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## Profilo corporeo e Rimodellamento Stomale: Valutazione e Esiti nella Chirurgia Intestinale



## HEALTH RELATED QUALITY OF LIFE

"<u>Health</u> is a state of complete physical, mental and social well-being and not merely the absence of disease" The domains of physical, emotional and social well-being are incorporated by this definition into the concept of quality of life.

World Health Organization. The first 10 years of the World Health Organization. Geneva, 1958.

"<u>Quality of life</u> is defined as an individual's perception of their position in life in the context of the culture and value system in which they live and in relation to their goals, expectations and standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, and their relationship to salient features of their environment"

Bowling A. Measuring Disease. Buckingham: Open University Press, 2001





"Quality of life is the gap between a person's expectations and achievement"

Calman KC. J Med Ethics 1984; 124: 10.

"<u>Health related quality of life</u> represents the functional effect that an illness and its consequent therapy have on a patient, as perceived by the patient him/herself"

Olweny CL. Quality of life in cancer care. Med J Aust 1993; 158: 429-432.

### BUT

'Scientists may use rating scales and visual analogue scales to measure pain, and they may even invent scoring systems quantifying types of handicaps; but when they talk about <u>measuring quality of life</u> they have gone <u>too far</u>'

Wulff H. J R Soc Med 1999; 92:549–52



Traditional outcome measures for assessing surgical procedure

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- 1. morbidity
- 2. mortality

## Why is it necessary to measure quality of life?

Today, indications for surgery are broader:

failure of medical therapy

poor quality of life on it self,

palliation of incurable diseases.

### In these situations the goal of surgery is not to improve survival but to improve quality of life

<u>Physiologic outcomes</u> provide information to the clinicians but are of limited interest to patients and often correlate poorly with well being.

**Quality of life** is a more patient orientated measure of outcome that provides a more formal means for the patient's judgement and desires to influence treatment decisions.





# Performing a Health Related Quality of Life (HRQOL) assessment



provides important information to

- patients
- caregivers
- health care providers



make feasible planning effective intervention on QoL issues

# PATIENT-REPORTED OUTCOME

Il termine *patient-reported outcome*, letteralmente 'esito riferito dal paziente', è stato introdotto nel 2000 dalla Food and Drug Administration (FDA), che nel 2009 ha pubblicato una guida sull'utilizzo di misure di esito riferite dal paziente rivolta alle industrie farmaceutiche, interessate ad inserire i risultati nel foglietto illustrativo del farmaco (*labeling claims*)<sup>1</sup>. Nella guida l'FDA definisce *patient-reported outcome* qualsiasi esito riguardante lo stato di salute riferito direttamente dal paziente, senza alcuna interpretazione da parte del clinico o di altri.

# • Introduction

# Patient reported outcome measures could help transform healthcare

Nick Black professor of health services research

BMJ 2013;346:f167 doi: 10.1136/bmj.f167 (Published 28 January 2013)

#### Box 1: Why consider patients' views?

Most healthcare aims to reduce symptoms, minimise disability, and improve quality of life-these are aspects that only patients can assess

Patients welcome being involved, and this may have health benefits in itself

Patients' response rates are invariably better than clinicians' (a patient only has to complete one questionnaire whereas a clinician has to do it for every patient)

The measure avoids observer bias (inevitable if asking clinicians to assess their own practice)

Considering patients' views increases public accountability of health services and healthcare professionals

# • Introduction

# Patient reported outcome measures could help transform healthcare

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#### Box 2: Example of a disease specific and a generic PROM

Disease specific PROM: Oxford Hip Score

Twelve questions about how the patient has been over the previous 4 weeks covering pain (4 items), mobility (3 items), and activities (5 items). Five possible answers scored from 0 to 4, creating overall scale of 0 (severe disease) to 48 (no problems).

Example questions:

During the past 4 weeks have you been able to climb a flight of stairs?

Yes, easily/With little difficulty/With moderate difficulty/With extreme difficulty/No, impossible

During the past 4 weeks how would you describe the pain you usually had from your hip? None/Very mild/Mild/Moderate/Severe

During the past 4 weeks could you do the household shopping on your own?

Yes, easily/With little difficulty/With moderate difficulty/With extreme difficulty/No, impossible

#### Generic PROM: EuroQol EQ-5D

Five questions seeking information that best describes the patient's health that day, covering mobility, self care, usual activities, pain/discomfort, anxiety/depression. Three possible answers: no problem; some problem; severe problem.

Example questions:

Self care: I have no problems with self care/I have some problems washing or dressing myself/I am unable to wash or dress myself.

Anxiety/depression: I am not/moderately/extremely anxious or depressed.

# PART 1. Quality of life after colorectal surgery for cancer

- 1. Health-related quality of life and functional results after rectal resection for cancer
- 2. Health-related quality of life and functional results after colectomy for cancer
- 3. Quality of life after transanal surgery for rectal cancer













Quality of life after surgery for rectal cancer

Health-related quality of life, faecal continence and bowel function in rectal cancer patients after chemoradiotherapy followed by radical surgery

Salvatore Pucciarelli • Paola Del Bianco • Fabio Efficace • Paola Toppan • Samantha Serpentini • Maria Luisa Friso • Sara Lonardi • Gian Luca De Salvo • Donato Nitti

185 consecutive patients underwent surgery after chemoradiotherapy from January 1994 to October 2004 38 patients died 147 still alive in October 2004 46 patients excluded because: -Not radical surgery, n=13 -Lost to follow-up, n=6 -Recurrence, n=8 -Not understanding Italian, n=2 101 eligible patients -Depression, n=1 -Second primary tumor, n=1 -Still with stoma, n=15 20 patients uncompleted questionnaires 81 (80%) included in the analysis.



#### Health-related quality of life, faecal continence and bowel function in rectal cancer patients after chemoradiotherapy followed by radical surgery

Salvatore Pucciarelli · Paola Del Bianco · Fabio Efficace · Paola Toppan · Samantha Serpentini · Maria Luisa Friso · Sara Lonardi · Gian Luca De Salvo · **Donato Nitti** 

Table 2 Bowel function of the           81 patients who returned the           seemplated questionnaires	Variable	N	Percent	
completed questionnaires	Bowel mov	vements/d	lay <sup>a</sup>	
	>3	36	46	
	≤3	43	54	
	Use of pad			
	Yes	35	43	
	No	46	57	
	Stool fracti	onation <sup>a</sup>		
	Yes	33	42	
	No	46	58	
	Urgency <sup>a</sup>			
	Yes	32	40	
	No	47	60	
	Enema/laxa	ative		
	Yes	24	30	
	No	57	70	
	Incomplete	bowel e	vacuation	
	Yes	24	30	
8 M	No	57	70	
<sup>a</sup> Missing: two patients				

Table 3 Faecal incontinence of the 81 patients who returned the completed questionnaires

Continence	Ν	Percent
Fully continent	5	6
Incontinent to gas	17	21
Incontinent to seepage	8	10
Incontinent to liquids or solids rarely	14	18
Incontinent to liquids or solids >monthly	16	20
Incontinent to liquids or solids >weekly	10	12
Incontinent to liquids or solids daily	6	7
Incontinent to liquids or solids >daily	4	5
Missing	1	1
Total	81	100.0

<sup>a</sup> Missing: two patients

in ne

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#### Health-related quality of life, faecal continence and bowel function in rectal cancer patients after chemoradiotherapy followed by radical surgery

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Comparison HRQOL outcomes with population-based norms

No clinically meaningful differences ( $\geq 10$  points) were observed between patients and healthy controls in terms of global health status/QOL as well as physical, role, social, emotional and cognitive functioning. However, the social functioning scale was lower than that of the general population (Fig. 2). As for symptom-related aspects, patients showed a meaningful improved score for pain (7.6 vs. 20.5;  $\Delta = 12.9$ ), but remarkably worse outcomes in terms of constipation (23.6 vs. 4.6;  $\Delta = 19$ ) and diarrhoea (16.5 vs. 2.6;  $\Delta = 13.9$ ) (Fig. 3).





