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New Approaches

Non-invasive measurement of intestinal tissue oxygen saturation for evaluation of reconstructed blood flow in rectal cancer surgery: the HiSCO-09 study

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Data availability statement

The data that support the findings of this study are not openly available due to (reasons of sensitivity e.g. human data) and are available from the corresponding author upon reasonable request.

Introduction

Anastomotic leakage (AL) is one of the most serious complications of colorectal cancer (CRC) surgery[1-3], and interruption to anastomotic blood flow is considered an important risk factor for its occurrence. .[4 5] The effectiveness of blood flow evaluation using indocyanine green fluorescence angiography (ICG-FA) has been verified in several clinical trials, [6-10] however this method of evaluation has limitations in terms of quantitation and objectivity, and carries a risk of anaphylaxis.

Considering these limitations, this study focused on the measurement of tissue oxygen saturation (rSO2) using INVOS™ (manufactured by Covidien), a device that employs near-infrared spectroscopy (NIRS) to quantitatively measure tissue oxygen saturation. NIRS-based rSO2 measurements have been widely used to monitor cerebral blood flow during cardiovascular surgery. The hypothesis of this study therefore was that rSO2 measurements using NIRS could be used to evaluate anastomotic blood flow in the bowel.[11 12]

To mitigate the risk of AL in left-sided colorectal surgery, preservation of the left colic artery (LCA) is frequently performed to maintain blood flow. In theory, preservation of the LCA may enhance blood flow to the site of the planned reconstruction. This multicentre prospective study was planned to examine the utility of rSO2 measurement using INVOS™ for assessing anastomotic intestinal blood flow, with or without preservation of the LCA, and evaluate whether this correlates with AL.

Methods

A multicentre prospective observational study was conducted at seven centres of the Hiroshima Surgical Study Group of Clinical Oncology (HiSCO). The inclusion criteria were patients with: 1. left-sided CRC who underwent reconstruction using the double-stapling technique with an automated suture device; 2. Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) 0 or 1; 3. American Society of Anesthetists (ASA) Physical Status class 1 or 2; 4. ages between 20 and 80 years at the time of consent. The exclusion criteria were patients who were: 1. scheduled to undergo more than one anastomosis ; 2. scheduled to undergo simultaneous resection of other organs due to multiple cancers; 3. suffering with intra-abdominal infection (peritonitis or abscess); 4. deemed ineligible by the physician in charge.

Consistent with the guidelines of the Declaration of Helsinki (Fortaleza, Brazil, October 2013), this study was approved by the Institutional Review Board and registered with the Japanese Clinical Trials Registry (UMIN-CTR000038179).

Near-infrared spectroscopy

Non-invasive tissue oxygenation was measured using an INVOS^{TM} 5100C oximeter (Medtronic, JA, USA). This monitor uses a light-emitting diode that generates near-infrared light at two wavelengths (730 and 810 nm), and two silicon photodiodes that act as light detectors. These data are interpreted as a single numerical value expressed as rSO2.

Measurement of rSO2 and study endpoints

The rSO2 values were measured at three locations both before and after division of the mesentery: the planned anastomosis site (B, E), 10cm on the oral side of the anastomosis (A, D), and 10cm on the anal side of the anastomosis (C, F) (**Figure 1A**). Measurements were taken by the operating surgeon, with no intervention or change to the operative strategy based on these measurements. Details of the surgical technique and methodology for acquiring the rSO2 measurements are presented in Supplementary Methods. . The primary endpoint was to explore variations in rSO2 values with or without LCA preservation. The secondary endpoint was to correlate rSO2 with AL.

Results

Between October 2019 and September 2021, 302 patients were enrolled of which 291 were included in the analysis. Eleven patients were excluded because of an inability to perform a double stapled anastomosis (N=6), failure of measurement (N=2), poor performance status (N=1), multiple cancers (N=1) or sensor failure (N=1). Patient characteristics and surgical outcomes are shown in **Supplementary Table 1**. LCA preservation was performed in 94 (32.3%) patients and postoperative AL occurred in 25 (8.6%).

