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Protocol for a multicentre, prospective, observational cohort study of variation in practice in perioperative analgesic strategies in elective laparoscopic colorectal surgery: the LapCoGesic Study

Northern Surgical Trainees Research Association (NoSTRA), Phillippa Burnell, Rachael Coates, Steven Dixon, Lucy Grant, Matthew Grey, Ben Griffiths, Mike Jones, Anantha Madhavan, Iain McCallum, Ross McClean, Karen Naru, Lydia Newton, Paul O'Loughlin, Fadlo Shaban, Anisha Sukha, Sameer Somnath, Syed Shumon, Deena Harji

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Department of Academic Surgery, University of Newcastle, Newcastle upon Tyne, UK

Correspondence to
Deena Harji; deena_harji@hotmail.com

ABSTRACT

Introduction: Laparoscopic surgery combined with enhanced recovery programmes has become the gold standard in the elective management of colorectal disease. However, there is no consensus with regard to the optimal perioperative analgesic regime in this cohort of patients, with a number of options available, including thoracic epidural spinal analgesia, patient-controlled analgesia, subcutaneous and/or intraperitoneal local anaesthetics, local anaesthetic wound infiltration catheters and transversus abdominis plane blocks. This study aims to explore any differences in analgesic strategies employed across the North East of England and to assess whether any variation in practice has an impact on clinical outcomes.

Methods and analysis: All North East Colorectal units will be recruited for participation by the Northern Surgical Trainees Research Association (NoSTRA). Data will be collected over a consecutive 2-month period. Outcome measures will include postoperative pain score, postoperative opioid analgesic use and side effects, length of stay, 30-day complication rates, 30-day reoperative rates and 30-day readmission rates.

Ethics and dissemination: Ethical approval for this study has been granted by the National Research Ethics Service. The protocol will be disseminated through NoSTRA. Individual unit data will be presented at local meetings. Overall collective data will be published in peer-reviewed journals and presented at relevant surgical meetings.

Strengths and limitations of this study

- A multicentre, prospective study with involvement from anaesthetists and surgeons.
- Capture of data from all hospitals across the North East.
- Ability to capture data from patients presenting to other hospitals within the region.
- No quality assurance of perioperative analgesic strategy employed.
- No quality assurance of standard of laparoscopic surgery.

INTRODUCTION

In recent times, patient outcomes have been vastly improved in colorectal surgery due to the widespread adoption of laparoscopic surgery.[1] The reduced surgical stress response observed in laparoscopic surgery translates clinically into reduced postoperative pain, earlier return of gastrointestinal function and reduced length of hospital stay.[1–6] The quest to maintain perioperative physiological status and reduce surgical stress has led to the development and employment of enhanced recovery programmes.[7–10] The core principles of enhanced recovery programmes focus on reducing surgical stress by maintaining postoperative physiological function and enhanced mobilisation following surgery. Key to the success of such enhanced recovery programmes is the use of an optimal analgesic regime which ensures adequate pain relief, enables early mobilisation and the early return of gastrointestinal function combined with a low side effect profile.

Early enhanced recovery programmes were developed to be used in open colorectal

surgery and recommended the use of thoracic epidural analgesia.[11 12] However, applying the same analgesic principles in the laparoscopic setting has not produced the same results in this cohort of patients, with reports of longer length of stay and delayed return of gastrointestinal function associated with the use of epidural analgesia.[13–15] This has led to a number of alternative analgesic strategies being employed in laparoscopic colorectal surgery, including the use of spinal analgesia,[15–19] patient-controlled analgesia (PCA),[20–22] subcutaneous and/or intraperitoneal local anaesthetics, local anaesthetic wound infiltration catheters[23 24] and transversus abdominis plane (TAP) blocks.[25–28] There have been a number of cohort studies and randomised controlled trials comparing different analgesic modalities with encouraging results; however, these studies are often single-armed or double-armed studies, comparing only one or two analgesic modalities. Other shortcomings of these studies are that they are often retrospective and single-centre studies, thus making it difficult to generalise the results. Consequently, there remains a lack of consensus on the optimal analgesic strategy in this cohort of patients,[11 29] thus leading to colorectal units employing analgesic regimes based on individual expertise and experience. The LapCoGesic Study aims to explore differences in analgesic strategies employed across the north-east region in patients undergoing elective laparoscopic colorectal surgery and to assess whether this variation in practice has an impact on clinical outcomes.

METHODS AND ANALYSIS

Study objectives

To explore differences in analgesic strategies employed across the north-east region in patients undergoing elective laparoscopic colorectal surgery and to assess whether variation in practice has an impact on clinical and patient-reported outcomes.

Study design

We aim to undertake a prospective, multicentre, observational cohort study of consecutive patients undergoing elective laparoscopic colorectal surgery, which will be led by the trainee research collaborative.