Analysis of morbidity and mortality, quality of life and bowel function after total colectomy with ileorectal anastomosis versus right and left hemicolectomy: A study to optimise the treatment of lynch syndrome and attenuated polyposis coli

Emanuele D.L. Urso <sup>a</sup>, Francesco Celotto <sup>a</sup>, Francesca Giandomenico <sup>b</sup>, Teresa Gavaruzzi <sup>b</sup>, Paola Del Bianco <sup>c</sup>, Lorella Lotto <sup>b</sup>, Gaya Spolverato <sup>a</sup>, Salvatore Pucciarelli <sup>a</sup>, Quoc Riccardo Bao <sup>a,\*</sup>

European Journal of Surgical Oncology 46 (2020) 1613-1619

	Group A	Group B	Group C	p value	p value
	TC-IRA (n = 55)	RH (n = 55)	LH/SI (n = 55)	A vs B	A vs C
Wound infection	3 (5%)	9 (16%)	0	0.12	0.24
UTI	3 (5%)	1 (2%)	4 (7%)	0.62	1
Abscess	3 (5%)	2 (4%)	0	1	0.24
Sepsis	0	1 (2%)	2 (4%)	1	0.49
Pulmonary	0	1 (2%)	3 (5%)	1	0.24
DVT	0	1 (2%)	0	1	1
PE	0	0	1 (2%)	1	1
Cardiac	1 (2%)	0	2 (4%)	1	1
Neurologic	1 (2%)	0	2 (4%)	1	1
Haemorrhage	0	1 (2%)	1 (2%)	1	1
Anastomotic leak	0	1 (2%)	2 (4%)	1	0.49
Other	2 (4%)	0	3 (5%)	0.49	1
Reoperation	4 (7%)	5 (9%)	1 (2%)	1	0.36
Overall	15 (27%)	16 (29%)	14(25%)	0.83	0.83
Severe (CD 3-4)	5 (9%)	6 (11%)	4 (7%)	0.75	0.73
Mortality (CD 5)	0	0	2 (4%)	1	0.49

Postoperative morbidity and mortality.

CD: Clavien-Dindo grade; DVT: deep venous thrombosis; LH/SI: Left Hemicolectomy/Sigmoidectomy; PE: pulmonary embolism; RH: Right Hemicolectomy; TC-IRA: Total Colectomy with Ileorectal Anastomosis; UTI: urinary tract infection.

Analysis of morbidity and mortality, quality of life and bowel function after total colectomy with ileorectal anastomosis versus right and left hemicolectomy: A study to optimise the treatment of lynch syndrome and attenuated polyposis coli

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#### European Journal of Surgical Oncology 46 (2020) 1613-1619



	Group A	Group B	Group C	p value	p value
	TC-IRA (n = 55)	RH (n = 55)	LH/SI (n = 55)	A vs B	A vs C
Age, years (range)	56 (31-81)	57 (31-80)	57 (25-86)	0.46	0.85
Sex, male (%)	35 (64%)	35 (64%)	35 (64%)	1	1
ECOG Performance status n (%)				0.97	0.93
0	4 (7%)	3 (6%),	6 (11%)		
1	28 (51%)	27 (49%)	27 (49%)		
2	17 (31%)	20 (36%)	18 (33%)		
3	6 (11%)	5 (9%)	4 (7%)		
BMI, Kg/m² (range)	24.8 (19-36)	24.6 (18-45.7)	26 (17.7-35.8)	0.70	0.78
Previous GI surgery, n (%)	22 (40%)	27 (49%)	27 (49%)	0.36	0.48
Neoadjuvant chemotherapy, n (%)	0 (0%)	1 (2%)	3 (6%)	0.32	0.08
Adjuvant chemotherapy, n (%)	20 (36%)	23 (42%)	26 (47%)	0.66	0.25
Tumor size, cm (range)	3 (0.4-23)	4(0.5-25)	3.7 (1-13.5)	0.09	0.36
Open procedure, n (%)	40 (73%)	44 (80%)	37 (67%)	0.46	0.53

LH/SI: Left Hemicolectomy/Sigmoidectomy. RH: Right Hemicolectomy. TC-IRA: Total Colectomy with Ileorectal Anastomosis.





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No difference in term of body image



Bowel function and quality of life after local excision or total mesorectal excision following chemoradiotherapy for rectal cancer

S. Pucciarelli<sup>1</sup>, F. Giandomenico<sup>1</sup>, A. De Paoli<sup>5</sup>, T. Gavaruzzi<sup>2</sup>, L. Lotto<sup>2,3</sup>, G. Mantello<sup>7</sup>, C. Barba<sup>8</sup>, P. Zotti<sup>6</sup>, S. Flora<sup>5,6</sup> and P. Del Bianco<sup>4</sup>



Fig. 1 Flow chart for the study. TME, total mesorectal excision



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 Table 2 Comparison of quality of life between local excision and total mesorectal excision groups according to the European Organization for Research and Treatment of Cancer QLQ-C30 questionnaire

		TME	P*
Physical functioning	89.7 (85.2, 94.1)	90.2 (86.2, 94.2)	0.568
Role functioning	90.8 (86.2, 95.4)	88.2 (82.9, 93.4)	0.402
Emotional functioning	85.4 (80.6, 90.1)	83.2 (77.8, 88.6)	0.949
Cognitive functioning	90.2 (85.9, 94.6)	84.1 (78.5, 89.8)	0.128
Social functioning	88.8 (83.0, 94.6)	83.9 (77.7, 90.0)	0.167
Global health status	75.3 (69.4, 81.2)	73.9 (67.6, 80.3)	0.981
Fatigue	12.2 (7.4, 16.9)	15.6 (11.0, 20.2)	0.198
Nausea/vomiting	2.9 (0.0, 6.7)	1.6 (0.0, 3.3)	0.796
Pain	5.5 (2.2, 8.7)	10.6 (5.3, 15.9)	0.287
Dysphoea	10.3 (5.1, 15.6)	4.8 (1.1, 8.5)	0.046
Insomnia	15.8 (9.5, 22.1)	14.5 (8.9, 20.2)	0.819
Appetite loss	4.0 (0.0, 8.4)	4.8 (1.5, 8.2)	0.306
Constipation	3.8 (0.3, 7.2)	19.8 (12.1, 27.4)	< 0.001
Diarrhoea	11.9 (5.9, 18.0)	21.6 (13.7, 29.5)	0.062
Financial problems	6.3 (2.2, 10.5)	10.6 (4.4, 16.8)	0.521