The rSO2 measurements are shown in **Figure 1B**. Both before and after mesenteric resection, rSO2 was significantly higher from the anal side to the oral side. Notably the rSO2 at point D (beyond the division of the vessel and after division of the mesentery) was clearly lower than that at all other points, suggesting that rSO2 reflects arterial blood flow.

Propensity score matching was used to allow independent assessment of changes in rSO2 associated with LCA preservation (**Supplementary Table 2**). In an analysis of 178 patients adjusted for patient factors, rSO2 was significantly higher with LCA preservation - at all measurement sites (**Supplementary Table 3**).

The rSO2 value at the anastomotic site (E) was lower in the AL group (69% vs. 77%, p=0.038); a ROC curve was generated to determine a cutoff value of 74%. Results of the univariate and multivariate analyses of AL are presented in **Table 1,** demonstrating that an rSO2 value of ≤74% at the anastomotic site (E) after division of the mesentery was an independent predictor of AL (OR, 3.35 [95%CI: 1.13–9.94], P =0.029).

Discussion

The need for precision surgery has led to the widespread use of intraoperative perfusion assessment with ICG-FA in gastrointestinal surgery. Jafari et al. reported the utility of ICG-FA in preventing AL6, however a subsequent multicentrerandomizedphase III clinical trial found that ICG-FA failed to decrease the occurrence of AL, although it permitted the visualisation of intestinal blood flow. [7] The study authors acknowledged that the early termination of the case series and the inability to quantitatively measure ICG-FA made it a subjective assessment of perfusion by the surgeon.

Several studies have assessed intestinal perfusion using rSO2 and new devices are also being evaluated for practical applications. [13] [14]In this study, the focus was on a quantifiable measure of rSO2 using INVOS™. The findings revealed that rSO2 was notably lower in areas distant from the nutrient vessels, that is, regions of increased ischaemia, both before and after division of the mesentery. These results suggest that rSO2 may be a valid means of quantitatively and objectively assessing intestinal blood flow. As the rSO2 value increases towards the oral side of the intestine, setting the anastomotic line with reference to the rSO2 value may prevent postoperative AL. In addition, the fact that rSO2 at the planned anastomotic site was an independent risk factor for AL is a novel finding.

This study focused on the changes in rSO2 with and without LCA preservation . Although LCA preservation may be beneficial in terms of blood flow, previous reports have yielded mixed results on the prevention of AL. [15-18] In the present study higher rSO2 readings were obtained with LCA-sparing, suggesting that this may be a viable means of maintaining good intestinal blood flow.

This study's main limitation is that whilst it is a multicentre prospective study it is not a randomized controlled trial, and due to the potential for confounders cannot directly evaluate the effectiveness of rSO2 quantification with INVOS™ for prevention of AL.

In conclusion, the use of INVOS™ to measure rSO2 may serve as a noninvasive, quantitative marker of intestinal perfusion andmay therefore have a role in reducing the incidence of AL. Furthermore, preservation of the LCA may be significant in maintaining intestinal blood flow, and further investigation is warranted to determine its role in the prevention of AL.

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Figure legends

Figure 1A

Locations of measurement for rSO2 are shown. Ten centimeters from the anal side of the planned anastomosis site (before mesenteric resection, point A; after mesenteric resection, point D), the planned anastomosis site (before mesenteric resection, point C; after mesenteric resection, point E), and 10 cm from the oral side of the planned anastomosis site (before mesenteric resection, point C; after mesenteric resection, point F). Point E indicates the blood flow at the reconstructed anastomosis site.

This figure shows a case without preservation of the left colic artery.

Figure 1B

Box plots of the rSO2 values of each site are shown. Both before and after mesenteric resection, rSO2 was significantly higher from the anal side to the oral side. Notably, the rSO2 at point D with no arterial inflow was clearly lower than that at other points, suggesting that rSO2 reflects arterial blood flow.

