Article:
EuroSurg Collaborative, (2020) Safety and efficacy of non-steroidal anti-inflammatory drugs to reduce ileus after colorectal surgery. British Journal of Surgery, 107 (2). e161-e169. ISSN 0007-1323

https://doi.org/10.1002/bjs.11326

Safety and efficacy of non-steroidal anti-inflammatory drugs to reduce ileus after colorectal surgery: international, prospective cohort study

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Running title: NSAIDs to reduce ileus after colorectal surgery

Category: Original Research

Main body word count: 3,257

MeSH Keywords: NSAIDs, colorectal surgery, postoperative ileus, anastomotic leak

Funding: No funding sources.

Contributions: All collaborators participated in data collection. Local and National Leads participated in study management with oversight from the Steering Committee. The Writing Group drafted and finalised the manuscript and all individuals agreed for its submission. The corresponding author attests that all listed collaborators meet required criteria and that no others have been omitted. JH is the statistical guarantor and SJC is the overall guarantor.

Acknowledgements: We are grateful to the European Society of Coloproctology (ESCP) Executive for providing facilities to host collaborator meetings in Berlin (Sep2017) and Nice (Sept 2018). We are grateful to the ESCP Cohort Studies & Audits Committee for their review of the study protocol and grateful to the the Dukes Club (UK), the Portuguese Surgical Research Collaborative (Portugal), the Young Group of the Italian Society of Colorectal Surgery, the Italian Surgical Research Group (Italy), the Australasian Students' Surgical Association, and the Clinical Trials Network of Australia and New Zealand (Australia & New Zealand) for assistance with study dissemination. We thank the Birmingham Surgical Trials Consortium at the University of Birmingham (UK) for support with online data capture and the Yorkshire Surgical Research Collaborative (UK) for access to unpublished data.

Competing interests: The corresponding author has completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declares: no support from any organisation for the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

Plain English Summary

Surgery on the bowel sometimes leads to a condition called ileus. This is where the bowel temporarily “goes to sleep” after surgery. It can cause vomiting, painful bloating, and often increases the length of hospital stay. Simple pain killers (called nonsteroidal anti-inflammatory drugs, or NSAIDs for short) may help to reduce ileus after bowel surgery.

An international study was performed by a collaboration of medical students and junior surgeons in early 2018. This was an observational study, meaning that patients’ normal clinical care was not changed. The investigators compared the time taken for ileus to end in patients who received NSAIDs and those who did not. They also looked at the safety of NSAIDs by monitoring the number of serious side effects occurring after surgery.

A total of 4164 patients having bowel surgery were included in the study. The average time taken for ileus to end was approximately 5 days, and was not reduced by using NSAIDs. However, use of NSAIDs after surgery was safe and seemed to reduce the need for other strong pain killers (such as morphine). This is important because morphine can cause many side effects such as constipation, nausea, and drowsiness.

Abstract

Introduction: Ileus is common after elective colorectal surgery and is associated with increased adverse events and length of stay. The aim was to assess the role of non-steroidal anti-inflammatory drugs (NSAIDs) for reducing ileus after surgery.

Methods: A prospective, multi-centre, cohort study was delivered by an international, student- and trainee-led collaborative group. Adult patients undergoing elective colorectal resection between January and April 2018 were included. The primary outcome was time to gastrointestinal recovery, measured using a composite measure of bowel function and oral tolerance. The impact of NSAIDs was explored using Cox regression analyses, including the results of a centre-specific survey of compliance to enhanced recovery principles. Secondary safety outcomes included anastomotic leak and acute kidney injury.

Results: 4164 patients were included with median age of 68 years (interquartile range: 57-75; 54.9% male). A total of 1153 (27.7%) received NSAIDs on post-operative days 1-3, of whom 1061 (92.0%) received non-selective cyclooxygenase inhibitors. After adjustment for baseline differences, the mean time to gastrointestinal recovery did not significantly differ between patients receiving and not receiving NSAIDs (4.6 vs. 4.8 days; HR: 1.04, 95% CI: 0.96-1.12, p=0.360). There were no significant differences in anastomotic leak rate (5.4% vs. 4.6%; p=0.349) or acute kidney injury (14.3% vs. 13.8%; p=0.666) between the groups. However, significantly fewer patients receiving NSAIDs required strong opioid analgesia (35.3% vs. 56.7%; p<0.001).

Conclusion: NSAIDs did not reduce the time for gastrointestinal recovery after colorectal surgery, but they were safe and associated with reduced post-operative opioid requirement.

Introduction

Ileus is common after colorectal surgery. It occurs in 10-20% of patients undergoing elective colonic resection, making it the most common complication ahead of anastomotic leak and surgical site infection.[1] In 2014, the Association of Coloproctology in Great Britain & Ireland (ACPGBI) identified ileus as an unmet clinical challenge.[2] Its clinical manifestations are profound, contributing to postoperative pain, vomiting, and malnutrition. Its burden on healthcare systems is also substantial, leading to a 70% increase in healthcare costs.[3]

Many strategies to reduce ileus have been tested in the past 20 years, but few have resulted in meaningful clinical benefits.[4] This may be attributed to an incomplete understanding of its pathophysiology and differences between experimental animals models and man.[5] Current evidence describes a complex relationship between inflammatory, neurogenic, and vagal mechanisms, which are exacerbated by the effects of opioid analgesia and other homeostatic imbalances.[6] To date, the most promising strategies have been those which aim to rationalise opioid-based analgesia (such as mu-receptor antagonists), and to moderate the post-operative inflammatory response (such as enhanced recovery protocols).[4]

Non-steroidal anti-inflammatory drugs (NSAIDs) are recommended by enhanced recovery protocols for their opioid-sparing and anti-inflammatory properties.[7] These may have benefits for the recovery of gastrointestiunal function. Recent meta-analyses of randomised controlled trials (RCTs) demonstrate a significant pooled benefit of NSAIDs to reduce ileus after colorectal surgery.[8,9] However, the use of NSAIDs in this setting is controversial due to the risk of acute kidney injury and conflicting reports of increased anastomotic leak.[10,11] NSAIDs may represent a simple and cost-effective intervention to reduce ileus, but further research is required to confirm their safety and efficacy in the context of colorectal surgery.

The primary aim of this study was to explore the relationship of NSAIDs with the recovery of gastrointestinal function (resolution of ileus) after colorectal surgery. It also aimed to explore key safety outcomes, when administered in the early post-operative period.

