Enhancing Recovery in Non-Critical Care Emergency Bowel Resection.

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ABSTRACT

Introduction: The aim of this study was to investigate the feasibility and safety of an enhanced recovery approach incorporating avoidance of routine post-operative nasogastric (NG) decompression and early oral fluids and diet when compared to traditional care in non-critical care (Level 0/1) patients following emergency bowel resection.

Method: A single centre comparative observational study was used to compare outcomes between two existing parallel groups of Level 0/1 emergency bowel resection patients. Strict inclusion criteria governed eligibility. Groups were differentiated according to presence (Traditional care, TRAD) or absence (Enhanced care, ERP) of NG tube at the end of surgery. The primary study outcome was toleration of oral fluid and diet. Secondary outcomes were post-operative complications and length of hospital stay. Study endpoints were inpatient discharge home, transfer to another speciality, death, insertion/re-insertion of NG tube and re-operation.

Results: Between October 2013 and February 2015, 61 patients (27 ERP, 34 TRAD) met the eligibility criteria. Study groups were comparable. On average, the ERP group tolerated oral fluids ($p=0.001$) and oral diet ($p=0.019$) significantly earlier than the TRAD group. No statistically significant differences were found between groups in incidence of post-operative complication ($p=0.589$), length of hospital stay ($p=0.189$) or study endpoints ($p=0.386$)

Conclusion: An enhanced care approach incorporating avoidance of routine NG decompression and re-introduction of early oral fluid and diet is tolerated in Level 0/1 emergency bowel resection patients with no significant difference in post-operative complication or length of hospital stay when compared to traditional care. This supports the feasibility and safety of an enhanced care approach in this patient group although further research is required in relation to those with intra-operative ischaemia.

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Abbreviations

ACPGBI	Association of Coloproctology of Great Britain and Ireland
APACHE	Acute Physiology and Chronic Health Evaluation
ARDS	Acute Respiratory Distress Syndrome
ASA	American Society of Anaesthiologists
ASGBI	Association of Surgeons of Great Britain and Ireland
BMI	Body Mass Index
CONSORT	Consolidated Standards of Reported Trials
CR-POSSUM	Colorectal POSSUM (see POSSUM)
CT	computerised tomography
DOH	Department of Health
ER	Enhanced recovery
ERP	Enhanced care group (Enhanced recovery pathway)
FET	Fishers exact test
GA	General Anaesthetic
GDFT	Goal Directed Fluid Therapy
GI	Gastrointestinal
ITU	Intensive Therapy Unit
IV	Intravenous
KGH	Kettering General Hospital
LA	Local Anaesthetic
NA	Not applicable
NB	Of note
NCEPOD	National Confidential Enquiry on Peri Operative Deaths
NCJ	Needle catheter jejeunostomy
NELSON	Northampton Electronic Library Search on Line
NELA	National Emergency Laparotomy Audit
NG	Nasogastric
NHS	National Health Service
NREC	NHS Research Ethics Committee
P-POSSUM	Portsmouth POSSUM (see POSSUM)

PCA	Patient Controlled Analgesia
POI	Post operative ileus
PONV	Post operative nausea and vomiting
POSSUM	Physiologic and Operative Severity Score for the enUmeration of Mortality and morbidity
RCT	Randomised Controlled Trial
SBRx	small bowel resection
TPN	Total Parenteral Nutrition
TRAD	Traditional Care Group
VTE	Venous Thrombo Embolus

Glossary

Bowel resection: encompasses both small and large bowel resection defined as any **open** surgical procedure which involves full resection, with or without formation of stoma and/or primary anastomosis, of the small bowel (jejunum, ileum), colon (caecum, ascending, transverse, descending and sigmoid), rectum or anus. NB: laparoscopic procedures and defunctioning stomas in the absence of full resection are **not** included in the term bowel resection for the purposes of this study.

Early oral diet: The post-operative re-introduction of oral fluids 'as tolerated' the evening of surgery and the re-introduction of oral diet 'as tolerated' from 08.00 the first day post-operatively.

Emergency is a general term used to differentiate and describe any patient or procedure which does not follow an elective (planned) pathway. The term encompasses all three of the NCEPOD (National Confidential Enquiry into Peri-operative Death, 2004) definitions: immediate (surgery within 2 hours of decision), urgent (surgery within 24 hours of decision) and expedited (surgery within days of decision).

Enhanced recovery: is defined as the avoidance of routine post-operative naso-gastric (NG) decompression and the early re-introduction of oral diet (see *early oral diet* above).

Inpatient transfer to another acute speciality: transfer to a higher level of care or to a medical speciality (for example, cardiology, respiratory)

Length of stay: Length of hospital inpatient stay measured in hours from the end of operation to the time of *surgical inpatient discharge*.

Non-critical care patient: a post-operative self-ventilating patient not requiring intensive support such as inotropes, haemodialysis, cardiac support or sedation. These patients may be nursed in a critical care or ward environment and align to Level 0 and 1 as defined by the Intensive Care Society (2009)

Mortality: Number of deaths occurring within the *length of stay*

Post-operative complications: defined as any deviation from the post-operative course occurring within the *length of stay*, encompassing all infectious or non-infectious complications classified according to source (abdominal or extra-abdominal)

Re-insertion of nasogastric (NG) tube: indicated in the event of post-operative ileus defined as clinical abdominal distension, accompanied by 2 episodes of vomitus >200mls within 4 hours in the absence of the passage of flatus or stool.

Re-operation: Defined as any re-operation or therapeutic radiological intervention (such as drainage) required to treat a post-operative complication

Surgical Inpatient discharge: defined as time surgically fit for discharge home or to a place of rehabilitation

Tolerance of oral diet: defined as the time in hours between the end of surgery and the time any solid diet (minimum 200 calories equivalent to 2 slices of toast and butter/bowl of cereal) is consumed without an episode of vomiting in the subsequent 4 hours.

Tolerance of oral fluid: defined as the time in hours between the end of surgery and the time 150-200mls of clear fluid (cup/glass of water/juice/black tea or

coffee) is ingested by mouth without an episode of vomiting or >100mls NG aspirate/free drainage (if NG tube in situ) in the subsequent 4 hours.

Traditional care: refers to the routine post-operative care following emergency bowel resection which involves NG decompression and only sips of water by mouth until resolution of bowel dysmotility defined for the purposes of this study as <100mls drainage or aspirate from NG tube in previous 4 hours or the passage of flatus or faeces.

Chapter 1: Introduction

'Enhanced recovery' is a multi-modal, fast-track, pathway of care which incorporates elements of best anaesthetic and surgical practice to minimise the stress of surgery for the individual and promote a quicker post-operative recovery. Since its adoption and implementation as the national standard of care for those undergoing *elective* colorectal surgery (DOH 2011), enhanced recovery has revolutionised traditional care of the elective colorectal surgical patient.

The Association of Surgeons of Great Britain and Ireland (Khan et al, 2009) advocate the implementation of enhanced recovery principles *where possible* in the *emergency* situation, however, very little has been published relating to enhanced recovery or elements of enhanced recovery in those undergoing *emergency* bowel resection outside a critical care environment. Traditional care therefore remains the norm for this patient group although there is evidence that elements of enhanced care are being adopted in practice (Stupples et al, 2013).

Emergency bowel surgery is known to be associated with an unacceptably high mortality and morbidity rate (NCEPOD 2011), reflecting fundamental differences between elective and emergency bowel resection patients which necessitate adaptations of existing enhanced pathways for applicability to the emergency situation. While nationally, the National Emergency Laparotomy Audit (NELA) is collecting data to support recommendations for best practice in emergency bowel surgery, the report on their first year of data collection (December 2013 - November 2014) has only recently been published (NELA 2015).

One of the key differences between enhanced and traditional care following bowel resection is the avoidance of naso-gastric (NG) decompression and the resumption of a normal diet within 6-24 hours post-operatively compared to the routine use of NG decompression and a restricted oral intake until bowel motility returns (clinically indicated by the passage of flatus or faeces 3-5 days post-operatively). The aim of this thesis is to investigate the feasibility and safety of an enhanced care approach (incorporating early oral feeding and avoidance of

routine NG decompression) when compared to traditional care (routine NG decompression and delayed feeding) in non-critical care patients following emergency bowel resection.

Chapter 2: Background

2.1: Enhanced recovery and bowel resection

Post-operative care following bowel resection traditionally involves routine naso-gastric (NG) decompression with only sips of water by mouth until the return of bowel motility. This care continues to be common practice for those undergoing *emergency* bowel resection as it is believed to prevent post-operative nausea and vomiting (PONV) and protect the newly formed surgical anastomosis (Lewis et al 2001).

However, in recent years, multi-modal, evidence based, fast track 'enhanced recovery' pathways (Fearon et al 2005; Khan et al 2009; DOH 2011) have revolutionised the care of *elective* bowel resection patients: Avoidance of routine naso-gastric decompression and resumption of a normal diet within 6-24 hours post-operatively has become the new norm for these patients.

Emergency bowel resection is associated with one of the highest surgical mortality rates with high risk emergency patients undergoing laparotomy (as an immediate life preserving procedure) reported to have a 1 in 4 risk of 30 day mortality (NCEPOD 2011). Overall mortality for emergency laparotomy (within which bowel resection is categorised) has been reported at 14.9%, rising by 4% for every decade of age over 50 years (Saunders et al, 2012), demonstrating a clear need to improve outcomes in this patient group. On a national basis, this is being addressed through modification of *processes* of care (that is, the prompt identification, assessment and early resuscitation of patients, timely access to theatre, early involvement of senior staff and access to appropriate levels of post-operative care) ensuring the requisite infrastructures are in place to support improvements in practice (NCEPOD 2011, Royal College of Surgeons 2011, Saunders et al 2012). In England and Wales these improvements are being monitored and reported on by the Royal College of Anaesthetists on behalf of the National Emergency Laparotomy Audit (NELA 2015).

Clinically, the Association of Surgeons of Great Britain and Ireland (ASGBI) advocate the application of enhanced recovery (ER) principles where possible in the emergency situation (Khan et al, 2009), however, fundamental differences between emergency and elective patients necessitate adaptations to existing elective ER pathways for applicability to emergency patients. In the absence of any published emergency guidelines, Stupples et al (2013) adapted the ASGBI elective guidelines (Khan et al, 2009) to retrospectively audit adoption of ER principles in emergency bowel resection patients (n=50). Detailed *in Appendix 1 (page 78)*, this audit found that out of 16 ER principles, 14 had been adopted with varying degree into the care of emergency bowel resection patients: Twenty one patients (42%) did not have routine post-operative naso-gastric decompression but only three patients (6%) were taking enteral diet (via mouth or feeding tube) within 48 hours of surgery.

Prior to April 2013, a review of the literature found no study focusing specifically on enhanced recovery in any *emergency* surgical population. Since then, two studies have been published, one of which focuses on emergency laparoscopic repair of perforated duodenal ulcer (Gonenc et al, 2014); the other (Lohsiriwat, 2014) on emergency surgery for obstructed colorectal carcinoma.

Gonenc et al (2014), as part of their enhanced protocol, removed the NG tube at the end of surgery and permitted oral fluids from day 1 post-operatively, building to soft and then full diet over subsequent days. In contrast, Lohsiriwat (2014) removed the NG tube in their enhanced group 24-48 hours post-operatively (when aspirate was less than 400mls) and then permitted build up to full diet.

2.2 Post-operative ileus

Multiple factors influence toleration of early diet however the specific concern following bowel resection is that intolerance is caused by post-operative ileus (POI) defined as the inhibition of propulsive bowel activity, manifested by abdominal distention, nausea, vomiting, and diet intolerance (Lubawski & Saclarides, 2008). Non-complicated ileus occurs in all patients undergoing bowel

resection; however, the duration of ileus corresponds poorly with the traditional methods of identifying resolution (that is, the presence of bowel sounds, passage of flatus or stool). Small bowel function is known to return within 6-12 hours after laparotomy, gastric function within 12-24 hours and large bowel function between 48-72 hours (Warren et al, 2011) yet Delaney (2004) reported 40% of patients undergoing laparotomy have a prolonged ileus of greater than 5 days.

A meta-analysis of 37 studies encompassing 6000 patients (Verma & Nelson, 2010) found those without routine post-operative NG decompression have an earlier return of bowel function, a decrease in pulmonary complications and no statistically significant difference in incidence of anastomotic leakage. Only one of these studies specifically focused on emergency (trauma) patients (Knoepp and Thomae, 1999). In addition, incidence of vomiting was found to be higher in those without NG decompression although this did not reach statistical significance and was offset against the discomfort patient's associate with an NG tube.

Andersen et al (2006, updated 2011) similarly found that early post-operative feeding (either by mouth or feeding tube within 24 hours of bowel resection) significantly reduced mortality when compared to delayed feeding in a meta-analysis of 14 studies (1224 patients). While not reaching statistical significance, this meta-analysis also found that those fed early had overall fewer post-operative complications (wound infection, anastomotic leak, intra-abdominal abscess, pneumonia) and a shorter length of hospital stay, although incidence of vomiting was higher in the early fed groups. Again only one of these studies (Kaur et al, 2005) specifically focused on emergency (post-laparotomy critical care) patients.

A relatively new and yet simple strategy found to reduce duration of post-operative ileus in those undergoing elective bowel resection is gum chewing. Several meta-analyses (Noble et al, 2009; Fitzgerald and Ahmed, 2009; Purkayastha et al, 2008; de Castro et al, 2008; Chan and Law, 2007) have

consistently shown significant reductions in duration of POI (as measured by time to first flatus and first stool) associated with gum chewing in elective bowel surgery patients. While the precise mechanism by which this works is unknown, no study has reported any adverse effects with chewing gum or increase in post-operative complications (Basaran and Pitkin 2009).

Pharmacological approaches to treating POI following bowel resection include the use of metoclopramide, erythromycin and neostigamine; however, most pharmacological interventions are confounded by the action of opiates although in clinical trials mu-opioid receptor antagonists such as alvimopam appear to be overcoming this problem when tested on elective GI and gynaecological patients, (Lubawski & Saclarides, 2008; Kehlet, 2008).

Enhanced recovery approaches integrate strategies to moderate incidence and duration of POI. However, while these strategies work synergistically to attenuate the surgical stress response and promote early return of gut function approximately 20% of elective patients fail to tolerate early diet (Stewart et al, 1998).

A fundamental difference between emergency and elective bowel surgery is the presenting condition of the bowel. In the emergency situation, owing to the acuity of aetiology, the bowel is often oedematous and/or ischaemic predisposing emergency patients to a higher risk of post-operative complication. The feasibility and safety of early feeding in this situation is therefore reviewed in the next chapter.

Chapter 3: Literature Review

3.1 Early feeding and emergency bowel resection

A literature review qualitatively summarises data collated from an array of primary studies on a chosen subject (Hutson, 2009). To promote methodological rigour and quality, this literature review was guided by the systematic and comprehensive approach described by Fink (2005).

3.1.1 Search parameters

The NELSON (Northampton Electronic Library Search On Line) search engine was used to search the 'Nursing and Health Profession' databases listed in *Appendix II (page 81)* and the Cochrane library for articles containing the following search terms: 'early feeding', 'colorectal surgery', 'intestinal anastomosis' and 'emergency'. These terms were searched individually and combined with Boolean operators such as 'and' and 'or' to increase sensitivity (Khan et al, 2003). The search was conducted in June 2015 and encompassed articles published since January 1979, the date of publication of one of the earliest critical care studies related to early feeding (Sagar et al, 1979).

3.1.2 Selection criteria

Articles were selected according to content and language criteria. Included articles had to meet all five of the following criteria:

1) *Study design*: any primary research study.
2) *Study intervention*: any comparison of outcomes between patients receiving early post-operative enteral feeding versus traditional post-operative nasogastric decompression and nil/sips of water by mouth until resolution of bowel motility

3) *Study population*: any adult patient (aged 18 years and over) undergoing emergency laparotomy and bowel/intestinal resection with or without covering stoma.
4) *Publication language*: Available in English
5) *Ethical considerations*: Documented evidence of approval from appropriate ethical committees for primary research studies.

These criteria ensured the selected articles were focused on the review subject (early feeding in emergency bowel resection) excluding studies which concentrated on elective or paediatric patients and studies which compared different types and/or routes of feeding.

The restriction to English language was necessary as the only resource available to aid translation was a web translator. If the selected study was not in electronic format or linked to the web translator, the resources to translate hard copy were not available.

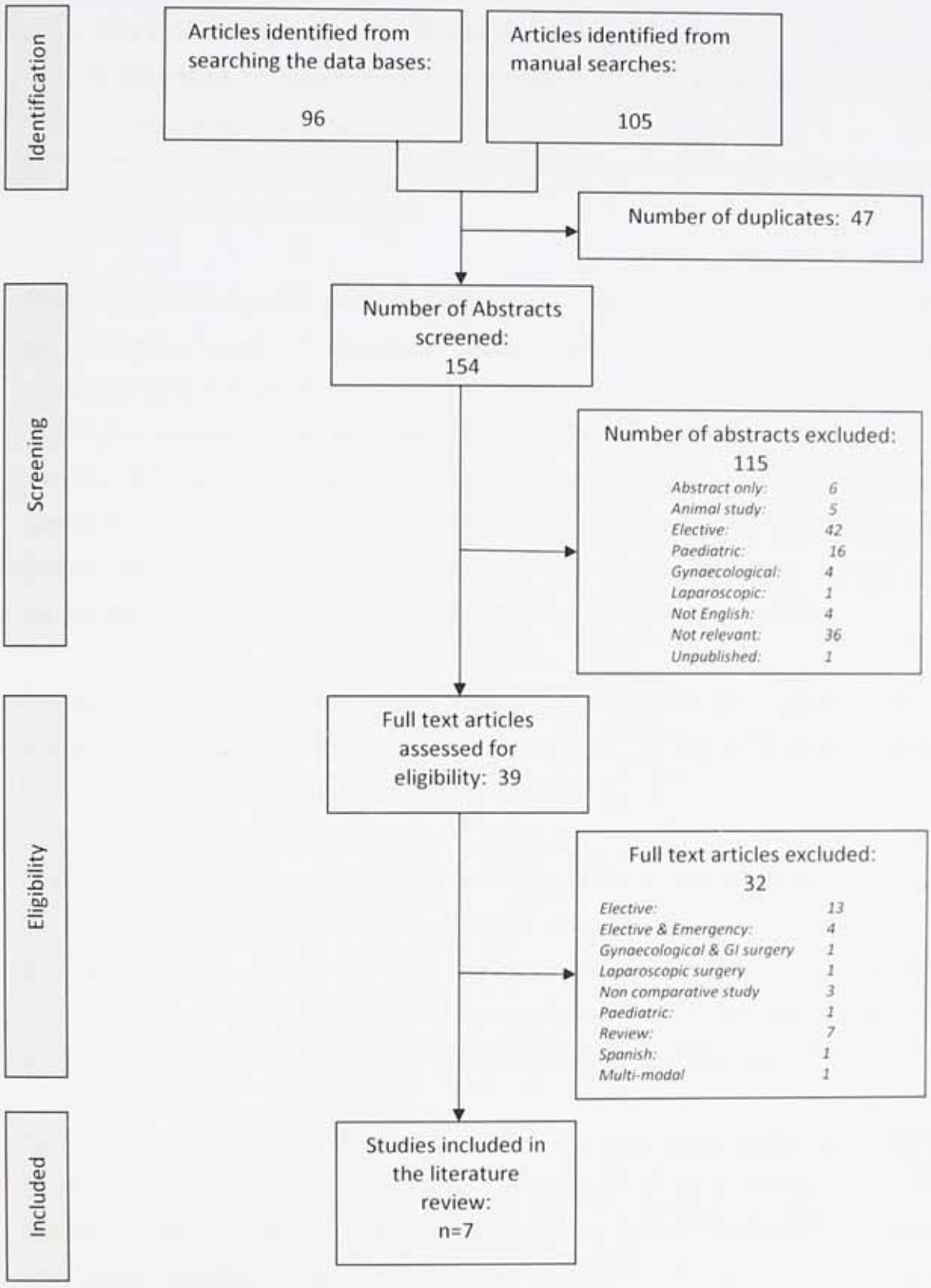
For the purpose of the literature review, systematic reviews and/or meta-analyses were classified as secondary research studies and therefore excluded from the review. However, secondary studies were screened for primary studies and used to inform the context of the thesis.