＊: $P < 0.05$

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Table 1 Risk factors for anastomotic leakagein univariate and multivariate analysis

		Univariate		p value	Multivariate		p value
		OR	95% CI		OR	95% CI	
Age (years)	≧65	1.25	0.54-2.94	0.603			
	<65	Reference					
Sex	Male	2.49	0.91-6.84	0.077			
	Female	Reference					
BMI	>25	1.24	0.48-3.23	0.655			
	≤25	Reference					
ECOG Performance Status	1	4.03	1.20-13.60	0.025	5.18	1.10-24.45	0.038
	0	Reference			Reference		
ASA-PS	2	2.79	0.64-12.23	0.173			
	1	Reference					
Diabetes	Present	2.44	0.99-6.01	0.052			
	Absent	Reference					
Steroid use	Present	5.70	0.99-32.78	0.051			
	Absent	Reference					
Anticoagulant drug use	Present	1.20	0.26-5.49	0.816			
	Absent	Reference					
Ischemic Heart Disease	Present	2.48	0.51-12.18	0.262			
	Absent	Reference					
Anaemia	Present	1.34	0.16-11.2	0.785			
	Absent	Reference					
Preoperative bowel obstruction	Present	2.62	0.81-8.47	0.107			
	Absent	Reference					
Neoadjuvant therapy	Present	8.06	2.41-26.94	＜0.001	1.04	0.19-5.72	0.96
	Absent	Reference			Reference		
Tumour Stage	Ⅲ-Ⅳ	1.73	0.74-4.02	0.203			
	0-Ⅱ	Reference					
Tumour Location	Mid-Low	4.83	2.07-11.29	＜0.001	5.24	1.56-17.67	0.008
	Upper	Reference			Reference		
Operation time (min)	≧262	6.19	2.56-14.98	＜0.001	4.61	1.40-15.12	0.012
	＜262	Reference			Reference		
Blood loss (ml)	≧38	3.57	1.55-8.21	0.003	1.93	0.66-5.63	0.227
	＜38	Reference			Reference		
Left colic artery	resection	6.08	1.40-26.36	0.016	5.34	1.06-26.95	0.043
	preservation	Reference			Reference		
Lateral lymph node dissection	Present	6.14	1.71-22.09	0.005	0.99	0.18-5.34	0.988

	Absent	Reference			Reference		
Number of Stapler Firings	≧3	6.14	1.71-22.09	0.005	3.30	0.65-16.72	0.150
	1-2	Reference			Reference		
Diverting stoma	Present	3.09	1.33-7.18	0.009	0.25	0.06-1.08	0.064
	Absent	Reference			Reference		
Transanal drain	Present	1.43	0.47-4.34	0.53			
	Absent	Reference					
rSO2(E)	≦74	3.06	1.28-7.34	0.012	3.35	1.13-9.94	0.029
	74＞	Reference			Reference		

rSO2(E): rSO2 measured at the planned anastomosis site after mesenteric resection.

Abbreviations: BMI, body mass index; PS, performance status; ASA-PS, American Society of Anesthesiologists Physical Status; LCA, left colic artery, CD, Clavien-Dindo Classification.