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	LE	TME	P*
Body image	86.8 (81.0, 92.6)	83.0 (77.5, 88.4)	0.142
Anxiety	77.6 (71.8, 83.4)	77.2 (70.5, 84.0)	0.755
Weight	86.2 (80.3, 92.1)	89.9 (85.3, 94.6)	0.361
Sexual function, men	56.1 (46.2, 66.0)	54.0 (44.8, 63.1)	0.776
Sexual function, women	83.3 (70.4, 96.3)	86.7 (75.0, 98.3)	0.743
Urinary frequency	19.3 (12.5, 26.0)	18.0 (13.0, 23.0)	0.789
Blood and mucus in stool	3.2 (1.1, 5.2)	4.5 (1.9, 7.1)	0.679
Stool frequency	14.7 (9.0, 20.4)	25.8 (18.8, 32.7)	0.016
Urinary incontinence	6.9 (2.0, 11.8)	9.0 (4.4, 13.6)	0.286
Dysuria	3.4 (0.8, 6.1)	3.2 (0.0, 6.8)	0.447
Abdominal pain	8.0 (3.9, 12.2)	7.9 (3.5, 12.4)	0.816
Buttock pain	6.9 (3.0, 10.8)	15.3 (8.8, 21.9)	0.074
Bloated feeling	13.8 (8.3, 19.2)	22.2 (16.2, 28.3)	0.031
Dry mouth	12.1 (6.7, 17.4)	10.1 (6.2, 13.9)	0.821
Hair loss	0.6 (0.0, 1.7)	4.2 (1.0, 7.4)	0.038
Trouble with taste	1.7 (0.0, 3.7)	6.9 (2.6, 11.2)	0.053
Flatulence	23.8 (16.8, 30.9)	34.5 (27.0, 42.1)	0.043
Faecal incontinence	17.4 (9.4, 25.3)	24.8 (17.1, 32.6)	0.108
Sore skin	11.6 (5.5, 17.6)	19.4 (11.9, 26.9)	0.127
Embarrassed by bowel movement	13.3 (5.2, 21.5)	18.2 (10.9, 25.5)	0.159
Impotence	39.0 (25.6, 52.5)	62.3 (51.1, 73.4)	0.011
Dyspareunia	10.4 (0.0, 21.1)	7.1 (0.0, 15.3)	0.756



Bowel function and quality of life after local excision or total mesorectal excision following chemoradiotherapy for rectal cancer

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#### *BJS* 2017; **104**: 138–147

S. Pucciarelli<sup>1</sup>, F. Giandomenico<sup>1</sup>, A. De Paoli<sup>5</sup>, T. Gavaruzzi<sup>2</sup>, L. Lotto<sup>2,3</sup>, G. Mantello<sup>7</sup>, C. Barba<sup>8</sup>, P. Zotti<sup>6</sup>, S. Flora<sup>5,6</sup> and P. Del Bianco<sup>4</sup>

 Table 4 Comparison of quality of life between local excision and total mesorectal excision groups according to the Memorial

 Sloan-Kettering Cancer Center Bowel Function Instrument

	LE	TME	P*
Frequency	21.9 (20.5, 23.3)	20.3 (19.0, 21.7)	0.099
Dietary	15.2 (14.1, 16.2)	14.2 (13.0, 15.3)	0.211
Urgency/soiling	15.7 (14.6, 16.8)	14.0 (12.6, 15.3)	0.080
Incomplete emptying after a bowel movement	3.7 (3.4, 4.0)	2.8 (2.5, 3.1)	< 0.001
Second bowel movement within 15 min	3.6 (3.3, 3.9)	3.0 (2.7, 3.3)	0.006
Knowing difference between gas and bowel movements	4.5 (4.3, 4.7)	4.1 (3.8, 4.4)	0.048
Unable to control passage of flatus	3.4 (3.0, 3.8)	3.1 (2.7, 3.5)	0.181
Total score	67.9 (64.1, 71.7)	60.9 (56.8, 64.9)	0.012

**Conclusion:** Patients who underwent local excision had a better quality of life and bowel function than those who underwent mesorectal excision.

Systematic Review

#### **Rectal Sparing Approaches after Neoadjuvant Treatment for Rectal Cancer: A Systematic Review and Meta-Analysis Comparing Local Excision and Watch and Wait**

Quoc Riccardo Bao <sup>1</sup>, Stefania Ferrari <sup>1</sup>, Giulia Capelli <sup>1,2</sup>, Cesare Ruffolo <sup>1</sup>, Marco Scarpa <sup>1,\*</sup>, Amedea Agnes <sup>3</sup><sup>(D)</sup>, Giuditta Chiloiro <sup>4</sup><sup>(D)</sup>, Elisa Palazzari <sup>5</sup>, Emanuele Damiano Luca Urso <sup>1</sup><sup>(D)</sup>, Salvatore Pucciarelli<sup>1</sup> and Gaya Spolverato<sup>1</sup>

Cancers 2023, 15, 465. https://doi.org/10.3390

	ww		LE			Odds Ratio		Odds Ratio	-
itudy or Subgroup						M-H, Random, 95% CI		M–H, Random, 95% CI	ć
V-Najami, 2021	4	42	6	22	23.9%	0.26 [0.07, 1.13]			
soglu, 2019	3	39	1	6	11.3%	0.42 [0.04, 4.82]			
Creavin, 2017	1	10	17	50	13.6%	0.22 [0.03, 1.85]	20-		
ee, 2021	2	14	3	30	16.2%	1.50 [0.22, 10.17]			
ark, 2019	5	32	0	42	8.4%	17.00 [0.90, 319.81]		-	
/accaro, 2016	2	23	0	7	7.5%	1.74 [0.07, 40.62]			7.5
Vang, 2022	5	36	0	6	8.0X	2.13 [0.10, 43.49]			
reom, 2019	1	15	2	25	11.0%	0.82 [0.07, 9.91]			
fotal (95% CI)		213		188	100.0%	0.80 [0.31, 2.01]		-	
otal events	23		29						
eterogeneity: Tau2 -	0.43; CI	1 <sup>2</sup> = 9.	29, df =	7 (P =	0.23); F	- 25%	0.01	0,1 1 10	100
est for overall effect							0.01	0.1 1 1'0 Favours [WW] Favours [LE]	100
	WW	1	LE			Odds Ratio		Odds Ratio	
tudy or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% Cl		M–H, Random, 95% Cl	k
-Najami, 2021	11	42	10	22	23.7%	0.43 [0.14, 1.26]			
soglu, 2019	6	39	1	6	8.7%	0.91 [0.09, 9.22]			
creavin, 2017	ĩ	10	3	50	8.4%	1.74 [0.16, 18.67]			
ee. 2021	â	14	4	30	14.4%	1.77 [0.34, 9.27]			
ark, 2019	10	32	3	42	18.1%	5.91 [1.47, 23.77]			
accaro, 2016	4	23	ő	7	5.5%	3.46 [0.17, 72.41]			··
Vang, 2022	7	36	ő	6	5.7%	3.10 [0.16, 61.22]			
eom, 2019	4	15	4	25	15.6%	1.91 [0.40, 9.14]			
otal (95% CI)		213		188	100.0%	1.60 [0.75, 3.42]			
Sen. (3379 C.)				100	100.070	1.00 [0.1 3, 3.42]			
Cotal augusts	45		26						
lotal events	46		25		0.000. 8	2014	7		
leterogeneity: Tau <sup>2</sup> -	0.32; C		76. df =	7 (P =	0.20); F	- 28%	0.01	0.1 1 10	100
leterogeneity: Tau <sup>2</sup> -	0.32; C		76. df =	7 (P =	0.20); f	- 26%	0.01	0.1 1 10 Favours (WW) Favours (LE)	100
leterogeneity: Tau <sup>2</sup> -	0.32; C	: (P = 0	76. df =		0.20); ř	= 26X Odds Ratio	0.01		
ieterogeneity: Tau <sup>2</sup> - lest for overall effect	0.32; Cl Z = 1.22 WW	t (P = 0	76, df = 1.22} LE	1			0.01	Favours [WW] Favours [LE]	
leterogeneity: Tau <sup>2</sup> - lest for overall effect itudy or Subgroup	0.32; Cl Z = 1.22 WW	t (P = 0	76, df = 1.22} LE	1		Odds Ratio	0.01	Favours [WW] Favours [LE] Odds Ratio	
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Systematic Review

#### **Rectal Sparing Approaches after Neoadjuvant Treatment for Rectal Cancer: A Systematic Review and Meta-Analysis Comparing Local Excision and Watch and Wait**

Quoc Riccardo Bao <sup>1</sup><sup>(D)</sup>, Stefania Ferrari <sup>1</sup>, Giulia Capelli <sup>1,2</sup><sup>(D)</sup>, Cesare Ruffolo <sup>1</sup><sup>(D)</sup>, Marco Scarpa <sup>1,\*</sup>, Amedea Agnes <sup>3</sup><sup>(D)</sup>, Giuditta Chiloiro <sup>4</sup><sup>(D)</sup>, Elisa Palazzari <sup>5</sup>, Emanuele Damiano Luca Urso <sup>1</sup><sup>(D)</sup>, Salvatore Pucciarelli <sup>1</sup> and Gaya Spolverato <sup>1</sup>

Cancers 2023, 15, 465. https://doi.org/10.3390/cancers15020465

#### 5. Conclusions

Rectal-sparing approaches in patients with a cCR or nCR after nCRT are used in a selected clinical setting, and comparative studies comparing specifically WW and LE are still lacking. Our meta-analysis did not report differences between WW and LE in terms of rectum-preservation, local control, and distant metastases.



