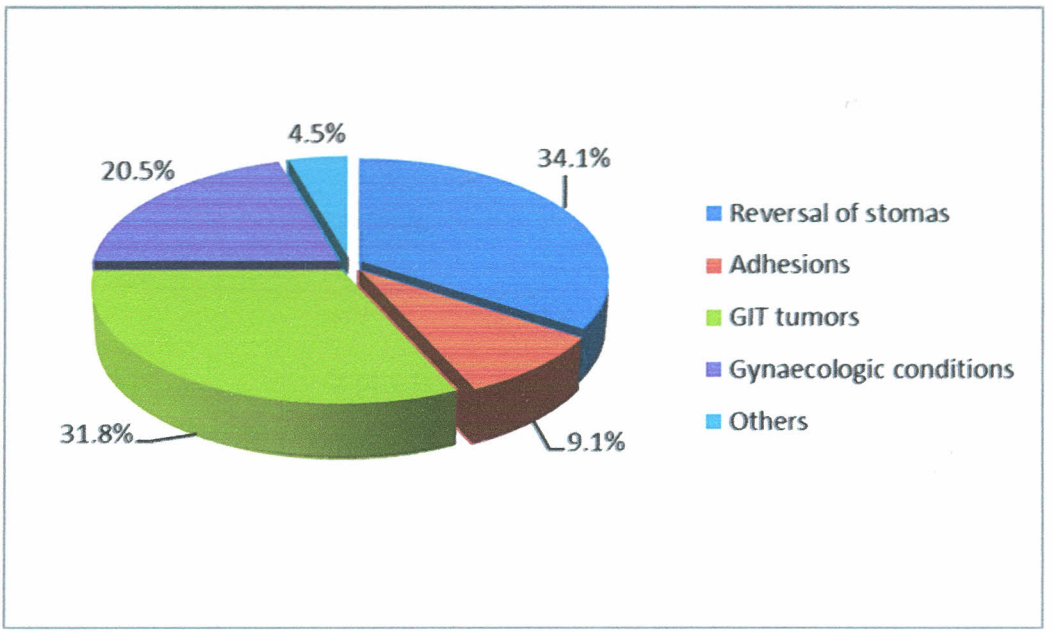


Figure 3.4 (b): Reasons for laparotomy in non-decompressed group



The summary of the various reasons for laparotomy is given in table 3.3 below.

Table 3.3: **Reasons for elective open laparotomy among patients in the non-decompressed and decompressed groups**

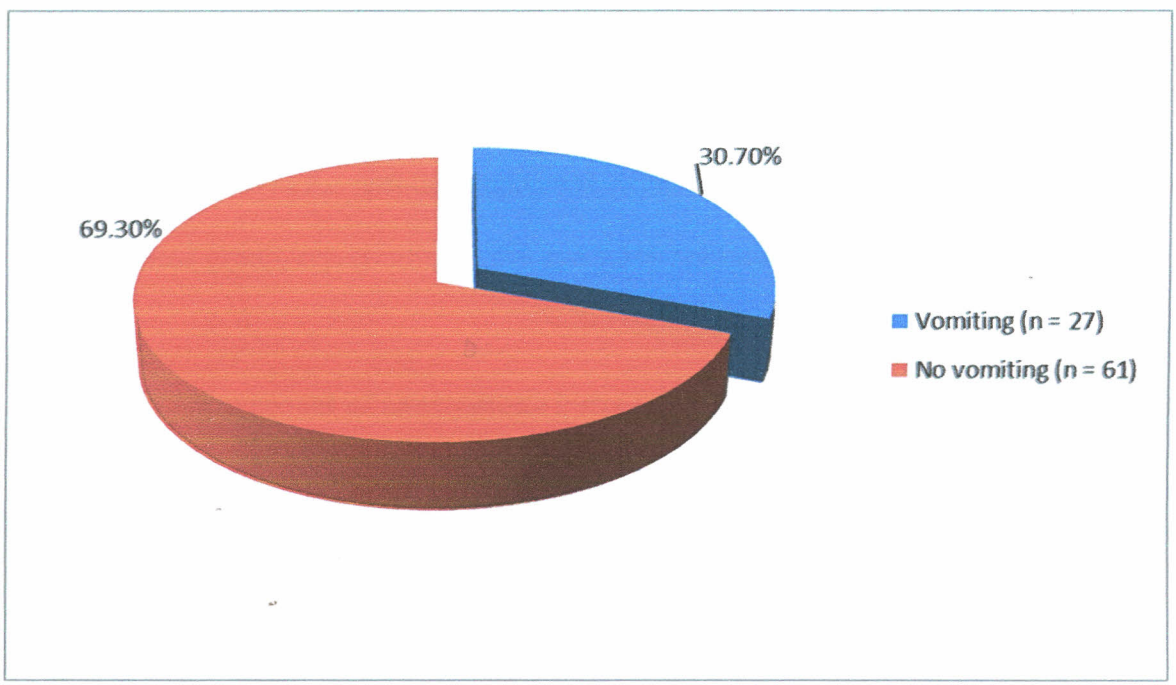
Diagnosis	Non-decompressed	Diagnosis	Decompressed
GIT		**GIT**	
Antral tumor	1 (2.27)	Cancer of stomach	2(4.55)
Fecal diversion(colostomy)	2 (4.55)	Cholelithiasis	1(2.27)
Cancer of the colon	1 (2.27)	Cancer of the colon	1(2.27)
pancreatic tumor	4 (9.09)	Pancreatic tumor	1(2.27)
Adhesions	4 (9.09)	Rectosigmoid tumor	2(4.55)
Cancer of stomach	8 (18.18)	Fecal diversion(colostomy)	6(13.64)
Reversal of gut stomas	15 (34.05)	Adhesions	3(6.82)
		Reversal of gut stomas	15 (34.05)
Gynecologic		**Gynecologic**	
Cancer of cervix	3 (6.82)	Cancer of cervix	4(9.09)
Cancer of ovary	2 (4.55)	Cancer of ovary	3(6.82)
ovarian cyst	1 (2.27)	Uterine fibroids	5(11.36)
uterine fibroids	3 (6.82)	Cancer of endometrium	1(2.27)