Figure 1A

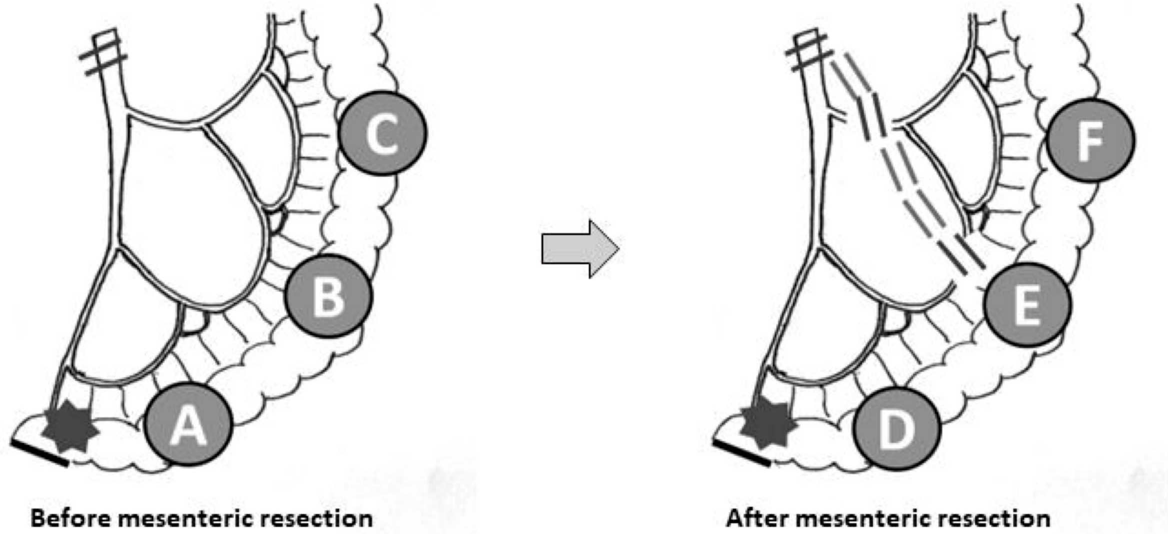
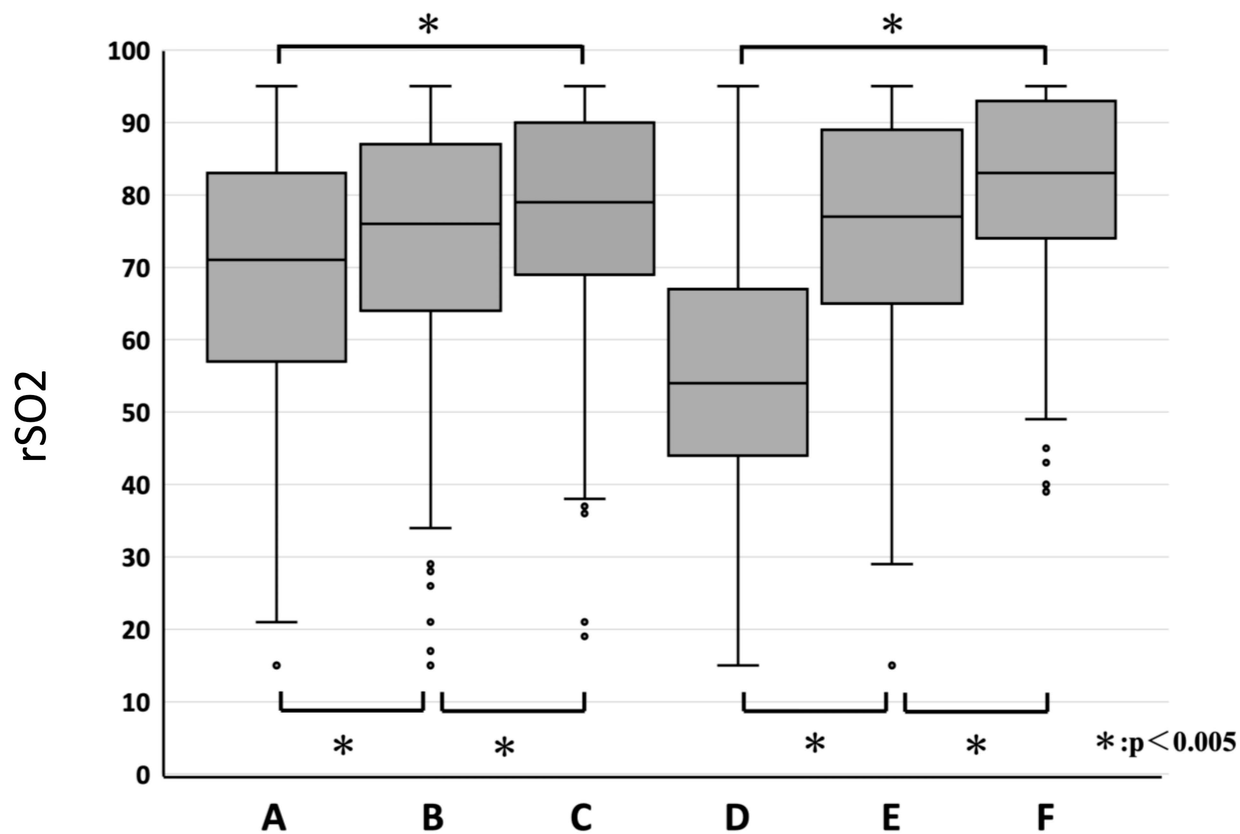


