

ENHANCED RECOVERY AFTER SURGERY (ERAS) PATHWAYS

PARESH C. SHAH MD FACS
VICE CHAIR OF SURGERY – DIRECTOR OF GENERAL
SURGERY

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Disclosure

Paresh C. Shah MD FACS

I have a relevant financial relationship with the following companies that may constitute a potential conflict of interest as it pertains to the content of my presentation:

Stryker	Consultant
EndoEvolution	Consultant/Equity
Olympus	Consultant
Arch Therapeutics	Consultant

ERAS Pathway

Multi-step, multi-modal process including up to 18 components

Includes pre-hospital (upto 1 month)

Intra-op, post-op and post discharge management components

Variable rates of compliance with all elements of pathway

Variable responses to pathway non compliance

What do we know from ERAS Data?

Earlier return of functional status

Reduced hospital stay

Reduced total cost of episode

Perfect compliance with all pathway steps is not critical

Equ

Better compliance does yield better performance

Equ

Equal or improved patient satisfaction

ERAS and MIS resections

Are ERAS pathway benefits preserved in laparoscopic surgery?

Does laparoscopic surgery offer a benefit distinct from ERAS?

Does laparoscopic surgery change some of the elements of the ERAS pathway?

Data Challenges

Variability in adherence to ERAS components across studies.

No standard reporting structure.

- SSI, Inpatient cost, Episode Cost, etc

Very few RCT's

- Most single center or case control
- MIS as subset analysis

Majority of data is from colorectal surgery

ERAS/ERP Compliance

Table A1. ERP Compliance

Intervention	Laparoscopy (n = 101)*		Open Surgery (n = 101)†		All Patients (n = 202)‡	
	No.	%	No.	%	No.	%
Preoperative intervention						
Preoperative patient education	78	77.2	82	81.2	160	79.2
Avoidance of mechanical bowel preparation (colon patients only)	42	58.3	48	64.9	90	61.6
Preoperative oral carbohydrate	62	61.4	65	64.4	127	62.9
Avoidance of long-acting sedatives	82	81.2	78	77.2	160	79.2
Intraoperative intervention						
Avoidance of drainage (colon patients only)	68	94.5	70	94.6	138	94.5
Thoracic epidural analgesia activated before skin incision	26	25.7	34	33.6	60	29.7
Intraoperative heating	73	72.3	76	75.2	149	73.8
Avoidance of nasogastric drainage at termination of operation	95	94.1	95	94.1	190	94.1
< 3 L infused intraoperatively	81	80.2	75	74.3	156	77.2
Postoperative intervention, day 0						
Oral fluid intake > 800 mL	18	17.8	21	20.8	39	19.3
Intake of nutritional supplement ≥ 200 mL	26	25.7	31	30.7	57	28.2
Mobilized	18	17.8	18	17.8	36	17.8
Postoperative intervention, day 1						
IV fluids terminated	56	55.5	43	42.6	99	49.0
Epidural used	50	49.5	65	64.4	115	56.9
Solid food eaten	54	53.5	41	40.6	95	47.0
Postoperative apertient administered (colon patients only)	37	51.4	42	56.8	79	54.1
Intake of nutritional supplement ≥ 200 mL	2	2.0	1	1.0	3	1.5
Mobilized	26	25.7	23	22.8	49	24.3
Postoperative intervention, day 2						
Urinary drainage stopped (colon patients only)	51	70.8	32	43.2	83	56.8
Termination of epidural	35	35.0	27	27.0	62	31.0