The reference lists of all selected articles were examined and screened to identify and include any other articles which met the selection criteria. This process was repeated with every new article located.

3.1.3 Included/Excluded studies

In total the search identified 201 articles of which 47 were duplicates and 115 did not meet the selection criteria as detailed in *Figure 1*. Of the remaining 39 full articles, 27 did not meet the selection criteria. A further four were excluded as:

Figure 1: Literature review process



a) either the nature of included patients (emergency/elective) was ambiguous (Kishore et al, 2014), or;

b) they included both emergency and elective patients without any clear stratification of results in their emergency groups (Hosseini et al, 2010; Lassen et al, 2008), or;

c) there was no comparison of stratified results with an equivalent traditional group (Verheijen et al, 2010).

After much consideration one other study (Lohsiriwat, 2014) was also excluded as, although it focused on emergency obstructed colorectal patients, it compared enhanced care to traditional care. While Lohsiriwat (2014) included early feeding (defined as removal of the NG tube at 24-48 hours post-op if aspirate <400mls in previous 24 hours) in their enhanced care group protocol, other enhanced strategies were also included in this protocol. Consequently, care between study groups differed in multiple dimensions and therefore the study reflects the synergistic effect of *multiple* enhanced strategies not just early feeding.

In total 7 studies (Kaur et al, 2005; Klappenbach et al, 2013; Lee et al, 2014; Malhota et al 2004; Moore et al 1986; Saad et al 2007 and Singh et al 1998) were included for review (summarised in *Table 1*).

Much debate went into the inclusion of one of these studies (Klappenbach et al, 2013) as it included a broadly heterogenous range of procedures (both open and laparoscopic) and patients (from the age of 14 years). However, in randomising and stratifying patients to high risk (bowel resection) and low risk groups, the study enabled extraction of relevant comparable data justifying inclusion.

Of the six other studies: four randomised controlled trials (Moore et al 1986, Singh et al 1998, Malhota et al 2004 and Kaur et al 2005) focused on early feeding via naso-enteric or jejeunostomy tube in critically ill patients following emergency intestinal resection or repair. All these studies demonstrate the feasibility of early tube feeding following emergency bowel resection and report

both significant reductions in incidence of major septic complications and an earlier return of bowel function in their early fed groups.

One other randomised controlled trial (Saad et al, 2007) focused on early *oral* feeding in emergency intestinal anastomosis surgery; however, in using total parenteral nutrition (TPN) for the control group, the findings of this study are confounded as TPN is known to be an independent factor for sepsis (Moore et al, 1989). The final study (Lee et al, 2014) retrospectively compared outcomes in two groups of patients following emergency intestinal resection. The groups were differentiated according to time diet was commenced (within or after 48 hours) but included both tube and oral feeding and those requiring mechanical ventilation post-operatively. Initially published in Korean, this study contains a few anomalies which may be a result of errors in translation.

3.1.4 Quality Appraisal

The multiplicity of included study designs limits the range of tools available to appraise the quality of included studies as not all quality measurement criteria are applicable to all study designs (for example; random allocation procedure in retrospective studies).

To address this problem, Hutson (2009) adapted a tool used by Di Blasi et al (2001) and Kleijnen et al (1994), demonstrating a 90% comparison in a simple reliability test of the adapted tool. The original tool (used for randomised controlled trials) ranks studies according to score: 8.0 -10.0 (very good); 7.0 - 7.9 (good); 5.0 - 6.9 (acceptable) and less than 5.0 (poor). The adapted tool excludes the randomisation and blinding criteria and adjusts the ranking as follows; 6.0 - 8.0 (very good); 5.0 - 5.9 (good); 3.0 - 4.9 (acceptable) and below 3.0 (poor). The original and adapted tool has been used to score and rank the quality of studies included in this review to support internal validity (see *Appendix III, page 82*). None of the included studies rated poor; one RCT scored very good (Malhotra et al, 2004); two RCT's (Klappenbach et al, 2013; Moore et al,

1986) and the retrospective study (Lee et al, 2014) scored good; the remaining studies scored acceptable.

3.1.5 Review Conclusions

Seven studies in total were identified relating specifically to early feeding following emergency bowel/gastrointestinal surgery. The findings of these studies are summarised in *Table 2*. Each study concluded that early enteral feeding is feasible and safe in this patient population with no study reporting any significant increase in major complication associated with early feeding.

However, the heterogeneity of included studies (diversity of patients, surgical procedures, surgical approach, underlying aetiologies, level of care and early feeding protocols) limits the ability to extrapolate conclusions in relation to *non-critical care* (Level 0/1) patients following emergency bowel *resection*. All except two studies (Moore et al, 1986; Klappenbach et al, 2013) commenced feeding at least 24 hours post-operatively, but only one of these studies (Klappenbach et al, 2013) focused on soft oral diet (opposed to liquid diet/tube feeding) within 24 hours of surgery.

The detrimental effects of under nutrition on recovery and healing have long been known (as summarised by Holmes, 2007). The catabolic effects of illness and surgery place those undergoing emergency bowel resection at risk of being under nourished, yet these patients continue to be routinely starved post-operatively. Oral diet is the simplest, cheapest and least invasive form of nutrition, however, this review has highlighted that few studies have investigated the feasibility of early oral intake in non-critical care (Level 0/1) emergency bowel resection patients.

Table 1: Summary of included studies: early feeding in emergency bowel resection

Author/Date Country	Study type	Type of patient	Sample size	Exclusions	Care Area	Early feeding group (EF)		Control/Traditional Care (CG)		Findings/Comments
						No in group	Protocol	No in group	Protocol	
Kaur et al (2005) India	Prospective RCT	Malnourished adults age 18 -70 years. Emergency exploratory laparotomy for non-traumatic perforation peritonitis: - duodenal/gastric ulcer - ileal perforation due to tuberculosis & typhoid fever - appendicular perforation - caecal perforation due to amoebic typhilitis	100	Dementia Diabetes Renal failure Hepatic failure	ITU	50	NG tube for decompression (in addition to NJ feeding tube). NG tube removed when aspirate minimal and tolerating 2000mls feed/day. Naso-jejeunal feeding tube placed at end of surgery. IV fluids 0-24hrs Tube feeding commenced 24 hours post-op at: 50mls/hr for 6 hours increased to 100mls/hr by 3rd post-operative day.	50	Standard care - not specified	Early enteral feeding via the NJ route is effective when used for the short term and leads to a reduction in septic complications in patients with perforation peritonitis and malnutrition. 54% tolerated regimen by 4th post-operative day 24% had minor complications and tolerated by 5th post-op day 22% had tube intolerance
Klappenbach et al (2013) Argentina	RCT	Patients age 14 years & over. Emergency abdominal surgery within 48 hours of admission (open & laparoscopic): - nonperforated appendicitis - perforated appendicitis - hernia/incisional hernia - cancer - trauma - cholecystitis - other (not stated) Stratified to high & low risk: <u>High risk</u>: - generalised peritonitis - intestinal obstruction	295	Concurrent abdominal surgery Oral incapacity (eg intubation) Oesophageal surgery Pancreatitis Re-operation within 1 month Under care of 2 surgeons who disagreed with protocol	NS	148 (52)	Commence soft diet by mouth within 24 hours of surgery	147 (49)	<u>Low risk patients</u>: NG tube removed on passage of flatus/stool and liquid diet commenced within 12 hours. Increase to soft diet after 12 hours. <u>High risk patients</u>: Fast for at least 3 days. From 3rd post-operative day remove NG tube and commence	Early feeding does not increase the complication rate after abdominal emergency surgery. Increased food intolerance (vomiting) in early fed group.

		- gastrointestinal perforation - anastomosis Low risk: - if not in high risk category							liquid diet over 24 hours if patient passed flatus/stool and no fluid levels on abdominal X-Ray. Progress to soft diet after 24 hours.	
Lee et al (2014) Korea	Retro-spective	Emergency bowel resection and/or anastomosis by single surgeon: - Gastric/ duodenal (11%) - Small bowel (51%) - Large bowel (38%) Oral feeding n=65 Tube feeding according to patient condition (eg: gastric procedure or mechanical ventilation) n=19	84	Appendectomy Cholecystectomy Primary repair of perforated viscera Adhesiolysis without bowel anastomosis Severe shock Sustained intestinal ischaemia Uncontrolled bowel perforation Short bowel syndrome More than 3 day stay in ITU	ITU + Ward	44	Enteral (liquid or soft diet via tube or mouth) within 48hrs of surgery provided patient meets study criteria: - Haemodynamic stability - secure bowel anastomosis/stoma - no ischaemic change observed in theatre.	40	Commencement of feed after 48 hours.	Early feeding after emergency GI surgery does not increase complication rates and is feasible in patients without severe shock or anastomotic instability. Prokinetics given if feed not tolerated (nausea/ vomiting/ileus/gastric residual volume greater than 300ml) NB: No detail regarding NG decompression in either group.
Malhota et al (2004) India	Prospective RCT	Emergency intervention for peritonitis following gut perforations caused by: - Peptic ulcer - trauma - enteric fever - malignancy Only patients undergoing primary repair (n=83) or anastomosis (n=81) were included. Age not stated	164	Defunctioning ileostomy	ITU	83	IV fluids. NG feed commenced 48 hours post-op at 50mls/hour.	81	IV fluids only until day 5 post-op then oral fluids commenced as able	Early enteral nutrition is safe and is associated with beneficial effects such as lower weight loss and early achievement of positive nitrogen balance when compared to traditional care in operated cases of gut perforation.

Moore et al (1986) USA	RCT	Emergency celiotomy patients with an abdominal trauma index (ATI) >15: - multiple injuries • stab wounds • gunshot wounds Colon injury in 19 patients	63	ATI<15 (ATI>40 excluded from analysis)	ITU	32	Needle catheter jejeunostomy (NCJ) inserted at end of operation. 12-18 hrs post-op ¼ strength enteral feed commenced at 50ml/hr Rate & concentration increased 8 hourly building to full strength feed at 125mls/hr by 72 hours post-op.	31	IVI for 5 days then Total Parenteral Nutrition if oral diet not tolerated by this time.	Immediate post-operative feeding by NCJ is simple, safe and feasible (in post celiotomy critically ill patients with multiple system trauma) decreasing the incidence of septic morbidity. ATI >40 associated with prohibitive intolerance of enteral feed.
Saad et al (2007) Eygpt	RCT	Patients aged 16 - 70 years undergoing emergency intestinal resection with or without covering stoma due to: - penetrating stab wound (22.5%) - ischaemia (35%) - Obstruction (27.5%) - blunt abdominal trauma (5%) - intussusception (5%) - other (5%) 77.5% = small bowel resection 12.5% = ileocolic 10.0% = colocolic	40	Chronic liver/ Renal/heart disease. Diabetes Peritonitis and massive resection	NS	20	NG tube removed in theatre. Oral fluids morning of post-op day 1 Solid food post-op day 2 if oral fluids tolerated.	20	Total Parenteral Nutrition (TPN) for 5 days post-op.	Early post-operative feeding is safe and tolerable after emergency intestinal resection anastomosis without increase in morbidity or mortality.
Singh et al (1998) India	Prospective randomised	Patients with non-traumatic intestinal perforation and peritonitis due to: - duodenal ulcer (44%) - gastric ulcer /gastric volvulus (9%) - typhoid perforation (37%) - tubercular perforation (9%) - Zollinger-Ellison syndrome (1%) Requiring primary closure, resection or exteriorisation of bowel.	43	Renal, cardiac or hepatic failure.	ITU	21	Feeding jejeunostomy tube sited in theatre: Feeding regimen: 12-24 hrs NaCl + Dext IV 24-48 hrs half strength feed at 50mls/hr 48-72 hrs half strength feed at 100mls/hr 72 hrs + full strength feed (2 litres/day)	22	IV fluids and electrolytes	Early total enteral nutrition is not only feasible but also beneficial in patients with peritonitis.

Table 2: Summary of outcomes as reported by study

Study		Major abdominal complications			Diet intolerance				Extra-abdominal complications				Time to return of bowel function (median)	Re-op	Death	LOS (Days)	Comments (Early fed group v Control Group)
		AL	BA	IAA	Ileus	N & V	Dia	AD	WC	Pulm	Sepsis	Other					
Kaur et al (2005)	EF	-	3	-	-	-	-	-	7	26	3	-	3.36 (days)	-	3	12.48	[a]combined bronchospasm & respiratory failure
	CG	-	4	-	-	-	-	-	8	27[a]	8	-	4.4 (days)	-	4	14.44	Major complications: 6 v 12 (P=0.001)
Klappenbach et al (2013)	EF	5	5	-	8	N24 V9	-	-	29	-	-	15[d] 45[e]	41.7 (hours)	6	4	4	Overall morbidity: 67 v 55 (p=0.1) [d]abdominal pain [e]non-SSI (surgical site infection)
	CG	2	8	-	9	N15 V9	-	-	29	-	-	9[d] 33[e]	50.7 (hours)	7	6	7.5	Overall food intolerance: 34 v 25 (p=0.2)
Lee et al (2014)	EF	1	-	1	4	-	3	-	11	6[f]	0	7	-	1	0	9	Inconsistencies in reporting overall intolerance. [f]p=0.001
	CG	0	-	1	5	-	0	-	9	19[f]	1	6	-	0	0	12	
Malhota et al (2004)	EF	7	4	-	*	13	16	20	27	21	20	-	-	-	12	10.59	Overall fewer complications in early fed group; complications resolved quicker in early fed group.
	CG	13	9	-	*	7	11	18	31	30	30	-	-	-	16	10.7	
Moore et al (1986)	EF	-	-	3	-	-	-	-	-	0	1	[i]9	-	0	1	25.3	[g]pneumothorax, pleural effusion, pneumonia [h]Septic complications (n=53) 1 v 7 (p<0.05) [i]see below Overall complications 14 v 15
	CG	-	-	7	-	-	-	-	-	4[g]	7[h]	4	-	2	2	28.6	
Saad et al (2007)	EF	-	0	-	-	4	1	3	3	2	-	-	-	0	0	4.4	?increased risk of sepsis with Total Parenteral Nutrition in Traditional Group
	CG	-	3	-	-	2	0	2	7	5	-	-	-	1	0	8.6	
Singh et al (1998)	EF	4	1	3	-	-	4	4	1	5	1	1	-	4	4	14	[j]Anastomotic and peri-jejeunostomy leaks combined. Overall septic complications: 8 v 22 (p<0.05). Early fed group had higher pre-operative sepsis score.
	CG	3[j]	1	8	-	-	0	0	4	9	2	2	-	3	4	13	

Key:
EF: Early fed group
CG: Control Group

AL: Anastomotic leak
AD: Abdominal Distension
BA: Burst abdomen (includes, abdominal dehiscence/complete wound dehiscence)
Dia: Diarrhoea

IAA: intra-abdominal abscess
LOS: length of stay
N & V: nausea & vomiting
Pulm: Pulmonary
Re-op: Re-operation

WC: Wound complications

[j]pneumatosis intestinalis, pancreatitis, small bowel obstruction, pericardial effusion, fat emboli, intraperitoneal haemorrhage, thrombosis (axillary & tibial artery graft)

3.2 Risk-adjusted scoring systems

Risk is inherent to all surgery, with the degree or level of risk for an individual dependent on multiple patient, surgeon and procedural factors, for example, pre-existing morbidity, current condition, emergency or planned procedure. However, from a governance, performance (and research) perspective there is a need to be able to standardise individual risk for accurate comparisons to be made. For these comparisons to be meaningful a risk adjusted scoring system is required which is able to consistently predict individual risk while accounting for the multiple factors and levels of risk across a given population.

The American Society of Anaesthiologists (ASA) developed one of the simplest scoring systems in 1941. This score grades risk on a scale of 1-5; ASA 1 equates to a normal healthy individual whereas ASA 5 represents a moribund individual not expected to survive 24 hours with or without surgery. Though still widely used and valid, this system is criticised for being too subjective. Conversely, an equivalent score (APACHE - Acute Physiology and Chronic Health Evaluation) used in intensive care, is considered to be too complex for general surgical use as it is comprised of between 14 and 34 variables (dependent on version) many of which are not routinely recorded outside an intensive care environment (Leung et al 2010).

The POSSUM (Physiologic and Operative Severity Score for the enUmeration of Mortality and morbidity) score was developed by Copeland et al (1991) specifically for use in surgical patients. Both the P-POSSUM (Portsmouth) and the CR-POSSUM (Colorectal) scores are derived from this original score. P-POSSUM (Prytherch et al, 1998) was developed to overcome limitations found in the original POSSUM, that is, the over-prediction of mortality in low risk patients and under-prediction of mortality in elderly and emergency patients while CR-POSSUM (Tekkis et al, 2004) was developed specifically to predict risk in colorectal patients. Tekkis et al (2003) on behalf of the Association of Coloproctology of Great Britain and Ireland (ACPGBI) also developed a simpler and more specific risk adjusted scoring system for

predicting risk in patients with colorectal cancer. This tool was updated in 2010 and can be accessed via http://www.riskprediction.org.uk/index-crc.php.