Setting

This study will take place across colorectal units across the North East of England over a consecutive period of 2 months. This region has the highest rate of elective laparoscopic resections for primary colorectal cancer in the UK according to the National Bowel Cancer Audit Report 2014.[30]

Recruitment

All patients undergoing an elective laparoscopic colorectal resection in the North East of England will be recruited into the study. According to the National Bowel Cancer Audit 2014, ~1257 patients underwent elective surgery for primary colorectal cancer in the North East of England over a 12-month period.[31] Based on these figures, minimum expected recruitment would be ~150 patients from 13 centres across the North East of England.

ELIGIBILITY CRITERIA

Inclusion criteria

All adult patients (aged >18 years) undergoing an elective laparoscopic (multiport or single-port) colorectal resection will be included in this study.

Table 1 Secondary outcome measures

Intraoperative analgesic regime	*Intravenous analgesia type and dose* Paracetamol, fentanyl, alfentanil, remifentanil, morphine *Spinal analgesia type and dose* Bupivacaine, fentanyl, morphine, diamorphine *Epidural analgesia type and dose* Bupivacaine and fentanyl infusion *TAP blocks* Local anaesthesia type and dose *Local anaesthesia wound infiltration* Type and dose
Postoperative analgesic regime	Paracetamol, non-steroidal analgesia, morphine patient-controlled analgesia, epidural analgesia, TAP blocks
Postoperative pain scores	Standardised pain scores will be collected as per the pain scales outlined on the National Early Warning Score charts. This pain scale is a visual analogue scale based on a scale of 0–10.
Postoperative opioid use	The postoperative oral morphine equivalent dose will be calculated for each patient on a daily basis up to 7 days postoperatively or day of discharge if this is earlier.
Length of stay	Postoperative HDU/ICU stay will be calculated. Total length of hospital stay will also be calculated from date of admission to date of discharge.
30-day complication rates	All-cause postoperative morbidity will be calculated as per the Clavien-Dindo classification. This will also include calculating 30-day reoperation rates.
30-day reoperation rates	All-cause readmission within the first 30 days postoperatively will be calculated.

HDU, high dependency unit; ICU, intensive care unit; TAP, transversus abdominis plane.

Table 2 Data fields

Patient age (whole years)	Years
Patient gender	Male, female
BMI	BMI in kg/m^2
BMI category	Underweight <18 kg/m^2 Normal 18–24.9 kg/m^2 Overweight 25–29.9 kg/m^2 Moderate obesity 30–34.9 kg/m^2 Severe obesity 35–39.9 kg/m^2 Very severe obesity >40 kg/m^2
ASA grade	I: A normal healthy patientII: A patient with mild systemic diseaseIII: A patient with severe systemic diseaseIV: A patient with severe systemic disease, ie, a constant threat to lifeV: A moribund patient who is not expected to survive without the operation
Admission date	DD/MM/YYY
Operation date	DD/MM/YYY
Primary operative indication	Colorectal malignancy, ulcerative colitis, Crohn's disease, diverticular disease, other (free text)
Primary operation type	Right hemicolectomy, left hemicolectomy, sigmoid colectomy, Hartmann's procedure, subtotal colectomy, anterior resection ±ileostomy, panproctocolectomy, abdominoperineal excision of the rectum
Surgeon grade	Consultant, registrar (ST3–8), non-training grade, post-CCT fellow
Anaesthetist grade	Consultant, registrar (ST3–8), non-training grade, post-CCT fellow, core anaesthetic trainee (CT1–2)
Intraoperative analgesia	Intravenous: paracetamol, NSAIDs, fentanyl, alfentanil, morphine, remifentanil infusion, other Spinal Anaesthesia: Bupivacaine, Fentanyl, Morphine, Diamorphine TAP blocks LA infiltration Epidural anaesthesia: bupivacaine and fentanyl, levobupivacaine
Intraoperative antiemetic use	Ondansetron, cyclizine, dexamethasone, droperidol, other
Intraoperative complication	No intraoperative complication, visceral injury, small bowel injury, colonic injury, ureteric injury, bladder injury, vascular injury, other injury (free text)
Conversion to open	Yes, no
Duration of operation (whole minutes)	Minutes
Blood loss	Millilitres
Extraction site size (cm)	Total size of extraction site wound in centimetres
Postoperative: ERAS pathway used	Yes, no
Postoperative: Acute Pain Service involved	Yes, no
Postoperative analgesia	Paracetamol, NSAIDs, morphine PCA, epidural, TAP blocks, other
Postoperative antiemetic use	Ondanestron, cyclizine, other
Day 1 postoperative lowest respiratory rate	Breaths/min
Day 1 postoperative lowest sedation score	AVPU Score
Postoperative pain scores at 24 and 48 hours and daily until 7 days postoperatively or discharge if before 7 days	0–10
Postoperative opioid analgesic use at 24 and 48 hours and daily until 7 days postoperatively or discharge if before 7 days	Milligrams
ITU discharge date	DD/MM/YYYY
HDU discharge date	DD/MM/YYYY
Date fit for discharge	DD/MM/YYYY
Date actual discharged	DD/MM/YYYY
Complications 30-day postoperatively	Yes, no
Complication type	Free text
Surgical complication grade (Clavien-Dindo classification)	None, I, II, III, IV, V
Readmission 30 days post discharge	Yes, no
Reoperation 30 days postoperatively	Yes, no

ASA, American Society of Anaesthesiologists; AVPU, alert, voice, pain, unresponsive; BMI, body mass index; CCT, Chicago Community Trust; ERAS, Enhanced Recovery After Surgery; HDU, high dependency unit; ITU, intensive therapy unit; LA, local anaesthetic; NSAIDs, non-steroidal anti-inflammatory drugs; PCA, patient-controlled analgesia; TAP, transversus abdominis plane.

