



# Impact of common surgical and anaesthetic strategies for pain control after elective gastrointestinal surgery: cohort study

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## Abstract

**Introduction:** Poor pain control after surgery is associated with chronic pain and opioid dependence. This study aimed to determine the incidence of patient reported pain control failure following gastrointestinal surgery, and to evaluate the impact of common preventative surgical and anaesthetic strategies.

**Methods:** Data were extracted from an electronic health record that linked real-time, ward-based pain scores with prescribing data. Adults undergoing major elective gastrointestinal surgery in 2011-18 were included. The primary endpoint was early pain control failure ( $\geq 1$  instances of moderate or severe pain on postoperative days 0-2). Secondary outcomes were late (postoperative days 3-5) and persistent (both early and late) pain control failure.

**Results:** Of 2238 patients, half underwent planned open surgery (50.3%, 1126/2238). Patient controlled analgesia (PCA) was initially used in 49.7% (1113/2238) and epidural in 35.0% (784/2238). Early (54%, 1211/2238), late (33.7%, 755/2238), and persistent (24.9%, 557/2238) pain control failures occurred frequently. In multivariable analyses, minimally invasive surgery was associated with fewer early, late, and persistent pain control failures than open surgery. There was no association between initial epidural analgesia and early or persistent pain control failure, but there was an association with increased late failure (OR 1.37, 95% CI 1.08-1.73,  $p=0.009$ ). Of patients with initial epidural analgesia, 39.3% (308/784) were subsequently converted to PCA.

**Conclusion:** Epidural analgesia offered no advantage over PCA, with pain control failure common irrespective of analgesic strategy. Increasing the uptake of minimally invasive surgery, through medical advances to down-stage disease, may offer a path to effectively improve postoperative pain failure.

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## Introduction

The most common complication experienced by the 260 million people<sup>1</sup> who undergo surgery worldwide each year is postoperative pain<sup>2,3</sup>. Modern practice has shifted from dismissing postoperative pain as an inevitable sequelae of surgery to recognising that perioperative teams should diligently manage acute pain<sup>4</sup>. However, the James Lind Alliance has identified a significant unmet need for research to inform strategies to reduce

postoperative pain<sup>5</sup>. A key challenge in postoperative pain control is balancing the risks of undertreatment against the potential complications of excess use of analgesics, particularly opiates<sup>6</sup>. Undertreatment of acute pain is associated with both delayed postoperative recovery and risk of chronic postsurgical pain (CPSP)<sup>7</sup>. In the short-term, both poor pain control and excessive opiate use can contribute to complications including pneumonia, ileus, delirium, and immobility leading to venous thromboembolism<sup>3,8,9</sup>. In the longer-term,

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undertreatment of acute pain and excessive in-hospital opiates are associated with chronic opiate use, contributing to the ongoing opioid crisis<sup>7,10-12</sup>.

Surgical strategies to reduce pain include minimally invasive surgery, whilst anaesthetic strategies include patient controlled analgesia (PCA), and local and regional analgesia techniques such as epidural analgesia. A large proportion of research and innovation in acute pain is in intensive care unit patients or is based in the USA. There is little high-quality data on pain control for gastrointestinal surgery patients who are cared for on general postoperative wards. The little data that does exist suggests that pain control is suboptimal in these patients<sup>13,14</sup>.

The Queen Elizabeth Hospital Birmingham's electronic health record captures patient pain scores at the point of care and is paired with electronic prescribing. The aim of this study was to use this quality, detailed data to determine the incidence of poor pain control following gastrointestinal surgery, and to evaluate the impact of key surgical and anaesthetic strategies that aim to improve pain control.

## Methods

### Data source

In 2005 the Prescribing Information and Communications System (PICS) electronic health record was introduced at the Queen Elizabeth Hospital Birmingham with built-in ward-based drug prescribing functions. During drug rounds nursing staff use PICS to record the time that drugs are administered to patients. Since June 2011, nursing staff have also used PICS to record patient reported pain scores at the point of care. Initially, pain scores were recorded using a 4-point verbal rating scale (0 – no pain at rest or on movement; 1 – no pain at rest, mild pain on movement; 2 – mild pain at rest, moderate pain on movement; 3 – continuous pain at rest, severe pain on movement). A decision was made by the hospital to switch to an 11-point verbal rating scale (rated 0 to 10) in December 2015. Hospital guidelines require pain scores to be recorded alongside each pulse or blood pressure measurement, as well as prior to each administration of analgesia. Consequently, in a postoperative ward setting pain should be measured a minimum of four times daily. The highest pain score for each postoperative day was extracted from the database.