All three POSSUM scores (POSSUM, P-POSSUM and CR-POSSUM) have been extensively tested in differing surgical populations and found to be reliable (Vather et al, 2006; Richards et al, 2010), however, accuracy of prediction between studies varies, with all agreeing there is as yet no ideal risk prediction tool. P-POSSUM compensates for the limitations of POSSUM making it generally the score of choice for high risk patients; however, P-POSSUM is comprised of multiple indicators, many of which are not readily available or recorded in routine practice compared to the 10 indicators of CR-POSSUM.

In summary, this chapter has reviewed the current literature relating to early feeding following emergency bowel resection and found that relatively few studies focus on oral feeding in non-critical care patients. In addition, the heterogeneity of these studies limits extrapolation of conclusions to non-critical care patients although their outcome measures and methods can be used to inform future study design. Homogeneity between study groups may be demonstrated by use of a risk-adjusted scoring system, accounting for multiple factors and levels of risk across a given population. This chapter therefore also reviewed available scoring systems to inform and assure selection of a reliable and valid system appropriate for emergency bowel resection patients. Choice of system in addition to research methods used in this study are detailed in Chapter 4.

Chapter 4: Research Methods

4.1 Aim of the study

The aim of this study is

> *to investigate the feasibility and safety of an enhanced recovery approach incorporating early oral fluids and diet and the avoidance of routine post-operative naso-gastric decompression in Level 0/1 patients following emergency bowel resection through comparison of post-operative outcomes between two existing parallel care groups, one receiving enhanced care, the other traditional care.*

4.2 Research paradigm

The study fits with a quantitative method of enquiry as it seeks to compare measurable outcomes between two groups. Quantitative research methods are informed by the epistemological perspective of empiricism which believes in a single, objectivity reality where all phenomena are observable and measurable, occurring as a result of external stimuli (cause). External stimuli may therefore be manipulated, controlled or reduced to test for causal relationships or associations (Holloway & Wheeler, 2010). Empirical enquiry encompasses a range of quantitative research designs and methods from the true experimental to comparative observational. In these latter studies, variables may not be manipulated, controlled or reduced but principles of empiricism inform design.

While objectivity is the governing principle of empirical enquiry, multiple factors (biases) affect objectivity across the research process. A systematic and rigorous process which incorporates strategies to promote objectivity and minimise bias is therefore fundamental to the validity and reliability of any empirical enquiry. This chapter details the processes and strategies used in this study to promote objectivity in line with the ethos of the research paradigm.

4.3 Definition of terms:

The full definition of terms used in this study are detailed in the *Glossary (page 10)*. This clarification promotes external validity through enabling appropriate interpretation and future application of study findings.

4.4 Study outcomes and endpoints:

4.4.1 Primary outcome:

The primary study outcome is a measure of the feasibility of enhanced care in Level 0/1 patients following emergency bowel resection. As the ability to tolerate early oral fluids and diet in the absence of routine post-operative NG decompression is critical to the feasibility of enhanced care in this patient group, the study uses ***toleration of post-operative oral fluids and diet*** as its primary outcome measure.

This is defined as the time in hours between the end of surgery (time into theatre recovery) and :

a) the time 150-200mls of clear fluid (cup/glass of water/juice/black tea or coffee) is ingested by mouth without an episode of vomiting or greater than 100mls NG aspirate/drainage (if NG tube in situ) in the subsequent 4 hours.
b) the time any solid diet (minimum 200 calories equivalent to 2 slices of toast and butter or a bowl of cereal) is consumed without an episode of vomiting in the subsequent 4 hours.

4.4.2 Secondary outcomes:

Secondary outcomes for the study align with indicators of safety. They are:

- *incidence of post-operative complications* defined as any deviation from the post-operative course occurring within the length of stay, encompassing all infectious or non-infectious complications classified according to source (intra-abdominal or extra-abdominal).

- *length of stay* defined as the time in hours from the end of operation to the time of *surgical inpatient discharge (*defined as the time the patient is discharged home or to a place of rehabilitation).

4.4.3 Study endpoints:

The study endpoints are: Surgical inpatient discharge; transfer to another speciality; re-insertion/insertion of naso-gastric tube; re-operation and death.

These endpoints reflect the potential eventualities for study patients. A single endpoint will be recorded for each patient. The recorded endpoint will be whichever of these eventualities occur first (for example, should a patient have insertion/re-insertion of post-operative NG tube and later undergo re-operation, the endpoint will be recorded as the insertion/re-insertion of NG tube). The endpoints are therefore treated as a single composite endpoint.

4.5 Study design

A single centre, comparative observational study using an existing parallel group design was selected to test the difference in patient outcomes between care groups. Resource availability limited the study to a single centre while existing practice (that is, the provision of enhanced or traditional care to emergency bowel resection patients) within that centre influenced the observational nature of the study. Existing practice within the study setting is dependent on the preference of the operating surgeon; two consultant colorectal surgeons routinely employ enhanced care for their emergency bowel resection patients while others take a more conservative (traditional) approach. (For details on sample allocation see *Section 4.5.4 page 35*)

Guyatt et al (1995) ranked study designs in terms of methodological strength; within this hierarchy, observational studies are placed at the lower end of the quantitative spectrum as methodologically they lack inherent strategies to minimise bias such as randomisation, blinding or matching. However, Barratt

(2009) argues that methodological strength is only one of the factors which influences the strength of a study: the conduct of a study can also influence the strength of evidence produced. A well conducted observational study may therefore produce more compelling evidence than a poorly conducted randomised controlled trial. In addition, a methodologically robust design may either not be ethically appropriate for the subject of investigation, or , the findings may not be directly relatable to practice as, in adhering to methodological rigour, study conditions are far removed from the practice situation. Petticrew & Roberts (2003) propose 'typologies of evidence' as an alternative to traditional 'hierarchies of evidence'. Instead of focusing on methodological strength, these typologies focus on the most appropriate design to answer the question - even should that design be traditionally considered weak.

This perspective supports selection of an observational design as the pragmatic choice in view of existing practice, available resource and the current limited evidence in relation to early feeding in Level 0/1 emergency bowel resection patients. The inherent methodological limitations of the design were acknowledged and strategies to minimise these limitations were employed throughout the study to promote internal validity.

4.5.1 Ethics

On application for NHS ethical approval, the committee viewed the study as a service evaluation (and therefore outside their remit) since it involved a comparison of existing practice with no intervention (See *Appendix IV (page 83)* for NREC communication). As such, ethical approval was sought and obtained from the local Governance Committees of both the University and the NHS Foundation Trust providing the study setting (*see Appendix V and VI, pages 84 and 85*).

4.5.2 Sample size

A priori analysis by G*Power (www.psycho.uni-duesseldorf.de/aap/projects/gpower/) calculated a sample size of 52 (26 in each group) had 80% power (Type 1 error 0.05) to detect a large effect (*d=0.8*) between groups (based on 2-tailed independent *t* test to calculate mean difference; *critical t = 2.008*). Attrition was estimated at 20% (n=10) based on data from elective studies (Stewart et al, 1998). It was therefore planned to collect data on 62 patients (31 in each group).

For ethical reasons, the study population comprised only those in need of emergency bowel resection presenting to the study setting. With approximately 180 patients undergoing emergency bowel surgery a year of which an estimated 40% meet the study inclusion criteria, the planned sample size was considered to be feasible and realistic for the study setting within the time constraints of the study. All patients who presented to the study setting between October 2013 and February 2015 **and** who met the study inclusion criteria were included in the study.

4.5.3 Inclusion and exclusion criteria.

Strict inclusion and exclusion criteria were used to determine individual eligibility and promote homogeneity between groups further promoting internal validity. Full study inclusion and exclusion criteria and their accompanying rationale are detailed in *Table 3* and *Table 4* . To promote rigour, an audit trail tracked potentially eligible patients and recorded the reason for their exclusion (where applicable) for the duration of the study. The findings of this audit trail are detailed in *Figure 2* (Chapter 5).

4.5.4 Sample allocation

All potential patients were checked for eligibility against the inclusion/exclusion criteria by the chief investigator. Eligible patients were allocated to study group according to the presence or absence of a nasogastric tube (NG) tube on return to the ward (Level 0/1) environment post-operatively. In line with

research governance, patient identity was replaced with a study number at the point of allocation, ensuring anonymity.

Patients with a nasogastric tube were allocated to the traditional care group (TRAD); those without an NG tube were allocated to the enhanced care group (ERP). In having this single criteria, confounding variables such as preference of differing surgeons or specific clinical issues (for example, a failed intra-operative leak test) were simplified and adherence to study protocol assured.

Table 3: Inclusion criteria and rationale

Inclusion Criteria		Rationale
I.1	Aged 18 years or over	Focus of study on adult patients
I.2	Any patient needing laparotomy on an emergency (unplanned) basis to relieve signs or symptoms of bowel obstruction, perforation, ischaemia or GI bleeding.	Focus of study on patients undergoing emergency bowel resection
I.3	Any patient undergoing small or large bowel resection with or without formation of stoma following emergency laparotomy	Ensure only patients undergoing bowel resection entered into study promoting homogeneity of sample.

Table 4: Exclusion criteria

Exclusion Criteria		Rationale
E.1	Aged under 18 years	Adolescent and paediatric patients
E.2	Any patient needing laparotomy on an emergency (unplanned) basis for any reason other than to relieve signs or symptoms of bowel obstruction, perforation, ischaemia or GI bleeding (for example, gynaecological, urological, or vascular surgery).	Focus of study on patients undergoing emergency GI resection
E.3	Any patient who does not undergo small or large bowel resection with or without formation of stoma following emergency laparotomy (for example: - Division of peritoneal adhesions - Over/under sewing of the bowel - Oesophageal, gastric or hepato-	Ensure only patients undergoing GI resection entered into study promoting homogeneity of sample.

	biliary surgery - splenic or pancreatic surgery)	
E.4	Laparoscopic procedures	Minimally invasive approaches are associated with faster return of bowel function than open procedures potentially confounding the results
E.5	Any patient requiring complex multi-organ surgery following emergency laparotomy	Increased likelihood of requiring Level 2/3 (critical) care post-operatively. Critical care pathway varies from study protocol
E.6	Any patient grading at ASA 4 or 5 pre-operatively	Increased likelihood of requiring Level 2/3 critical care post-operatively. Critical care pathway varies from study protocol
E.7	Any patient receiving regular warfarin or other **therapeutic** anti-coagulation or anti-platelet therapy pre-operatively	Increased risk of thrombotic and/or haemorrhagic complications post-operatively necessitating individualised care
E.8	Any patient who has undergone a prior laparotomy in the last 12 months.	Increased risk of post-operative complications necessitating individualised care
E.9	Any patient requiring parenteral nutrition	Enteral nutrition route not functional
E.10	Any patient with an inability to take oral nutrition (for example, decreased consciousness, a priori feeding tube in situ, post-operative nasogastric feed)	Focus of study on oral intake
E.11	Any patient with diabetes	Surgical stress response affects insulin resistance. Those with diabetes have a pre-existing insulin resistance which may influence post-operative outcome.
E.12	Any patient requiring critical care post-operatively (Level 2 or above as defined by the Intensive Care Society 2009)	Critical care pathway varies from study protocol
E.13	Any patient already involved in an interventional research study	Potential for effect of other study/intervention to confound results.
E.14	Any surgery (other than that in E8 above) requiring general anaesthesia within one month prior to emergency laparotomy.	More than one general anaesthetic within a 4-6 week period is known to increase risk of respiratory complications.
E.15	Any patient requiring steroidal/biological treatment for acute exacerbation of inflammatory bowel disease prior to emergency laparotomy	Immunosuppressive effects of these medications increase the risk of post-operative complications necessitating individualised care.

4.5.5 Data collection

Data collection tools were developed to ensure demographic, pre-operative, intra-operative and post-operative parameters which could be used to test for homogeneity between groups were collected in addition to outcome data. The pre/intra/post-operative care parameters focus on applicable elements of enhanced recovery (Fearon et al 2005) and incorporate a risk-adjusted scoring system to enable standardised comparisons both internally (between groups) and externally (between studies).

Available risk-adjusted scoring systems are reviewed in *Section 3.2 (page 29)*. This highlights that of the three POSSUM scores (POSSUM, P-POSSUM and CR-POSSUM) any could be used for the study as each have their strengths and limitations. However, CR-POSSUM became the score of choice as, compared to the other two POSSUM scores, it is comprised of 10 readily available and recorded indicators, increasing the likelihood that a comparable score could be calculated for each study patient.

The data collection forms are detailed in *Appendix VII (page 87)*. No major changes were necessary to these forms following review after an initial pilot on 5 patients.

A single person (the author) collected data promoting standardisation. To ensure this remained constant across the duration of the study, the location of the source of required data, definitions of complications and exemplars and categories of pre-existing morbidities adapted from Grocott et al (2007) were incorporated into the data collection tools (*Appendix VII, page 87*).

Where possible data was collected prospectively on a daily basis from existing medical and nursing documentation until a study endpoint was reached. However, resource limitations and the 24 hour nature of emergency surgery dictated that a large proportion of data collection was retrospective. To ensure all potential patients were captured, the local National Emergency Laparotomy Audit (NELA) data was reviewed on a monthly basis. Any eligible patient

identified from this review who underwent emergency bowel resection on or after 01/10/2013 had data collected retrospectively from their written patient records and/or centralised electronic sources (for example, results reporting).

Both a strength and a limitation of retrospective data collection was the quality of medical and nursing records. Of consistently high standard were fluid charts, medication charts, anaesthetic records and operative notes enabling relatively easy collation of key data. However, of poorer quality was documentation relating to time (but not date) of decision to operate, time, toleration and quantity of first diet post-operatively and time to first flatus/bowel movement. To address these limitations:

a) in the event that there was no clearly documented time of decision to operate, the time the pre-operative imaging (normally a CT (computerised tomography) scan) was electronically recorded on the reporting system was substituted.
b) if there was no diet sheet documenting time and quantity of first post-operative diet, the nursing care plan was scrutinised for the time and date of the earliest post-operative entry which indicated the individual was tolerating (and taking) 'light diet' opposed to 'soup and sweet'.
c) if there was no clear documentation relating to passage of flatus or faeces post-operatively (for example, a stool chart), the medical and nursing records were scrutinised for the time and date of the earliest post-operative entry which indicated either of these events had occurred.

As data collection progressed, it also became apparent that there were variations in management of the naso-gastric tube in the traditional study group. In particular, while some patients adhered to the original study definition (NG decompression and only sips of water by mouth until resolution of bowel dysmotility defined for the purposes of this study as <100mls drainage or aspirate from NG tube in previous 4 hours or the passage of flatus or faeces), others either had their tube removed without it first being spigoted, or were permitted to drink freely while the tube was in situ and/or spigoted. Significantly, a few of this latter group were tolerating oral fluids while the tube

remained in situ, that is they were drinking 150-200mls of water with less than 100mls nasogastric aspirate/drainage or vomit in the subsequent 4 hours. The definition of tolerance of oral fluids was therefore re-defined to encompass this latter group and the data already collected on eleven patients reviewed. None of this data required amending.

4.5.6 Data analysis

Data was coded and input into SPSS (IBM Corp. Released 2013. IBM Statistics for Windows, Version 22.0. Armonk, New York. IBM Corp) for statistical analysis by the author. Descriptive statistics have been used to describe the inclusion/exclusion audit trail and the demographic characteristics of the study groups. Normally distributed continuous data were tested using the independent groups t test. Continuous data which did not meet the assumptions of normality were tested using the Mann-Whitney test. Differences in categorical data were tested using Chi square test or where appropriate 2-sided Fisher's exact test (FET). The decision level for statistical significance was set at $p<0.05$.

The results of these analyses are detailed in Chapter 5.

Chapter 5: Results

5.1 Included patients:

Between 01/10/2013 and 10/02/2015, two hundred and fifty six patients underwent emergency laparotomy within the study setting. Sixty one (23.8%) of these patients met the study inclusion criteria. Twenty seven(44%) were allocated to the enhanced care (ERP) study group and 34 (56%) to the traditional care (TRAD) study group according to presence or absence of NG (nasogastric) tube at the end of surgery as detailed in the adapted CONSORT flow diagram (*Figure 2*).

5.2 Study endpoints

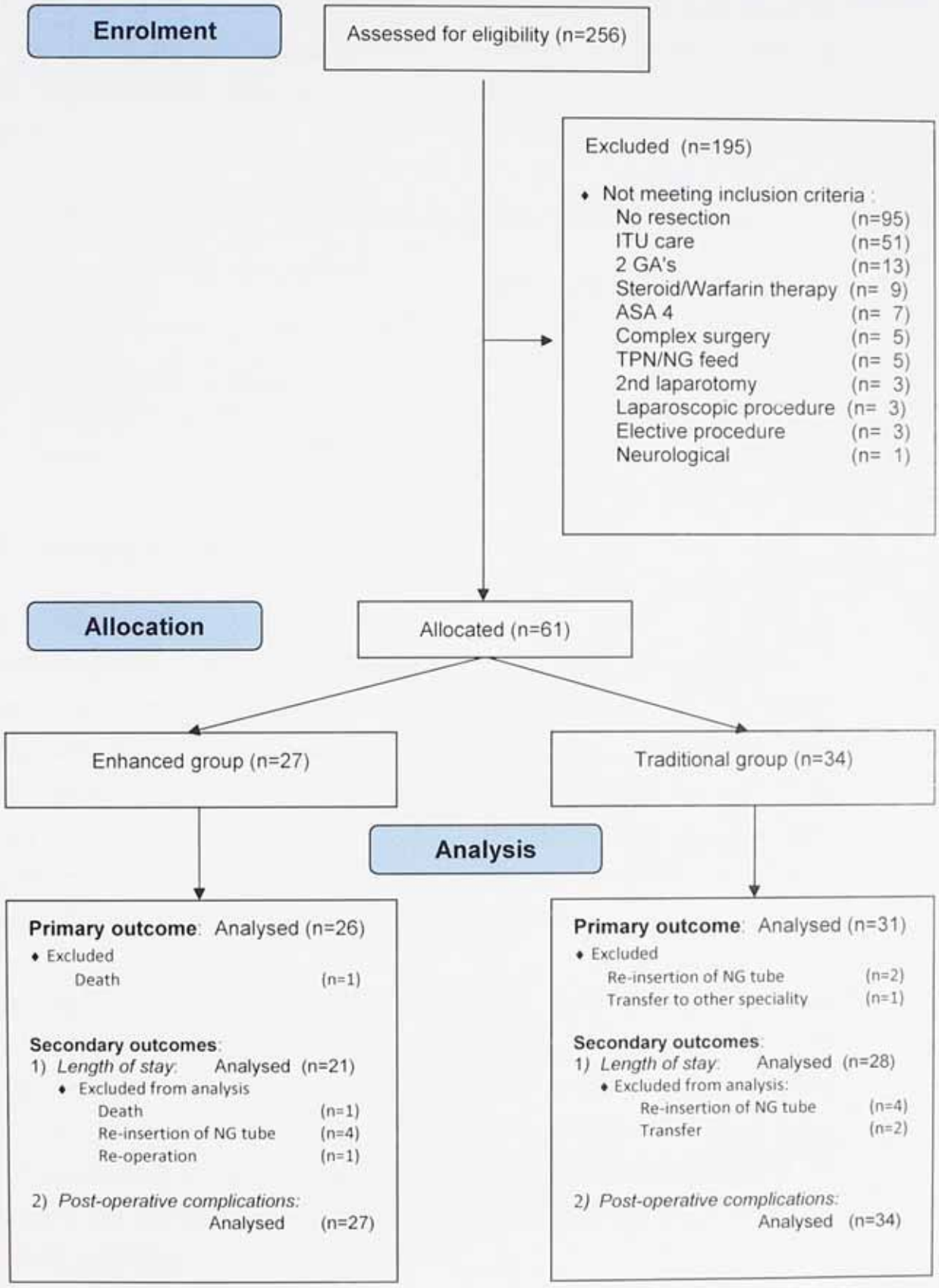
Twelve (19.7%) patients (6 in each group) had a study endpoint other than 'inpatient discharge' as detailed in *Table 5*. No significant difference was found between groups in study endpoint (*FET = 3.806, p = 0.386*).