Exclusion criteria

Patients undergoing emergency surgery, a diagnostic laparoscopy, or with a pre-existing chronic pain or fatigue syndromes, chronic opioid use and cognitive impairment will be excluded from the study.

Outcome measures

The primary outcome measure is postoperative pain scores at 24 hours. This is the recommended outcome measure by the Royal College of Anaesthetists to assess the efficacy of postoperative analgesia.[32] Secondary outcome measures will include postoperative opioid analgesic use, total length of stay, 30-day postoperative complication rates, complication grade according to the Clavien-Dindo classification, and 30-day reoperative and readmission rates (table 1).

Data collection and data management

Each participating local hospital will be responsible for identifying potentially eligible patients for study recruitment. The principal investigator team will consist of a consultant surgeon, consultant anaesthetist and two trainees from surgery or anaesthesia. Patients will be identified from three clinical areas—outpatient clinic, preoperative assessment clinic and daily elective operating lists—to ensure all potentially eligible patients are captured.

A standardised data collection spreadsheet (Excel 2010; Microsoft, Redmond, Washington, USA) will be used at each centre with predefined data fields. Following completion of the study, all anonymised data will be submitted centrally via a secure, password-protected website. The required anonymous data fields of this spreadsheet are shown in table 2. All anonymised data will be subsequently analysed. Outcome data specific to each surgeon who participates in the study will not be collected or analysed.

Statistical analysis

The results of this study will be prepared in accordance with guidelines set by the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for observational studies.[33]

Data will be collected and analysed in clinically relevant categories with χ^2 or Mann-Whitney U tests employed to detect differences between groups. Multivariable binary logistic regression will be used to test the influence of clinically plausible variables (ie, analgesic regime, operation type, operative indication, etc) on the outcome measures, to produce adjusted OR and 95% CI. Excel 2010 will be used for data handling, and statistical modelling in SPSS V.22. Statistical significance is defined as $p \leq 0.05$ in all analyses.

Ethical approval

Ethical approval for this study has been obtained from the National Research Ethics Committee (REC number 15/NE/0110). As this study does not impact on clinical care, individual patient consent will not be sought. Local ethical approval will be sought at each participating centre.

Dissemination

The protocol will be disseminated through the Northern Surgical Trainees Research Association (NoSTRA). All protocol documents and relevant clinical toolkits will be made available through the NoSTRA website (http://www.nostragroup.co.uk/projects/lapcogesic). Individual unit data will be presented at local meetings. Overall collective data will be published in peer-reviewed journals and presented at relevant surgical meetings. It is anticipated the results from this prospective study will help inform ongoing clinical research and will be used to inform commissioning and implement changes within the National Health Service (NHS).

DISCUSSION

Currently, in the UK, there is no agreed consensus on the optimal perioperative analgesic strategy in patients undergoing elective laparoscopic colorectal resections. A prospective survey carried out by the Enhanced Recovery After Surgery (ERAS) society in 2013 identified there was huge variation in current clinical practice with regard to optimal analgesic modality in this cohort of patients.[34] However, the limitations of this study include the small sample size and the large number of anaesthetists surveyed. Our study is novel in that it investigates current analgesic strategy employed and its subsequent impact on clinical and patient-reported outcomes with collaborative support from surgeons and anaesthetists. The data generated from this prospective, multicentre, observational cohort study will help identify and plan future areas of research, to evaluate the efficacy of multimodal analgesic regimes in elective laparoscopic colorectal practice, to develop a consensus over appropriate clinical end points, to accumulate data for generation of power calculations, to qualitatively analyse patient, surgeon and anaesthetic values and opinions, to achieve consensus on a trial question and its target population, with an overall aim to inform the design of a phase III randomised controlled trial.

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Collaborators Northern Surgical Trainees Research Association, PB, RC, SD, LG, MG, BG, DH, MJ, AM, IM, RM, KN, LN, PO, FS, AS, SSo and SSh.

Contributors All authors have equally contributed to the writing and development of this manuscript. DH, BG, SSo, KN, PO and IM contributed to study concept, design and development. DH, SSh, LN, PB, RC and AM were responsible for manuscript writing. DH, RM and MJ were responsible for data analysis and statistical input. MJ, FS, AS, MG, LG and SD were responsible for data acquisition. BG, PO, SSo and KN were responsible for final manuscript approval.

Competing interests None declared.

Ethics approval National Research Ethics Committee—York.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The data amassed from this study will be available to the NoSTRA collaborative.

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