### Inclusion criteria

The PICS system was used to identify all adult patients (age 16 years and above) who underwent elective small bowel or colorectal resection, reversal of stoma, or stoma formation from 1 October 2011 to 10 November 2018. To ensure that primary endpoint data was available, only patients with a hospital length of stay of two days or longer were included. Patients were excluded if they were transferred directly from the operating theatre to the intensive care unit, as pain management protocols and nursing staff levels for patients on the intensive care unit are substantially different to those for ward-based patients. The day of surgery was defined as postoperative day zero.

### Analgesic interventions

Unless contraindicated, all patients were prescribed regular paracetamol and regular non-steroidal anti-inflammatory drugs (NSAID), such as ibuprofen 400mg three times daily. In addition, patients received one of three main analgesia strategies:

- Epidural: typically 0.125% I-Bupivacaine and 2mcg/ml Fentanyl in a 500ml bag run at 1-15ml/hour, with rate titrated for optimal pain control under the supervision of the acute pain service. The acute pain service was delivered by acute pain specialist nurses and consultant anaesthetists with an interest in pain management. If following titration it was not possible to ensure good pain control with epidural, patients were converted to PCA.
- PCA: typically intravenous morphine 100mg in 100ml, with 1mg boluses with a 5 minute lockout.
- Other: regular weak opiates (30-60mg codeine phosphate four times daily or 50-100mg tramadol four times daily), with Oramorph as required for breakthrough pain. For escalation, patients were prescribed strong opiates (e.g. intravenous morphine sulfate) as required.

Based on the drugs administered postoperative days 0-5, patients were classified as having received initial epidural, PCA, or other analgesia strategy. Secondary insertion of epidural (i.e. after the patient had left the operating theatre) was very rare. Therefore, if a patient received both epidural and PCA within that period, they were recorded as having initially received an epidural strategy, with subsequent conversion to PCA.

### Primary outcome measure

The primary outcome measure was early pain control failure. Each patients' highest recorded pain score was extracted from PICS for each of the first five postoperative days. On the 4-point VRS, pain control failure was defined as at least one patient recorded score of 2 or greater, and on the 11-point VRS it was defined as a score of 5 or greater. These cut-offs were based on Royal College of Anaesthetists guidance<sup>15</sup>. Early pain control failure was defined as at least one episode of moderate or severe pain on postoperative days 0-2. Late pain control failure was similarly defined based on pain measurements recorded on postoperative days 3-5. Persistent pain control failure was defined as experiencing both early and late pain control failure.

### Explanatory variables

Use of preoperative chronic pain medication (i.e. gabapentin, pregabalin, amitriptyline, morphine sulfate slow release, buprenorphine patches, fentanyl patches, oxycontin) was extracted from the PICS system. Postoperative use of weak (codeine, dihydrocodeine, tramadol) and strong opiates (tramadol, oxynorm, oramorph, morphine injection) on postoperative days 0-5 was ascertained from PICS. Patients were recorded as having received no opiates, weak opiates only, or strong opiates. Electronic operation notes were reviewed to ascertain the site of operation (small bowel, colon, rectum), whether there was a resection of bowel, and the operative approach. Approach was classified as planned open surgery, completed minimally invasive (laparoscopic or robotic) surgery, or minimally invasive converted to open surgery.

### Statistical analysis

Testing between categorical demographics and outcome groups was performed with the Chi-squared test. Following univariable analysis, a multivariable logistic regression model was used to identify risk factors for early pain control failure. Variables included in the model were selected a-priori based on clinical relevance and included age, sex, use of chronic pain medications pre-operatively, operative approach (open, laparoscopic, laparoscopic converted to open), procedure performed (small bowel resection, ileostomy closure, colonic resection, colostomy closure, rectal resection), and initial analgesic strategy (epidural, PCA, other). Secondary analyses were completed with multivariable logistic regression models to identify risk factors for late and persistent pain control failures. An additional variable included in the model for late pain

control failure was whether the patient had experienced early control failure. Age was modeled as a continuous variable with corresponding odds ratios (ORs) relating to per-year increase. An OR of greater than 1 indicated increased risk of pain control failure. ORs are reported with 95% confidence intervals (CIs). A P-value of <0.05 was considered to be statistically significant. Analyses were carried out in Stata (Version 15, Stata Corp., College Station, Texas).