Table 5: Summary of study endpoints by group

Endpoint	n	ERP	TRAD	p
		n	n	
Inpatient discharge	49	21	28	0.386
Death	1	1	0	
Transfer to another speciality	2	0	2	
Reinsertion of NG tube	8	4	4	
Re-operation	1	1	0	
Total	**61**	**27**	**34**	

Patients with an endpoint other than 'inpatient discharge' were included in analysis of demographic characteristics and the secondary outcome 'post-operative complications' (n=61) but excluded from analysis of the secondary outcome 'length of stay' (n=49).

Figure 2: Adapted CONSORT flow diagram



Four patients, detailed in *Table 6*, were excluded from analysis of the primary outcome 'toleration of oral fluid and diet' (n=57) as their endpoints occurred prior to their commencement of oral diet. No statistically significant difference was found between study groups in these excluded patients (*FET=3.138, p=0.5*).

Table 6: Endpoints causing exclusion from analysis of primary outcome

Endpoint	n	ERP	TRAD	*p*
		n	n	
Death	1	1	0	0.5
Transfer to another speciality	1	0	1	
Re-insertion of NG tube	2	0	2	
Total	**4**	**1**	**3**	

5.3 Sample characteristics:

5.3.1 Demographic characteristics

The demographic characteristics of the two groups are summarised in *Table 7*. Twenty six patients (41%) were male (9 in the ERP group, 16 in the TRAD group) and 36 (59%) were female (18 in each study group). The mean age of both the ERP group and the TRAD group was 63.5 years (ERP Range: 27-89 years, SD 14.11. TRAD Range: 33-91 years, SD 13.81). No statistically significant differences were found in either gender ($\chi^2(1)=1.172$, $p=0.279$) or age ($t(59)= 0.003$, $p=0.998$) distribution between groups.

The mean Body Mass Index (BMI) was slightly higher in the ERP group (27.74; Range 19-42, SD 5.3) than the TRAD group (25.4; Range 14-35, SD 5.52) but this was not found to be statistically significant ($t(58)= 1.665$, $p=0.101$). Conversely the median CR-Possum score was slightly lower in the ERP group (3.28; IQ range 2.59) than the TRAD group (3.89; IQ range 6.15) but again this difference was not found to be statistically significant ($U=343.5$, $z=-1.68$, $p=0.093$) .

Table 7: Demographic characteristics

Characteristic	n	%	Study group		Equality tests			
			ERP	TRAD	*t*	χ^2	*df*	*p*
Gender:					-			
Male	25	*41*	9	16				
Female	36	*59*	18	18		1.172	1	*0.279*
	(61)	*(100)*	(27)	(34)				
Mean Age (years)			63.5	63.5	0.003	-	59	*0.998*
Range (years)	(61)	*(100)*	27 - 89	33 - 91				
SD			14.44	13.81				
Mean Body Mass Index (BMI)	(60)	*(98)*	27.74	25.4	1.665	-	58	*0.101*
Range			19 - 42	14 - 35				
SD			5.3	5.52				
CR-POSSUM					-	-	-	[U]*0.093*
Median	(61)	*(100)*	3.28	3.89				
IQ range			2.59	6.15				

Key: SD Standard Deviation
IQ interquartile
[U] Mann Whiney *U* test

5.3.2 Surgical characteristics

The surgical characteristics of the two groups are summarised in *Table 8*. Forty six patients (75.4%) had a large bowel resection, 12 patients (19.7%) had a small bowel resection (SBRx) and 3 patients (4.9%) had a combined large and small bowel procedure. Fifty four patients (88.5%) had one of four operative procedures: 20 patients (11 in ERP group and 9 in traditional group) had a Right Hemicolectomy, 16 patients (6 in ERP group, 10 in TRAD group) had a Hartmann's procedure, 12 patients (3 in ERP group and 9 in TRAD group) had a Small Bowel Resection (SBRx) and 6 patients had a Sigmoid Colectomy (4 in the ERP group, 2 in the TRAD group). Three patients (4.9%), all in the ERP group, had a Left Hemicolectomy and one patient (1.6%) in the TRAD group had a Subtotal Colectomy. The remaining 3 patients (4.9%), all in the TRAD group, had one of 3 combined procedures (Right Hemicolectomy /Hartmann's procedure with SBRx or Sigmoid Colectomy with formation of ileostomy). No statistically significant difference (*FET = 10.419, p=0.144*) was found between groups in operative procedure.

Eighteen patients (30%) had formation of a stoma as part of their operative procedure (6 in the ERP group and 12 in the TRAD group); seventeen of the

Table 8: Surgical characteristics

Characteristic	n	%	Study Group					
			ERP	TRAD	χ^2	t	df	p
Procedure								
Right hemicolectomy	20	*32.8*	11	9	-	-	-	*0.144*
Hartmann's	16	*26.2*	6	10				
Small Bowel Resection (SBRx)	12	*19.7*	3	9				
Sigmoid colectomy	6	*9.8*	4	2				
Left hemicolectomy	3	*4.9*	3	0				
Hartmanns & SBRx	1	*1.6*	0	1				
Subtotal colectomy	1	*1.6*	0	1				
Right hemicolectomy & SBRx	1	*1.6*	0	1				
Sigmoid colectomy & ileostomy	1	*1.6*	0	1				
	(61)	*(≈100)*	(27)	(34)				
Stoma								
Yes	18	*30*	6	12	1.236	-	1	*0.266*
No	43	*70*	21	22				
	(61)	*(100)*	(27)	(34)				
Histology						-		
Malignant	20	*33*	7	13	1.035		1	*0.309*
Benign	41	*67*	20	21				
	(61)	*(100)*	(27)	(34)				
Cause								
Perforation	12	*19.7*	8	4	-	-	-	*0.014**
Perforation + abscess/peritonitis	5	*8*	4	1				
Ischaemia	12	*19.7*	2	10				
Ischaemia + abscess/peritonitis	2	*3.3*	1	1				
Stricture/stenosis (benign)	4	*6.6*	0	4				
Inflammatory mass/abscess	6	*9.8*	5	1				
Dukes A + perforation	1	*1.6*	0	1				
Dukes B	2	*3.3*	2	0				
Dukes C	9	*14.8*	3	6				
Dukes C + perforation/peritonitis	3	*4.9*	1	2				
Metastatic disease	4	*6.6*	1	3				
Other malignancy	1	*1.6*	0	1				
	(61)	*(≈100)*	(27)	(34)				
Time of operation								
Morning (08.00 - 11.59)	16	*26.2*	7	9	-	-	-	*0.264*
Afternoon (12.00 - 16.59)	26	*42.6*	9	17				
Evening (17.00 - 23.59)	18	*29.5*	11	7				
Night (00.00 - 07.59)	1	*1.6*	0	1				
	(61)	*(≈100)*	(27)	(34)				
Duration of operation								
Mean time (hours: mins)	3: 25	-	3: 23	3: 27	-	0.310	59	*0.758*
Range (hours: mins)	1: 10 - 6: 10		1: 10 - 5: 15	1: 30 - 6: 10				
SD	0: 58		0: 55	1: 01				

Key: SD Standard deviation
*significant at $p<0.05$

stomas were colostomies, one was an ileostomy. The reason for surgery was found to be benign for 41 (67%) patients (20 in the ERP group, 21 in the TRAD group) and malignant for 20 (33%) patients (7 in the ERP group, 13 in the TRAD group). No statistically significant difference was found between study groups for either formation of stoma ($\chi^2(1) = 1.236$, $p = 0.266$) or histological findings ($\chi^2(1) = 1.035$, $p = 0.309$); however, when the underlying

cause (that is, for example, perforation/ischaemia/peritonitis) was analysed, a statistically significant difference was found between groups (*FET = 19.856, p=0.014*).

One patient underwent surgery between the hours of 00.00 and 06.59; twenty six (42.6%) patients had their surgery in the afternoon (between 12.00 and 16.59 hours), 18 (29.5%) in the evening (between 17.00 and 23.59 hours) and 16 (26.2%) in the morning (between 07.00 and 11.59 hours). The mean duration of operation in the ERP group was 3 hours 23 minutes (Range: 1 hr 10 minutes to 5 hrs 15 minutes, SD: 55 minutes) and the TRAD group 3 hours 27 minutes (Range: 1 hr 30 minutes to 6 hrs 10 minutes, SD: 1 hour 1 minute). No statistically significant difference was found between groups in timing of operation (*FET=3.741, p = 0.264*) or mean duration of operation (*t(59) = 0.310, p=0.758).*

5.3.3 Pre-operative characteristics

The pre-operative characteristics of the two groups are detailed in *Table 9*. No patient received sedative pre-medication (n=61). Fifty nine (96.7%) patients received VTE (Venous-Thrombo-Embolus) prophylaxis. Two patients (one in each group) did not receive VTE prophylaxis either due to a contraindication (secondary to lymphoma) or refusal.

Thirty three (55%) patients (n=60 owing to missing data) received pre-operative therapeutic antibiotics (17 in the ERP group, 16 in the TRAD group). Forty five (73.8%) patients were CEPOD category 'Urgent' (23 in the ERP group, 22 in the TRAD group), 10 patients (16.4%) were CEPOD category 'Expedited' (4 in the ERP group, 6 in the TRAD group) and 6 patients (9.8%), all in the TRAD group, were CEPOD category 'Emergency'. No statistically significant differences were found between study groups in characteristics of urgency of surgery (CEPOD category: *FET = 5.748, p=0.067*), use of pre-operative therapeutic antibiotics ($\chi^2(1)=1.999$, *p=0.157)* or VTE prophylaxis *(FET = 0.28, p = 1).*

Table 9: Pre-operative characteristics

Characteristic			ERP	TRAD	Equality test		
PRE-OPERATIVE	n	%	n	n	χ^2	df	P
CEPOD category							
Emergency (within 2 hours)	6	*9.8*	0	6	-	-	0.067
Urgent (within 24 hours)	45	*73.8*	23	22			
Expedited	10	*16.4*	4	6			
	(61)	*(100)*	(27)	(34)			
VTE prophylaxis							
Yes	59	*96.7*	26	33	-	-	1
Contraindicated/refused	2	*3.3*	1	1			
	(61)	*(100)*	(27)	(34)			
Therapeutic Antibiotics							
Yes	33	*55*	17	16	1.999	1	0.157
No	27	*45*	9	18			
	(60)	*(100)*	(26)	(34)			
Sedative pre-medication							
No	61	*100*	27	34	-	-	-

5.3.4 Operative characteristics

The operative characteristics of the two groups are detailed in *Table 10*. No statistically significant differences were found between study groups in any of the operative characteristics tested.

Every patient (n=61) received intra-operative warming therapy and fifty nine (96.7%) patients received antibiotic therapy intra-operatively, either on induction or as part of an ongoing course of therapeutic antibiotics; one patient in each group (3.3%) did not receive intra-operative antibiotic therapy (FET = 0.28, *p=1)*. Thirty eight (63%) patients (n=60) had some form of goal directed fluid therapy (classified as use of oesophageal doppler, or, presence of an arterial or central line). Oesophageal doppler was used for 4 ERP patients and 3 TRAD patients; 9 ERP patients and 18 TRAD patients had an arterial line and 4 TRAD patients had a central line. No statistically significant difference (*FET = 6.58, p=0.078*) was found between study groups in mechanisms of goal directed fluid therapy (GDFT). Both groups (n=56) had a median volume of 3000mls (IQ range 1000mls for ERP group, 1475mls for TRAD group) infused intra-operatively. No statistically significant difference

(*U=349.5, z=-0.592, p=0.554*) was found in the median volume of infused intra-operative intravenous fluids

Table 10: Operative characteristics

Characteristic	All		ERP	TRAD	Equality tests	
OPERATIVE	n	%	n	n	*U*	*p*
Warming agents						
Yes	61	*100*	27	34	-	-
Intra-operative AB's						
Yes/on therapeutic course	59	*96.7*	26	33	-	1
No	2	*3.3*	1	1		
	(61)	*(100)*	(27)	(34)		
Goal directed fluid therapy (GDFT)					-	0.078
Oesophageal Doppler	7	*11.7*	4	3		
Arterial Line	27	*45*	9	18		
Central line	4	*6.7*	0	4		
No GDFT	22	*36.7*	13	9		
	(60)	*(≈100)*	(26)	(34)		
Median intra-operative fluid volume (mls)			3000	3000	349.5	0.554
IQ range (mls)	(56)	-	1000	1475		
Incision:					-	1
Midline laparotomy	58	*95.1*	26	32		
Transverse	2	*3.3*	1	1		
Right oblique	1	*1.6*	0	1		
	(61)	*(100)*	(27)	(34)		
Type of anastomosis					-	0.264
Stapled	25	*41*	9	16		
Sutured	17	*27.9*	11	6		
Stapled & Sutured	3	*4.9*	1	2		
No anastomosis	16	*26.2*	6	10		
	(61)	*(100)*	(27)	(34)		
Wound drain					-	0.512
Yes	48	*81.4*	23	25		
No	11	*18.6*	3	8		
	(59)	*(100)*	(26)	(33)		

Fifty eight patients (95.1%) had a midline incision, 2 patients (1 in each group) had a transverse incision and 1 patient in the ERP group had a right lateral incision. Forty five (73.8%) patients had a surgical anastomosis; 25 of these were stapled (9 in the ERP group, 16 in the TRAD group), 17 were sutured (11 in ERP, 6 in TRAD) and 3 were both stapled and sutured (1 in ERP and 2 in TRAD). No statistically significant difference was found between groups in type of incision (*FET=1.022, p=0.1*) or type of anastomosis (*FET=3.993, p=0.264*). Forty eight (81.4%) patients (n=59) had a wound drain (23 in the

ERP group and 25 in the TRAD group); 2 patients had missing data (one in each group). No statistically significant difference was found between groups in presence or absence of wound drain *(FET=1.748, p=0.512)*.

5.3.5 Post-operative characteristics

The post-operative characteristics of the two groups are detailed in **Error! Reference source not found.**. No statistically significant differences were found between study groups in any of the post-operative characteristics tested.

Table 11: Post-operative characteristics

Characteristic	All		ERP	TRAD	Equality tests			
POST-OPERATIVE	n	%	n	n	χ^2	*U*	*df1*	*p*
Level of care					0.219	-	1	0.640
Level 0	41	*67.2*	19	22				
Level 1	20	*32.8*	8	12				
	(61)	*(100)*	(27)	(34)				
Type of analgesia					-	-	-	0.620
Epidural	13	*21.3*	4	9				
Morphine PCA	10	*16.4*	5	5				
LA block + PCA	38	*62.3*	18	20				
	(61)	*(100)*	(27)	(34)				
Post-operative AB's					-	-	-	0.71
Therapeutic	50	*83.3*	21	29				
Prophylactic	9	*15*	5	4				
No post-op antibiotics	1	*1.7*	0	1				
	(60)	*(100)*	(26)	(34)				
Urinary catheter					-	-	-	1
Yes	59	*96.7*	26	33				
No	2	*3.3*	1	1				
	(61)	*(100)*	(27)	(34)				
NG tube removal					-	-	-	-
Mean time (hours)	(34)	-	0	39.1				
Range (hours)			0	6.08-106.58				
SD			0	23.35				
First flatus/bowel movement					-	269		0.194
Median time (hours)	(53)	-	100.59	83.75				
IQ Range (hours)			43.25	45.25				

Key: PCA Patient Controlled analgesia
LA local anaesthetic
AB's antibiotics
SD standard deviation
IQ interquartile

Forty one (67.2%) patients were nursed immediately post-operatively on the ward (Level 0) and 20 (32.8%) were nursed in a higher level of care (Level 1). There was no statistically significant difference between groups and level of post-operative care ($\chi^2(1)=0.219$, $p=0.640$). Thirty eight (62.3%) patients (18 in the ERP group and 20 in the TRAD group) had a local anaesthetic (LA) block in conjunction with an intravenous morphine patient controlled analgesia (PCA) for initial post-operative pain relief. Ten (16.4%) patients (5 in each group) had a PCA without LA block and 13 (21.3%) patients (4 in the ERP group and 9 in the TRAD group) had an epidural for initial post-operative pain relief. No statistically significant difference was found between groups in type of initial post-operative pain relief ($FET = 1.253$, $p = 0.620$).