Methods

Ethics & Governance

The study protocol was developed by an international management group with input from patient representatives. The protocol was registered prospectively on the Research Registry Service (www.researchregistry.com) (UIN 3072) and published prior to study initiation.[12] Study approvals and requirements for individual patient consent were satisfied according to country-specific regulations. This manuscript is the first analysis of the international IMAGINE study and is reported in line with the strengthening the reporting of observational studies in epidemiology (STROBE) statement.[13]

Study Design

A prospective, multi-centre, observational study was delivered by a student- and trainee-led collaborative group with a track-record of international research.[14] The study design was informed by an external pilot study in a comparable patient cohort in the United Kingdom.[15] A 17-item, pre-study survey of compliance to enhanced recovery principles was completed by representatives of participating hospitals before the start of data collection (Suppl. File 1) and used to produce a score (ERAS score). To determine the accuracy and completeness of data, an independent validation exercise was pre-planned in at least 10% of centres. This comprised two domains: the first was data accuracy, determined by assessing the accuracy of 10 planned data points; the second was case ascertainment, determined by assessing the accuracy of participant eligibility. No changes to the final dataset based on this exercise was planned, but an accuracy of ≥95% in each domain was considered sufficient for validation.

Study Setting

Hospitals performing elective colorectal surgery in Europe, Australasia, and South Africa were eligible to enrol in the study. Each hospital enrolled consecutive patients in up to three, 14-day data collection periods between January and April 2018.

Eligibility Criteria

Adult patients having elective colorectal resection via open, laparoscopic, or robotic approaches for any indication (malignant or benign) were eligible. Procedures performed via a trans-anal approach, or performed for primary gynaecological, hepatobiliary, urological, or vascular pathologies were excluded. Return to theatre was considered to represent an acute episode and was not eligible. Elective appendicectomy was excluded, unless a more extensive colorectal resection was undertaken. Patients undergoing restoration of intestinal continuity were included and will be reported elsewhere.[12]

Outcome Measures

The primary outcome was time to gastrointestinal recovery. The validated GI-2 measure was used, defined compositely as the time taken for patients to tolerate solid food and to pass stool.[16] This included soft food, but not liquids. Secondary outcomes were postoperative complications occurring within 30 days of surgery. The Clavien-Dindo scale was used to classify each patient's highest encountered complication: no complication (grade 0); minor complication (grades I-II); and major complication (grades III-V).[17] Anastomotic leak was defined as bowel leakage detected radiologically or at the time of re-operation. Acute kidney injury (AKI) was defined according to the Kidney Disease Improving Global Outcomes (KDIGO) serum creatinine-based criteria.[18]

Explanatory Variables

The main variable of interest was early administration of NSAIDs after surgery. Patients were considered to have received a course of NSAIDs if received on at least two days (≥1 dose per day) within the first three postoperative days. Variables including the American Society of Anesthesiologists (ASA) score, body mass index (BMI), and smoking status were collected for risk adjustment. Other variables of interest were those known to affect gastrointestinal recovery after surgery. These included: cardiovascular and metabolic diseases (chronic obstructive pulmonary disease (COPD), ischaemic heart disease, peripheral vascular

disease, and diabetes mellitus), previous abdominal surgery, operative approach, transfusion of red cells, postoperative administration of strong opioids (defined as at least two days of oral or parenteral treatment within the first three postoperative days) and centre-specific compliance to enhanced recovery principles.[19] Examples of strong and weak opioids relevant to this study are provided in Suppl. Table 1.

Sample Size Considerations

A detailed statistical analysis plan and power calculation has been published previously.[12] The study was powered based on a comparison of GI-2 between patients who received NSAIDs and those who did not. Based on data from an external pilot study, we estimated that it would be feasible to recruit approximately 3500 participants during the study period, and that the NSAID administration rate would be approximately 15%.[20] A power calculation assuming these values returned a minimal detectable difference in GI-2 of 0.2 days between groups (5% alpha; 80% power). A difference in GI-2 of one day was considered clinically meaningful when applied to real practice, hence the study was sufficiently powered for this clinical difference.

Statistical Analysis

Patient demographics, perioperative variables, and safety outcomes were compared between treatment groups using Chi-square tests for nominal variables, and Mann-Whitney tests for nominal or and continuous variables.

Univariable analysis was performed using a Cox regression model, with the differences across treatment groups quantified using Kaplan-Meier curves and the mean times to GI-2. Multivariable Cox regression models were then produced to identify independent predictors of the time to GI-2. The maximum follow-up time was 10 days, with patients censored at this point if GI-2 had not been achieved. Since achieving GI-2 was treated as the “event” in the analyses, a hazard ratio (HR) >1 was indicative of a greater hazard of achieving GI-2 and, accordingly, a shorter time to GI-2.

In the main analysis, patients were censored at discharge or inpatient death, as the time to GI-2 was not known in these patients. However, this may have violated the assumption of non-informative censoring. Patients that were discharged would have been deemed fit at this point, and so likely would have achieved GI-2 soon after. In the cases of inpatient deaths, patients would have had no opportunity to achieve GI-2, even if follow-up had been extended indefinitely. As such, a sensitivity analysis was performed that treated patients discharged prior to achieving GI-2 as having achieved GI-2 on the day of discharge. Those who died in hospital prior to achieving GI-2 were treated as not having achieved GI-2 by day 10, rather than being censored at the point of death in this sensitivity analysis.

A multivariable analysis of the safety outcomes was then performed, to assess whether any of these were independently associated with NSAID use. Length of stay was highly skewed, so was dichotomised for analysis, based on the median value. All outcomes were analysed using multivariable binary logistic regression models. The NSAID group was entered into each model as a predictor, with a backwards stepwise approach used to select other pre- and perioperative factors that were independently associated with the outcome being considered.

All analyses were performed using IBM SPSS 22 (IBM Corp. Armonk, NY), with $p<0.05$ deemed to be indicative of statistical significance throughout.

Results

Study cohort

Data were available for 4164 patients, with median age of 68 years (interquartile range: 57 – 75) and of whom 54.9% (n=2288) were male. Of these, 3638 (87.4%) received an anastomosis. Between post-operative days 1 and 3, 1153 (27.7%) received an early course of NSAIDs, of which 1061 (92.0%) were non-selective and 92 (8.0%) were cyclo-oxygenase (COX)-2-selective agents. Data validation was performed on 892 patients from 111 centres (21.4% sample of the total cohort), with 95.9% data accuracy and 99.7% case ascertainment.

Patient demographics

Some differences in baseline patient variables were observed between treatment groups (Table 1). Patients receiving NSAIDs were significantly younger (median: 66 vs. 68 years; $p<0.001$), more likely to be smokers (17.9% vs. 15.2%; $p=0.033$) and had lower ASA grades ($p=0.040$) and ERAS scores ($p<0.001$) than those not treated with NSAIDs. A significant difference in surgical pathology was also identified ($p=0.013$), with NSAIDs used more frequently in patients treated for malignancy.