### Study approval

This study was registered as clinical audit at University Hospitals Birmingham NHS Foundation Trust (CARM-11953).

## Results

### Patient demographics

A total of 2238 eligible patients were identified (Supplementary Figure 1). Half the patients underwent planned open surgery (50.3%, 1126/2238), with the remainder undergoing minimally invasive surgery (44.0%, 985/2388) or minimally invasive converted to open surgery (5.7%, 127/2238, Table 1). Procedures included colonic resection (38.9%, 870/2238), rectal resection (26.9%, 601/2238), small bowel resection (7.3%, 164/2238), and ileostomy (15.8%, 353/2238) and colostomy (11.2%, 250/2238) formation or reversal. An open approach was most frequently used for small bowel procedures (Supplementary Figure 2). Overall, 20.8% (465/2388) of patients were taking chronic pain medications preoperatively.

### Analgesia strategies

The initial analgesia strategy was most frequently PCA (49.7%, 1113/2238). Of the 784 patients who initially received an epidural, 308 were subsequently converted to a PCA (39.3%, 308/784, Supplementary Table 1). Epidurals were more frequently used than PCA in patients who underwent planned open surgery (Supplementary Figure 3) and colorectal resection (Table 1). Overall, 39.4% (881/2238) of patients received strong opiates postoperatively and 13.0% (290/2238) received weak opiates only postoperatively.

### Early pain control failure

Over half the patients experienced early pain control failure (54.1%, 1211/2238). Early failures occurred more frequently in patients with an initial epidural analgesia strategy than those with an initial PCA strategy (58.3% versus 53.2% respectively). Early pain control failure was associated with strong opiate use on univariable

analysis (OR 1.82, 95% CI 1.53-2.16,  $p < 0.001$ , Table 2). Compared to patients whose initial analgesia strategy was PCA, patients with an epidural were more likely to require strong opiates (OR 1.63, 95% CI 1.35-1.96,  $p < 0.001$ ), whereas other (non-PCA, non-epidural) patients were less likely to require them (OR 0.73, 95% CI 0.56-0.95,  $p = 0.018$ ).

### Late and persistent pain control failure

A third of patients experienced a late pain control failure (33.7%, 755/2238) and a quarter experienced persistent pain failure (24.9%, 557/2238, Supplementary Table 2). Compared to those with an initial PCA strategy, patients initially managed with epidural experienced more late (44.6% versus 30.2%) and persistent (33.2% versus 22.4%) pain control failures. Both late (OR 2.18, 95% CI 1.82-2.60,  $p < 0.001$ ) and persistent (OR 2.37, 95% CI 1.95-2.88,  $p < 0.001$ ) pain control failures were associated with strong opiate use on univariable analysis (Table 2).

### Predictors of pain control failure

In multivariable analyses, female sex, pre-existing use of chronic pain medications, and rectal resection were

found to be independent predictors of early pain control failure, whereas increasing age and minimally invasive surgery were associated with reduced risk (Table 3). An initial epidural analgesia strategy was not associated with early pain control failure (OR 1.09, 95% CI 0.88-1.36,  $p = 0.423$ ).

Similar patient and procedure factors were found to be associated with late and persistent pain control failures (Tables 4 and 5). In both analyses, female sex and pre-existing use of chronic pain were independently associated with increased pain control failure, and increasing age and minimally invasive surgery were independently associated with reduced pain control failure. Rectal resection predicted persistent but not late pain control failure. Early pain control failure independently predicted late pain control failure (OR 3.05, 95% CI 2.50-3.73,  $p < 0.001$ ). An initial epidural analgesia strategy was associated with late (OR 1.37, 95% CI 1.08-1.73,  $p = 0.009$ ) but not persistent (OR 1.25, 95% CI 0.98-1.61,  $p = 0.075$ ) pain control failure.