3.9 Outcomes

Vomiting

As shown in Figure 3.5, the overall prevalence of vomiting following surgery among the 88 patients in the study was 30.7% (n = 27).

Figure 3.5: Prevalence of vomiting following laparotomy among both non-decompressed and decompressed groups



The prevalence of vomiting was 29.6% (n = 13) among the non-decompressed patients compared to a prevalence of 31.8% (n = 14) among decompressed patients. Vomiting in the post-operative period did not show a significant association with non-decompression or decompression as shown in Table 3.4 (chi square = 0.0534, df = 1, p = 0.817).

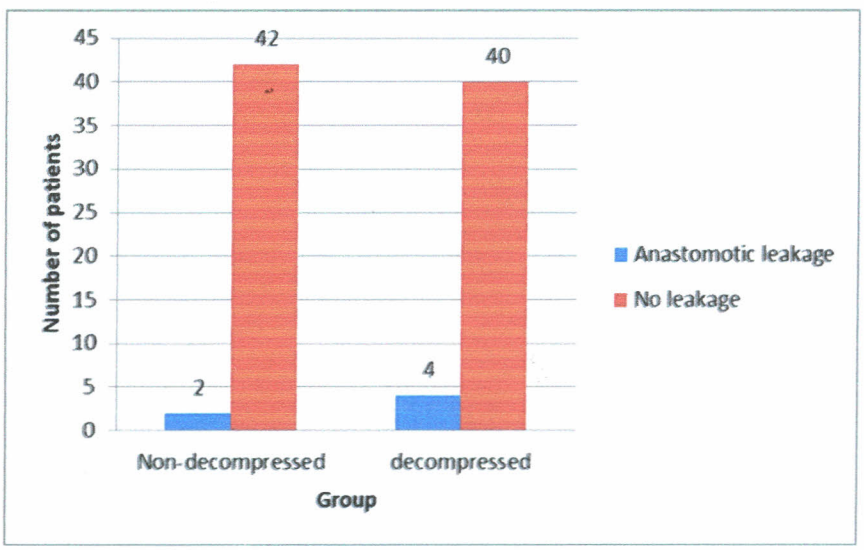
Table 3.4: Overall prevalence of vomiting and prevalence according to group

	Vomiting			
	Yes, n (%)	No, n (%)	Chi square	P value
Group				
Non-decompressed	13 (29.6)	31 (70.4)	0.0534	0.817
NGT decompression	14 (31.8)	30 (68.2)		

Anastomotic leak

Anastomotic leaks occurred in 6 out of the 88 study patients (Table 3.5 and figure 3.6). Two of these patients were in the non-decompressed group while the remaining four patients were in the decompressed group, representing 4.6% and 9.1% respectively.