Operative and post-operative treatment

Differences in operative and post-operative factors were also observed between treatment groups (Table 2). Patients receiving NSAIDs were more likely to have had open surgery (40.3% vs. 35.6%; $p=0.001$) and to have undergone a left colonic resection (25.0% vs. 21.7%; $p=0.024$). Where C-reactive protein (CRP) levels were recorded between post-operative days 1-3, these were significantly lower in patients treated with NSAIDs (median 100 vs. 118mg/L; $p<0.001$). Patients receiving NSAIDs were significantly less likely to be treated with strong opioids (35.3% vs. 56.7%; $p<0.001$), intravenous patient-controlled analgesia (25.0% vs. 41.1% $p<0.001$), and wound catheters (3.3% vs. 5.9%; $p<0.001$). However, patients receiving

NSAIDs were significantly more likely to receive pro-kinetic drugs (40.8% vs. 31.0%; p<0.001) and to require red cell transfusion (10.8% vs 8.6%; p=0.036) post-operatively.

Gastrointestinal Recovery

A total of 3716 (89.2%) patients achieved GI-2 within the first ten post-operative days. Of the remainder, 189 (4.5%) achieved GI-2 after more than ten days, 232 (5.6%) were discharged prior to day ten without having achieved GI-2, and 27 (0.6%) died as inpatients before achieving the outcome. Univariable analyses of the times to GI-2 are presented in Figure 1. In the main analysis, the time to GI-2 was significantly lower in patients treated with NSAIDs, with a mean of 4.6 days, compared to 4.8 days in those not receiving NSAIDs (HR: 1.08, 95% CI: 1.00-1.16, p=0.043). Sensitivity analysis returned a similar difference, but this did not reach significance (mean: 4.5 vs. 4.7 days, HR: 1.06, 95% CI: 0.99-1.14, p=0.088).

Multivariable analysis

Since a range of demographic and treatment factors differed across the treatment groups, a multivariable analysis was performed to assess whether NSAID usage was independently associated with GI-2 (Table 3a and 3b). The main analysis found female sex (p=0.009), insulin-controlled diabetes (p=0.009), increasing ERAS scores (p=0.003), minimally invasive operative approach (p<0.001) and the formation of a new ileostomy (p<0.001) to be associated with a significantly shorter time to GI-2. Longer times to GI-2 were observed in patients with a higher CRP on POD 1-3 (p<0.001), and in those treated with strong opioids (p<0.001), epidural catheters (p=0.036), intravenous patient-controlled analgesia (p=0.019), pro-kinetic drugs (p=0.009) and red cell transfusion on POD 1-10 (p=0.005). After accounting for these factors, the use of NSAIDs was not found to be independently associated with the time to GI-2 (HR: 1.04, 95% CI: 0.96-1.12, p=0.360). The sensitivity analysis returned consistent results (HR: 1.04, 95% CI: 0.96 – 1.11, p=0.353).

Safety outcomes

On univariable analysis, no significant difference in length of stay was observed between patients treated with and without NSAIDs, with medians of 8 days (IQR: 6-11) in both groups (p=0.635; Table 4). The rate of anastomotic leak was similar in both groups (5.4% vs 4.6%; p=0.349), with subgroup analyses finding this difference to remain non-significant for each type of resection (Suppl. Table 2). The rates of Intra-abdominal collection (5.7% vs. 6.4%; p=0.431), acute kidney injury (14.3% vs. 13.8% p=0.666), and readmission (9.5% vs. 8.8%; p=0.506) were similar in both groups, although patients treated with NSAIDs had a significantly lower rate of pneumonia (3.4% vs. 4.9%, p=0.043). There was no significant difference in overall rates of complications (p=0.251), with minor complications occurring in 44.1% vs. 43.7%, and major complications in 9.0% vs. 10.7% of patients receiving NSAIDs and no NSAIDs, respectively.

The analysis was then repeated using a multivariable approach, to account for the potentially confounding effect of other pre- and perioperative factors. This returned results that were consistent with the univariable analysis above, with no significant differences in safety outcomes detected between the NSAID groups (Table 5, Suppl. Table 3a-c). The difference in the rates of pneumonia identified on univariable analysis narrowly missed significance in the multivariable model, with an odds ratio of 0.72 (95% CI: 0.50 – 1.04, p=0.077) for the NSAID vs. no NSAID group.

Discussion

This was a large, observational study providing validated data on the safety of NSAIDs after colorectal surgery and their relationship with gastrointestinal recovery. Their use in the early post-operative period was not found to be significantly associated with increased rates of anastomotic leak or acute kidney injury. NSAIDs were not associated with significantly improved gastrointestinal recovery when modelled using multivariable models, but they were associated with a reduced need for strong opioid analgesia after surgery.

The use of NSAIDs after colorectal surgery is controversial. NSAIDs are recommended by enhanced recovery protocols to optimise pain management and to reduce opioid-related adverse effects.[7] NSAIDs may also improve the recovery of bowel function; a recent meta-analysis of high quality RCTs demonstrated that NSAIDs reduce the times to first flatus and stool by 18 and 10 hours respectively.[8] The mechanism for this is unclear, but current evidence suggests a combination of reduced mu-receptor agonism and inhibition of COX enzymes, which reduce neuromuscular dysfunction.[6] In contrast, reservations over the use of NSAIDs are common. NSAIDs may increase the risk of acute kidney injury, which is common after major abdominal surgery (14.2%), and associated with excessive 1-year mortality.[21,22] NSAIDs are also known to inhibit platelet aggregation, and were associated with a small increase in red cell transfusion in the current study (10.8% vs 8.6%); this was in the absence of excess rates of complications overall. Finally, previous studies have associated NSAIDs with increased anastomotic leak after elective and emergent colorectal resection.[10,11] In a recent meta-analysis, diclofenac was associated with an increased rate of leak (OR 2.79; 95% CI 1.96-3.96) but ketorolac was not (OR 1.36; 95% CI 0.89-2.06).[23] This association remains inconclusive and yet to be corroborated in studies with a low risk of bias.

Fewer patients who received NSAIDs in the current study required strong opioid analgesia. The prescription of opioids after surgery has become a topical issue, due to their profile of adverse effects and contribution to national opioid epidemics.[24] Many interventions to reduce opioids in the postoperative period have been explored, including epidural and wound catheter

systems. Unfortunately, many of these are invasive, are associated with infective complications, or are restrictive for mobility and enhanced recovery. Despite the apparent association of NSAIDs with reduced opioid requirements, only one quarter of patients received a relevant dose in the current study, which is consistent with previous reports.[19] This is surprising, since NSAIDs are widely recommended by international enhanced recovery guidelines.[7] It is possible that this reflects a lack of equipoise across the colorectal community, influenced by conflicting safety data. Differences between international sub-communities cannot be excluded and warrant further investigation. Although this study did not consider the role of specific NSAIDs, it adds to a growing body of data that support their safety.