Every patient (n=61) except 2 (one in each group) had a urinary catheter in situ post-operatively and every patient (n=60) except one in the TRAD group received post-operative antibiotics. Of these 59 patients , 50 (85%) received therapeutic antibiotics (21 in the ERP group and 29 in the TRAD group) and 9 (15%) received prophylactic antibiotics (5 in the ERP group and 4 in the TRAD group). No statistically significant difference was found between groups in use of therapeutic or prophylactic antibiotics ($FET=1.335$, $p=0.71$). The duration of routine NG decompression in the TRAD group (n=34) was measured in hours from the end of operation (time into recovery) to the documented time *either* the NG tube was removed *or* the patient tolerated 150-200mls clear fluid (water/juice/black tea or coffee) following spigot of the NG tube without an episode of vomiting or >100mls aspirate/free drainage in the subsequent 4 hours. The mean duration of routine NG decompression as defined above was 39.1 hours (Range 6.08 -106.58 hours, SD 23.35 hours). No patient in the ERP group had an NG tube in situ on arrival into recovery.

Data was recorded for 53 patients (22 in the ERP group and 31 in the TRAD group) on time to passage of first flatus/bowel movement post-operatively. The median time to first flatus/bowel movement in the ERP group was 100.59 hours (IQ range 43.25 hours) compared to 83.75 hours (IQ range 45.25 hours) in the

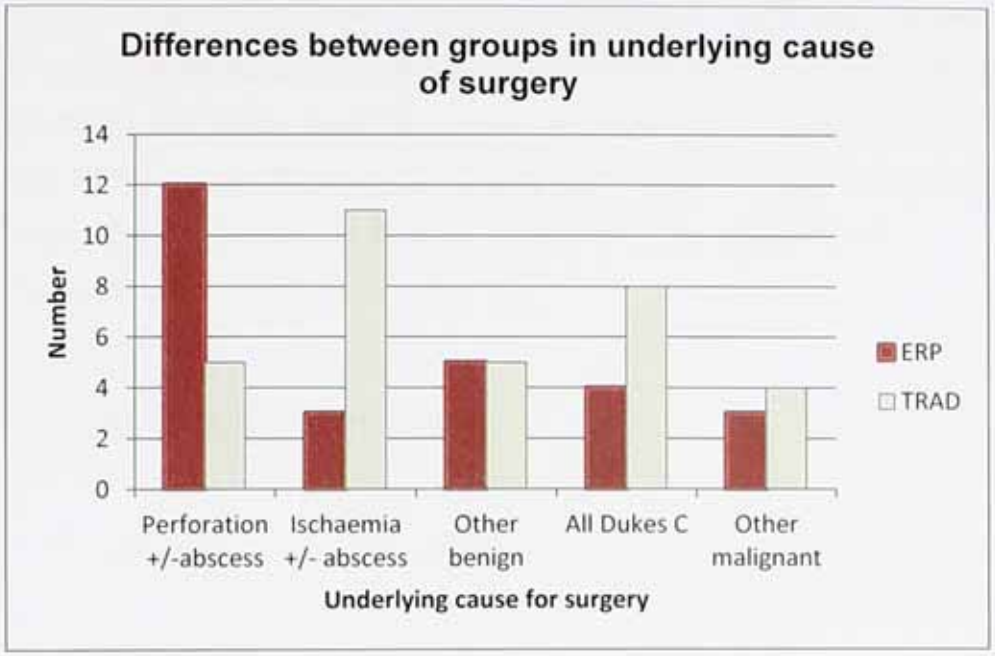
TRAD group. This represented a small to medium size effect (*r = -0.179/d=-0.*364) but was not found to be statistically significant (*U=269, z=-1.3, p=0.194*).

5.3.6 Summary of sample characteristics

No statistically significant differences were found between study groups in 25 (96.2%) of the 26 sample characteristics reported in sections 5.3.1 - 5.3.5. This demonstrates a strong comparison between study groups supporting the validity of study findings and evidencing minimal systematic bias. The single characteristic found to be statistically different between groups related to underlying cause. However, when this was classified according to histological finding (benign/malignant) no statistically significant difference was found suggesting the difference in underlying cause lies *within* one of the two histological groups.

Descriptive analysis of underlying causes of surgery highlights that there is a single dominant *malignant* cause for surgery (Dukes classification C colorectal carcinoma) accounting for 19.7% of all cases (when all Duke C patients are combined). Conversely, there are *two* dominant *benign* causes for surgery (perforation and ischaemia) accounting for 27.9% and 23% of all cases respectively (again combining all cases, that is, with and without abscess). Each of these cases have an approximate two thirds/one third split between groups, however, as highlighted in *Figure 3* this split is inconsistent in cases of perforation where the majority (70.6%) received enhanced care while in cases of ischaemia and Dukes C the majority (78.6% and 66.6% respectively) received traditional care. Although re-analysis of underlying cause when grouped as shown in Figure 3 found no statistically significant difference between groups (*FET 8.446, p=0.073*) the clinical significance of this is discussed in Chapter 6 (*Section 6.4, page 67*)

Figure 3: Differences between groups in underlying cause of surgery



5.4 Primary Outcome: Toleration of oral fluids and diet

As the re-introduction of oral fluids precedes the re-introduction of oral diet post-operatively, toleration of oral fluids and oral diet were analysed separately.

5.4.1 Toleration of oral fluids

For the purpose of this study, tolerance of oral fluids is defined as the ingestion by mouth of 150-200mls clear fluid (cup/glass of water/juice/black tea or coffee) without an episode of vomiting or >100mls NG aspirate/free drainage (if NG tube in situ) in the subsequent 4 hours.

One patient in the TRAD group did not tolerate oral fluids prior to their study endpoint (transfer to another speciality) and was excluded from analysis (n=60). Time to toleration of oral fluid for the 33 patients in the TRAD group was normally distributed ($D(33)=0.138$, $p = 0.110$) but significantly not

normally distributed (*D(27)=0.216, p=0.002*) for the 27 patients in the ERP group; variances between groups were equal (*F (1,58) = 0.454, p=0.503*). On average, patients in the ERP group (*Mdn=19.25 hours, IQ range 23.09 hours)* tolerated oral fluids significantly earlier (*U=213.5, z = -3.447, p = 0.001*) than the TRAD group (*Mdn=44.58 hours, IQ range 34.29 hours*) representing a large effect *r=-0.445* (*d=-0.994*). These findings are detailed in *Table* 12.

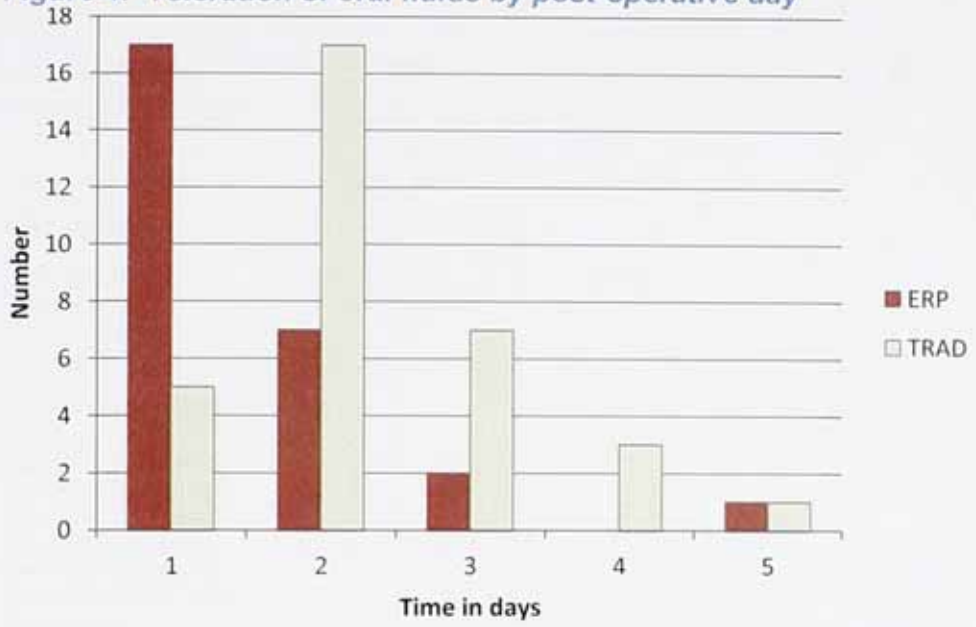
Table 12: Toleration of oral fluids

Outcome	ERP		TRAD		*U*	*z*	*p*
n = 60	**27**		**33**				
Toleration of oral fluids Median time (hours) IQ range (Hours)	19.25 23.09		44.58 34.29		213.5	-3.447	0.001*
Time to toleration of oral fluids (days): Day 1 (0 - 23.99 hours) Day 2 (24 - 47.99 hours) Day 3 (48 - 71.99 hours) Day 4 (72 - 95.99 hours) Day 5 (96 - 119.99 hours)	n 17 7 2 0 1 (27)	% *63* *26* *7.4* *0* *3.7* *(≈100)*	n 5 17 7 3 1 (33)	% *15* *52* *21* *9* *3* *(100)*	-	-	0.001*

Key: IQ interquartile
*significant at $p < 0.05$

Categorising time of toleration to oral fluid into 24 hour time periods (days) post-operatively, as detailed in *Figure 4* and *Table* 12 also found a statistically significant difference (*FET=15.683, p=0.001*) between study groups in post-operative day to toleration of oral fluid.

Figure 4: Toleration of oral fluids by post-operative day



5.4.2 Toleration of oral diet

Four patients (including the patient excluded from analysis in Section 5.4.1) were excluded from analysis of toleration of oral diet (n=57) as they reached a study endpoint prior to tolerating oral diet (see *Table 6*).

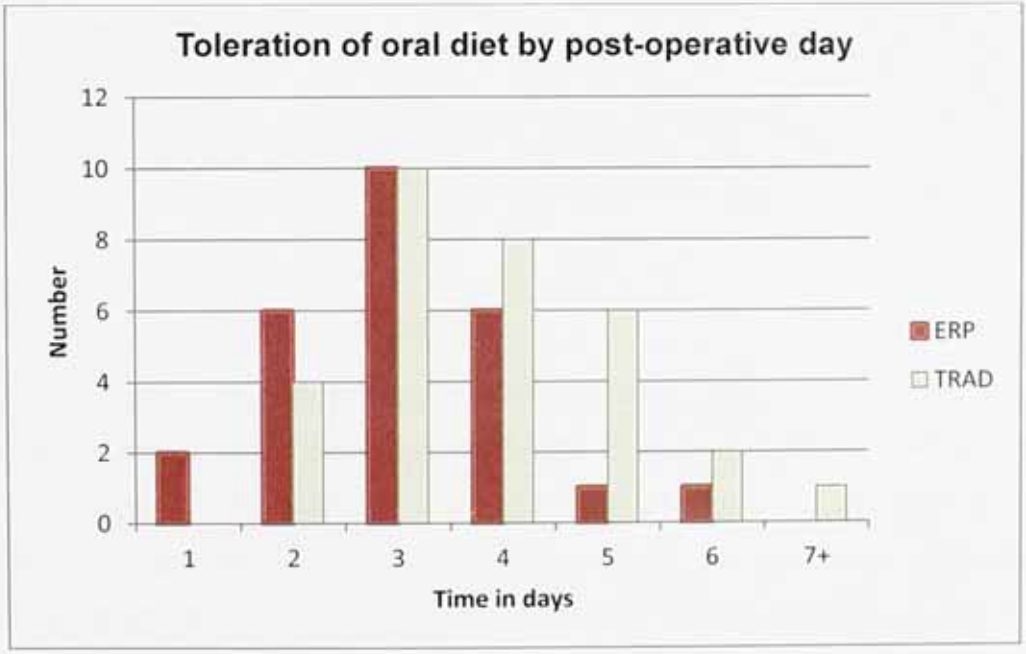
Time to toleration of oral diet was found to be normally distributed for the 26 patients in the ERP group ($D(26) = 0.112$, $p = 0.2$) and the 31 patients in the TRAD group ($D(31) = 0.115$, $p = 0.2$). Levene's test found equal variances between groups ($F(1, 55) = 1.46$, $p = 0.232$). Patients in the ERP group (*M = 63.63 hours, Range 19.75 - 113.33 hours, SE = 5.27*) on average, tolerated oral diet earlier than those in the TRAD group (*M = 83.53 hours, Range 37.08 - 192.33 hours, SE = 6.18*) as summarised in *Table 13* and *Figure 5*. This difference was significant $t(55)=-2.42$, $p = 0.019$ representing a medium to large effect $r = 0.31$ *(d=0.65)*.

Table 13: Toleration of oral diet

Outcome	ERP		TRAD		t	df	p
n = 57	26		31				
Toleration of oral diet Mean time (hours) Range (Hours) Standard Error	63.63 (19.75-113.33) 5.27		83.53 (37.08-192.33) 6.18		-2.42	55	**0.019***
Time to toleration of oral diet (days):	N	%	N	%			
Day 1 (0 - 23.99 hours)	2	*7.7*	0	*0*			
Day 2 (24 - 47.99 hours)	6	*23.1*	4	*12.9*	-	-	**0.315**
Day 3 (48 - 71.99 hours)	10	*38.5*	10	*32.3*			
Day 4 (72 - 95.99 hours)	6	*23.1*	8	25.8			
Day 5 (96 - 119.99 hours)	1	*3.8*	6	19.4			
Day 6 (120 - 143.99 hours)	1	*3.8*	2	6.4			
Day 7+ (144hrs +)	0	*0*	1	3.2			
	(26)	*(100)*	(31)	(100)			

Key: *significant at $p < 0.05$

Figure 5: Toleration of oral diet by post-operative day



5.5 Secondary outcomes:

5.5.1 Length of inpatient stay

Forty nine patients had inpatient discharge as their endpoint (see *Table 5* for details of other endpoints). Time to inpatient discharge was normally distributed for the 21 patients in the ERP group ($D(21) = 0.181$, $p = 0.071$) but significantly not normally distributed for the 28 patients in the TRAD group ($D(28) = 0.240$, $p < 0.001$). Patients in the ERP group (*Mdn* = 157.75 hours, IQ range 98.79) on average, were discharged home earlier than those in the TRAD group (*Mdn* = 163.38 hours, IQ range 91.34 hours). This difference was not found to be statistically significant by the Mann Whitney independent U test ($U = 229$, $z = -1.313$, $p = 0.189$), representing a small to medium sized effect $r = -0.19$ (*d=0.39*). *Table 14* summarises these findings.

Table 14: Length of inpatient stay

Length of Inpatient Stay	ERP	TRAD	U*	z	p
n = 49	21	28	229	-1.31	0.189
Length of stay (hours) Median *(Mdn)* IQ range	157.75 98.79	163.38 91.34			
Key: *Mann Whitney Independent U test					

5.5.2 Post-operative complications

5.5.2.1 *Incidence of post-operative complications*

Endpoints other than inpatient discharge occurred due to post-operative complications; all 61 patients were therefore included for analysis of post-operative complications. *Table 15* summarises the incidence and type of post-operative complications between groups. Twenty seven patients (44%) experienced at least one post-operative complication (13 in the ERP group and 14 in the TRAD group). Three of these patients, all in the TRAD group, had two post-operative complications (for analysis purposes each of these

patients were only counted once). Chi square test found no statistically significant difference between groups and overall incidence of post-operative complication ($\chi^2(1) = 0.296$, $p = 0.589$).

Table 15: Post-operative complications

Post-Operative Complications	n	ERP	TRAD	χ^2	*df*	*p*
Incidence of complication						
Yes	27	13	14	0.296	1	0.589
No	34	14	20			
	(61)	(27)	(34)			
Type of complication:						
1) Intra-abdominal						
Ileus[a]	6	4	2			
Ileus + Cardiac arrythmia (CA)[a]	1	0	1			
Ileus + Respiratory infection[a]	1	0	1			
Nausea	1	0	1			
Anastomotic dehiscence[b]	1	1	0			
Intra-abdominal collection	1	1	0			
Mesenteric ischaemia[c]	1	0	1			
Ureteric injury	1	1	0			
Total	(13)	(7)	(6)	1.205	2	0.548
2) Extra-abdominal:						
a) Infectious						
Respiratory Infection (RI)	2	1	1			
RI + Hypotension	1	0	1			
ARDS[c]	1	0	1			
Wound infection	4	2	2			
Sepsis (unknown source)	1	0	1			
Sub-Total	(9)	(3)	(6)			
b) Non-infectious						
Cardiac arrhythmia	1	1	0			
Cardiac ischaemia[d]	1	1	0			
Oedema	1	0	1			
Neurological	2	1	1			
Sub-Total	(5)	(3)	(2)			
Total	(14)	(6)	(8)			

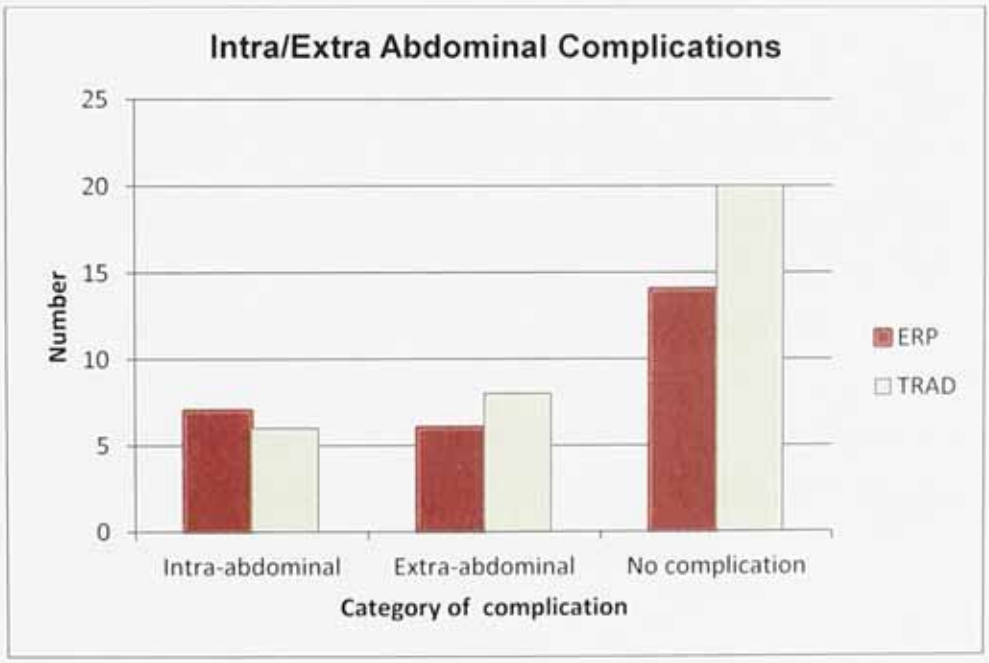
Key:
[a]endpoint = re-insertion of NG tube
[b]endpoint = re-operation
[c]endpoint = transfer to another speciality
[d]endpoint = death
ARDS: acute respiratory distress syndrome

5.5.2.2: Sub-analysis:

Post-operative complications were categorised according to intra or extra abdominal aetiology and further divided into infectious and non-infectious subgroups (as detailed in *Table 15*).

a) *Intra/Extra abdominal complications*: For the purpose of this analysis, the 2 patients in the TRAD group with both intra and extra abdominal complications were classified as intra-abdominal. Thirteen patients (7 in the ERP group and 6 in the TRAD group) had an intra-abdominal complication; 14 patients (6 in the ERP group and 8 in the TRAD group) had an extra-abdominal complication (Figure 6). Chi square test found no statistically significant difference between study groups and these subcategories of complication ($\chi^2(2) = 1.205$, $p = 0.548$).