Patient Reported Outcomes for ERP

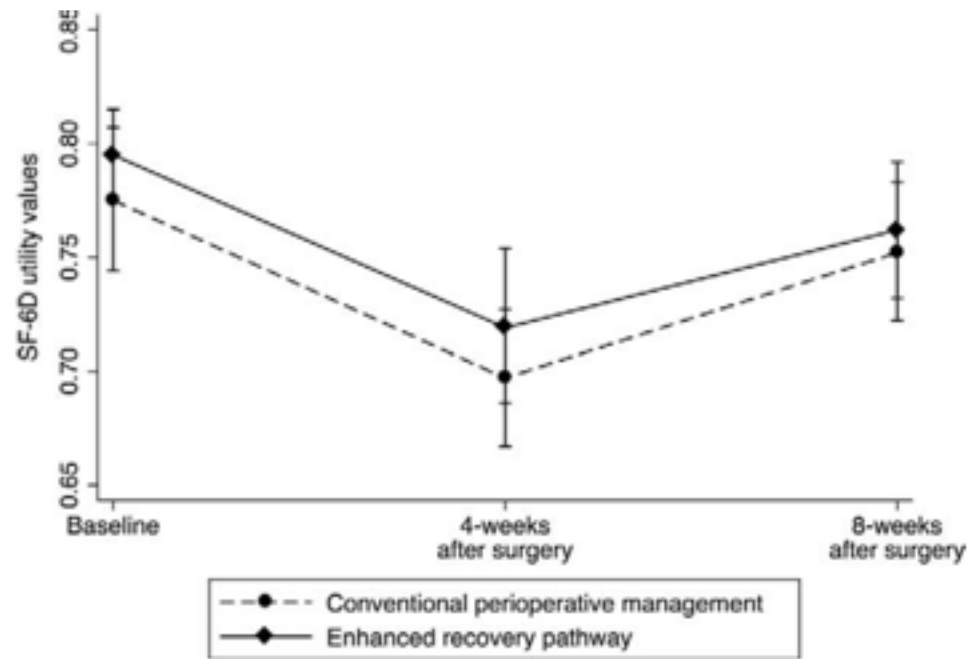


FIGURE 2. Comparison of mean SF-6D scores between patients managed by conventional perioperative management and patients managed by an ERP

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What do we know from MIS data?

Shorter Length of stay (LOS)

Earlier return to functional status

Lower pain levels

Slightly higher OR Cost

Lower overall cost of care for the admission

Complication and readmission rates are either equivalent or lower compared to open surgery.

MIS vs Open in ERAS/ERP Programs

TAPA Study – Study Design published 2010

- No follow up published

LAFa Trial – Multicenter trial

- LOS shorter

EnROL Trial – Multicenter with emphasis on cancer resections

- LOS Shorter
- PRO unchanged

Randomized clinical trial comparing laparoscopic and open surgery for colorectal cancer within an enhanced recovery programme

P. M. King¹, J. M. Blazeby³, P. Ewings⁴, P. J. Franks⁵, R. J. Longman¹, A. H. Kendrick⁶,
R. M. Kipling² and R. H. Kennedy¹

Departments of ¹Surgery and ²Anaesthetics, Yeovil District Hospital, Yeovil, ³Departments of Social Medicine and Clinical Sciences at South Bristol, University of Bristol, Bristol, ⁴Research and Development Department, Taunton and Somerset Hospital, Taunton, ⁵Centre for Research and Implementation of Clinical Practice, Thames Valley University, London and ⁶Department of Respiratory Medicine, Bristol Royal Infirmary, Bristol, UK
Correspondence to: Mr R. H. Kennedy, East Somerset NHS Trust, Yeovil BA21 4AT, UK (e-mail: kennr@est.nhs.uk)