Strengths of the current study are recognised. First, the definition of ileus is variable and often arbitrary, which is problematic for performing robust clinical trials and commissioning new treatments in clinical practice.[25] This study used a validated measure of gastrointestinal recovery (GI-2), which reduced variation in defining ileus across a multicentre centre setting.[16] Secondly, in recognising that some patients are discharged prior to achieving GI-2 (i.e. prior to the passage of stool), a prospective sensitivity analysis was pre-planned.[12] This helped to increase the study's generalisability across settings where variable criteria for hospital discharge may exist. Other strengths of the study include its delivery across a student- and trainee-led collaborative network (facilitating a large and real-life snapshot of clinical practice), a prospective validation exercise (confirming the quality of data arising from multiple sources), and the administration of a centre-specific survey of enhanced recovery (allowing clinically-relevant adjustment of results within statistical models).

The main weakness of the study was its observational design, with the decision to prescribe NSAIDs being at the discretion of the clinical team. As such, there is the potential for selection bias, highlighted by the difference in patient demographics and postoperative characteristics between treatment groups. To account for this, multivariable analyses were performed to adjust for potentially confounding factors. However, there are likely to be other important factors that were not measured or adjusted for in this study, meaning that residual selection

bias may persist. Another potential weakness was the statistical power of the analysis. A sample size calculation determined that a sample of 3500 would be sufficient to detect a difference in time to GI-2 of 0.2 days between groups. This target was satisfied, but the calculation did not account for the presence of selection bias, which after multivariable adjustment, produced a smaller adjusted effect of NSAIDs. Despite this, the observed difference of 0.2 days on univariable analysis was small. Even if the statistical power was increased, the clinical relevance of such a small effect size would be questionable. Finally, the use of NSAIDs was considered relevant only if administered in the early postoperative period (days 1-3). Whilst the pathophysiology of anastomotic leak is not necessarily homogenous in all srettings, this is justified since the impact of NSAIDs on normal anastomotic healing (reduced anastomotic COX-2) is evident by the third postoperative day in pre-clinical models.[26]

Although the current observational data do not support the efficacy of NSAIDs to reduce ileus after colorectal surgery, there remains a good case for their use in the postoperative setting. Previous data relating to the risk of acute kidney injury are strong and the use of NSAIDs in this setting must be done according to appropriate patient selection. Previous data on the risk of anastomotic leak are inconsistent and not supported by the current study. For as long as NSAIDs are endorsed by evidence-based enhanced recovery guidelines, their use (both clinically and investigatory) remains justified. Moving forward, an assessment of equipoise is required to explore factors that may influence the use of NSAIDs after colorectal surgery. To ensure applicability of future results, an agreed approach for measuring gastrointestinal recovery is required.[25] The measure used in this study is already validated, but further consultation must confirm its acceptance amongst the academic community. Then, a high quality RCT is indicated to explore the effectiveness of NSAIDs for improving gastrointestinal recovery, including assessments of cost-effectiveness and patient benefit. Future work may continue to explore safety, but the value of more observational data is limited. Efforts to explore this in an interventional setting requires appreciation of the necessarily large sample size to study an uncommon event (such as anastomotic leak). The academic community must consider how this can be achieved with a collaborative and efficient approach.

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Table 1 – Patient demographics by NSAID usage

	N	NSAIDs (>1 Day on POD 1-3) No	Yes	p-Value
Patient Demographics				
Age (Years)	4162	68 (57-75)	66 (55-74)	**<0.001**
Sex (% Male)	4164	1654 (54.9%)	634 (55.0%)	1.000
BMI (kg/m^2)	4159			0.050*
<18.5		79 (2.6%)	37 (3.2%)	
18.5 - 24.9		1168 (38.8%)	476 (41.4%)	
25.0 - 30.0		1135 (37.7%)	419 (36.4%)	
>30.0		626 (20.8%)	219 (19.0%)	
Current Smoker	4155	455 (15.2%)	206 (17.9%)	**0.033**
ASA Grade	4160			**0.040***
1		320 (10.6%)	147 (12.8%)	
2		1700 (56.5%)	656 (56.9%)	
3		904 (30.1%)	318 (27.6%)	
4-5		84 (2.8%)	31 (2.7%)	
Previous Abdominal Surgery	4163	1206 (40.1%)	497 (43.1%)	0.078
Existing Stoma	4163			0.351
No		2784 (92.5%)	1079 (93.6%)	
Ileostomy		116 (3.9%)	42 (3.6%)	
Colostomy		110 (3.7%)	32 (2.8%)	
History of IHD	4164	361 (12.0%)	131 (11.4%)	0.592
History of PAD	4164	177 (5.9%)	82 (7.1%)	0.151
History of COPD	4164	214 (7.1%)	76 (6.6%)	0.587
History of DM	4164			0.082
No		2528 (84.0%)	960 (83.3%)	
Diet/Tablet Controlled		387 (12.9%)	140 (12.1%)	
Insulin Controlled		96 (3.2%)	53 (4.6%)	
ERAS Score	4164			**<0.001***
< 12		564 (18.7%)	367 (31.8%)	
12 - 13		718 (23.8%)	274 (23.8%)	
14 - 15		725 (24.1%)	275 (23.9%)	
16+		1004 (33.3%)	237 (20.6%)	
Underlying Pathology	4164			**0.013**
Diverticular Disease		160 (5.3%)	79 (6.9%)	
IBD		309 (10.3%)	91 (7.9%)	
Malignancy		2354 (78.2%)	925 (80.2%)	
Other Benign		188 (6.2%)	58 (5.0%)	

Data are reported as N (%), with p-values from Chi-square tests, or as median (interquartile range), with p-values from Mann-Whitney tests, unless stated otherwise. Bold p-values are significant at p<0.05. *p-Value from Mann-Whitney test, as the factor is ordinal.