# • PART 2. Quality of life after restorative proctocolectomy for ulcerative colitis

- 1. Health related quality of life after restorative proctocolectomy for ulcerative colitis: long-term results. (*Italian Patients*)
- 2. Long-term functional outcome and quality of life after stapled restorative proctocolectomy (USA patients)
- 3. Quality of life after restorative proctocolectomy for ulcerative colitis: role of different questionnaires.
- 4. Long term functional results and quality of life after restorative proctocolectomy (*Canadian patients*).
- 5. Predicting health related quality of life after restorative proctocolectomy
- 6. Predicting health related quality of life after colectomy and ileostomy
- 7. Role of body image after restorative proctocolectomy

#### Total proctocolectomy

•





long-term results after restorative proctocolectomy

# Health-related Quality of Life after Restorative Proctocolectomy for Ulcerative Colitis: Long-term Results



Marco Scarpa, M.D.,<sup>1</sup> Imerio Angriman, M.D.,<sup>1</sup> Cesare Ruffolo, M.D.,<sup>1</sup> Antonio Ferronato, M.D.,<sup>2</sup> Lino Polese, M.D.,<sup>1</sup> Michela Barollo, M.D.,<sup>1</sup> Alessandro Martin, M.D.,<sup>2</sup> Giacomo C. Sturniolo, M.D.,<sup>2</sup> Davide F. D'Amico, M.D.<sup>1</sup>

### Aims:

- to evaluate the long term HRQL of patients submitted to RPC and its modifications after a 5 year follow-up
- to identify any peculiar risk factor for a worst outcome.



Scarpa et al.: Proctocolectomy and Health-related Quality of Life

Characteristic	RPC patients	UC patients	Healthy subjects
Total patients (no.)	36	36	36
Mean age (years)	$40 \pm 11$	$41 \pm 14$	39 ± 13
Male/female ratio	27/9	20/16	20/16
Married/single ratio	23/13	21/15	18/18
Daily stool frequency	$5.8 \pm 1.8$	$3.5 \pm 3.4^*$	
Rectal bleeding	5	8	
Weight loss	0	5*	
Occasional fecal incontinence	14	3	
Medical therapy	13	34*	
Hemoglobin (g/dl)	$13.8 \pm 1.3$	$12.9 \pm 1.7^*$	
WBC (no./µl)	$6550 \pm 1340$	$7360 \pm 2780$	
ESR (mm/hr)	$11.2 \pm 6.8$	$27.3 \pm 26.4^*$	
Albuminemia (mg/dl)	$3.6 \pm 0.7$	$3.0 \pm 0.7^{*}$	

Table 1. Patients' characteristics.

RPC: restorative pretocolectomy; UC: ulcerative colitis; WBC: white blood cell count; ESR: erythrocyte sedimentation rate. \*RPC vs. UC patients: p < 0.05.

# Health-related Quality of Life after Restorative Proctocolectomy for Ulcerative Colitis: Long-term Results

WORLD Journal of SURGERY • Zild to the base

Marco Scarpa, M.D.,<sup>1</sup> Imerio Angriman, M.D.,<sup>1</sup> Cesare Ruffolo, M.D.,<sup>1</sup> Antonio Ferronato, M.D.,<sup>2</sup> Lino Polese, M.D.,<sup>1</sup> Michela Barollo, M.D.,<sup>1</sup> Alessandro Martin, M.D.,<sup>2</sup> Giacomo C. Sturniolo, M.D.,<sup>2</sup> Davide F. D'Amico, M.D.<sup>1</sup>

Table 2. Scores of all functions in operated patients, UC patients, and healthy controls.

Parameter	Controls $(n = 36)$	Remission/mild $(n = 22)$	Moderate $(n = 9)$	Severe $(n = 5)$	RPC $(n = 36)$
Intestinal symptoms	$1.5 \pm 1.9$	$3.5 \pm 3.2^*$	$7.4 \pm 5.4^{*}$	$12.4 \pm 5.2^*$	$4.6 \pm 3.0^{*,**}$
Systemic symptoms	$1.9 \pm 2.4$	$4.0 \pm 4.0^{*}$	$8.7 \pm 3.7^*$	$8.6 \pm 4.8^*$	$4.3 \pm 3.5^{***}$
Emotional function	$2.1 \pm 1.9$	$4.5 \pm 4.5^*$	$10.8 \pm 4.2^*$	$9.4 \pm 5.9^*$	$4.8 \pm 3.7^{*,**}$
Social function	$0.1 \pm 0.4$	$1.8 \pm 2.9^{*}$	$4.4 \pm 3.4^{*}$	$5.8 \pm 5.9^*$	$2.0 \pm 2.9^{*,**}$
Total HRQL score	$5.6 \pm 4.9$	$13.8 \pm 12.8^*$	$30.3 \pm 12.6^*$	$36.2 \pm 20.7^*$	$15.7 \pm 10.9^{*,**}$

HRQL: health-related quality of life.

\*p < 0.01 versus controls; \*\*p < 0.05 versus moderate and severe UC.



•The patients who underwent RPC obtained significantly **better** scores than those who suffered of moderate or severe UC (p<0.01).



•On the other hand they obtained HRQL scores **similar** to those affected by remission or mild UC (p=0.27) but significantly **worse** scores than healthy controls (p<0.01).

#### long-term results after restorative proctocolectomy

### Health-related Quality of Life after Restorative Proctocolectomy for Ulcerative Colitis: Long-term Results

Marco Scarpa, M.D.,<sup>1</sup> Imerio Angriman, M.D.,<sup>1</sup> Cesare Ruffolo, M.D.,<sup>1</sup> Antonio Ferronato, M.D.,<sup>2</sup> Lino Polese, M.D.,<sup>1</sup> Michela Barollo, M.D.,<sup>1</sup> Alessandro Martin, M.D.,<sup>2</sup> Giacomo C. Sturniolo, M.D.,<sup>2</sup> Davide F. D'Amico, M.D.<sup>1</sup>