Single Center, Single Surgeon

Included cost analysis

Included patient reported outcomes

British Journal of Surgery 2006; 93: 300–308

King et al

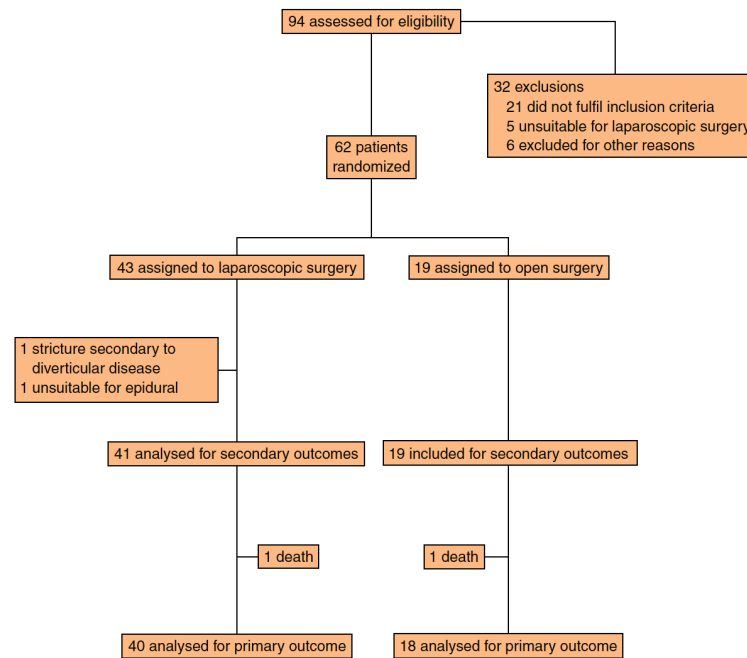


Fig. 1 Trial profile

British Journal of Surgery 2006; 93: 300–308

Table 3 Primary outcomes

	Laparoscopic surgery (n = 40)	Open surgery (n = 18)	Ratio of laparoscopic to open surgery*	P†
Postoperative stay (days)	5.2 (4.2, 6.5)	7.4 (6.0, 9.2)	0.68 (0.49, 0.93)	0.018
Postoperative and convalescent stay (days)	5.4 (4.2, 6.8)	7.4 (6.0, 9.2)	0.69 (0.49, 0.78)	0.036
Postoperative, convalescent and readmission stay (days)	5.5 (4.3, 7.0)	8.3 (6.3, 10.8)	0.63 (0.44, 0.90)	0.012

Values are geometric mean (95 per cent confidence intervals). *Open surgery as reference group, adjusted for cancer site. †ANOVA (F test).

Table 4 Secondary clinical outcomes

	Laparoscopic surgery (n = 41)	Open surgery (n = 19)	Odds ratio‡ laparoscopic <i>versus</i> open	P
Readmission	2	5	0.13 (0.02, 0.79)	0.027¶
Blood loss > 100 ml	11	18	0.02 (0.002, 0.16)	< 0.001¶
Major morbidity	6	5	0.40 (0.10, 1.66)	0.208¶
Postoperative blood transfusion	6	2	1.50 (0.27, 8.30)	0.640¶
Epidural insufficiency requiring opioid supplements	9	14	0.09 (0.03, 0.34)	< 0.001¶
Antiemetic injections per patient*	3 (0–14)	7 (0–18)		0.002**
Duration of surgery (min)†	187 (168, 207)	140 (121, 163)	1.29 (1.12, 1.49)§	0.001
Intravenous fluids within 48 h of surgery (ml)†	5195 (4380, 6162)	6200 (4721, 8142)	0.82 (0.61, 1.11)§	0.196

Values are numbers of patients, except *median (range) and †geometric mean (95 per cent confidence interval). ‡Laparoscopic *versus* open resection, adjusted for cancer site, with 95 per cent confidence intervals, except §ratio of laparoscopic to open surgery, with open surgery as reference group. ¶logistic regression (Wald test); **Mann–Whitney *U* test; ||ANOVA (F test).

King et al

Table 5 Total cost of care for patients in the enhanced recovery programme randomized to open and laparoscopic procedures

	Laparoscopic surgery (n = 41)	Open surgery (n = 19)	Mean difference*
Theatre costs including preoperative and recovery costs	2885.7	1964.1	- 921.6 (-1250.6, -586.0)
Hospital (hotel) costs including intensive and high-dependency care	2277.8	2291.3	13.5 (-1860.1, 2173.2)
Postoperative costs including reoperations	287.2	1039.7	752.5 (-278.5, 2466.6)
Chemotherapy and radiotherapy	175.5	176.5	1.0 (-126.9, 138.1)
Follow-up costs by 3 months	359.6	593.6	234.0 (-5.8, 501.7)
Indirect costs	447.6	721.7	274.1 (-386.2, 983.2)
Total	6433.4	6786.9	353.5 (-2167.1, 2991.5)

Values are mean pounds sterling, derived from bootstrap estimates (10 000 iterations), with confidence intervals at the 2.5 and 97.5 percentiles. *Open minus laparoscopic surgery costs.

In conclusion, this study suggests that laparoscopic resection of colorectal cancer within an enhanced recovery programme may provide the best short-term clinical outcomes for patients with resectable colorectal cancer.