Figure3.6: occurrences of anastomotic leaks in non-decompressed and decompressed groups



There was no statistically significant association between occurrence of anastomotic leaks and the use of NGT decompression (chi square = 0.715, df = 1, p = 0.398).

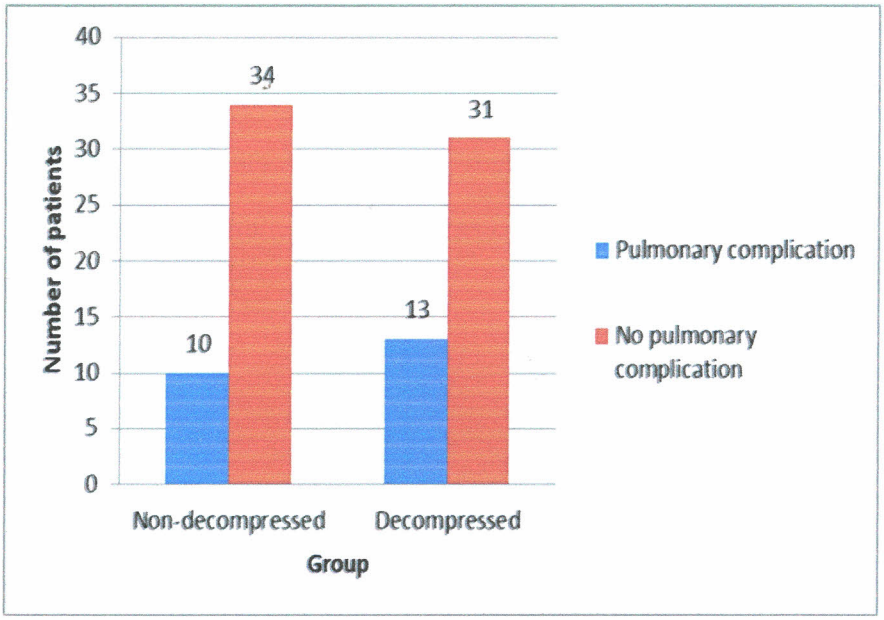
Table 3.5: Occurrence of anastomotic leaks among patients on NGT decompression and non-decompression

	Anastomotic leak			
	Yes, n (%)	No, n (%)	Chi square	P value
Group				
Non-decompressed	2 (4.6)	42(95.4)		
NGT decompression	4 (9.1)	40 (90.9)	0.715	0.398

Pulmonary complications

Approximately one-quarter (26.1%, n = 23) of all patients in the study developed pulmonary complications.

Figure 3.7: Occurrences of pulmonary complications in non-decompressed and decompressed groups



As shown in Table 3.6 below and figure 3.7 above the occurrence of these complications was slightly but not significantly higher among patients in the NGT decompressed (29.6%) compared to non-decompressed (22.8%) group (chi square = 0.530, df = 1, p = 0.467).

Table 3.6: Occurrence of pulmonary complications in non-decompressed and decompressed groups

	Pulmonary complication			
	Yes, n (%)	No, n (%)	Chi square	P value
Group				
Non-decompressed	10 (22.8)	34 (77.3)		
NGT decompressed	13 (29.6)	31 (70.4)	0.530	0.467

Length of hospital stay

There was a statistically significant association between decompression or non-decompression and the length of hospital stay (t-test p value = 0.0004). On average, patients managed using NGT decompression stayed in hospital for a significantly longer period than those in the non-decompressed group. The average length of stay for the non-decompressed group was 5.19 days (SD 1.35) compared to 8.67 days (SD 5.58) for the NGT decompressed group (difference -3.48 days, 95%CI -5.35 to -1.61)

Table 3.7: T-test comparison of length of stay for patients in non-decompressed and decompressed groups

	Number of patients	Average (SD) hospital stay in days	95% CI	P value
Group				
Non-decompressed	44	5.19 (1.35)	4.73 to 5.63	0.0004
NGT decompressed	44	8.67 (5.58)	6.95 to 10.39	
Difference		-3.48	-5.35 to -1.61	

4.0 DISCUSSION

Prophylactic nasogastric decompression after laparotomy is still practiced in KNH by many surgeons without clear guidelines. Traditionally it has been viewed as a preventive measure against adverse effects like vomiting, anastomotic leak and pulmonary complications[2]. This in effect has been thought to reduce the length of hospital stay. Studies which have been conducted in various centers have demonstrated the contrary[2, 3, 8, 10,19,25,26].