Figure 1B



Noninvasive measurement of intestinal tissue oxygen saturation using near-infrared light for objective and quantitative evaluation of reconstructed intestinal blood flow in rectal cancer surgery -the HiSCO-09 study-

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Supplementary Materials - Index

Supplementary Methods

Details of surgery and measurement of rSO2

Conventional open surgery was performed in patients with bulky tumourrs or a history of major abdominal surgery. The remaining patients underwent laparoscopic surgery via the medial-to-lateral approach. Vascular ligation with lymph node dissection was performed in the standard manner. Preservation of the left colic artery (LCA) was left to the preference of the surgeon in charge. As in the pilot study, measurements were performed on INVOS™ commercially available probes with sterile ultrasound covers. All surgeons performed the measurements without any problems. Measurements of rSO2 were performed three times, and the median value was recorded. The results of the three measurements were analysed using the intraclass correlation coefficient(ICC), and all sites from site A to site F were found to be free of variation(ICC(1,3): >0.9). Reconstruction was performed using an end-to-end double stapling technique with a circular stapler. The creation of a diverting stoma, transanal drain insertion, intraperitoneal drain insertion, and reinforcement of the anastomosis (such as supplementary post-anastomotic ligation) were performed at the discretion of the surgeon.

Definition of anastomotic leakage

Anastomotic leakage (AL) was diagnosed based on clinical symptoms and signs such as changes in drain colouration and the presence of fever with peritonitis. On radiographic examination, AL was diagnosed based on the presence of contrast leakage on digestive tract radiography, gas accumulation around the anastomosis site, and/or discontinuity of the intestinal wall on computed tomography. Alwas also classified using the Clavien–Dindo Classification.

Statistical analysis

Categorical variables are shown as frequencies and percentages, and continuous variables as median and range. Fisher's exact test was used to compare categorical variables between the LCA preservation and non-preservation groups. Multiple logistic regression analysis was used for multivariate analysis. Propensity score matching was implemented to account for differences in patient characteristics with and without LCA preservation. We used propensity score models adjusted for anticoagulant drug use, neoadjuvant therapy, disease stage, and institution. Propensity score matching was

implemented using a nearest-neighbor strategy. We used a 1:1 ratio within a caliper width of 0.2 of the standard deviation of the logit of the propensity score.
Statistical significance was set at $P < 0.05$. All statistical calculations were performed using the statistical software program JMP software, ver15.0(SAS Institute Inc., Cary, NC, USA).

Suplementary Tables

Supplementary Table 1. Patient characteristics and surgical outcomes

Characteristic		Patients, No. (%)
Age (years)	median (range)	67 (34-79)
Sex	Male	184 (63.2%)
	Female	107 (36.8%)
BMI	median (range)	22.6 (15.7- 34.1)
PS	0	275 (94.5%)
	1	16 (5.5%)
ASA-PS	1	54 (18.6%)
	2	237 (81.4%)
Diabetes		51 (17.5%)
Steroid use		6 (2.1%)
Anticoagulant drug use		20 (6.9%)
Ischemic Heart Disease		11 (3.8%)
Anaemia		8 (2.7%)
Preoperative bowel obstruction		22 (7.6%)
Neoadjuvant therapy		13 (4.5%)
Stage	0	1 (0.3％)
	Ⅰ	139 (47.8%)
	Ⅱ	67 (23.0%)
	Ⅲ	67 (23.0%)
	Ⅳ	17 (5.9%)
Location	Sigmoid	72 (24.7%)
	Upper rectum	141 (48.5%)
	Mid rectum	49 (16.8%)
	low rectum	29 (10.0%)
Approach	Laparoscopic	255 (87.6%)
	Robot-assisted	32 (11.0%)
	Open	4 (1.4%)
Operation time	median (range)	220 (110 – 545)
Blood loss (ml)	median (range)	19 (0 – 400)
LCA	preservation	94 (32.3%)
	non-preservation	197 (67.7%)
Lateral lymph node dissection		12 (4.1%)
Number of Stapler Firings	≧3	12 (4.1%)
	1-2	279 (95.9%)
Diverting stoma		65 (22.2%)
Transanal drain		230 (79.0％)
Anastomotic Leakage	CD ALL grade	25（8.6％）