**Table 1: Patient demographics stratified by initial analgesia strategy**

		PCA (n=1113)	Epidural (n=784)	Other† (n=341)	Total (n=2238)	P-value
Age (SD)		57.6 (18.3)	60.0 (16.9)	56.6 (18.5)	58.3 (17.9)	0.003
Sex, n (%)	Female	498 (44.7)	325 (41.5)	150 (44.0)	973 (43.5)	0.355
	Male	615 (55.3)	459 (58.5)	191 (56.0)	1265 (56.5)	
Preoperative chronic pain medications, n (%)	No	1003 (90.1)	465 (59.3)	305 (89.4)	1773 (79.2)	<0.001
	Yes	110 (9.9)	319 (40.7)	36 (10.6)	465 (20.8)	
Operative approach, n (%)	Open	355 (31.9)	574 (73.2)	197 (57.8)	1126 (50.3)	<0.001
	MIS	693 (62.3)	150 (19.1)	142 (41.6)	985 (44.0)	
	MIS converted to open	65 (5.8)	60 (7.7)	2 (0.6)	127 (5.7)	
Procedure, n (%)	Ileostomy procedures*	110 (9.9)	55 (7.0)	188 (55.1)	353 (15.8)	<0.001
	Small bowel resection	56 (5.0)	98 (12.5)	10 (2.9)	164 (7.3)	
	Colostomy procedures*	107 (9.6)	55 (7.0)	88 (25.8)	250 (11.2)	
	Colonic resection	497 (44.7)	331 (42.2)	42 (12.3)	870 (38.9)	
	Rectal resection	343 (30.8)	245 (31.3)	13 (3.8)	601 (26.9)	
Postoperative opiates, n (%)	None	545 (49.0)	340 (43.4)	182 (53.4)	1067 (47.7)	<0.001
	Weak opiate	164 (14.7)	67 (8.6)	59 (17.3)	290 (13.0)	
	Strong opiate	404 (36.3)	377 (48.1)	100 (29.3)	881 (39.4)	

\*formation/reversal †Analgesia strategies not including an epidural or PCA

MIS: minimally invasive surgery; PCA: patient controlled analgesia; SD: standard deviation



		<b>Early (n=1211)</b>	<b>Late (n=755)</b>	<b>Persistent (n=557)</b>
Age (SD)		55.0 (18.1)	54.3 (17.8)	52.1 (17.7)
Sex, n (%)	Female	556 (45.9)	355 (47.0)	273 (49.0)
	Male	655 (54.1)	400 (53.0)	284 (51.0)
Preoperative chronic pain medications, n (%)	No	923 (76.2)	530 (70.2)	381 (68.4)
	Yes	288 (23.8)	225 (29.8)	176 (31.6)
Operative approach, n (%)	Open	647 (53.4)	460 (60.9)	349 (62.7)
	MIS	489 (40.4)	243 (32.2)	170 (30.5)
	MIS converted to open	75 (6.2)	52 (6.9)	38 (6.8)
Procedure, n (%)	Ileostomy procedures*	195 (16.1)	114 (15.1)	87 (15.6)
	Small bowel resection	96 (7.9)	69 (9.1)	55 (9.9)
	Colostomy procedures*	131 (10.8)	76 (10.1)	55 (9.9)
	Colonic resection	443 (36.6)	274 (36.3)	195 (35.0)
	Rectal resection	346 (28.6)	222 (29.4)	165 (29.6)
Analgesic strategy, n (%)	PCA	592 (48.9)	336 (44.5)	249 (44.7)
	Epidural	457 (37.7)	350 (46.4)	260 (46.7)
	Other†	162 (13.4)	69 (9.1)	48 (8.6)
Postoperative opiates, n (%)	None	492 (40.6)	248 (32.9)	167 (47.7)
	Weak opiate	164 (13.5)	116 (15.4)	83 (13.0)
	Strong opiate	555 (45.8)	391 (51.8)	881 (39.4)

\*formation/reversal †Analgesia strategies not including an epidural or PCA

MIS: minimally invasive surgery; PCA: patient controlled analgesia; SD: standard deviation

## Discussion

Pain after major elective gastrointestinal surgery was common and not adequately controlled with current anaesthetic strategies, creating a cycle of opiate use. The only strategy that was associated with reduced pain was minimally invasive surgery, although its implementation was limited to 40-60% of cases, both within this study and across Europe<sup>16</sup>. Early pain failure was found to be associated with a 3.6 times greater odds of late pain failure, indicating that salvage is challenging once pain occurs. Given that revolutionary new pain medications are unlikely to come to the market in the near future, greater adoption of minimally invasive (laparoscopic, robotic, trans-orifice) surgical strategies is likely to offer the greatest and earliest benefit to patients by preventing severe postoperative pain. Treatments aimed at down-staging disease will support uptake of minimally invasive techniques by permitting smaller operations.