#### Table 3. Risk factors that could influence the HRQL in operated patients.

Factors influencing HRQL	HRQL score	HRQL score	p
Sex: females vs. males	$18.7 \pm 9.3 (n = 9)$	$14.7 \pm 11.4 \ (n = 27)$	0.17
Age: $< 40$ vs. $> 40$ years	$17.5 \pm 11.1 (n = 19)$	$13.6 \pm 10.6 (n = 17)$	0.14
Education: secondary vs. high school	$17.0 \pm 10.6 (n = 18)$	$14.3 \pm 11.4 (n = 18)$	0.35
Marriage status: married vs. singles	$14.7 \pm 10.8 (n = 23)$	$17.3 \pm 11.4 (n = 13)$	0.25
Fertility after RPC: yes vs. no	$12.0 \pm 10.1 (n = 8)$	$16.7 \pm 11.1 (n = 28)$	0.14
Job after RPC: yes vs. no	$15.0 \pm 10.8$ $(n = 28)$	$17.1 \pm 12.0 (n = 8)$	0.34
Type of IPAA: hand sewn vs. stapled	$12.4 \pm 12.5 (n = 11)$	$17.1 \pm 10.1 (n = 25)$	0.12
Type of operation: elective vs. emergency	$15.7 \pm 10.5 (n = 24)$	$15.5 \pm 12.2 (n = 12)$	0.48
Type of operation: 3 stages vs. 2 stages	$16.1 \pm 11.4$ $(n = 18)$	$15.2 \pm 10.7$ (n = 18)	0.40
No. of operations: $< 2 \text{ vs.} > 3$	$13.8 \pm 10.2$ $(n = 18)$	$16.1 \pm 11.4$ $(n = 18)$	0.27
Age at UC diagnosis: $< 20$ vs. $> 20$ years	$21.3 \pm 10.5 (n = 9)$	$13.8 \pm 10.6$ ( $n = 27$ )	0.03
Age at stoma closure: $< 20$ years vs. $> 20$ years	$19.1 \pm 12.0 (n = 7)$	$14.9 \pm 10.7 (n = 29)$	0.18
UC duration: $< 1$ vs. $> 1$ year	$16.8 \pm 11.8 (n = 9)$	$15.3 \pm 10.4 (n = 27)$	0.35
Follow-up duration: $< 5$ vs. $> 5$ years	$16.0 \pm 9.9$ ( $n = 12$ )	$15.5 \pm 11.5 (n = 24)$	0.45
Rectal stenosis/sinus tracts: yes vs. no	$22.6 \pm 12.8$ $(n = 6)$	$14.3 \pm 10.1 (n = 30)$	0.04
Pouchitis: yes vs. no	$24.4 \pm 8.2$ ( $n = 7$ )	$13.6 \pm 10.3 (n = 29)$	< 0.01
Medical therapy: yes vs. no	$25.4 \pm 7.6$ (n = 12)	$10.8 \pm 8.9 (n = 24)$	< 0.01
Daily bowel movement: $< 5$ vs. $> 5$	$12.6 \pm 10.5 (n = 18)$	$18.7 \pm 10.7 (n = 18)$	0.04
Incontinence episodes: yes vs. no	$17.5 \pm 10.6 (n = 14)$	$14.5 \pm 10.9 (n = 22)$	0.14
Rectal bleeding: yes vs. no	$15.1 \pm 11.2$ $(n = 28)$	$17.5 \pm 10.3 (n = 8)^{-1}$	0.30

#### IPAA: ileal pouch-anal anastomosis.



The most critical factors that influence HRQL outcome are use of **drugs**, presence of **pouchitis** or **pelvic complications**, number of daily **bowel movements** and **age at UC diagnosis**.







## Long-Term Functional Outcome and Quality of ANNALS OF SURGERY Life After Stapled Restorative Proctocolectomy © 1999 Lippincott Williams & Wilkins, Inc.

Victor W. Fazio, MB, MS, Micheal G. O'Riordain, MD, Ian C. Lavery, MB, BS, James M. Church, MD, Patrick Lau, MD, Scott A. Strong, MD, and Tracy Hull, MD

PATIENT CHARACTERISTICS

Table I. FATIENT	CHARACTERISTICS
Final pathologic diagnosis	
Mucosal ulcerative colitis	775 (79.3%)
Indeterminate colitis	123 (12.6%)
Crohn's colitis	34 (3.5%)
Familial adenomatous polyposis	37 (3.8%)
Other	8 (0.8%)
Gender	
Male	535 (54.8%)
Female	442 (45.2%)
Pouch Type	
J	783 (80.1%)
S	189 (19.3%)
Other	5 (0.5%)
Age	
At Surgery	Median 37 yr (interquartile range 28–46 yr)
At Onset of Disease	Median 27 yr (interquartile range 20–36 yr)
Duration of Disease Before	Median 6.5 yr
Surgery	(interquartile range 2.7–12.6 yr)

Table 1

Cleveland Global Quality of Life Score (Fazio Score) (Example)

Please rate the following on a scale of 0-10 (where 10 is the best)

Current Quality of Life	9
Current Quality of Health	10
Current Energy Level	7

**Figure 1.** Sample Cleveland Global Quality of Life (CGQL) form. The patient is asked to score each of the three items in the right-hand column. In this case, the patient scored 9, 10, and 7 for the quality of life, quality of health, and energy level, respectively. These scores were added and the total divided by 30 to give a final score of 0.867 in this case.



#### Long-Term Functional Outcome and Quality of ANNALS OF SURGERY Life After Stapled Restorative Proctocolectomy Col. 230, No. 4, 575–586 © 1999 Lippincott Williams & Wilkins, Inc.

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#### Table 2. CORRELATION BETWEEN SF-36 AND CGQL

	CGQL	Quality of Life	Energy Level	Quality of Health
SF-36 (Overall)	0.74*	0.61*	0.67*	0.65*
Physical functioning	0.46*	0.35*	0.41*	0.45*
Role physical	0.53*	0.44*	0.48*	0.48*
Bodily pain	0.45*	0.37*	0.41*	0.46*
General health	0.62*	0.53*	0.52*	0.60*
Vitality	0.70*	0.50*	0.73*	0.57*
Social functioning	0.57*	0.53*	0.48*	0.55*
Role emotional	0.31*	0.27*	0.29*	0.26*
Mental health	0.46*	0.43*	0.43*	0.41*
* . 0.004				

\* p < 0.001



**Figure 3.** Scores for individual items of the SF-36 for 163 patients randomly selected from the study cohort. Scores are transformed and expressed on a scale of 0 to 100. Mean patient scores are shown by the shaded bars; standard deviations are shown by the error bars. Norms for the mean values for each item of the SF-36 for the general U.S. population are shown by the heavy black line. For both scales, higher scores represent a better quality of life. It is apparent that there is no difference between the scores of patients after pelvic pouch surgery and the general U.S. population for any of the eight items of the SF-36.



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**Figure 4.** Percentage of patients with diurnal ( $\Box$ ) or nocturnal ( $\blacksquare$ ) seepage and/or diurnal ( $\triangle$ ) or nocturnal ( $\blacktriangle$ ) pad usage during the four time periods studied after surgery. There were no significant changes in the incidence of seepage or pad usage with time after surgery.



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## Table 4. EFFECT OF TIME AFTER SURGERY ON SOCIAL, WORK, SEXUAL, AND DIETARY RESTRICTIONS, APPETITE, PRESENCE OF URGENCY AND STOOL FREQUENCY

		Interval After Surgery (yr)				
		0–2	2–5	5–8	>8	p Value
Social Restriction	Yes	10.5	12.1	9.0	10.3	
	No	89.5	87.9	91.0	89.7	NS (*)
Work Restriction	Yes	12.3	14.0	12.6	13.1	
	No	87.7	86.0	87.4	86.9	NS (*)
Sexual Restriction	Yes	12.7	14.4	10.4	8.0	
	No	87.1	85.6	89.3	92.0	NS (*)
Dietary Restriction	Yes	32.8	32.7	31.2	33.5	
	No	67.2	67.3	68.8	66.5	NS (*)
Appetite	Poor	1.8	1.6	1.3	1.1	
	Fair	11.8	7.5	7.3	5.1	
	Good	86.4	90.8	91.4	93.8	0.019 (*)
Urgency	Never	52.8	51.6	49.3	57.2	
	Sometimes	41.9	43	41.9	34.3	
	Always	5.3	5.4	8.8	8.4	0.014 (*)
Stool Frequency	Day	$6.2 \pm 2.7$	$5.7 \pm 2.8$	$5.6 \pm 4.6$	5.0 ± 1.8	< 0.001 (†)
	Night	$1.3 \pm 1.3$	$1.4 \pm 1.3$	$1.4 \pm 1.3$	$1.3 \pm 1.3$	NS (†)

Stool frequencies are expressed as means (± standard deviation) and all other values are expressed as percentages of respondents at that time interval. Statistics were performed using the chi square test (\*) or analysis of variance (†).