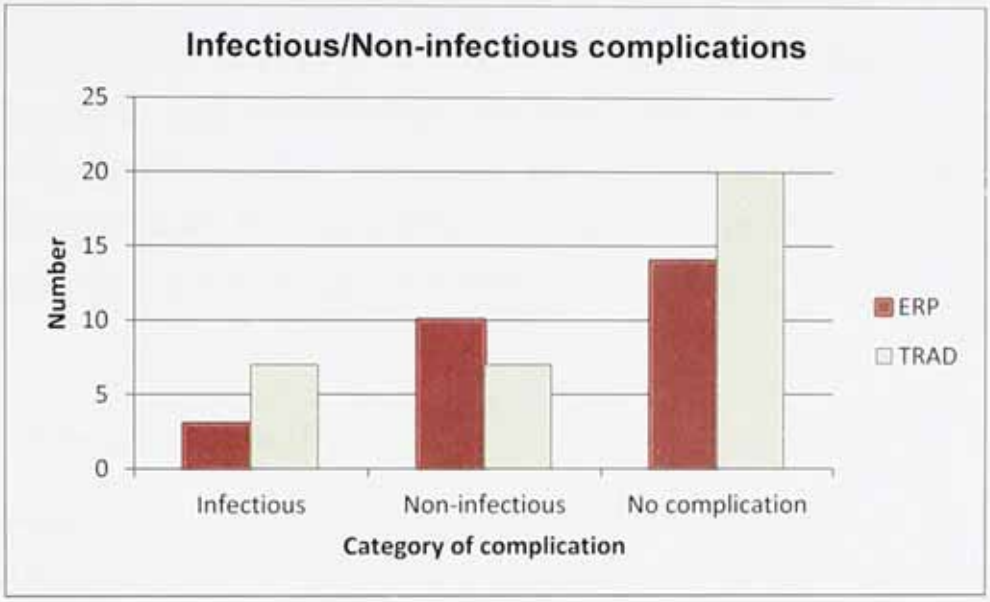
Figure 6: Intra/Extra abdominal complications



b) *Infectious/Non-infectious complications:* For the purpose of this analysis one patient in the TRAD group with an infectious and non-infectious complication (see *Table 15)* was classified as infectious. Ten

patients (3 in the ERP group and 7 in the TRAD group) had an infectious complication; 17 patients (10 in the ERP group and 7 in the TRAD group) had a non-infectious complication (*Figure 7*). Fishers exact test found no statistically significant association (FET = 2.339, $p = 0.335$) between infectious status of complication and study group.

Figure 7: Infectious/Non-infectious Complications



c) *Vomiting:* This was classified as a post-operative complication only when incidence of vomiting became prolonged (indicating an ileus), otherwise it was recorded as an indicator of dietary intolerance. In total 19 patients (31%) had at least one episode of vomiting post-operatively (8 in the ERP group and 11 in the TRAD group). Chi square test found no statistically significant difference ($\chi^2(1) = 0.52$, $p = 0.82$) between groups in incidence of post-operative vomiting.

The statistical and clinical significance of these results and their associated implications for practice are discussed in the following chapter (Chapter 6).

Chapter 6: Discussion and implications for practice

This study has found that avoidance of routine NG decompression and early introduction of post-operative oral fluids and diet are tolerated in Level 0/1 emergency bowel resection patients with no statistically significant difference in post-operative complication when compared to those receiving traditional care. This demonstrates that early feeding and avoidance of routine NG decompression is feasible in Level 0/1 emergency bowel resection patients and suggests that these patients may safely avoid routine post-operative NG decompression and re-commence oral fluids and diet as they feel able. However, methodological limitations and clinical significance influence applicability of study findings to practice. These findings therefore need to be discussed from both a clinical and statistical perspective.

6.1 Toleration of oral intake

The observational nature of the study limited control over how or when oral fluids and diet were re-introduced in practice. For patients to be *able* to tolerate oral fluid and diet within 24-48 hours of surgery (as shown in *Figures 4 and 5, pages 54 and 55*), it follows that they must have been offered oral fluid and diet within this time period, in turn confirming that study groups received different nutritional care dependent on presence or absence of NG tube as per study protocol.

However, *permission* to recommence oral intake was dependent on the study group (ERP group, early feeding v TRAD group, delayed feeding) creating a known time differential between groups. To ensure study findings are a valid reflection of toleration of oral intake rather than a reflection of this difference in permission to recommence oral intake between groups, careful consideration needs to be given to how toleration has been defined and measured and how multiple factors which affect an individual's ability and will to ingest have been accounted for.

In restricting the study's inclusion criteria to *oral* intake and excluding those who received tube feeding or were physically or psychologically unable to eat, included patients (once permitted to drink and eat) were able to control what, when and how much they wanted to ingest post-operatively.

The idea of 'patient-controlled diet' was first investigated in elective bowel resection patients by Han-Geurts et al (2001) and is reflected in the emergency studies by Saad et al (2007) and Klappenbach et al (2013). Clinically, this approach empowers the individual and enables them to adjust their ingestion at early signs of intolerance (nausea, abdominal distension/bloating) in contrast to those receiving 'enforced' tube feeding where any adjustment is dependent on the care giver and tends to be in response to late manifestations of intolerance (vomiting/increased gastric aspirate and/or diarrhoea). While all patients following bowel resection are initially predisposed to diarrhoea/loose stool, tube feeding increases the incidence of this as demonstrated in the studies by Lee et al (2014), Malhotra et al (2004) and Singh et al (1998).

Patient-controlled diet is therefore associated with self management of early intolerance, aided where necessary with anti-emetics. In defining 'tolerance' in fixed terms (see *Glossary, page 10*) the study mitigates the impact of self-management as only when the defining criteria are met is toleration achieved, irrespective of events (such as nausea and vomiting) which may have preceded that point in time. By default, intolerance is therefore defined (and recorded as a post-operative complication or study endpoint) only when signs and symptoms of intolerance are uncontrolled by self management techniques (as above) or prolonged (indicating ileus), requiring additional investigation (for example, radiographic imaging) or intervention (such as re-insertion of NG tube).

In using these definitions of tolerance as *measures* of tolerance, they do not account for the time difference in *permission* to recommence oral intake between groups. However, from a clinical perspective, such a measure would

be meaningless as it is accepted practice that delayed feeding is an integral part of traditional care. With 24 ERP patients (86%) tolerating oral fluids within 48 hours of surgery and 18 (69%) tolerating oral diet within 72 hours of surgery, compared to 22 (66%) and 14 (45%) TRAD patients respectively, the measure of tolerance used is clinically appropriate to demonstrate that patient controlled oral intake in Level 0/1 patients following emergency bowel resection is tolerated and that toleration occurs significantly earlier than dictated by traditional care.

However, any study findings are dependent on the reliability and validity of collected data. Although a minority of study patients had data collected both prospectively and retrospectively, the majority of patients had data collected retrospectively from their health care records. As legal records of care the study accepted the face value of these records and potential observer or participant bias was minimised.

Professional, organisational and local record keeping standards govern standards of record keeping in health care, however, multiple factors influence the quality of record keeping in practice. Post-hoc analysis confirmed all Level 0 patients (and level 1 patients when at Level 0) received care in the same post-operative ward minimising the effect of any cultural variation in documentation. Although this standardised format enabled consistency and easy identification of key data promoting reliability, inconsistencies in recording of specific care events had the potential to significantly limit the reliability of study data.

To overcome this limitation, the study standardised data collection as detailed in *Section 4.5.5* (*page 38*). However, as a result of maintaining validity, these strategies create a conservative effect on study data suggesting specific events may actually occur in practice earlier than recorded for the study. In addition, potential interpretative bias was further minimised through use of a single data collector.

Despite these limitations, the study highlights that traditional care is changing. With a mean duration of NG decompression of 38.91 hours and 22 patients (66%) in the (TRAD) group tolerating oral fluid within 48 hours of surgery, the suggestion is that duration of routine NG decompression is much shorter than typically quoted in the literature and removal is no longer dependent on first flatus/bowel movement which occurred on average (in the TRAD group) 88.49 hours post-operatively. It must, however, be noted that this time to first flatus/bowel movement is purely descriptive and no reliable comparison can be made between groups in this event owing to inconsistencies in recording of primary data as detailed in *Section 4.5.5 (page 38)*.

These observed changes in traditional care may be a reflection of both the shifting attitudes and beliefs voiced by the ASGBI in its consensus opinion (Khan et al, 2009) and an effect of national standardisation of emergency laparotomy care as outlined by the Royal College of Surgeons (2011) and the Royal College of Anaesthetists on behalf of NELA (2015). The lack of significant difference between study groups in pre, intra and post-operative care characteristics (*Section 5.3, page 43*) supports this standardisation suggesting that with the exception of NG decompression and commencement of oral intake, elements of care for emergency Level 0/1 bowel resection patients incorporate principles of enhanced care where possible. In the absence of randomisation, these findings also promote the internal validity of this study, supporting homogeneity between study groups.

Strict inclusion and exclusion criteria accompanied by clarity of terminology (*see Glossary, page 10*) were used to promote external validity in the study, however, this was at the expense of statistical power. Much consideration was given to extending the inclusion criteria to encompass those undergoing emergency adhesiolysis (increasing sample size and therefore statistical power) as an analysis of excluded patients found this group represented a similar number of patients to the study sample with a similar ward/critical care split. However, while this group clearly warrants evaluation in relation to early feeding, it was concluded that these patients are a separate population with

their own specific problems. To avoid confounding study results they therefore remained excluded.

In retaining the original study inclusion/exclusion criteria, 80.4% of included patients (including those who had a combined procedure) underwent an emergency large bowel resection. This is the highest proportionate representation of included emergency large bowel procedures of all the studies reviewed in *Table 1 (page 25)*. From a clinical perspective, this is highly significant as heterogeneity of included procedures has been a major limitation in extrapolation of existing findings to practice.

Post-hoc analysis (by G*Power) calculated the study sample achieved 80% power (Type I error 0.05) to detect a medium to large effect *(d=0.77)* between groups (2-sided independent *t* test *critical t = 2.005*). The study was therefore adequately powered to detect the large effect (d=0.994) found between groups in toleration of oral fluid but a larger sample is required to detect smaller effect sizes. This becomes particularly relevant when interpreting findings in relation to post-operative complications.

6.2 Post-operative complications

Statistically, the study found no significant difference between groups in overall incidence of post-operative complications, suggesting that early feeding is safe in this patient group. However, while a complication may not be statistically significant, the type and severity of a complication may have great clinical significance.

Emergency bowel resection is known to be associated with a higher risk of post-operative complication than elective bowel resection (NCEPOD 2011), however, incidence of post-operative complication is influenced by multiple patient and surgeon factors. Two of these are the pre-existing nutritional state of the patient and the presence or absence of sepsis. Using the mean Body Mass Index (BMI) as an indicator, the study group was well nourished with the

ERP group having a slightly higher mean BMI (27.74) than the TRAD group (25.4). This highlights that the nutritional characteristics of the study group are very different from the malnourished critical care patients studied by Kaur et al (2005), Moore et al (1986) and Singh et al (1998) suggesting that when compared to these patients, the study group may be potentially less susceptible to infectious complications.

Conversely, pre-existing sepsis such as abscess or peritonitis can increase susceptibility to infectious complications. Twenty seven patients (44%) had findings of localised or free pus at operation (14 in the ERP group, 13 in the TRAD group). As contamination is one of the operative indicators used by the CR-Possum score to calculate predictive risk, the median CR-Possum score may also be used as an indicator of pre-operative sepsis although in this instance P-Possum would have been more specific as it uses both contamination at operation and White Cell Count as indicators. With both groups having a relatively low CR-Possum score (ERP 3.28 v TRAD 3.8), this suggests the study group were closer in characteristic to elective colorectal patients than emergency peritonitic critical care laparotomy patients. For clarity, the individual CR-Possum score of each study patient was calculated retrospectively following histological confirmation of malignancy status and actual reporting of contamination found intra-operatively. The study median CR-Possum is therefore a more accurate reflection of predictive risk than the prospective score calculated pre-operatively in clinical practice.

Anastomotic leak, intra-abdominal abscess and abdominal dehiscence are three of the major complications associated with bowel resection; in elective colorectal surgery the Association of Surgeons of Great Britain and Ireland (ASGBI 2010) quote incidence of anastomotic leak ranges from 0-4% for intra-peritoneal anastomosis and 1-19% for extra-peritoneal anastomosis. By comparison, incidence of anastomotic leak and intra-abdominal abscess found in the emergency studies reviewed in Chapter 3, ranged from 1.2% (Lee et al, 2014) to 16.3% (Singh et al, 1998) for anastomotic leak and 2.4% (Lee et al 2014) to 25.6% (Singh et al, 1998) for intra-abdominal abscess.

In this study, no patient had abdominal dehiscence; one patient (in the ERP group) admitted with localised perforation and peritonitis had an anastomotic leak following sigmoid colectomy (intra-peritoneal anastomosis), and another ERP patient also admitted with localised perforation and peritonitis developed an intra-abdominal abscess following a Hartmann's procedure. The patient with anastomotic leak required re-operation but the patient with intra-abdominal abscess was managed conservatively. Incidence of both anastomotic leak and intra-abdominal abscess in this study is therefore 1.6% with overall incidence of major complication 3.3%, again comparable with elective colorectal patients and the most recently published emergency study (Lee et al, 2014).

Post-operative ileus (defined by re-insertion of NG tube) and wound infection were the most common complications occurring in the study groups. Incidence of re-insertion of NG tube was slightly higher in the ERP group (n=4) than the TRAD group (n=2) equating to 9.5% of patients not tolerating early diet; however, no difference was found between groups in incidence of vomiting. This is in contrast to the majority of both elective and emergency studies which commonly report a higher incidence (but not a significant difference) of vomiting in their early fed groups. This may be due to how vomiting was recorded in this study (that is, vomiting prior to toleration of oral fluids and diet was only classified as a complication if it became clinically significant requiring re-insertion of NG tube) or it may be due to the shorter mean duration of NG decompression observed in the TRAD group compared to other studies. Of note, the mean duration of NG decompression in this study combined with the standardisation of pre, intra and post-operative characteristics place the TRAD group closer in characteristic to an equivalent emergency enhanced group studied by Lohsiriwat (2014).

Many studies focusing on early feeding have found significant reductions in infectious complications in their early fed groups (Singh et al 1998, Malhotra et al 2004, Lee et al 2014) particularly in relation to respiratory and wound sepsis. While not significantly different, the findings of this study are

consistent with these reductions: three patients in the ERP group had infectious complications (11%) compared to 7 patients in the TRAD group (20.6%). Aside from early diet, the only other observable difference in care between the two groups which could influence this finding relates to pre-operative antibiotic therapy with proportionately more patients (62%) in the ERP group receiving pre-operative antibiotic therapy than in the TRAD group (42%).

6.3 Length of stay

In both elective and emergency studies early fed groups are commonly reported to have a shorter length of hospital stay than control groups (Kaur et al 2005, Klappenbach et al 2013, Lee et al 2014, Saad et al 2007). This study also found that the ERP group had a shorter mean length of hospital stay than the TRAD group but this was not statistically significant. While this suggests that Level 0/1 emergency bowel resection patients recover marginally quicker in the absence of routine NG decompression and early re-introduction of oral diet, no comparison can be made between elective and emergency patients in the overall duration of hospital stay owing to the unplanned nature of emergency patients and the associated (often complex) social issues which affect capacity and discharge once the individual is medically fit. In addition, 29.5% of study patients (6 in the ERP group, 12 in the TRAD group) had formation of a new stoma. Independence in stoma care is an essential criteria for discharge in these patients, lack of this independence may be an additional issue when looking at duration of hospital stay in this patient group.

6.4 Systematic bias and clinical implications

In the absence of randomisation or blinding, systematic bias remains a potential limitation of the study. As the CR-Possum score is calculated from a range of demographic, physiological and operative parameters (*see Appendix VII, page 87*), it may be used to indicate systematic bias since a statistically significant difference in median CR-Possum score between groups would suggest one group is 'fitter' than the other (thereby indicating the presence of a

bias). While the enhanced group had a slightly lower median CR-Possum score than the traditional group this was not found to be statistically significant, indicating that any systematic bias within the study is minimal, strengthening study validity.

However, a limitation to using the CR-POSSUM score as an indicator of bias is that while it accounts for operative contamination (pus/faecal matter) and malignancy status, it does not differentiate between benign and *early* (Dukes A and Dukes B) malignant causes for surgery. This limitation becomes relevant when the statistically significant difference found on initial analysis of the *underlying cause* for surgery is considered in conjunction with the lack of corresponding statistically significant difference in *histological* cause (benign/malignant) (*see Section 5.3.6, page 51*). This suggests the difference in underlying cause lies within one of the histological groups

Further analysis of study groups identified two underlying causes (perforation with or without abscess and ischaemia with or without abscess) accounted for over 50% of included patients (n=31). However, the distribution of these patients between groups was unequal with the majority (70.6%) of perforation cases in the ERP group but the majority of ischaemia cases (78.6%) in the TRAD group. While a consistent two thirds/one third split in favour of traditional care would be representative of the number of surgeons within the study setting using enhanced care in their emergency patients, an inconsistent split suggests an independent (and unaccounted for) factor influences surgical choice in favour of enhanced care in cases of perforation (a surgical selection bias).

Clinically, the presence or absence of ischaemia at point of operation (intra-operative ischaemia) may account for this factor as ischaemia, particularly transmural ischaemia (necrotic bowel) is associated with increased morbidity and mortality (Weisner et al, 2003). Sub-analysis of those with ischaemia (n=14) and perforation (n=17) against study endpoints reflect this increase, finding patients with ischaemia had twice the proportionate incidence of an

endpoint other than inpatient discharge compared to those with perforation (36% v 18%).