British Journal of Surgery 2006; 93: 300–308

EnROL Study

Multi-center trial

Colo-rectal Cancer resections in the setting of an established ERP

Double Blinded for effect of MIS resections vs open

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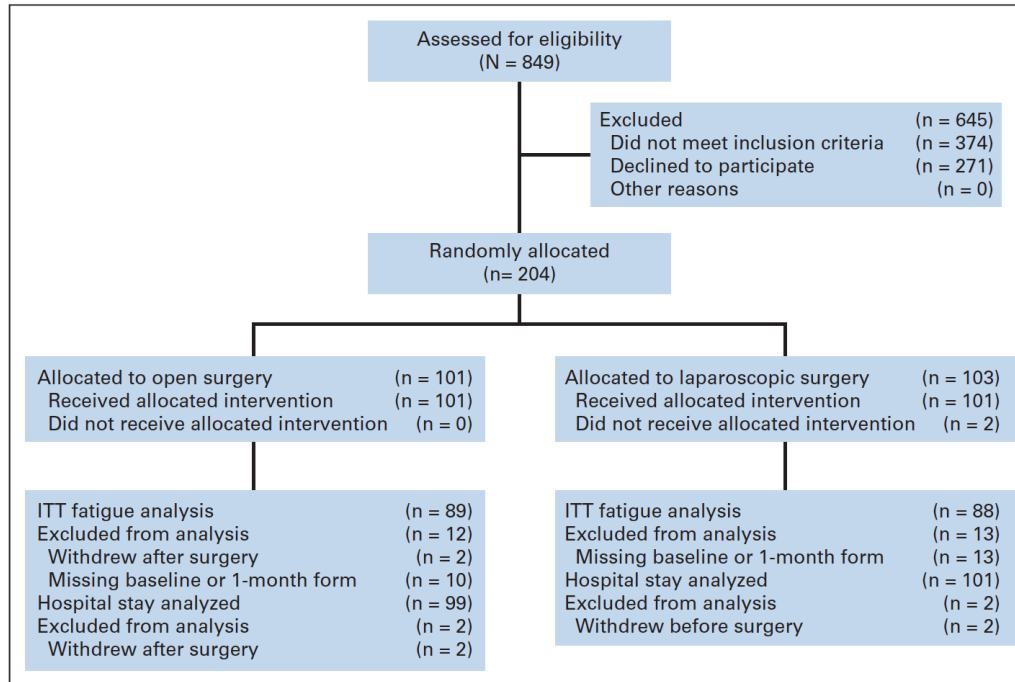
JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Multicenter Randomized Controlled Trial of Conventional Versus Laparoscopic Surgery for Colorectal Cancer Within an Enhanced Recovery Programme: EnROL

Robin H. Kennedy, E. Anne Francis, Rose Wharton, Jane M. Blazeby, Philip Quirke, Nicholas P. West, and Susan J. Dutton

EnROL



J Clin Oncol 32:1804-1811. © 2014 by American Society of Clinical Oncology

EnROL – Length of Stay

pLOS: Lap 5 (4-6) vs Open 6 (4-9) $p=0.011$

- Primary hospital stay

TLOS: Lap 5 (4-9) vs Open 7 (5-11) $p=0.033$

- Total hospital stay including readmissions

J Clin Oncol 32:1804-1811. © 2014 by American Society of Clinical Oncology

EnROL – Patient Reported Outcomes

Table 3. Results for Patient-Reported Outcomes

Scale/Subscale	Laparoscopy		Open Surgery		Difference		P
	Adjusted Mean	95% CI	Adjusted Mean	95% CI	Adjusted Mean	95% CI	
MFI-20 physical fatigue*†	12.2	11.3 to 13.1	12.1	11.2 to 13.1	-0.06	-1.37 to 1.25	.93
General fatigue‡	11.7	10.9 to 12.6	11.5	10.6 to 12.3	-0.28	-1.52 to 0.95	.65
Activity‡	12.8	11.9 to 13.8	12.5	11.6 to 13.5	-0.26	-1.63 to 1.10	.71
Motivation‡	9.5	8.7 to 10.4	9.3	8.5 to 10.1	-0.24	-1.44 to 0.96	.70
Mental fatigue‡	7.6	6.8 to 8.4	7.4	6.6 to 8.2	-0.17	-1.29 to 0.95	.76
SF-36 physical health‡	57.8	54.0 to 61.7	55.9	52.1 to 59.7	-1.94	-7.36 to 3.49	.48
Physical functioning‡	58.6	53.7 to 63.5	58.2	53.4 to 63.0	-0.41	-7.32 to 6.50	.91
Role—physical‡	40.8	35.1 to 46.6	41.5	35.9 to 47.2	0.72	-7.40 to 8.84	.86
Bodily pain‡	66.0	61.0 to 70.9	62.0	57.0 to 66.9	-4.01	-11.07 to 3.05	.26
General health‡	64.3	60.7 to 67.9	62.5	58.9 to 66.0	-1.87	-6.97 to 3.23	.47
SF-36 mental health‡	62.8	58.9 to 66.8	60.1	56.1 to 64.0	-2.76	-8.41 to 2.88	.33
Vitality‡	47.5	43.0 to 52.0	44.4	39.9 to 49.0	-3.07	-9.54 to 3.40	.35
Social functioning‡	61.3	54.9 to 67.6	57.9	51.6 to 64.2	-3.34	-12.32 to 5.63	.46
Role—emotional‡	67.2	60.8 to 73.7	65.6	59.2 to 72.0	-1.66	-10.81 to 7.49	.72
Mental health‡	74.0	70.3 to 77.7	72.6	68.9 to 76.3	-1.40	-6.67 to 3.86	.60

Abbreviations: ANCOVA, two-way analysis of variance; MFI, Multidimensional Fatigue Inventory; SF, Short Form.
 *Primary outcome.
 †ANCOVA adjusted for baseline physical fatigue, cancer site, age, stoma, and metastasis.
 ‡ANCOVA adjusted for baseline physical fatigue, cancer site, and age.