In this study, common complications were looked at among eighty eight patients who were randomized into non-decompressed and decompressed groups. The incidence of vomiting did not differ significantly between the non-decompressed and decompressed groups (29.6% versus 31.8%, p=0.817). However there was a slightly higher rate in the former group of patients. Some series of studies have demonstrated otherwise[2, 3, 25].

Nelson et al in a meta-analysis[2] of twenty eight studies where 4198 patients who underwent laparotomies(2108 decompression group and 2087 selective/ non-decompression group) reported rates of 11% and 15% respectively. This did not reach statistical significance. Nicolas et al in France[3] among patients who underwent partial or total gastrectomy found the rate of vomiting in the non-decompressed to be slightly higher than in the decompressed (21% versus 29%, p=0.04) however, it was not statistically significant.

In a Pakistan study[25] Zeeshan et al in Benazir Bhutto Hospital reported a higher rate in patients who had selective decompression as compared to routine decompression (28% versus 20%, p=0.28) among patients who underwent gut resection and anastomosis. The findings of this study

demonstrate that non-decompression slightly reduces the rate of vomiting. This is contrary to the findings in studies cited above.

Among the eighty eight patients studied six had anastomotic leak. Two patients were in the non-decompression group representing 4.6% whereas four were in the decompression group representing 9.1 %(p=0.398). All the patients who developed a leak were re-operated and did well post-operatively. Other studies have also reported similar findings[2,19,25]. Nelson et al in a meta-analysis[2] found the rate of anastomotic leaks to be 2.3% and 2.6% in non-decompressed and decompressed respectively, though it was not statistically significant. Doglietto et al in Italy[19] reported rates of 5.8% and 6.9% (p=0.71) in the non-decompressed and decompressed respectively among patients undergoing total gastrectomy. Zeeshan et al demonstrated[25] rates of 1.66% and 3.33 %(p=0.55) in patient selectively decompressed and those routinely decompressed respectively. Both Doglietto and Zeeshan did not find any statistical significance.

Though the difference in this outcome between the two groups did not reach statistical significance (p=0.398), there appears to be a tendency of developing a leak in those patients who undergo decompression. These findings agree with the other cited studies.

Pulmonary complications tended to be higher in the decompressed group as compared to the non-decompressed group (29.6% versus 22.8%, p=0.467), though it was not statistically significant. These rates are generally higher compared with studies done elsewhere[2, 19]. A meta-analysis[2] done by Nelson et al found the rates to be 6% and 9%(p=0.07) in patients who were not

decompressed as compared to those who were decompressed respectively. The Italian gastrectomy study group [19] reported a higher rate in those in the decompression group as opposed to the non-decompression group (12.1% versus 8.3%, p=0.33 respectively). Despite my findings, there was no statistical significance. Zeeshan et al found[25] the rate to be slightly higher in the non-decompressed group 19.4% as compared to the decompressed group 20 % (p=0.06), even though it was not statistically significant. The study agrees with the others in terms of higher rates of pulmonary complications in the decompressed group.

Duration of hospital stay was longer in the decompression group as compared to non-decompression group (8.67 versus 5.19 days, SD 5.58 versus 1.35 respectively, p=0.0004). Decompression patients have also been observed to have a longer hospital stay in other studies[26]. At Mulago hospital in Uganda Ocen et al found that among patients who underwent laparotomy the decompressed stayed in hospital for a significantly longer duration as compared to those who were not decompressed(11.0 days $\pm$ 2.54 days versus 7.7 days $\pm$ 2.2 days, p<0.0001). Nadim et al however[26] demonstrated that even though the decompressed group had a longer hospital stay, it was not statistically significant (p>0.05).

Findings in this study generally do not point to any significant benefits associated with the use of nasogastric decompression after laparotomy. Patients who are not decompressed seem to have better outcomes than those who are decompressed. Again patients who are decompressed tend to stay longer in hospital compared to the non-decompressed.

4.1 Conclusion

The use of nasogastric decompression after elective laparotomy does not reduce the occurrence of complications in KNH. Patients who do not undergo decompression generally have better outcome as opposed to those who are decompressed. Decompressed patients had a significantly longer length of hospital stay. The use of nasogastric decompression after laparotomy needs to be reviewed and guidelines developed.

4.2 Recommendations

(i) There is need for evaluation of the utility of nasogastric decompression after laparotomy.

(ii) There is need for a similar study in emergency laparotomy.

(iii) There is need to develop guidelines for nasogastric decompression after laparotomies.

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APPENDICES

APPENDIX I: DATA COLLECTION SHEET

Groups: 1. Non- Decompressed 2. Decompressed

Study number.....

1. Pre-surgery

   (i) Demographic information.