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Figure 5. Quality of life as measured by the Cleveland Global Quality of Life (CGQL) in patients with (A) incontinence, (B) work restriction, (C) social restriction, and (D) sexual restriction. Open squares represent CGQL scores in patients with incontinence or work, social, or sexual restrictions; closed squares represent CGQL scores in patients without these complaints. Values are mean scores, and the error bars represent the standard errors of the means. Incontinence and work, social, or sexual restrictions all result in a significantly lower CGQL at each time point studied. \*p < 0.001; #p < 0.05 (analysis of variance).









#### Long-Term Functional Outcome and Quality of ANNALS OF SURGERY Life After Stapled Restorative Proctocolectomy <sup>Vol. 230, No. 4, 575–586</sup> © 1999 Lippincott Williams & Wilkins, Inc.

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Table 6. SATISFACTION WITH SURGERY						
		Postoperative Time Interval (yr)				
	0–2	2–5	5–8	>8		
Patient would recommend pouch to others Patient would have pouch again "Happiness with surgery" (scale 0–10) (mean $\pm$ S.E.M.)	98.0% 94.8% 8.92 ± 0.06	98.1% 96.7% 9.13 ± 0.06	98.3% 96.8% 9.24 ± 0.07	97.7% 96.0% 9.29 ± 0.11		

### Conclusions

Long-term quality of life after ileal pouch surgery is excellent and the level of continence is satisfactory. This surgery is an excellent long-term option in patients requiring total proctocolectomy. The CGQL is a simple, valid, and reliable measure of quality of life after pelvic pouch surgery and may well be applicable in many other clinical conditions.
role of different questionnaires

# Quality of Life After Restorative Proctocolectomy for Ulcerative Colitis

#### Different Questionnaires Lead to Different Interpretations

Marco Scarpa, MD; Cesare Ruffolo, MD; Lino Polese, MD; Alessandro Martin, MD; Renata D'Incà, MD; Giacomo C. Sturniolo, MD; Davide F. D'Amico, MD; Imerio Angriman, MD

### Arch Surg. 2007;142:158-165

# Aim:

• to validate an Italian version of CGQL

 to assess the HRQL of our patients with CGQL and PIBDQ to understand if the different results might be explained by different interpretations of the long-term outcome of the two questionnaires.



Table 1. Patient Characteristics for the Italian CGQL Instrument vs the SF-36 Analysis\*

Characteristic	Patients With UC (n = 24)	Patients With CD (n = 24)	Healthy Controls (n = 24)
Age, y†	43 ± 13 (42)	39 ± 13 (35)	41 ± 16 (50)
Male-female ratio	14:10	14:10	9:15
Daily stool frequency+	$4 \pm 3 (4)$	3 ± 2 (3)	NA
Rectal bleeding	5	2	NA
Weight loss	5	7	NA
Occasional fecal incontinence	3	5	NA
Disease activity index score <sup>+</sup>	153 ± 46 (131)	300 ± 137 (294)	NA
Medical therapy	17	23	NA

Abbreviations: CD, Crohn disease; CGQL, Cleveland Global Quality of Life; NA, data not applicable; SF-36, 36-Item Short-Form Health Survey; UC, ulcerative colitis.

\*Data are given as number of patients unless otherwise indicated.

+Data are given as mean ± SD (median).

‡The Seo index was used for patients with UC, and the Crohn's Disease Activity Index was used for patients with CD

Characteristic	Patients Who Underwent RPC (n = 40)	Patients With UC (n = 43)	Healthy Controls (n = 44)
Age, y†	42 ± 12 (40)	42 ± 13 (40)	39 ± 13 (36)
Male-female ratio	29:11	22:21	17:27
Daily stool frequency+	6 ± 2 (5)	3 ± 2 (2)‡	NA
Rectal bleeding	4	14‡	NA
Weight loss	1	8‡	NA
Occasional fecal incontinence	10	8	NA
Medical therapy	6	37‡	NA

#### Table 2. Patient Characteristics for the Italian CGQL Instrument vs the PIBDQL Instrument Analysis\*



role of different questionnaires

# Quality of Life After Restorative Proctocolectomy for Ulcerative Colitis

#### Different Questionnaires Lead to Different Interpretations

Marco Scarpa, MD; Cesare Ruffolo, MD; Lino Polese, MD; Alessandro Martin, MD; Renata D'Incà, MD; Giacomo C. Sturniolo, MD; Davide F. D'Amico, MD; Imerio Angriman, MD

Arch Surg. 2007;142:158-165

# Construct validity of the Italian CGQL

Construct	Italian CGQL	Quality of Life	Quality of Health	Energy Level
Italian CGQL vs SF-36*				
Physical functioning	0.62	0.62	0.58	0.59
Role physical	0.54	0.56	0.49	0.48
Bodily pain	0.58	0.59	0.55	0.52
General health	0.70	0.68	0.63	0.63
Vitality	0.71	0.62	0.61	0.73
Social functioning	0.62	0.52	0.47	0.68
Role emotional	0.57	0.52	0.47	0.54
Mental health	0.62	0.49	0.53	0.64
SF-36 (overall)	0.77	0.70	0.67	0.76
CGQL vs disease activity				
CDAI	-0.66†	-0.54†	-0.53†	-0.70†
Seo index	-0.42†	-0.64†	-0.33	-0.41†

Abbreviations: CDAI, Crohn's Disease Activity Index; CGQL, Cleveland Global Quality of Life; SF-36, 36-Item Short-Form Health Survey. \*P<.001 for all correlation values.



Italian CGQL single item and the overall scores correlated strongly with all Italian SF36 domains (all four CGQL item, p<0.001).



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# Arch Surg. 2007;142:158-165

Table 4. Italian CGQL and PIBDQL Discriminant Ability Obtained by the Comparison Between the 3 Groups With 1-Way ANOVA Followed by the Least Significant Difference Post Hoc Test

Variable	RPC Group	UC Group	Healthy Control Group
PIBDQL score*	14.9 ± 11.3	22.4 ± 15.2	9.6 ± 6.6
P value†			
RPC group	NA	.004	.04
UC group	.001	NA	<.001
Healthy control group	.22	<.001	NA
Italian CGQL score*	7.6 ± 1.3	6.5 ± 1.8	8.0 ± 1.0

Abbreviations: ANOVA, analysis of variance; CGQL, Cleveland Global Quality of Life; NA, data not applicable; PIBDQL, Padova Inflammatory Bowel Disease Quality of Life; RPC, restorative proctocolectomy; UC, ulcerative colitis. \*Data are given as mean ± SD.

# Italian CGQL and PIBDQL discriminant ability:

•**PIBDQL** scores of RPC patients were significantly *better* than those of UC patients and significantly *worse* than those of healthy controls.