ASA: American Society of Anesthesiologists; BMI: body mass index; COPD: chronic obstructive pulmonary disease; DM: diabetes mellitus; ERAS: enhanced recovery after surgery; IBD: inflammatory bowel disease; IHD: ischaemic heart disease; PAD: peripheral vascular disease; POD: Post-operative day

Table 2 – Operative and post-operative treatment factors by NSAID usage

	N	NSAIDs (>1 Day on POD 1-3) No	Yes	p-Value
Operative Factors				
Operative Approach	4164			**0.001**
Minimally Invasive		1685 (56.0%)	621 (53.9%)	
Minimally Invasive - Converted to Open		254 (8.4%)	67 (5.8%)	
Open		1072 (35.6%)	465 (40.3%)	
Resection Type	4157			**0.024**
Colonic - Right		1109 (36.9%)	400 (34.8%)	
Colonic - Left		653 (21.7%)	287 (25.0%)	
Rectal		1047 (34.8%)	408 (35.5%)	
Total		198 (6.6%)	55 (4.8%)	
Formation of New Stoma	4164			0.104
No		2032 (67.5%)	817 (70.9%)	
Ileostomy		551 (18.3%)	193 (16.7%)	
Colostomy		428 (14.2%)	143 (12.4%)	
CRP Recorded (POD 1-3)	4161	2378 (79.0%)	785 (68.2%)	**<0.001**
CRP Level (mg/L, POD1-3)	3163	118 (67-191)	100 (37-169)	**<0.001**
Treatment on POD 1-10				
Strong Opioid for >1 Day on POD1-3	4164	1707 (56.7%)	407 (35.3%)	**<0.001**
Epidural Catheter	4163	561 (18.6%)	201 (17.4%)	0.395
IV PCA	4163	1237 (41.1%)	288 (25.0%)	**<0.001**
Wound Catheter	4163	179 (5.9%)	38 (3.3%)	**<0.001**
Chewing Gum	4160	152 (5.1%)	71 (6.2%)	0.166
Pro-Kinetic Drugs	4162	932 (31.0%)	471 (40.8%)	**<0.001**
Red Blood Cells	4164	260 (8.6%)	124 (10.8%)	**0.036**
Mu-Opioid Antagonists	4163	41 (1.4%)	23 (2.0%)	0.158

Data are reported as N (%), with p-values from Chi-square tests, or as median (interquartile range), with p-values from Mann-Whitney tests. Bold p-values are significant at $p<0.05$. Total colectomy includes total and sub-total colon resection; CRP: C-Reactive Protein; IV PCA: Intravenous patient-controlled analgesia POD: Post-operative day.

Table 3a – Multivariable analysis of time to GI-2 (part 1)

	Main Analysis		Sensitivity Analysis	
	HR (95% CI)	**p-Value**	**HR (95% CI)**	**p-Value**
NSAIDs on POD1-3	1.04 (0.96 - 1.12)	0.360	1.04 (0.96 - 1.11)	0.353
Age (Years)		0.783		0.422
<60	-	-	-	-
60-69	0.99 (0.90 - 1.08)	0.780	0.98 (0.90 - 1.08)	0.712
70-79	0.95 (0.87 - 1.05)	0.340	0.93 (0.85 - 1.02)	0.142
80+	0.96 (0.85 - 1.08)	0.503	0.93 (0.83 - 1.05)	0.242
Sex (Male)	0.91 (0.85 - 0.98)	**0.009**	0.91 (0.85 - 0.97)	**0.003**
BMI (kg/m^2)		0.209		0.309
<18.5	0.92 (0.75 - 1.13)	0.429	0.89 (0.73 - 1.08)	0.244
18.5 - 24.9	-	-	-	-
25.0 - 30.0	0.96 (0.89 - 1.04)	0.287	0.98 (0.91 - 1.06)	0.632
>30	0.91 (0.83 - 1.00)	0.040	0.93 (0.85 - 1.02)	0.111
Current Smoker	0.99 (0.91 - 1.09)	0.877	0.99 (0.91 - 1.09)	0.892
ASA		0.249		**0.046**
1	-	-	-	-
2	0.96 (0.86 - 1.07)	0.471	0.96 (0.86 - 1.06)	0.411
3	0.91 (0.80 - 1.03)	0.140	0.88 (0.78 - 1.00)	**0.045**
4 - 5	0.81 (0.64 - 1.03)	0.091	0.77 (0.61 - 0.97)	**0.024**
Previous Abdominal Surgery	1.03 (0.96 - 1.11)	0.371	1.02 (0.95 - 1.09)	0.562
Existing Stoma		0.094		0.073
No	-	-	-	-
Ileostomy	1.18 (0.99 - 1.41)	0.067	1.19 (0.99 - 1.41)	0.060
Colostomy	1.14 (0.95 - 1.37)	0.174	1.15 (0.96 - 1.37)	0.137
History of IHD	1.01 (0.91 - 1.13)	0.833	1.00 (0.90 - 1.11)	0.987
History of PAD	0.99 (0.86 - 1.14)	0.890	1.02 (0.89 - 1.17)	0.767
History of COPD	0.97 (0.85 - 1.11)	0.679	0.97 (0.85 - 1.11)	0.672
History of DM		**0.019**		**0.016**
No	-	-	-	-
Diet/Tablet Controlled	1.07 (0.97 - 1.19)	0.171	1.08 (0.98 - 1.20)	0.125
Insulin Controlled	1.27 (1.06 - 1.51)	**0.009**	1.26 (1.06 - 1.50)	**0.009**
ERAS Score		**0.003**		**<0.001**
< 12	-	-	-	-
12 - 13	1.15 (1.05 - 1.27)	**0.003**	1.19 (1.08 - 1.31)	**<0.001**
14 - 15	1.18 (1.07 - 1.30)	**0.001**	1.23 (1.12 - 1.36)	**<0.001**
16+	1.16 (1.06 - 1.28)	**0.002**	1.26 (1.14 - 1.38)	**<0.001**

Results are from multivariable Cox regression models, which were based on N=4131 after excluding cases with missing data. Since achieving GI-2 was treated as the "event" in the analyses, a hazard ratio (HR)>1 was indicative of a greater hazard of achieving GI-2 and, accordingly, a shorter time to GI-2, as per the Methods. The remainder of the models are reported in Table 3b. Bold p-values are significant at p<0.05.