Epidural analgesia was found to have no clear advantage over PCA, even after adjusting for procedure type.

The shortcomings of epidurals were evident, as around 40% of patients were subsequently switched PCA. This is consistent with small randomised trials in laparoscopic surgery, that found epidurals to have limited or no superiority for pain control compared to PCA<sup>17-19</sup>. The disadvantages of epidurals include restricting patients' movement, slower recovery, and complications<sup>20</sup>. This pragmatic observational study tested real-world application of epidurals and PCA (stage 4 IDEAL study<sup>21</sup>) over a seven-year period, with patients treated by a large number of anaesthetists. PCA may be preferred even in major open surgery, as it is less time-consuming than epidural catheter placement and avoids rare but catastrophic complications of epidural haematoma and infection.

This large cohort study benefited from being based on electronic health record data, with patient reported pain measurements recorded at the point of care by nursing staff trained in pain assessment. Although the frequency and timing of pain outcome assessment was not strictly protocolised, it is likely that by measuring pain levels

**Table 3: Univariable and multivariable models for early pain control failure**

		Univariable			Multivariable		
		OR	CI	P-value	OR	CI	P-value
Age		0.98	0.97 to 0.99	<0.001	0.98	0.97 to 0.99	<0.001
Sex	Male				Reference		
	Female	1.24	1.05 to 1.47	0.012	1.25	1.05 to 1.49	0.012
Preoperative chronic pain medications	No				Reference		
	Yes	1.50	1.22 to 1.85	<0.001	1.31	1.04 to 1.66	0.020
Operative approach	Planned open				Reference		
	Completed MIS	0.73	0.61 to 0.87	<0.001	0.79	0.64 to 0.99	0.039
	MIS converted to open	1.07	0.74 to 1.55	0.730	1.04	0.70 to 1.55	0.833
Procedure	Colonic resection				Reference		
	Ileostomy closure*	1.19	0.93 to 1.52	0.171	1.03	0.75 to 1.43	0.843
	Small bowel resection	1.36	0.97 to 1.91	0.074	1.06	0.74 to 1.52	0.741
	Colostomy closure*	1.06	0.80 to 1.41	0.680	0.96	0.70 to 1.31	0.784
	Rectal resection	1.31	1.06 to 1.61	0.012	1.33	1.07 to 1.65	0.010
Analgesic strategy	PCA				Reference		
	Epidural	1.23	1.02 to 1.48	0.028	1.09	0.88 to 1.36	0.423
	Other†	0.80	0.62 to 1.02	0.066	0.78	0.58 to 1.05	0.102

\*formation/reversal †Analgesia strategies not including an epidural or PCA

CI: confidence interval; MIS: minimally invasive surgery; OR: odds ratio PCA: patient controlled analgesia

**Table 4: Univariable and multivariable models for late pain control failure**

		Univariable			Multivariable		
		OR	CI	P-value	OR	CI	P-value
Age		0.98	0.97 to 0.99	<0.001	0.98	0.97 to 0.99	<0.001
Sex	Female				Reference		
	Male	1.24	1.04 to 1.45	0.016	1.21	1.01 to 1.47	0.043
Preoperative chronic pain medications	No				Reference		
	Yes	2.20	1.79 to 2.71	<0.001	1.54	1.21 to 1.96	<0.001
Operative approach	Planned open				Reference		
	Completed MIS	0.47	0.39 to 0.57	<0.001	0.57	0.45 to 0.72	<0.001
	MIS converted to open	1.00	0.69 to 1.46	0.984	0.94	0.63 to 1.41	0.763
Procedure	Colonic resection				Reference		
	Ileostomy closure*	1.04	0.80 to 1.35	0.785	1.01	0.71 to 1.44	0.953
	Small bowel resection	1.58	1.12 to 2.22	0.009	1.02	0.70 to 1.48	0.929
	Colostomy closure*	0.95	0.70 to 1.29	0.742	0.90	0.63 to 1.28	0.556
	Rectal resection	1.27	1.02 to 1.59	0.030	1.21	0.95 to 1.53	0.118
Early pain control failure	No				Reference		
	Yes	3.57	2.94 to 4.32	<0.001	3.05	2.50 to 3.73	<0.001
Analgesic strategy	PCA				Reference		
	Epidural	1.86	1.54 to 2.26	<0.001	1.37	1.08 to 1.73	0.009
	Other†	0.59	0.44 to 0.79	<0.001	0.55	0.39 to 0.78	0.001