No Differences in PRO between Lap vs Open

J Clin Oncol 32:1804-1811. © 2014 by American Society of Clinical Oncology

Cost-effectiveness of Enhanced Recovery Versus Conventional Perioperative Management for Colorectal Surgery

Lawrence Lee, MD, MSc,* Juan Mata, MD,* Gabriela A. Ghitulescu, MD,† Marylise Boutros, MD,†
 Patrick Charlebois, MD,* Barry Stein, MD,* A. Sender Liberman, MD,* Gerald M. Fried, MD,*
 Nancy Morin, MD,† Franco Carli, MD, MPhil,‡ Eric Latimer, PhD,§ and Liane S. Feldman, MD*

TABLE 5. Results of Sensitivity and Subgroup Analyses

	Incremental Costs (95% CI)	Incremental Quality-adjusted Days (95% CI)	ICER
<i>Sensitivity analyses</i>			
Complete case analysis	-2987 (-6040 to -108)	+0.58 (-0.90 to 2.05)	Dominant
Uniform unit costs	-5421 (-8842 to -2443)	+0.87 (-1.23 to 2.97)	Dominant
Uniform preemployment salary*	-2311 (-5226 to 130)	+0.87 (-1.23 to 2.97)	Dominant
<i>Subgroup analyses</i>			
Employment status			
Employed	-4194 (-7556 to -608)	+1.33 (-1.23 to 3.89)	Dominant
Unemployed	-1094 (-6216 to 2420)	+0.84 (-2.41 to 4.09)	Dominant
Surgical approach			
Laparoscopic	-2251 (-5072 to -566)	+1.19 (-1.64 to +4.04)	Dominant
Open	-1346 (-7501 to 4371)	+0.55 (-1.09 to 2.20)	Dominant
Yes	-942 (-5516 to 3604)	+0.02 (-3.93 to 3.99)	Potentially Cost-effective
No	-2503 (-6486 to 657)	+0.86 (-1.47 to 4.14)	Dominant
Complications			
No complications	-2500 (-4334 to -718)	+0.86 (-2.57 to 4.30)	Dominant
Any complications	-3102 (-8938 to 1768)	+0.78 (-1.80 to 3.36)	Dominant

Note that incremental costs are calculated from a societal perspective. Confidence intervals were derived from the 2.5th and 97.5th percentile bootstrapped estimates.

*Canadian median salary.

Lafa Study

Multicenter (9) trial

Randomized, Double Blind to 4 groups

Laparoscopic vs open and Conventional vs Fast track

Laparoscopy in Combination with Fast Track Multimodal Management is the Best Perioperative Strategy in Patients Undergoing Colonic Surgery

A Randomized Clinical Trial (Lafa-study)

Malaika S. Vlug, MD, PhD, Jan Wind, MD, PhD,* Markus W. Hollmann, MD, PhD, DEAA,†
Dirk T. Ubbink, MD, PhD,‡ Huib A. Cense, MD, PhD,§ Alexander F. Engel, MD, PhD,¶
Michael F. Gerhards, MD, PhD,** Bart A. van Wagensveld, MD, PhD,†† Edwin S. van der Zaag, MD,‡‡
Anna A.W. van Geloven, MD, PhD,§§ Mirjam A.G. Sprangers, PhD,¶¶ Miguel A. Cuesta, MD, PhD,*** and
Willem A. Bemelman, MD, PhD,* on behalf of the collaborative Lafa study group*