ASA: American Society of Anesthesiologists; BMI: body mass index; COPD: chronic obstructive pulmonary disease; DM: diabetes mellitus; ERAS: enhanced recovery after surgery; IHD: ischaemic heart disease; PAD: peripheral vascular disease; POD: Post-operative day

Table 3b – Multivariable analysis of time to GI-2 (part 2)

	Main Analysis		Sensitivity Analysis	
	HR (95% CI)	**p-Value**	**HR (95% CI)**	**p-Value**
Pathology		0.131		0.192
Malignancy	-	-	-	-
IBD	1.11 (0.97 - 1.26)	0.116	1.11 (0.98 - 1.26)	0.094
Diverticular Disease	1.13 (0.98 - 1.31)	0.096	1.08 (0.94 - 1.25)	0.290
Other Benign	0.96 (0.84 - 1.11)	0.618	0.95 (0.83 - 1.09)	0.495
Operative Approach		**<0.001**		**<0.001**
Minimally Invasive	-	-	-	-
MI - Converted to Open	0.75 (0.66 - 0.86)	**<0.001**	0.78 (0.69 - 0.88)	**<0.001**
Open	0.73 (0.68 - 0.78)	**<0.001**	0.71 (0.66 - 0.76)	**<0.001**
Resection Type		0.051		0.067
Colonic - Right	-	-	-	-
Colonic - Left	1.12 (1.01 - 1.23)	0.024	1.10 (1.00 - 1.20)	0.052
Rectal	1.09 (1.00 - 1.20)	0.061	1.07 (0.98 - 1.17)	0.133
Total	0.96 (0.82 - 1.11)	0.562	0.92 (0.79 - 1.07)	0.291
Formation of New Stoma		**<0.001**		**<0.001**
No	-	-	-	-
Ileostomy	1.35 (1.22 - 1.49)	**<0.001**	1.27 (1.15 - 1.40)	**<0.001**
Colostomy	0.99 (0.89 - 1.10)	0.823	0.95 (0.86 - 1.06)	0.343
CRP (mg/L, POD1-3)		**<0.001**		**<0.001**
<80	-	-	-	-
80 - 159	0.91 (0.83 - 1.00)	0.052	0.90 (0.82 - 0.98)	**0.019**
160+	0.68 (0.62 - 0.75)	**<0.001**	0.66 (0.60 - 0.72)	**<0.001**
Not Measured	0.89 (0.81 - 0.98)	**0.017**	0.89 (0.81 - 0.97)	**0.008**
Strong Opioid (for >1 Day on POD1-3)	0.87 (0.81 - 0.94)	**<0.001**	0.86 (0.80 - 0.92)	**<0.001**
Epidural Catheter (on POD 1-10)	0.91 (0.83 - 0.99)	**0.036**	0.89 (0.81 - 0.97)	**0.007**
IV PCA (on POD 1-10)	0.91 (0.84 - 0.98)	**0.019**	0.91 (0.85 - 0.98)	**0.016**
Wound Catheter (on POD 1-10)	1.02 (0.88 - 1.18)	0.821	1.04 (0.90 - 1.20)	0.614
Chewing Gum (on POD 1-10)	1.03 (0.89 - 1.19)	0.712	1.04 (0.90 - 1.20)	0.581
Pro-Kinetic Drugs (on POD 1-10)	0.91 (0.85 - 0.98)	**0.009**	0.88 (0.82 - 0.95)	**<0.001**
Red Blood Cells (on POD 1-10)	0.84 (0.75 - 0.95)	**0.005**	0.81 (0.72 - 0.92)	**<0.001**
Mu-Opioid Antagonists (on POD 1-10)	1.17 (0.89 - 1.53)	0.266	1.21 (0.93 - 1.57)	0.149

Results are from multivariable Cox regression models, which were based on N=4131 after excluding cases with missing data. Since achieving GI-2 was treated as the “event” in the analyses, a hazard ratio (HR)>1 was indicative of a greater hazard of achieving GI-2 and, accordingly, a shorter time to GI-2, as per the Methods. Total colectomy includes total and sub-total colon resection. The remainder of the models are reported in Table 3a. Bold p-values are significant at p<0.05.

CRP: C-Reactive Protein; IV PCA: Intravenous patient-controlled analgesia POD: Post-operative day.

Table 4 – Safety outcomes by NSAID usage within 30 days of surgery

	N	NSAIDs (>1 Day on POD 1-3) No	Yes	p-Value
Post-Operative Length of Stay (Days)**	4156	8 (6-11)	8 (6-11)	0.635
Anastomotic Leak***	3628	120 (4.6%)	56 (5.4%)	0.349
Intra-Abdominal Collection	4161	194 (6.4%)	66 (5.7%)	0.431
Pneumonia	4161	146 (4.9%)	39 (3.4%)	**0.043**
Acute Kidney Injury	3710	377 (13.8%)	139 (14.3%)	0.666
Readmission	4151	265 (8.8%)	109 (9.5%)	0.506
Clavien-Dindo Grade	4160			0.251*
None		1370 (45.6%)	540 (46.8%)	
Grade 1-2		1314 (43.7%)	509 (44.1%)	
Grade 3-5		323 (10.7%)	104 (9.0%)	

Data are reported as N (%), with p-values from Chi-square tests, or as median (interquartile range), with p-values from Mann-Whitney tests, unless stated otherwise. Bold p-values are significant at $p<0.05$. POD: Postoperative day.

*p-Value from Mann-Whitney test, as the factor is ordinal
**Values were truncated at 30 days
***Excludes the N=526 patients with no anastomosis

Table 5 – Summary of multivariable analyses of safety outcomes within 30 days of surgery

	Univariable Analysis		Multivariable Analysis	
	Odds Ratio (95% CI)	**p-Value**	**Odds Ratio (95% CI)**	**p-Value**
Post-Op. LOS >8 Days	0.93 (0.81 – 1.06)	0.279	0.87 (0.75 - 1.02)	0.083
Anastomotic Leak*	1.17 (0.84 – 1.61)	0.357	1.14 (0.82 - 1.59)	0.424
Intra-Abdominal Collection	0.88 (0.66 – 1.18)	0.387	0.87 (0.65 - 1.16)	0.338
Pneumonia	0.69 (0.48 – 0.98)	**0.040**	0.72 (0.50 - 1.04)	0.077
Acute Kidney Injury	1.05 (0.85 – 1.30)	0.648	1.04 (0.83 - 1.29)	0.755
Readmission	1.08 (0.86 – 1.37)	0.507	1.09 (0.86 - 1.38)	0.480
Clavien-Dindo Grade 3-5	0.82 (0.65 – 1.04)	0.102	0.83 (0.65 - 1.04)	0.110

Analyses were performed using univariable or multivariable binary logistic regression models. The multivariable models used a backwards stepwise approach to variable selection, and considered NSAID usage alongside all pre- and peri-operative factors from Table 3a-b for inclusion. Further details about the methodology used, and the full multivariable models are reported in Suppl. Table 3a-c. Odds ratios are for the NSAID, relative to no NSAID group. Bold p-values are significant at $p<0.05$. *Excludes the N=526 patients with no anastomosis. LOS=length of stay.