   Unit number.....

   Age.....

   Gender: Male [ ] Female [ ]

   (ii) Diagnosis.....

   (iii) Indication for surgery.....

   (iv) Date of recruitment into study ...../...../.....

2. Intra-operative

   Type of procedure done.....

3. Post-operative follow up.

   (i) Presence of vomiting YES [ ] NO [ ]

   (ii) Pulmonary complications YES [ ] NO [ ]

   (iii) Anastomotic leak YES [ ] NO [ ]

   (iv) Duration of hospital stay in days.....

   (v) Duration of nasogastric tube in place (days).....

APPENDIX II: CONSENT BY PARTICIPATING PATIENT

Study No..... **Hospital No**.....

Purpose of the study

The purpose of this study is to determine the utility of nasogastric decompression after laparotomy at Kenyatta National Hospital. The information gathered will be used to improve the management of patients undergoing open laparotomy.

Risks and benefits

The study will provide clinicians with essential information on utility of nasogastric decompression after laparotomy and therefore aid them in improving clinical management of these particular patients. There is no harm or risk anticipated for participating in this study. However, during the study if the researcher identifies a complication on you he will recommend or refer you appropriately. No additional tests outside the usual ones for treatment will be carried out and no extra cost to you will be incurred in participating in this study.

Voluntary participation

Participation in this study is out of your free will. Medical care will not be denied in case you decline to participate in the study. You may terminate participation at any time with no consequences whatsoever.

Confidentiality

All information will be treated with confidentiality. Your identity will not be published whatsoever.

I the undersigned have been explained to and understand the above and voluntarily accept to participate in the study.

Signature/Thumb print .....

Patient/Next of kin Tel. 1 (Patient)..... Tel.2 (Next of kin).....

Dr. Basweti Wilfred Obino 0721257075 Chairman KNH/UON-ERC 0722708808

APPENDIX III: KIBALI CHA RUHUSA

Nambari ya utafiti..... **Nambari ya hospitali.....**

Sababu ya utafiti

Sababu ya utafiti huu ni kuthibitisha manufaa ya utumishi wa "nasogastric decompression" baada ya upasuaji wa tumbo. Utafiti huu utafanyika katika hospitali kuu ya Kenyatta na matokeo yake yatatumiwa kupendekeza njia za kuboresha matibabu kwa wagonjwa ambao wanafanyiwa upasuaji wa tumbo.

Hatari na manufaa

Utafiti huu utaimarisha ujuzi wa madaktari kwa wagonjwa ambao wanafanyiwa upasuaji wa tumbo. Hatutarajii hatari zozote kwako unaposhiriki kwenye utafiti huu. Iwapo wakati wa utafiti, mtafiti atagundua shida katika matibabu yako, atapendekeza au kukutuma kwa matibabu yanayofaa. Utafiti huu hautakugharimu fedha zaidi.

Uhusika kwa hiari

Kuhusika kwa utafiti huu ni kwa hiari yako mwenyewe na hauwezi kushurutishwa. Utahudumiwa hata kama utakataa kuhusika kwa huu utafiti. Una uhuru kutamatisha kuhusika wakati wowote bila madhara yoyote yale.

Usiri

Habari zozote utakazotoa zitawekwa kwa siri na jina lako halitachapishwa popote.

Ninathibitisha yakuwa nimefahamu yale nimeelezewa na mtafiti na nimekubali kwa hiari yangu mwenyewe kuhusika katika utafiti huu.

Sahihi/kidole cha Gumba(kushoto).....

(mhusika/jamaa wa karibu) simu 1(mhusika).....simu 2(jamaa wa karibu).....

Daktari Basweti Wilfred Obino 0721257075 Mwenyekiti KNH/UON-ERC 0722708808

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14th July 2011

Dr. Wilfred Obino Basweti
Dept.of Surgery
School of Medicine
University of Nairobi

Dear Dr.Basweti

Research Proposal: "Outcomes in Nasogastric Non-decompressed versus decompressed groups after elective open laparotomy at KNH: A prospective randomized study" (P150/04/2011)

This is to inform you that the KNH/UON-Ethics & Research Committee has reviewed and **approved** your above revised research proposal . The approval periods are 14th July 2011 13th July 2012.

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given. Clearance for export of biological specimens must also be obtained from KNH/UON-Ethics & Research Committee for each batch.

On behalf of the Committee, I wish you a fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of the data base that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely

PROF A N GUANTAI
SECRETARY, KNH/UON-ERC

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The Dean, School of Medicine, UON
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