Annals of Surgery Volume 254, Number 6, December 2011

Lafa

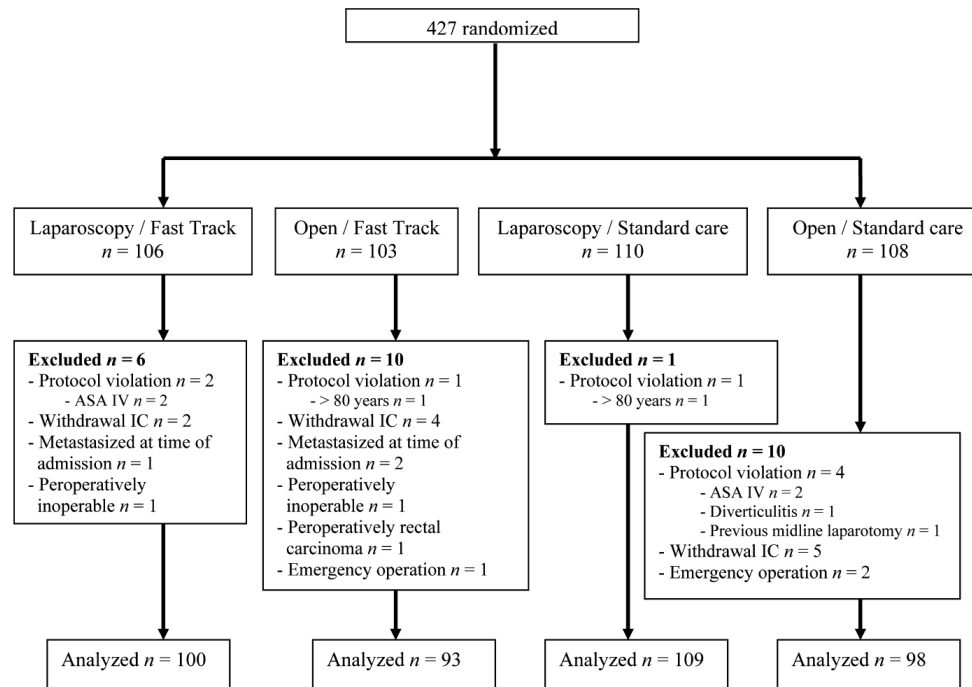


FIGURE 1. Study flow.

TABLE 3. Postoperative Data

	Laparoscopy and Fast Track (n = 100)	Open and Fast Track (n = 93)	Laparoscopy and Standard care (n = 109)	Open and Standard care (n = 98)	P
Total hospital stay, median (IQR), days	5 (4-8)	7 (5-11)	6 (4.5-9.5)	7 (6-13)	<0.001*†
Postoperative hospital stay, median (IQR), days	5 (4-7)	6 (4.5-10)	6 (4-8.5)	7 (6-10.5)	<0.001*‡
(b) Acceptance of discharge	4 (3-6)	5 (4-7)	5 (4-6)	7 (5-12)	
In-hospital costs					
University hospitals, median (IQR, €)	10,594 (5461-16,763)	12,805 (6847-20,658)	11,967 (6222-17,039)	10,479 (6608-16,875)	0.56*
Teaching hospitals, median (IQR, €)	5768 (4873-8917)	5497 (4506-6513)	6228 (5280-6604)	5650 (4836-8003)	0.41*

*Kruskal-Wallis test/Groups individually tested by mann-whitney *u* test.

†Significant difference between Lap/FT and Open/FT (0.008)/Lap/FT and Lap/Standard (0.026)/Lap/FT and Open/Standard (0.000)/Lap/Standard and Open/Standard (0.010).

‡Significant difference between Lap/FT and Open/FT (0.005)/Lap/FT and Lap/Standard (0.020)/Lap/FT and Open/Standard (0.000)/Open/FT and Open/Standard (0.032)/Lap/Standard and Open/Standard (0.004).