•CGQL scores of RPC patients were significantly better than those of UC patients and *similar* to those of healthy controls

Table 5. Italian CGQL and PIBDQL Discriminant Ability Obtained by the Comparison Between the 5 Groups With 1-Way ANOVA Followed by the Least Significant Post Hoc Test

			UC Group		Healthy Cantral
Variable	RPC Group	Severe	Moderate	Mild	Healthy Control Group
PIBDQL score*	14.9 ± 11.3	48.5 ± 12.4	21.6 ± 10.9	16.5 ± 10.3	9.6 ± 6.6
P value†					
RPC group	NA	<.001	.04	.52	.01
UC group					
Severe	<.001	NA	<.001	<.001	<.001
Moderate	.06	<.001	NA	.14	<.001
Mild	.07	<.001	.65	NA	.005
Healthy control group	.18	<.001	.005	.003	NA
Italian CGQL score*	7.6 ± 1.3	4.2 ± 2.3	6.8 ± 1.2	$7.0 \pm 1.4$	8.0 ± 1.0

ANOVA followed by LSD post-hoc test.



role of different questionnaires

# Quality of Life After Restorative Proctocolectomy for Ulcerative Colitis

Different Questionnaires Lead to Different Interpretations

Marco Scarpa, MD; Cesare Ruffolo, MD; Lino Polese, MD; Alessandro Martin, MD; Renata D'Incà, MD; Giacomo C. Sturniolo, MD; Davide F. D'Amico, MD; Imerio Angriman, MD

Arch Surg. 2007;142:158-165

# Conclusion

The difference of the interpretation of the same HRQL can be attributed to the different discriminant ability of the two questionnaires.

According to the PIBDQL score RPC patients experience a HRQL similar to mild/ remission UC patients and this matching seems consistent with postoperative bowel function.





# Validation of an English Version of the Padova Quality of Life Instrument to Assess Quality of Life Following Ileal Pouch Anal Anastomosis

Marco Scarpa • Charles J. Victor • Brenda I. O'Connor • Zane Cohen • Robin S. McLeod J Gastrointest Surg (2009) 13:416–422 DOI 10.1007/s11605-008-0775-5

# Aims:

- 1. To validate an English version of PIBDQ
- 1. To identify the possible predictors of HRQL in RPC patients with a disease specific questionnaire

# Validation of an English Version of the Padova Quality of Life Instrument to Assess Quality of Life Following Ileal Pouch Anal Anastomosis

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	Respondents	Non-respondents	P value
N	955 (69%)	419 (31%)	
Male/female			
Female	475 (49.7%)	153 (36.5%)	< 0.01
Male	480 (50.3%)	266 (63.5%)	
Diagnosis			
UC	875 (91.6%)	359 (85.7%)	< 0.01
FAP	34 (3.6%)	38 (9.1%)	
IC	23 (2.4%)	10 (2.4%)	
CD	18 (1.9%)	12 (2.9%)	
Mean age (years)	45 (12)	42 (11)	< 0.01
Mean follow-up (months)	109 (70)	98 (70)	< 0.01
Mean age at diagnosis (years)	29 (11)	26 (10)	< 0.01
Mean age at first operation (years)	36 (11)	32 (11)	< 0.01
Pouch type			
J	826 (89.6%)	361 (86.1%)	0.982
S	129 (10.4%)	57 (13.9%)	
Unknown	0	1 (0.2%)	
IAA			
Stapled	806 (84.4%)	349 (83.3%)	0.663
Hand Sewn	149 (15.6%)	70 (16.7%)	
Number of operations			
1 Stage	219 (22.9%)	92 (21.9%)	0.818
2 Stages	541 (56.6%)	243 (57.9%)	
3 Stages	174 (18.2%)	72 (17.2%)	
IAA leak	89 (9.3%)	43 (10.2%)	0.601



Pelvic Pouch Follow up: clinical activty SIBDQ: short disease specific HRQL SF36: generic HRQL PIBDQ: disease specific



#### Validation of an English Version of the Padova Quality of Life Instrument to Assess Quality of Life Following Ileal Pouch Anal Anastomosis

Marco Scarpa · Charles J. Victor ·



•67% of patients fully continent during the day time during the night time 54% fully continent,

- •The mean bowel movement frequency in the 24 hours was 7.7+/-3.2.
- •Night bowel movements affected the 89% of patients.



J Gastrointest Surg (2009) 13:416–422 DOI 10.1007/s11605-008-0775-5



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Table 2 Test-Retest Reliability of the PIBDQL

	Intestinal symptoms	Systemic symptoms	Emotional function	Social function	Overall
Time 1	8.2 (3.4)	6.6 (5.0)	3.8 (4.9)	2.4 (2.6)	10.8 (12.3)
Time 2	8.0 (3.9)	6.0 (5.3)	4.8 (5.2)	2.6 (3.6)	12.3 (15.9)
ICC	0.788	0.733	0.701	0.785	0.784

ICC intraclass correlation coefficient comparing results at time 1 and time 2



No statistically significant difference was demonstrated after 20 days in the same patients.







#### Validation of an English Version of the Padova Quality of Life Instrument to Assess Quality of Life Following Ileal Pouch Anal Anastomosis

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Table 3	Assessment of	Construct	Validity	of the	PIBDQL (	(Versus SF-36)
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	Physical function	Role physical	Bodily pain	General health	Vitality	Social function	Role emotional	Mental health	Overall SF-36 score
Intestinal symptom	-0.329	-0.319	-0.409	-0.426	-0.398	-0.345	-0.279	-0.322	-0.456
Systemic symptom	-0.508	-0.539	-0.553	-0.678	-0.736	-0.556	-0.445	-0.561	-0.739
Emotional function	-0.440	-0.501	-0.457	-0.610	-0.625	-0.598	-0.511	-0.670	-0.701
Social function	-0.494	-0.540	-0.422	-0.499	-0.472	-0.502	-0.391	-0.396	-0.588
Total PIBDQL	-0.521	-0.563	-0.554	-0.676	-0.686	-0.605	-0.490	-0.598	-0.759

Correlation coefficients are negative because of the opposite orientation of the instruments. p < 0.001 for all correlations

English PIBDQL correlation with SIBDQ and SF36.

p<0.0001 for all the correlations.





### Validation of an English Version of the Padova Quality of Life Instrument to Assess Quality of Life Following Ileal Pouch Anal Anastomosis

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	-		
Predictors	Mean total PIBDQ (SD)	ANOVA p level	Multiple regression p level
Gender		0.002	0.007
Female	22.5 (13.9)		
Male	19.7 (12.7)		
Follow up <sup>a</sup>		0.015	
FU <12 months	18.6 (12.9)	0.368	0.189
FU 12-59	22.8 (13.3)		0.072
FU 60-119	21.8 (13.9)	0.848	0.116
FU >120	19.5 (12.9)	0.017	0.288
Diagnosis <sup>b</sup>		0.020	
UC	20.8 (13.0)		0.002
IC	24.7 (15.1)	0.680	0.801
CD	30.9 (23.0)	0.016	0.001
FAP	19.9 (13.1)	0.997	0.023
Pouch configuration		0.049	0.740
J	21.4 (13.3)		
S	18.8 (13.9)		
IPAA Type:		0.018	0.205
Handsewn	21.6 (14.3)		
Stapled	18.6 (13.1)		
Pouch Reconstruction		0.017	0.058
Yes	26.4 (17.9)		
No	21.0 (13.1)		

Good discriminative ability



RPC patients have a long term low rate of incontinence, sexual impairment, job/leisure restrictions and an acceptable stool frequency.

The English version of the PIBDQL questionnaire for RPC patients demonstrated to have good test-retest reliability, internal consistency and construct validity.

<u>CD</u> patients experienced a worse long term HRQL than UC or FAP patients even when their functional results are good **I**this indication for RPC should be, if possible, avoided.