Ischaemia is reported to be present in cases of stricture and although it may be a primary cause of perforation in necrotic bowel (Weisner et al, 2003), other common benign aetiologies of lower gastro-intestinal perforation in England (pre-disposing inflammatory disease such as diverticulitis and appendicitis, direct injury and underlying drug therapy) are much less frequently associated with ischaemia (Samy et al, 2014). This is reflected in the distribution of the studies' other two benign underlying causes of surgery, inflammatory mass/abscess and stricture/stenosis. Although the number of these cases are small (5 in each group), 100% of inflammatory cases occur in the ERP group whereas 100% of stricture/stenosis cases occur in the TRAD group.

Of the seven studies included in the literature review (*Table 1*), only Lee et al (2014), published in English after the commencement of this study, explicitly acknowledges ischaemia, using an *'absence of ischaemic bowel change in theatre*' as one of three eligibility criteria for early feeding in their study (in addition to haemodynamic stability and anastomotic integrity/covering stoma). These criteria not only work to minimise selection bias through standardisation but also provide a useful guide for any team wishing to implement or investigate early oral feeding in their Level 0/1 emergency bowel resection patients *in the absence of intra-operative ischaemia*.

While the other 6 studies included in the literature review are randomised controlled trials, which by design minimise systematic bias, none explicitly discuss the issue of ischaemia, exclude patients with ischaemia or overtly state group characteristics in terms of ischaemia or perforation although this may be implied from information on 'diagnosis' and 'indications for surgery'. Consequently, although these studies may have included patients requiring surgery due to an ischaemic cause, there is a lack of clarity regarding both the number and distribution of these patients and the stage of their ischaemia (reversible, partial or transmural). This highlights a need for further studies to

investigate the feasibility and safety of early feeding in emergency bowel resection in the presence of intra-operative ischaemia. To be clinically relevant, these studies need to specify and/or stratify results by stage of ischaemia.

Although this study included patients with a documented underlying cause of ischaemia (as reported in operation notes and/or histology reports), those at increased risk of ischaemia (for example those on therapeutic anticoagulation) were excluded and those with a Stage III ischaemia should have been excluded due to requiring Level 2 or above critical care (in line with Intensive Care Society guidelines, 2009). Consequently, the 3 included patients with ischaemia in the enhanced group most likely had a Stage I or II ischaemia. However, with two of these patients having a study endpoint other than inpatient discharge, the study provides insufficient evidence to support the continuation of early feeding in Level 0/1 emergency bowel resection patients with intra-operative ischaemia.

6.5 NELA (National Emergency Laparotomy Audit)

The National Emergency Laparotomy Audit (NELA) is monitoring national compliance with standards for emergency laparotomy care across 195 centres in England and Wales. In June 2015, just prior to completion of this thesis, NELA published their first report (NELA 2015) based on data collected between December 2013 and November 2014, a time period which ran concurrently with this study. While local NELA data was used to identify potentially eligible patients, less than 25% of local patients (23.8%) fulfilled study eligibility requirements. Accounting for the systematic bias relating to intra-operative ischaemia, in reality this number is even lower. If the actual proportion is conservatively estimated at 10%, with NELA having collected data on 20,000 procedures in their first year, nationally the number of emergency laparotomy patients who may be eligible for early oral feeding equates to approximately 2,000 a year.

Although within the wider context of emergency laparotomy this represents a relatively small (and probably the 'fittest' proportion) of patients, it could be argued that any safe, potentially cost effective but certainly cost neutral improvement in care such as early oral feeding, indirectly benefits all emergency patients through releasing human, physical and financial resource for investment into those who require more intensive care, the availability and accessibility of which is a key determining factor in reducing overall mortality in this patient group.

6.6 Theoretical Speculation

The design of this study was strongly influenced by the wealth of existing evidence supporting enhanced recovery in elective bowel surgery (Fearon et al 2005; Khan et al 2009). While adaptations were necessary for applicability to the emergency situation, the findings of this study suggest that the principles and theory of enhanced recovery are equally applicable to the emergency as the elective setting.

Enhanced recovery evolved as a multi-modal approach to moderating the catabolic effect of the surgical stress response, a series of hormonal and metabolic changes thought to originate as a healing mechanism in injured animals but no longer believed to be necessary in contemporary surgical practice (Desborough 2000).

Multiple anaesthetic and surgical strategies including avoidance of sedative pre-medication, use of selective anaesthetic agents, intra-operative warming, oxygenation, systemic opiate avoidance and goal directed fluid therapy are known to contribute towards this moderation and work synergistically to attenuate the surgical stress response and promote early return of gut function (Kehlet 2008). The homogeneity of patient characteristics suggests these strategies are now common to all bowel resection patients and may be one reason why the study found those in the traditional group had a shorter mean duration of NG decompression than typically quoted in the literature and there

was no statistically significant difference between groups in incidence of vomiting.

However, compared to the pre-operative anabolic state of elective patients (due to reduced fasting, avoidance of mechanical bowel preparation and carbohydrate loading), pre-operative emergency patients are in an already stressed (catabolic) state (due to their presenting symptoms, acute injury and/or associated sepsis). Prolonged catabolism induces a state of fatigue (Braga et al, 2009) and therefore the role of pre-operative optimisation in mitigating the stress response to acute injury and reducing the further insult of surgery cannot be underestimated in these patients although the study lacks specific data in this respect.

Post-operatively, return of bowel function has traditionally been associated with passage of flatus or faeces, however, this is recognised to correlate poorly with clinical condition and does not reflect return of gastric or small bowel function (Holte & Kehlet 2000). Since colonic motility is stimulated by the gastro-colic reflex which occurs after food ingestion, it would appear logical that early feeding could therefore promote return of colonic motility post-operatively although surgical disruption of the pelvic nervous plexus may influence this in practice (Warren et al 2011) explaining why a comparable proportion of both elective and emergency patients fail to tolerate early oral diet.

With a median time to toleration of oral fluids in the ERP group of 19.25 hours, the findings of the study suggest gastric and small bowel function returns within a comparable time to elective patients, negating the need for routine NG decompression. The discomfort of an NG tube may also present a psychological barrier to ingestion which may influence duration of ileus and the will to ingest. In addition, routine NG decompression appears to be associated with increased post-operative respiratory complications, possibly due to bacterial migration across normal defence mechanisms (Verma & Nelson 2010).

Conversely, early enteral nutrition has been shown to have a beneficial effect on gut mucosa, reducing translocation of bacteria and subsequent sepsis, promoting bowel motility and improving both anastomotic and wound healing (Andersen et al 2011). This suggests the presence and/or expectation of food itself has a role in promoting early return of gut function negating the traditional belief that routine NG decompression and starvation is necessary to protect the healing surgical anastomosis from the increased intra-luminal pressures of digestive peristalsis and contraction.

While these mechanisms may promote recovery and induce feelings of hunger, patients need to be informed of expectations and eventualities with regard to their recovery pathway to empower them to take control. A central component of elective enhanced recovery is pre-operative psychological preparation (Khan et al 2009), however, due to their presenting condition, this degree of preparation is often not possible in emergency patients, highlighting a need for both medical and nursing staff to present consistent post-operative information. The positive influence of study patients being cared for in an environment familiar with enhanced recovery may therefore have influenced study outcomes as staff were aware of and confident in enhanced principles, promoting self management strategies once oral intake was permitted. This reflects the importance of a multi-disciplinary approach in the psychological as well as the physiological recovery of emergency patients.

Enhancing recovery following emergency bowel resection would therefore appear to be influenced by a multitude of physiological, psychological, organisational and resource factors. However, while this study has demonstrated the feasibility and safety of avoiding routine NG decompression and reintroducing oral intake as tolerated in Level 0/1 patients following emergency bowel resection, it highlights that this is tolerated better in the absence of intra-operative ischaemia suggesting that duration, type and severity of acute injury in conjunction with patient characteristics influence individual patient recovery. This may be due to the effects of prolonged

catabolism, highlighting a need for further research into optimal pre-operative resuscitative strategies in this patient group.

Chapter 7: Summary and Recommendations for Practice

In summary, this study demonstrates that early oral feeding in the absence of routine post-operative NG decompression *and intra-operative ischaemia* is feasible and safe *in the study population* supporting continued use of the enhanced recovery pathway *in the study setting*. Explicit use and dissemination of eligibility criteria as suggested by Lee et al (2014) could further improve this pathway, aid transparency and promote standardisation of care across the setting.

The identification of a surgical selection bias relating to the presence or absence of ischaemia at operation (intra-operative ischemia) means any generalisation of study findings can only be applicable to equivalent Level 0/1 emergency bowel resection patients *without intra-operative ischaemia*.

In identifying the source of this bias, the study has contributed to the wider body of knowledge relating to early feeding following emergency bowel resection as it provides evidence of an implicit factor which influences choice of post-operative pathway (early feeding or traditional care). Of the reviewed studies, only one (Lee et al, 2014) specifically acknowledged (and excluded) ischaemia, none of the other studies provided any information relating to ischaemia either in their exclusion criteria or study characteristics.

This lack of evidence in relation to early feeding following emergency bowel resection due to ischaemia highlights the need for further study to examine the feasibility and safety of early feeding in this patient sub-group. Specifically, studies are needed which differentiate and classify the stage of ischaemia for relevance to practice.

Enteral (oral or tube) feeding is only possible in those with a functioning gastrointestinal tract (Braga et al, 2009). In focusing on tolerance of early fluids and diet in Level 0/1 emergency bowel resection patients without intra-operative ischaemia, this study evidences that post-operatively the gastro-

intestinal tract regains function much earlier than conventionally believed in these patients, contributing to the growing evidence in support of early feeding in this patient group. In comparison with the existing literature, homogeneity is a particular strength of the study having 80% of included patients undergoing a large bowel resection (to date the highest proportionate representation within the literature).

In conclusion, there appears to be little purpose in continuing routine post-operative naso-gastric decompression and restricted oral intake in Level 0/1 emergency bowel resection patients *in the absence of intra-operative ischaemia*. Avoiding routine post-operative naso-gastric decompression and permitting these patients to resume oral intake as they feel able after surgery not only empowers the individual but may result in improved outcomes through a reduction in infectious complications.

A large scale, multi-centre randomised controlled trial of early feeding in emergency bowel resection patients without intra-operative ischaemia is needed to strengthen this evidence. However, the changes in traditional care evidenced in this study may make this ethically challenging as more surgeons adopt and evidence the benefits of early feeding in this patient group. The study recommends that following local standardisation of the enhanced pathway, nutritional post-operative care for these patients should focus on the nutritional value of *what* they can eat, not *when* they can eat.

APPENDICES

Appendix I Publications and National Presentations

a) Stupples C, Medhi MM and El-Rabaa S (2013). Enhanced recovery and emergency laparotomy - a retrospective baseline audit. BRITISH JOURNAL OF SURGERY. Vol 100. Supplement 7. p168.
(Full abstract on page 79 of this thesis)

b) Stupples C, Medhi MM and El-Rabaa S (2012). Enhanced recovery and emergency laparotomy - a retrospective baseline audit. Abstract 12016. 2nd ERAS UK conference. Cheltenham.

http://www.erasuk.net/uploads/2/6/4/0/26401678/brochure_draft_23_oct.pdf

c) Stupples C, Campbell J, El-Rabaa S (2015). Enhancing recovery in non-critical care emergency bowel resection patients. Abstract accepted for presentation at 5th ERAS UK Conference, Edinburgh, November 2015
(ERAS UK Abstract decision email on page 80 of this thesis)

such as sex, age and co-morbidities were recorded. Types of surgery and post operative outcomes in terms of discharge or mortality were highlighted.
Results: During the study period 1324 patients were admitted of which 158 were 80 or over. Our study population of 80+ who underwent surgery was 23 patients. There were 15 males and 8 females. Mean age was 85 (Range 80, 91). Most common co-morbidity was IHD (16 patients) and most common surgery was laparotomy (6 cases). The mean duration of in-patient hospital stay was 17 days. 5 patients died in the post operative period (2 post laparotomy, 2 post vascular intervention and 1 other). The mortality rate for this group was 21%.
Conclusion: The very aged patient group account for 10% of all acute surgical admission. Those undergoing emergency surgery have a significant survival potential and should be considered for surgery in the emergency setting based on needs and not age alone.

Emergency Surgery 0301

Good outcomes are achievable in emergency GI surgery in a large teaching hospital

K. Pearson*, L. Graham, I. Fecher, J. Knight

University Hospital Southampton, UK

Background: Within the NHS 170,000 patients undergo emergency abdominal surgery each year. Recent reports have highlighted that emergency surgical care is suboptimal with a wide variation in outcomes across hospital trusts. Reported mortality rates are typically 15-20%, rising to 40% in elderly patients with annual intensive care costs of £88 million. The national laparotomy network audit is underway but will not report for several years. In response to these publications and prior to the implementation of an emergency surgery service, we analysed the outcomes of patients undergoing emergency GI surgery in a large teaching hospital.
Methods: Retrospective analysis of a prospectively-entered database of all patients undergoing NCEPOD graded emergency or urgent laparotomy requiring small or large bowel resection.
Results: Over the 22-month audit period 167 patients (42% male) underwent surgery. The median age was 68 years and 24% patients were over 80 years. 80% patients were ASA grade 3 or above. 42% of procedures were performed during the evening or night. A consultant surgeon was recorded as the primary operator in 37% and a consultant anaesthetist was present in 42% of cases. 54% of patients went to intensive/high care. 30-day mortality rate was 6% (15% in over 80s) and 1-year mortality rate was 24% (30% in over 80s).
Conclusion: This audit has shown a low mortality rate in a high risk group of patients which compares well to nationally reported outcomes. The introduction of a consultant-led emergency surgery service should further improve care. Ongoing audit is required.

Emergency Surgery 0430

Appendiceal inflammation affects the length of stay following appendicectomy amongst children: A myth or reality?

K. Siddique*

East Kent Hospitals NHS Foundation Trust, Ashford, UK

Background: The effect of the severity of appendiceal inflammation on post-operative stay in children following appendicectomy has shown conflicting results. This study was conducted to determine the association between the severity of appendiceal inflammation and post-operative stay amongst children undergoing open appendicectomy.
Methods: A retrospective cohort study was conducted at a District General Hospital and included all children (1–16 yrs.) who underwent appendicectomy between Jan. 2007- Dec. 2008. The association of post-operative stay with severity of appendiceal inflammation and post-operative complications was assessed by log rank test and Cox Proportional hazards model.
Results: Total number of patients was 204. Females were 54.9% while the rest were male with a mean age of 12.5 ± 3 yrs. The mean post-operative stay was 2.32 days (95% CI 2.14-2.51). A perforated appendix, histological inflammation and post-operative complications were significantly associated with prolonged post-op stay on univariable analysis (p-value < 0.05). Whereas, the multivariable analysis showed that the post-operative stay was significantly prolonged only in case of either perforated appendix or post-operative complications while it remained unaffected by the histological inflammation.
Conclusion: Severe inflammation of appendix in children presenting as either a perforation or post-operative complications is significantly associated with a prolonged post-operative hospital stay.

Emergency Surgery 0479

Enhanced recovery and emergency laparotomy – a retrospective baseline audit

C. Stupples, M. M. Masood*, S. El-Rabba

Kettering General Hospital, UK

Background: Implementation of enhanced recovery (ER) principles in the emergency situation is advocated by the ASGBI (2009). However, to date, no data has been published specifically relating to ER and emergency colorectal surgery. This audit was undertaken to obtain a baseline of current ER activity in emergency colorectal surgical patients with the aim of actively implementing ER in this patient group.
Methods: The case notes of the first 50 patients who met the inclusion criteria were retrospectively audited against adapted clinical standards for enhanced recovery.
Results: 22 male and 28 female patients were audited. Age range was 27–88 years; mean age: 64.5 years (SD 16.7). 8 patients were NCEPOD category immediate, 35 urgent and 7 expedited. Mean CR-Portsm score by NCEPOD category were 22, 8.8 and 3.7 respectively. Actual incidence of mortality was 3 (6%). 27 (54%) had formation of a stoma. 13 (26%) patients went to ITU post-operatively, 17 (34%) to Level 1 care and 20 (40%) went to the ward. Mean adoption of ER components ranged from 0–100%. Categorised according to rate of adoption:

Low (0–22%)	Goal directed fluid therapy (0%); high peri-operative oxygenation (0%); curtailed fasting (2%); early diet (6%); minimal incisions (22%).
Medium (42–58%)	Avoidance of nasogastric tubes (42%); restricted IV fluids (46%); early mobilisation (54%); avoidance of systemic opiates (57%); pre-operative information (58%).
High (84–100%)	Wound drain (84%); epidural analgesia/local anaesthetic blocks (88%); VTE prophylaxis (90%); IV antibiotic therapy (99%); avoidance of sedative pre-med (100%); avoidance of hypothermia (100%).

Conclusion: This audit highlights a clear need for research into the applicability and benefits of enhanced recovery in emergency colorectal surgical patients as fundamental differences between elective and emergency patients preclude any direct comparison of results. The majority of ER principles have been adopted in emergency colorectal surgery. Further research is needed particularly in relation to tolerance of pre and post-operative enteral nutrition to promote ER in this patient group.

Emergency Surgery 0482

Use of laparoscopic appendicectomy (LA) in a paediatric population in a DGH setting

H. Sekhar*, A. Konarski, A. Horsley, C. J. Smart, B. Darmas

Stepping Hill Hospital, Stockport, UK

Background: Appendicectomy remains the most commonly performed emergency paediatric operation. The benefits of LA in the paediatric population

Appendix 1c: ERAS UK Conference Abstract Decision

ERAS UK Conference Abstract Decision
Fiona Carter [erasukcontact@gmail.com]

Sent: 03 September 2015 22:08

To: caroline.stupples@kgh.nhs.uk

Dear Caroline,

I am pleased to inform you that your abstract:

15019 Enhancing Recovery in non-critical care emergency bowel resection

has been accepted for **poster presentation** for the 5th ERAS UK Conference, 6th November, Edinburgh.

Please confirm that you wish to take up this offer to present your work at our conference **as soon as possible,** quoting the **abstract code**. Once we have received your confirmation, we will provide you with further details regarding poster preparation etc.

In order to present your work at the conference, you will need to **register** – the early bird registration rate is available until **17th September 2015**.