NYU Experience

ERP for all elective colon surgery

Established MIS Colo-Rectal program

90% Laparoscopic resections

Implemented ERAS/ERP in 2015

Prospective tracking of outcomes

Unpublished data

NYU ERAS Experience

Standardized bowel prep and CHX body wash, permissive hydration

Peri-op alvimopan, gabapentin, tylenol, heparin

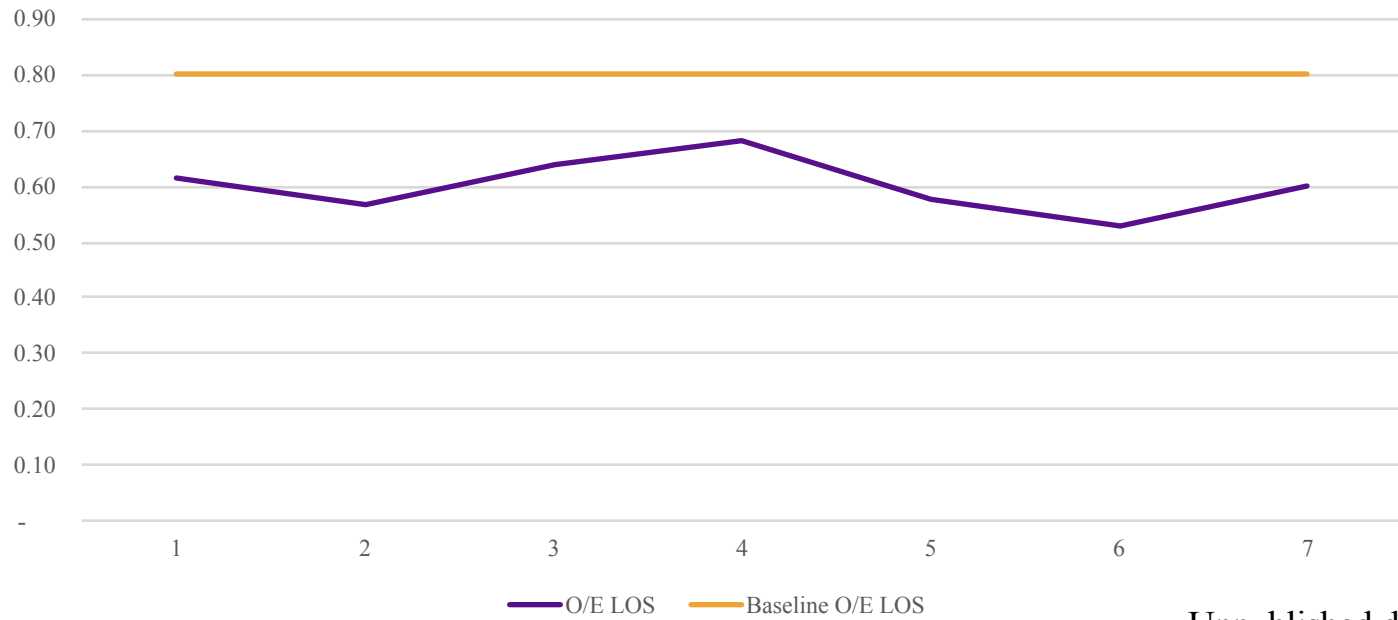
Intra-op fluid and temperature control

Post op diet and ambulation

Added Intra-op instrument change bundle in 2016

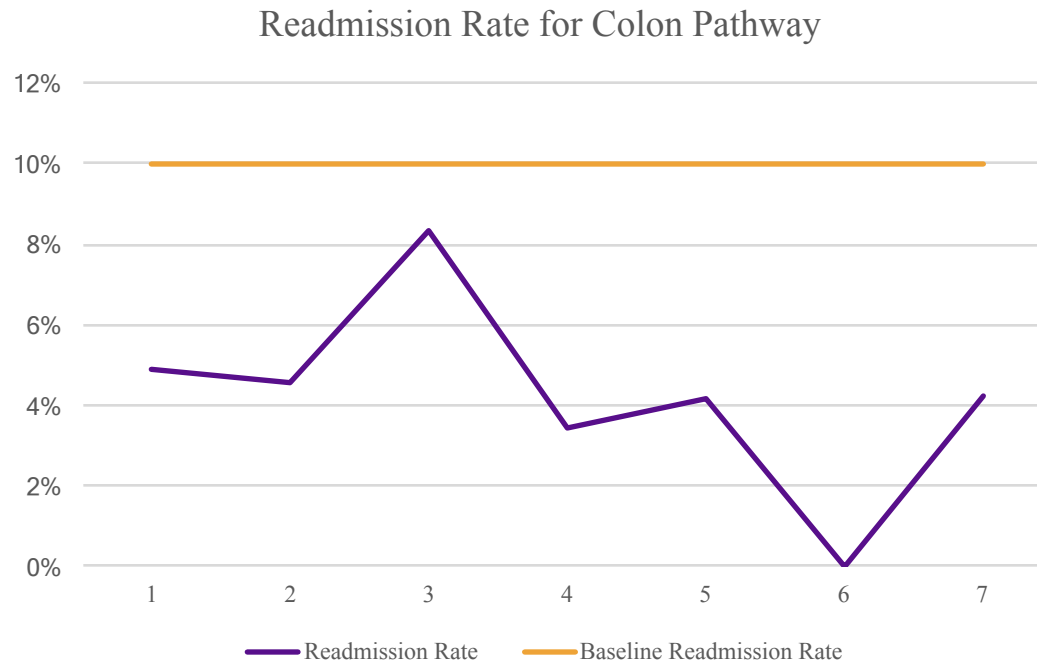
NYU Experience

O/E LOS For Colon Pathway



Unpublished data

NYU Experience



Unpublished data

NYU Experience

Implementation of ERP improved outcomes in existing MIS program

Decreased overall LOS and O/E LOS significantly

Reduced rate of readmissions overall

No change in peri-op morbidity or complications

Unpublished data

Epidural?