\*formation/reversal †Analgesia strategies not including an epidural or PCA

CI: confidence interval; MIS: minimally invasive surgery; OR: odds ratio PCA: patient controlled analgesia

Table 5: Univariable and multivariable models for persistent pain control failure							
		Univariable			Multivariable		
		OR	CI	P-value	OR	CI	P-value
Age		0.97	0.96 to 0.98	<0.001	0.97	0.96 to 0.98	<0.001
Sex	Female	Reference					
	Male	1.34	1.11 to 1.63	0.002	1.40	1.14 to 1.71	0.001
Preoperative chronic pain medications	No	Reference					
	Yes	2.22	1.79 to 2.77	<0.001	1.67	1.30 to 2.13	<0.001
Operative approach	Planned open	Reference					
	Completed MIS	0.46	0.38 to 0.57	<0.001	0.53	0.41 to 0.69	<0.001
	MIS converted to open	0.95	0.64 to 1.42	0.804	0.89	0.58 to 1.37	0.604
Procedure	Colonic resection	Reference					
	Ileostomy closure*	1.13	0.85 to 1.51	0.401	1.04	0.72 to 1.51	0.826
	Small bowel resection	1.75	1.22 to 2.51	0.002	1.15	0.78 to 1.69	0.488
	Colostomy closure*	0.98	0.70 to 1.37	0.890	0.85	0.58 to 1.24	0.399
	Rectal resection	1.31	1.03 to 1.66	0.027	1.37	1.06 to 1.76	0.015
Analgesic strategy	PCA	Reference					
	Epidural	1.72	1.40 to 2.11	<0.001	1.25	0.98 to 1.61	0.075
	Other	0.57	0.41 to 0.80	0.001	0.50	0.34 to 0.74	0.001

\*formation/reversal †Analgesia strategies not including an epidural or PCA

CI: confidence interval; MIS: minimally invasive surgery; OR: odds ratio PCA: patient controlled analgesia

prior to administration of analgesia, peak pain levels were reliably recorded. The visual analogue scale used was a single dimension instrument and did not capture more global patient satisfaction or quality of life. A pain related VAS is frequently used for pain assessment in clinical studies as it offers high inter-rater correlation and validity, but it remains a uni-dimensional, subjective instrument<sup>22,23</sup>. Although this study was based on data from a single centre, its generalisability is increased by reflecting the practice of a large number of trainee and consultant anaesthetists and surgeons who participated in the management of patients at this large tertiary centre over a 7-year period.

Opioid prescribing has significantly increased in UK general practice in the past two decades<sup>24</sup> and there is an increasing focus on the relationship between postoperative pain management and chronic opiate usage<sup>10, 11</sup>. This study was not able to address chronic opiate usage, as the PICS database has no access to community opiate prescribing and usage data. We did not capture data on measures including wound based local anaesthetic infusion catheters or transversus abdominis plane (TAP) blocks. Implementation of these multimodal

interventions is highly variable<sup>25</sup>, and they were not in common practice within the hospital during the study period. Most studies testing these interventions have been small, single practitioner trials, providing little generalisable evidence<sup>26-29</sup>.

The study was conducted during a period of integration of minimally invasive surgical techniques in to routine practice. Greater adoption of these strategies may offer the best means of safely improving postoperative pain control. Future research should focus on strategies to promote its widespread adoption. This may include testing treatments aimed at down-staging disease, for example testing local excision of rectal cancer, or targeted chemotherapy down-staging of colonic cancer. Increasing the dissemination of laparoscopy, introducing cheaper robotics to reduce training times, and technological advancements that support the development of trans-orifice techniques in specialist centres can ensure that less invasive surgery is available for more patients in the future.

#### Conflict of interest

The authors have no conflicts of interest

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