CD grade3＞	21（7.2％）

Abbreviations: BMI, body mass index; PS, performance status; ASA-PS, American Society of Anesthesiologists Physical Status; LCA, left colic artery; CD, Clavien-Dindo Classification

Supplementary Table 2. Propensity score matching of left colic artery preservation and resection groups

Characteristic		Before matching			After matching		
		Patients, No. (%)		p value			p value
		LCA non-preservation N=197	LCA preservation N=94		LCA non-preservation N=74	LCA preservation N=74	
Age (years)		67 (37-79)	68.5 (34-79)	0.682	68 (38-79)	68 (42-79)	0.345
Sex	Male	129 (65.5%)	55 (58.5%)	0.298	47 (63.5%)	44 (59.5%)	0.736
	Female	68 (34.5%)	39 (41.5%)		27 (36.5%)	30 (40.5%)	
BMI	25＞	149 (75.6%)	61 (64.9%)	0.069	17 (23.0%)	25 (33.8%)	0.202
	≤25	48 (24.4%)	33 (35.1%)		57 (77.0%)	49 (66.2%)	
PS	0	186 (74.7％)	89 (94.7％)	1.000	68 (91.9％)	71 (96.0％)	0.494
	1	11 (5.6％)	5 (5.3％)		6 (8.1％)	3 (4.0％)	
ASA-PS	1	38 (19.3%)	16 (17.0%)	0.748	17 (22.3%)	13 (17.6%)	0.540
	2	159 (80.7%)	78 (83.0%)		57 (77.0%)	61 (82.4%)	
Diabetes		33 (16.8%)	18 (19.2%)	0.624	14 (18.9%)	10 (13.5%)	0.504
Steroid use		5 (2.5%)	1 (1.1%)	0.668	1 (1.4%)	1 (1.4%)	1.000
Anticoagulant drug use		9 (4.6%)	11 (11.7%)	0.044	6 (8.1%)	6 (8.1%)	1.000
Ischemic Heart Disease		8 (4.1%)	3 (3.2%)	1.000	2 (2.7%)	1 (1.4%)	1.000
Anemia		8 (4.1%)	1 (1.1%)	0.280	3 (4.1%)	1 (1.4%)	0.620
Preoperative bowel obstruction		17 (8.6%)	5 (5.3%)	0.477	7 (9.5%)	4 (5.4%)	0.533
Neoadjuvant therapy		13 (6.6%)	0 (0.0%)	0.011	0 (0.0%)	0 (0.0%)	-
Stage	0-Ⅱ	128 (65.0%)	79 (84.0%)	＜0.001	60 (81.1%)	59 (79.7%)	1.000
	Ⅲ-Ⅳ	69 (35.0%)	15 (16.0%)		14 (18.9%)	15 (20.3%)	
Location	S-Upper	146 (74.1%)	69 (73.4%)	0.888	57 (77.0%)	56 (75.7%)	1.000
	Mid-Low	51 (25.9%)	25 (26.6%)		17 (23.0%)	18 (24.3%)	
Anastomotic Leakage	CD-ALL Grade	23 (11.7%)	2 (2.1%)	0.006	9 (12.2%)	1 (1.4%)	0.018

Abbreviations: BMI, body mass index; PS, performance status; ASA-PS, American Society of Anesthesiologists Physical Status; LCA, left colic artery; CD, Clavien-Dindo Classification.

Supplementary Table 3. Tissue oxygen saturation (rSO_2) at each measurement site in left colic artery (LCA) resection and preservation groups

	LCA resection N=74	LCA preservation N=74	p value
A	65 (15-95)	75 (15-95)	0.021
B	69 (15-95)	80 (26-95)	<0.001
C	78.5 (19-95)	84 (49-95)	0.013
D	53 (15-94)	60 (15-91)	0.009
E	68.5 (29-95)	79 (15-95)	<0.001
F	80 (39-95)	87.5 (45-95)	0.003

Variables are expressed as median (range).See Figure 1 for measurement sites