I look forward to hearing from you,

Dr Fiona Carter

On behalf of the ERAS UK Conference Organising Committee

erasukcontact@gmail.com

01935 315052

www.erasuk.net

Appendix II Nursing and Health Profession Databases

Database (alphabetical order)
AMED (Allied and complementary medicine)
BMJ Journals
British Medical Journal Archive
CINAHL Plus with Full Text
Ingenta Connect
Intermid (Archive of the British Journal of Midwifery from 1995)
Internurse
Medline
Ovid
PsycNET
PubMed Central
Science Direct
Taylor & Francis online
Web of Science

Appendix III Quality appraisal screen

Study	A	B	C	D	E	F	G	H	I	J	Total
RCT'S:											
Kaur et al (2005)	1.0	1.0	0.0	1.0	0.5	1.0	N/A	1.0	0.0	1.0	**6.5**
Klappenbach et al (2013)	1.0	0.0	1.0	1.0	0.5	1.0	N/A	1.0	0.5	1.0	**7.0**
Malhotra et al (2004)	1.0	1.0	1.0	1.0	0.5	1.0	N/A	1.0	0.5	1.0	**8.0**
Moore & Jones (1986)	1.0	1.0	1.0	0.5	0.5	1.0	N/A	1.0	0.5	0.5	**7.0**
Saad et al (2007)	1.0	0.0	1.0	1.0	0.0	1.0	N/A	1.0	0.0	1.0	**6.0**
Singh et al (1998)	1.0	0.0	0.0	1.0	0.5	1.0	N/A	1.0	0.5	1.0	**6.0**
Retrospective:											
Lee et al (2014)	1.0	0.0	N/A	1.0	0.0	1.0	N/A	1.0	0.0	1.0	**5.0**

Note: 1.0 = yes; 0 = No; 0.5 = description was unclear or only some of the interventions, measurements of outcome or data presentations met requirements of study.

Key:
A = well described inclusion criteria
B = At least 50 patients per group
C = Random allocation procedure described
D = Presentation of all baseline characteristics
E = Less than 10% dropouts described
F = Interventions well described (nature, number, duration of treatments)
G = Double-blinding
H = Effect of measurement relevant and well described
I = Intention to treat analysis
J = Presentation of results in such a manner that analysis can be checked

Appendix IV NREC letter (July 2013)

Proportionate review booking confirmation 13/SS/0141

From **Bailey, Alex** Alex.Bailey@nhslothian.scot.nhs.ukhide details

To **'carolinestupples@aol.com'** carolinestupples@aol.com

CC **Clearie, Joyce** Joyce.Clearie@nhslothian.scot.nhs.uk

Dear Caroline,

Thanks for taking the time to speak to me.

In summary, if the study is classified as research it will require review by a REC that can review Mental Capacity Act studies. This is because (even though you aren't taking consent) you will be undertaking intrusive (i.e. where consent would normally be obtained) research on adults lacking capacity.
Therefore we would have to remove it from the proportionate review process and you would need to submit it to an appropriate REC for full review.

In my opinion, the study can be seen as a service evaluation of standard care in the unit. There is no change to patient care and you are effectively implementing a rigorous formalised approach to collecting this data. Consent is not required for a service evaluation.
As a service evaluation, I would be happy to produce a letter stating that this study doesn't require NHS ethical review that will be suitable for R&D any for future publication(s).

If you could let Joyce and I know which approach you would like to take, we will take the appropriate action.

Regards,

Alex

Alex Bailey
Scientific Officer
South East Scotland Research Ethics Service
Waverley Gate
Edinburgh
EH1 3EG
Phone: 0131 465 5679 (35679)

Appendix V KGH Audit Office email

From: Dalziel Alli
Sent: Mon 02/09/2013 11:26
To: Stupples Caroline
Subject: Enhancing Recovery following emergency bowel resection audit

Dear Caroline, regarding our previous meeting to discuss the clinical audit 'Enhancing Recovery following emergency bowel resection'

I am now in receipt of the clinical audit registration form and can confirm that the Clinical Audit Department has approved the audit

It will now be included into the Trust's Clinical Audit Plan 2013/14 where it will be monitored there in.

Kind Regards

Alli

Alli Dalziel | Senior Clinical Audit Facilitator | Quality Governance | 2nd Floor Thorpe House | Kettering General Hospital NHS Foundation Trust | Rothwell Road | Kettering | Northants | NN16 8UZ | Tel: 01536 491586

Appendix VI Science Research Degrees Board Communication

From: Watson David
Sent: 23 September 2013 12:31
To: Stupples Caroline; Stupples Caroline Elizabeth
Cc: Campbell Jackie; Rogers Stephen
Subject: Feedback from research Ethics Committee

Dear Caroline

The Research Ethics Committee considered your proposal and ethics section last week.

The Committee noted that the NHS has classed the project as an audit or evaluation and therefore ethical approval did not fall under the auspices of the NHS. The letter from Kettering General Hospital granting permission to undertake the project there was also noted. The submission was thorough and associated documents met all requirements. The researcher was asked to

1) Update Section 11 to reflect the current approval status/process.

2) Confirm that the researcher will comply with any NHS and/or KGH processes or protocols for accessing records.

Subject to this the proposal was given full approval.

If you could send me your response, the Chair will take action to approve it.

Best wishes

David

David Watson
Postgraduate Research Manager
The University of Northampton
Boughton Green Road
Northampton
NN2 7AL

free. You should undertake your own virus checking. The right to monitor E-mail communications through our networks is reserved by us.

Appendix VII Data Collection Tools

Summary of Demographic, Chronological and Endpoint Data

Gender: M F BMI: _____ Age: _____

OPERATIVE PARAMETERS

Operative Procedure: _____

Findings: Benign: _____ Malignant: _____

Formation of stoma Yes No

	If Yes: Type of stoma					
					Loop Colostomy	End Ileostomy
ASA Grade	1	2	3	4	5	
Grade of surgeon	Consultant		Registrar		SHO	
Grade of anaesth	Consultant		Registrar		SHO	
Incision	Transverse		Selected midline		Midline	
Level of anastomosis	_____					
Type of anastomosis	Sutured		Stapled		No anastomosis	
	End to end		Side to side			
Type of analgesia	Epidural		Morphine PCA		Morphine PCA + TAP/LA block	

Dates and times of:				**Total time from admission:**	
				Days	Hours
Admission:	__/__/__	__:__ hours			
Scan CT/US	__/__/__	__:__ hours	NA	____	__:__
Decision to operate:	__/__/__	__:__ hours	NR	____	__:__
Operation:	__/__/__	__:__ hours	NA	____	__:__
Time into recovery	__/__/__	__:__ hours	NA		
Time to Ward	__/__/__	__:__ hours			
Complications	Y N	If Y, record on post-op complications sheet			
Re-operation	Y N	If Y, record on post-op complications sheet			
NGT removal	__/__/__	__:__ hours	NA		
Toleration first drink	__/__/__	__:__ hours			
Toleration first food	__/__/__	__:__ hours			
Time to endpoint	__/__/__	__:__ hours	Total LOS:	____	__:__

Tick type of endpoint:

- □ Inpatient discharge
- □ Transfer to another speciality
- □ Death
- □ Re-insertion of NG tube
- □ Re-operation

PRE-ADMISSION CO-MORBIDITIES (Pre-existing co-morbidities)

Morbidity Type	*Criteria (Adapted from Grocott et al 2007)*	Yes - Detail	No
Pulmonary	A requirement for oxygen, inhalation or oral therapy to treat or prevent exacerbations of underlying disease. *Eg: COPD; Asthma, Malignancy*		
Infectious	Admitted on a course of antibiotic therapy for treatment or prevention of a known infectious source. *Eg: UTI, Chest infection, Abscess*		
Renal	eGFR <60/Creatinine >90		
Gastro-intestinal	Any benign or malignant disorder of the GI tract either proven by diagnostic testing or being empirically treated OR greater than 1 week history of reduced appetite, nausea, vomiting, change in bowel habit, abdominal pain or unexplained weight loss. *Eg: Inflammatory bowel disease, Hepatobiliary disease, Gastritis/Oesophagitis*		
Cardio-vascular	Undergoing diagnostic testing or therapy for any of the following: myocardial infarction or ischemia, hypertension, atrial or ventricular arrhythmias. Current anti-coagulation or anti-platelet therapy (excluding aspirin 75mg od). *Eg: MI, Angina, Ischaemic Heart Disease, Hypertension*		
Neuro-logical	Any focal neurological deficit, confusion, delirium, or coma. *Eg: CVA, Epilepsy, Dementia, Parkinsonism*		
Haema-tological	Any known clotting disorder or regular requirement for any of the following: packed erythrocytes, platelets, fresh-frozen plasma, cryoprecipitate or Vit K . *Eg: Anaemia, Sickle Cell Disease, Leiden Factor V, PE, DVT*		
Wound	Any break in skin integrity with or without fistulous tract present for greater than one week requiring healthcare intervention. *eg: Pressure ulcer, Leg ulcer, chronic wounds*		
Endocrine	A requirement for therapy to treat known endocrine imbalance *Eg: Hypo/hyperthyroidism/Diabetes*		

PRE-OPERATIVE MORBIDITY (New morbidities between admission and surgery)

Morbidity Type	*Criteria (Adapted from Grocott et al 2007)*	Yes - Detail	No
Pulmonary	A requirement for oxygen, inhalation or oral therapy to treat or prevent exacerbations of underlying disease.		
Infectious	Commenced antibiotic therapy for treatment (WCC >11.0; CRP >5)		
Renal	eGFR <60; long term urinary catheter in situ. *Eg: Chronic Renal Failure*		
Gastro-intestinal	Any benign or malignant disorder of the GI tract either proven by diagnostic testing or being empirically treated OR greater than 1 week history of reduced appetite, nausea, vomiting, change in bowel habit, abdominal pain or unexplained weight loss. *Eg: Inflammatory bowel disease, Hepatobiliary disease, Gastritis/Oesophagitis*		
Cardio-vascular	Undergoing diagnostic testing or therapy for any of the following: myocardial infarction or ischemia, hypertension, atrial or ventricular arrhythmias. History of peripheral vascular disease or any open or endovascular arterial surgery or repair. Current anti-coagulation or anti-platelet therapy (excluding aspirin 75mg od). *Eg: MI, Angina, Ischaemic Heart Disease, Hypertension*		
Neuro-logical	Any focal neurological deficit, confusion, delirium, or coma. *Eg: CVA, Epilepsy, Dementia*		
Haema-tological	Any known clotting disorder or regular requirement for any of the following: packed erythrocytes, platelets, fresh-frozen plasma, cryoprecipitate or Vit K . *Eg: Anaemia, Sickle Cell Disease, Leiden Factor V, PE, DVT*		
Wound	Any break in skin integrity with or without fistulous tract present for greater than one week requiring healthcare intervention. *eg: Pressure ulcer, Leg ulcer, chronic wounds*		
Endocrine	A requirement for therapy to treat known endocrine imbalance *Eg: Hypo/hyperthyroidism*		

Pre-operative Physiological parameters required for CR Possum Score: (Circle appropriate)

Age (years)		<61	61-70	71-80	>80
Cardiac		No/Mild Failure	Moderate Failure	Severe Failure	
Systolic BP	_____	100-170	>171 or 90-99	<89	
Pulse Rate	_____	40-100	101-120	>121 or <39	
Hb (g/dl)	_____	13-16	10-12.9 or 16.1-18	<9.9 or >18.1	
Urea	_____	<10	10.1-15	>15.1	

Operative parameters required for CR Possum Score:

Operation type	Minor	Intermediate	Major	Complex
Peritoneal Contamination	None/serous Fluid	local pus	Pus, blood or free bowel content	
Malignancy status	No Cancer/ Dukes A/B	Dukes C/T3	Dukes D/T4	
CEPOD	Elective/ Expedited	Urgent (within 24 hrs)	Emergency (within 2 hrs)	

CR POSSUM Score: _____ www.riskprediction.org.uk/index-ce.php

Standard Pre-operative Care

Care	Criteria	Yes	No	NA
Diet	Tolerating oral diet up to 6 hrs pre-operatively If N:			
	NGT in situ			
	Vomiting			
	Awaiting theatre time			
VTE	AES stockings applied			
	Prophylactic enoxaparin given If Y: Dose (circle approporiate) 20mg od 40mg od 40mg bd 60mg bd			
IVA/B's	Given prior to surgery If Y: Type and dose (circle appropriate) Co-amoxiclav 1.2g or Cefuroxime 750mg Metronidazole 500g Other: _____			
	Given on induction If Y: Type and dose (tick appropriate) Co-amoxiclav 1.2g or Cefuroxime 750mg Metronidazole 500g Other: _____			
	Continued after surgery If Y: Type and dose (tick appropriate) Co-amoxiclav 1.2g or Cefuroxime 750mg Metronidazole 500g Other: _____			
Pre-med	Sedative pre-med given			

Standard Peri-operative Care

Care	Criteria	Y	N	NA
Hypothermia	Warming agents (Bair-Hugger/warmed fluids) used intra-operatively			
Goal Directed Fluid Therapy	LiDco, Doppler, A-line or Central line used intra-operatively (Circle which)			
	Total Volume fluid infused peri-operatively			
Wound Drain	Insertion of drain			
	Rationale for drain			
Urinary catheter	Inserted prior to surgery			
	Inserted in theatre			

LIST OF ABBREVIATIONS USED IN DATA COLLECTION SHEETS			
AES	Anti-embolic stockings	LOS	Length of stay
ASA	American Society of Anaesthiologists	M	male
bd	Twice daily	ml/hr	Millilitres per hour
BP	Blood pressure	mg	milligrams
BMI	Body Mass Index	MI	Myocardial Infarction
°C	Degrees centigrade/celsius	N	No
CEPOD	Confidential Enquiry on Peri-Operative Deaths	NA	Not applicable
COPD	Chronic Obstructive Pulmonary Disease	NG(T)	Naso-gastric tube
CRP	C Reactive Protein	NR	Not recorded
CR-POSSUM	Colorectal post-operative surgical score of mortality	NSAID	Non-steroidal anti-inflammatory drugs
CT	Computerised tomography	od	Once daily
CVA	Cerebro-vascular accident	PCA	Patient controlled analgesia
DVT	Deep Vein Thrombosis	PE	Pulmonary Embolus
eGFR	Estimated Glomerular Filtration Rate		
F	Female	SHO	Senior House Officer
g	grams	TAP	Trans abdominus planus
GI	Gastro-intestinal	UTI	Urinary tract Infection
Hb (g/dl)	Haemoglobin in grams per decilitre	US	Ultrasound
hrs	hours	Vit K	Vitamin K
IV	Intravenous	VTE	Venous thrombo-embolus
IVAB	Intravenous antibiotics	WCC	White Cell count
LA	Local anaesthetic	Y	Yes

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DAILY POST-OPERATIVE MONITORING FORM (Definitions and coding on reverse)

Key: Y/√ = Yes N/X = No NA/- = Not applicable

Date															
Post-op day / Intervention	Op	1	2	3	4	5	6	7	8	9	10	11	12	13	14
NG tube in situ															
NG tube spigoted If Y time:															
NG tube removed If Y time:															
Oral fluids commenced															
Oral fluids tolerated If Y time:															
Oral diet commenced															
Oral diet tolerated If Y time:															
Vomiting															
No of episodes vomiting															
Anti-emetic given															
If Yes, Type: Cyclizine															
Metaclopramide															
Ondansetron															
Other: _____															
Bowels opened If Y time:															
NG re-inserted Time															
Epidural/PCA in situ (Circle): If N, time removed:															
Urinary catheter in situ															
IV fluids in progress															
IV Paracetamol given															
Oral paracetamol given															
Opiate analgesia Type															
NSAID given Type															
IV Antibiotic therapy If Y Type:															
Mobility level															
New pyrexia >38°C															
New raised WCC															
Post-operative complication															
Study endpoint															

Mobility level:
0 = bed bound
1 = bed to chair
2 = mobilising with assistance,
3 = mobilising independently (with or without mobility aid)

Opiate analgesia: codeine, morphine or tramadol given after epidural/PCA discontinued

Definitions and coding for Post-operative complications (alphabetical order)

A Post-operative complication is defined as any deviation from the normal post-operative course occurring within the length of hospital inpatient stay, encompassing all infectious or non-infectious complications. Potential significant complications and their definitions include the following. These are not exhaustive. **Should a complication occur which is not accounted for please detail and code below.**

Complication	Code	Definition
Anastomotic dehiscence	AD	Synonymous with anastomotic leak or breakdown but NOT anastomotic bleed. Characterised by clinical signs and symptoms of fever, ileus or faecal drainage from peri-anastomotic drain. Diagnosed by radiological imaging, at re-operation or autopsy.
Cardiac	CA	**Arrythmia**: Any new cardiac arrhythmia seen on ECG requiring review and intervention by the cardiology specialist team
	CI	**Ischaemia**: Any new chest pain associated with ischaemic changes on ECG requiring review and intervention by cardiology specialist team
DVT	D	Deep Vein Thrombosis either empirically diagnosed and therapeutic anticoagulation commenced or confirmed by radiological imaging.
Haemorrhage	H	Any bleeding post-operatively resulting in patient becoming haemodynamically unstable and requiring either: packed erythrocytes, platelets, fresh-frozen plasma, cryoprecipitate, Vit K or re-operation.
Hypotension (in the absence of haemorrhage)	Hy	Requiring fluid therapy >200ml/hr or pharmacological therapy to maintain normotension
Ileus	I	More than 2 episodes of vomitus >250ml in 4 hours in absence of the passage of flatus or stool. Indication for re-insertion of NG tube.
Intra-abdominal abscess	IAA	Synonymous with pelvic abscess, deep abscess, abdominal or pelvic collection but NOT peritonitis. Confirmed by radiological imaging or re-operation. Requiring surgical, radiological or antibiotic intervention.
Neurological	N	New focal neurological deficit, confusion, delirium, or coma
Pulmonary embolus	PE	Either diagnosed by radiological imaging or patient commenced on anti-coagulation treatment
Renal (Kidney or urinary)	KF	**Failure**:Presence of oliguria <500 ml/24 hr; increased serum creatinine (>30% from preoperative level)
	KI	**Infection**: New pyrexia >38°C empirically treated as urinary source or confirmed with positive urine culture
Respiratory	RF	**Failure**: A new requirement for oxygen or respiratory support to maintain arterial blood gases within normal limits in the absence of clinical signs of respiratory infection.
	RI	**Infection**: A new requirement for oxygen or respiratory support in the presence of clinical signs of respiratory infection confirmed by positive sputum culture, radiographic evidence or new pyrexia >38°C
Sepsis (unknown origin)	S	Temperature of >38°C or a new rise in WCC or CRP, source unknown, with or without positive blood culture being empirically treated.
Wound/fascia dehiscence	WD	Any deep breakdown of the wound in the absence of infection
Wound infection	WI	Any superficial or deep incisional (but NOT intra-abdominal) infection characterised by the presence of erythema, seroma or discharge of pus with or without a positive bacterial culture.
Other		

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