Suppl. Table 1 – Examples of strong versus weak opioids

Strong Opioids	**Weak Opioids**
Morphine sulphate	Codeine (includes preparations of co-codamol)
Diamorphine	Tramadol
Oxycodone	Dihydrocodeine
Buprenorphine	
Alfentanil	
Fentanyl	
Hydromorphone	

Preparations may include oral, intravenous, intramuscular, subcutaneous, or epidural

Suppl. Table 2 – Anastomotic leak by NSAID usage and resection type

	NSAIDs (>1 Day on POD 1-3)		p-Value
	No	Yes	
Anastomotic leak by colorectal resection type*			
Colonic - right	44/1056 (4.2%)	25/387 (6.5%)	0.071
Colonic - left	22/577 (3.8%)	14/268 (5.2%)	0.345
Rectal	48/812 (5.9%)	16/345 (4.6%)	0.380
Total	6/143 (4.2%)	1/42 (2.4%)	0.588

Data are reported as N (%), with p-values from Chi-square tests. Significance set at $p<0.05$.
POD: Postoperative day. Total colectomy includes total and sub-total colon resection
*Anastomotic leak within 30 days

Suppl. Table 3a – Multivariable analyses of safety outcomes within 30 days of surgery

	Post-Op. LOS >8 Days		Anastomotic Leak*		Intra-Abdominal Collection	
	OR (95% CI)	p-Value	OR (95% CI)	p-Value	OR (95% CI)	p-Value
NSAIDs on POD1-3	0.87 (0.75 - 1.02)	0.083	1.14 (0.82 - 1.59)	0.424	0.87 (0.65 - 1.16)	0.338
Age (Years)		**<0.001**	-	NS	-	NS
<60	-	-	-	-	-	-
60-69	1.02 (0.85 - 1.23)	0.825	-	-	-	-
70-79	1.15 (0.96 - 1.39)	0.132	-	-	-	-
80+	1.63 (1.29 - 2.07)	**<0.001**	-	-	-	-
Sex (Male)	1.30 (1.13 - 1.49)	**<0.001**	1.43 (1.04 - 1.97)	**0.028**	-	NS
BMI (kg/m^2)		0.056		**0.039**	-	NS
<18.5	1.57 (1.03 - 2.41)	**0.036**	1.74 (0.72 - 4.17)	0.216	-	-
18.5 - 24.9	-	-	-	-	-	-
25.0 - 30.0	1.15 (0.99 - 1.35)	0.070	1.19 (0.82 - 1.73)	0.348	-	-
>30	1.19 (0.98 - 1.43)	0.073	1.76 (1.17 - 2.63)	**0.006**	-	-
Current Smoker	1.17 (0.97 - 1.41)	0.096	-	NS	1.46 (1.07 - 2.00)	**0.017**
ASA		**<0.001**				
1	-	-	-	-	-	-
2	1.45 (1.15 - 1.82)	**0.002**	-	-	-	-
3	2.21 (1.71 - 2.86)	**<0.001**	-	-	-	-
4-5	2.72 (1.69 - 4.38)	**<0.001**	-	-	-	-
Previous Abdominal Surgery	-	NS	-	NS	1.35 (1.04 - 1.74)	**0.022**
History of IHD	-	NS	-	NS	1.44 (1.01 - 2.05)	**0.041**
History of PAD	0.70 (0.53 - 0.93)	**0.013**	-	NS	-	NS
History of COPD	-	NS	-	NS	-	NS
History of DM	-	NS		0.082		
No	-	-	-	-	-	-
Diet/Tablet Controlled	-	-	1.51 (1.01 - 2.25)	0.043	-	-
Insulin Controlled	-	-	1.55 (0.76 - 3.14)	0.228	-	-
ERAS Score		**<0.001**	-	NS	-	NS
< 12	-	-	-	-	-	-
12-13	0.75 (0.62 - 0.92)	**0.005**	-	-	-	-
14-15	0.74 (0.60 - 0.90)	**0.003**	-	-	-	-
16+	0.60 (0.50 - 0.73)	**<0.001**	-	-	-	-
Operative Approach		**<0.001**	-	NS		**0.005**
Minimally Invasive	-	-	-	-	-	-
MI - Converted to Open	1.89 (1.48 - 2.43)	**<0.001**	-	-	1.70 (1.09 - 2.64)	**0.018**
Open	3.48 (3.01 - 4.02)	**<0.001**	-	-	1.49 (1.13 - 1.95)	**0.004**
Resection Type		**0.007**	-	NS	-	NS
Colonic - Right	-	-	-	-	-	-
Colonic - Left	0.99 (0.82 - 1.19)	0.920	-	-	-	-
Rectal	1.26 (1.05 - 1.52)	**0.013**	-	-	-	-
Total	1.53 (1.12 - 2.10)	**0.008**	-	-	-	-
Formation of New Stoma		**<0.001**		0.069		0.055
No	-	-	-	-	-	-
Ileostomy	2.22 (1.81 - 2.72)	**<0.001**	1.40 (0.95 - 2.06)	0.087	1.35 (0.98 - 1.86)	0.066
Colostomy	2.37 (1.91 - 2.94)	**<0.001**	0.64 (0.33 - 1.24)	0.186	1.41 (1.00 - 1.99)	0.050

Analyses were performed using multivariable binary logistic regression models. In each case, the NSAIDs variable was entered into the model, and a backwards stepwise approach was used to select independent predictors of the outcomes being considered. All factors from Table 3a, as well as pathology, operative approach, resection type and formation of new stoma were considered for inclusion in the models. Only those factors that were included in the final models for at least one of the outcomes being reported are tabulated above. Bold p-values are significant at p<0.05. Total colectomy includes total and sub-total colon resection. ASA: American Society of Anesthesiologists; BMI: body mass index; CI: confidence interval; COPD: chronic obstructive pulmonary disease; DM: diabetes mellitus; ERAS: enhanced recovery after surgery; IHD: ischaemic heart disease; LOS: length of stay; NS; not selected for inclusion by the stepwise

procedure; OR: odds ratio; PAD: peripheral vascular disease; POD: Post-operative day. *Excludes the N=526 patients with no anastomosis.