Randomized Clinical Trial on Epidural Versus Patient-controlled Analgesia for Laparoscopic Colorectal Surgery Within an Enhanced Recovery Pathway

Martin Hübner, MD, Catherine Blanc, MD,† Didier Roulin, MD,* Michael Winiker, MD,* Sylvain Gander, MD,† and Nicolas Demartines, MD, FACS, FRACS**

Annals of Surgery Volume 261, Number 4, April 2015

Epidural in MIS resections

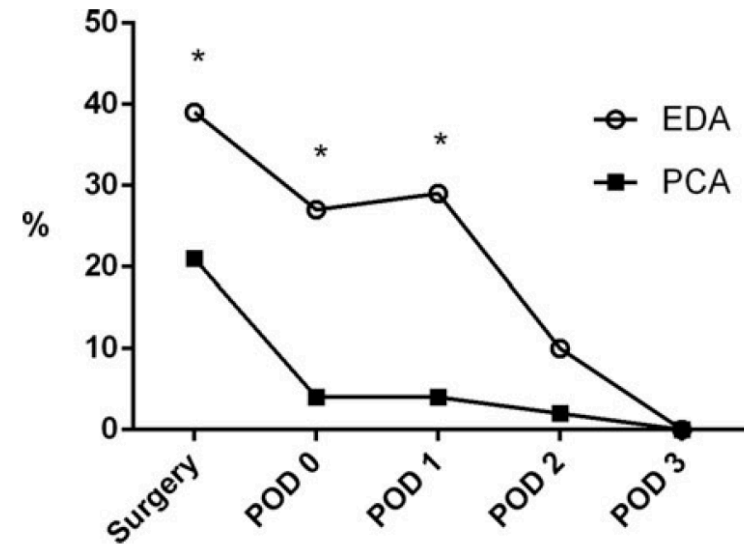
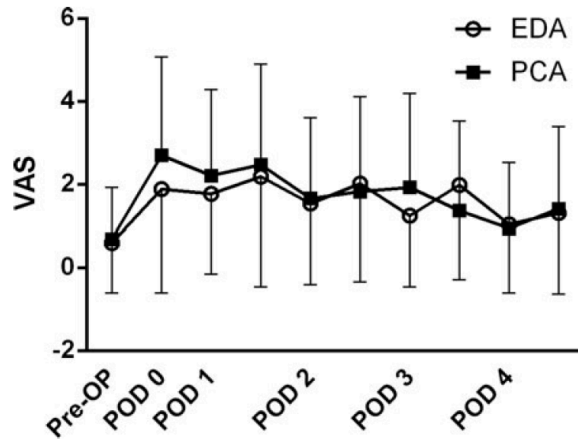


FIGURE 2. Perioperative vasopressor requirements. The percentage of patients in the EDA group (white circles) and the PCA group (black rectangles), respectively, requiring vasopressor treatment during and after laparoscopic colorectal surgery. *Statistical significance ($P < 0.05$).

Annals of Surgery Volume 261, Number 4, April 2015

Are ERAS and MIS synergistic or does one cancel the other out?

ERAS benefits are maintained regardless of approach: open or MIS

ERAS can make open surgery LOS approximate MIS without ERAS

ERAS benefits are less significant in MIS surgery, but still present over conventional peri-operative management

Most of the benefit appears to come from the MIS approach with regards to functional recovery and milestones for discharge readiness

Patient Reported Outcomes do not appear to improve

The combination of MIS and ERAS appear to have an additive effect

This is consistent across specialty applications (GYN, HPB, GI)

Are ERAS and MIS synergistic or does one cancel the other out?

MIS approaches allow for some modification of ERAS components

Most centers with MIS do not use epidural analgesia

TAP block utilization appears higher in MIS

HALS appears to manifest more closely with open than pure MIS

Robotic and laparoscopic are equivalent

What are the questions that we are asking?

Are ERAS pathway benefits preserved in laparoscopic surgery? **YES**

Does laparoscopic surgery offer a benefit distinct from ERAS? **YES**

Does laparoscopic surgery change some of the elements of the ERAS pathway? **MAYBE**

Conclusions

ERAS is a significant milestone in improving process of care for better outcomes

MIS is a significant milestone in technical surgery for better outcomes

ERAS and MIS together offer the best available treatment program where feasible and appropriate.

We need standardization of reporting for surgical outcomes