Suppl. Table 3b – Multivariable analyses of safety outcomes within 30 days of surgery

	Pneumonia		Acute Kidney Injury	
	OR (95% CI)	**p-Value**	**OR (95% CI)**	**p-Value**
NSAIDs on POD1-3	0.72 (0.50 - 1.04)	0.077	1.04 (0.83 - 1.29)	0.755
Age (Years)		**0.002**		**<0.001**
<60	-	-	-	-
60-69	1.30 (0.80 - 2.09)	0.288	1.25 (0.94 - 1.67)	0.126
70-79	1.85 (1.17 - 2.92)	**0.009**	1.62 (1.23 - 2.14)	**<0.001**
80+	2.57 (1.53 - 4.32)	**<0.001**	2.40 (1.74 - 3.31)	**<0.001**
Sex (Male)	1.72 (1.24 - 2.38)	**0.001**	1.50 (1.22 - 1.83)	**<0.001**
BMI (kg/m^2)		0.052	-	NS
<18.5	1.48 (0.61 - 3.61)	0.389	-	-
18.5 - 24.9	-	-	-	-
25.0 - 30.0	1.48 (1.03 - 2.13)	0.034	-	-
>30	1.74 (1.15 - 2.63)	0.009	-	-
Current Smoker	1.62 (1.10 - 2.38)	**0.015**	1.26 (0.97 - 1.63)	0.080
ASA		**0.037**		**<0.001**
1	-	-	-	-
2	2.04 (0.93 - 4.49)	0.074	1.37 (0.92 - 2.04)	0.127
3	2.75 (1.23 - 6.15)	**0.014**	2.35 (1.56 - 3.55)	**<0.001**
4-5	1.55 (0.49 - 4.93)	0.455	3.97 (2.21 - 7.14)	**<0.001**
History of COPD	2.00 (1.29 - 3.08)	**0.002**	-	NS
ERAS Score	-	NS		**0.003**
< 12	-	-	-	-
12-13	-	-	0.69 (0.52 - 0.91)	**0.009**
14-15	-	-	0.68 (0.51 - 0.90)	**0.007**
16+	-	-	0.62 (0.47 - 0.81)	**<0.001**
Operative Approach		0.057		**<0.001**
Minimally Invasive	-	-	-	-
MI - Converted to Open	0.75 (0.40 - 1.40)	0.368	1.38 (0.97 - 1.97)	0.076
Open	1.36 (0.99 - 1.87)	0.054	1.52 (1.24 - 1.87)	**<0.001**
Resection Type		**<0.001**	-	NS
Colonic - Right	-	-	-	-
Colonic - Left	0.37 (0.23 - 0.61)	**<0.001**	-	-
Rectal	0.56 (0.37 - 0.85)	**0.007**	-	-
Total	0.87 (0.45 - 1.66)	0.668	-	-
Formation of New Stoma		**0.049**		**<0.001**
No	-	-	-	-
Ileostomy	1.63 (1.05 - 2.55)	**0.031**	1.97 (1.54 - 2.52)	**<0.001**
Colostomy	1.58 (0.98 - 2.55)	0.061	1.59 (1.22 - 2.07)	**<0.001**

Analyses were performed using multivariable binary logistic regression models. In each case, the NSAIDs variable was entered into the model, and a backwards stepwise approach was used to select independent predictors of the outcomes being considered. All factors from Table 3a, as well as pathology, operative approach, resection type and formation of new stoma were considered for inclusion in the models. Only those factors that were included in the final model for at least one of the outcomes being reported are tabulated above. Bold p-values are significant at p<0.05. Total colectomy includes total and sub-total colon resectionASA: American Society of Anesthesiologists; BMI: body mass index; CI: confidence interval; COPD: chronic obstructive pulmonary disease; DM: diabetes mellitus; ERAS: enhanced recovery after surgery; IHD: ischaemic heart disease; LOS: length of stay; NS; not selected for inclusion by the stepwise procedure; OR: odds ratio; PAD: peripheral vascular disease; POD=Post-operative day.

Suppl. Table 3c – Multivariable analyses of safety outcomes within 30 days of surgery

	Readmission		Clavien-Dindo Grade 3-5	
	OR (95% CI)	**p-Value**	**OR (95% CI)**	**p-Value**
NSAIDs on POD1-3	1.09 (0.86 - 1.38)	0.480	0.83 (0.65 - 1.04)	0.110
Age (Years)		0.057		
<60	-	-	-	-
60-69	0.92 (0.69 - 1.21)	0.544	-	-
70-79	0.98 (0.75 - 1.29)	0.898	-	-
80+	0.58 (0.38 - 0.87)	0.009	-	-
Sex (Male)	-	NS	1.43 (1.16 - 1.77)	**0.001**
ASA	-	NS		**<0.001**
1	-	-	-	-
2	-	-	1.39 (0.93 - 2.07)	0.106
3	-	-	2.12 (1.41 - 3.18)	**<0.001**
4-5	-	-	2.38 (1.27 - 4.46)	**0.007**
Previous Abdominal Surgery	-	NS	1.32 (1.07 - 1.62)	**0.010**
History of DM		**0.013**	-	NS
No	-	-	-	-
Diet/Tablet Controlled	1.45 (1.07 - 1.97)	**0.016**	-	-
Insulin Controlled	1.65 (0.99 - 2.72)	0.052	-	-
Operative Approach	-	NS		**0.007**
Minimally Invasive	-	-	-	-
MI - Converted to Open	-	-	1.36 (0.95 - 1.97)	0.097
Open	-	-	1.40 (1.12 - 1.73)	**0.003**
Formation of New Stoma		**<0.001**	-	NS
No	-	-	-	-
Ileostomy	2.00 (1.56 - 2.58)	**<0.001**	-	-
Colostomy	1.29 (0.94 - 1.77)	0.114	-	-

Analyses were performed using multivariable binary logistic regression models. In each case, the NSAIDs variable was entered into the model, and a backwards stepwise approach was used to select independent predictors of the outcomes being considered. All factors from Table 3a, as well as pathology, operative approach, resection type and formation of new stoma were considered for inclusion in the models. Only those factors that were included in the final model for at least one of the outcomes being reported are tabulated above. Bold p-values are significant at $p<0.05$. ASA: American Society of Anesthesiologists; BMI: body mass index; CI: confidence interval; COPD: chronic obstructive pulmonary disease; DM: diabetes mellitus; IHD: ischaemic heart disease; LOS: length of stay; NS; not selected for inclusion by the stepwise procedure; OR: odds ratio; PAD: peripheral vascular disease; POD: Post-operative day.

Figure 1 – Kaplan-Meier curves of time to GI-2

Plotted points are the Kaplan-Meier estimated cumulative GI-2 rates on each post-operative day (POD). The points have been connected using straight lines, rather than the conventional stepped lines, in order to more clearly highlight the differences between groups. The definitions of GI-2 used are as described in the methods. Briefly, the main analysis censors patients at discharge or death without achieving GI-2, whilst the sensitivity analysis treats patients discharged without GI-2 as achieving the outcome on this day, with inpatient deaths treated as being censored on POD 11. Means represent the average times to GI-2 in the two groups, and hazard ratios (HRs) and p-values are from univariable Cox regression models.

Suppl. File 1 – Outline of pre-study, centre-specific ERAS survey

A pre-study, centre-specific survey of compliance to enhanced recovery principles was completed by representatives of participating hospitals before the start of data collection

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