<u>Female</u> patients reported a significantly higher frequency of sexual impairment and a higher rate of pouch reconstruction than male patients I worse HRQL scores

In patients who had their <u>pouch redone</u> the English PIBDQL scores were significantly worse even if the functional parameters seemed to not be affected I reconstructive surgery after pouch failure should be proposed to very committed patients. predicting quality of life after restorative proctocolectomy



#### Restorative proctocolectomy for inflammatory bowel disease

The Padova prognostic score for colitis in predicting long-term outcome and quality of life

Marco Scarpa · Claudia Mescoli · Massimo Rugge · Renata D'Incà · Cesare Ruffolo · Lino Polese · Davide F. D'Amico · Giacomo C. Sturniolo · Imerio Angriman

#### Table 1 Patients' demographics and preoperative medical history

	Frequency or median (range)
Number of patients	58
Male/female ratio	38/20
Age at onset of IBD colitis (years)	26 (5-56)
Age at RPC (years)	38 (20-68)
Age at time of survey (years)	44 (22-86)
Indication for RPC	
Toxic megacolon	5
Severe colitis	24
Resistance to medical therapy	24
Dysplasia/cancer	5
Timing of surgery	
Elective	39
Urgency	19

Int J Colorectal Dis (2009) 24:1049–1057 DOI 10.1007/s00384-009-0700-8

BACKGROUND: In 10-20% of cases, it is impossible to distinguish between ulcerative colitis and Crohn's colitis, affecting the possibility to predict the long-term outcome after restorative proctocolectomy (RPC). The study aimed to assess the accuracy of a new prognostic score for inflammatory bowel diseases (IBD) colitis [the Padova Prognostic Score for Colitis (PPSC)] in predicting long-term clinical/functional outcome and quality of life after RPC.

#### predicting quality of life after restorative proctocolectomy

#### Restorative proctocolectomy for inflammatory bowel disease

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MATERIALS AND METHODS: The PPSC was created by the integration of histological and clinical information. The accuracy of the PPSC was tested in predicting long-term clinical outcome (i.e. pouch complications/survival) and quality of life of 58 consecutive patients who had undergone RPC in our institute from 1984 to 2004.



Int J Colorectal Dis (2009) 24:1049-1057

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Fig. 2 PPSC items frequency and PPSC score distribution in the study population



#### 18/01/16

predicting quality of life after restorative proctocolectomy

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The PPSC predicted pouch fistulae (accuracy = 84.5%; sensitivity = 50%; specificity = 90%) and changes in sexual life (accuracy = 71%; sensitivity = 23%; specificity = 87%). The PPSC also predicted the PIBDQL score with an accuracy of 62%, a sensitivity of 28% and a specificity of 97%, whilst it predicted the CGQL score with an accuracy of 29%, a sensitivity of 12% and a specificity of 80%. The PPSC failed to predict pouchitis or pouch failure.



#### predicting quality of life after restorative proctocolectomy

#### Azienda Ospedale Università di Padova

#### Restorative proctocolectomy for inflammatory bowel disease

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	RPC patients	Healthy controls	Mann-Whitney U test
			p value
Patients	58	80	
Intestinal symptoms	4 (0-14)	1 (0-8)	< 0.01
Systemic symptoms	4 (0–11)	2 (0-11)	0.03
Emotional function	5 (0-20)	2 (0–18)	< 0.01
Social function	1 (0–14)	0 (0–9)	< 0.01
Total PIBDQL score	14.5 (0-52)	7 (0-45)	< 0.01
Patients	42	69	
Current quality of life	8 (5-10)	8 (4–10)	0.08
Current quality of health	7.75 (3-10)	8 (6-10)	< 0.01
Current energy level	7.50 (3-10)	8 (4–10)	0.42
Total CGQL score	7.50 (4-10)	8 (5-10)	0.06
		<b>X</b>	

CONCLUSIONS: The Padova Prognostic Score for Colitis proved effective in predicting pouch fistulae or abscesses, but not pouchitis and pouch failure. The PPSC was accurate in predicting disease-specific quality of life.

**Original article** 



Diverting loop ileostomy after restorative proctocolectomy<sup>.</sup> predictors of poor outcome and poor quality of life

Colorectal Disease, 12, 914-920

M. Scarpa\*, C. Ruffolo†, R. Boetto†, A. Pozza†, L. Sadocchi† and I. Angriman† \*Department of Surgery, Veneto Oncological Institute (IOV-IRCCS), Padova, Italy and †Department of Surgical and Gastroenterological Sciences, University of Padova, Padova, Italy

AIM: Diverting loop ileostomy is used to minimize the impact of anastomotic complication after restorative proctocolectomy (RPC). However, the ileostomy itself may have complications and therefore affect quality of life (QOL). The aim of this study was to analyse the predictors of complications of the ileostomy formation and closure and of the QOL of these patients. Table I Patients' characteristics at the first stage of RPC.

	Number of patients or median (range)
Number of patients	44
Gender (men/women)	26/18
Age at operation (years)	41 (24–71)
Age at study (years)	47 (26–73)
Two-stage RPC/three-stage RPC	30/14
Emergency/elective RPC	14/30
BMI at RPC	20 (14-33)
Standard rod/'ring' rod	21/23
Co-morbidity	17 Patients
	4 Arthritis
	3 Endocrine diseases
	3 Dermatitis
	2 Had had pancreasectom
	2 Atherosclerosis
	1 Discal hernia
	1 Haemolytic anaemia
	1 Primary sclerosing
	cholangitis
Indication for RPC	40 UC
	2 Indeterminate colitis
	2 FAP
Postoperative complications	5 Obstruction episodes
	5 Wound infection
	2 Postoperative bleeding
	1 Retrograde ejaculation
	Reoperation: 0
Harvey–Bradshaw activity index at RPC	7 (2–15)

RPC, restorative proctocolectomy; BMI, Body Mass Index; UC, ulcerative colitis; FAP, familial adenomatous polyposis.



**Original article** 



#### Diverting loop ileostomy after restorative proctocolectomy: predictors of poor outcome and poor quality of life *Colorectal Disease*, **12**, 914–920

#### M. Scarpa\*, C. Ruffolo†, R. Boetto†, A. Pozza†, L. Sadocchi† and I. Angriman†

\*Department of Surgery, Veneto Oncological Institute (IOV-IRCCS), Padova, Italy and †Department of Surgical and Gastroenterological Sciences, University of Padova, Padova, Italy



METHOD: Forty-four consecutive patients who underwent RPC were enrolled. Records of the ileostomy follow-up were retrieved from a prospectively collected database and QOL was assessed with the Stoma-QOL questionnaire. Ileostomy site coordinates were measured. Univariate and multivariate analysis were performed.

Figure 1 Ileostomy coordinates.

**Original article** 



#### Diverting loop ileostomy after restorative proctocolectomy: predictors of poor outcome and poor quality of life *Colorectal Disease*, **12**, 914–920

M. Scarpa\*, C. Ruffolo†, R. Boetto†, A. Pozza†, L. Sadocchi† and I. Angriman†

\*Department of Surgery, Veneto Oncological Institute (IOV-IRCCS), Padova, Italy and †Department of Surgical and Gastroenterological Sciences, University of Padova, Padova, Italy

Outcome's measure	Predictors	Kendall's τ	<i>P</i> -level	Multiple regression's $\beta$	<i>P</i> -level	Regression model
Parastomal hernia	Gender (male or female)	0.20	0.050	-0.36	0.057	$R^2 = 0.32, P < 0.027$
	Timing of surgery (elective or emergency)	-0.20	0.053	-0.48	0.017	,,,
	Disease activity (Harvey–Bradshaw)	0.26	0.059	-0.06	0.728	
Stenosis	Distance from umbilicus	0.24	0.021			
Dermatitis	Gender	0.30	0.005	0.151	0.260	$R^2 = 0.40, P < 0.001$
	Standard rod and ring rod	-0.23	0.027	-0.252	0.049	
	Distance from bisiliac line	-0.24	0.024	-0.243	0.069	
	Stoma retraction	0.50	0.000	0.473	0.001	
Stomal complication	Ileostomy site (right or left)	-0.28	0.007	-0.26	0.071	$R^2 = 0.32, P < 0.026$
ŕ	Distance from umbilicus	0.22	0.035	0.29	0.049	
Stoma-QOL score	Parastomal hernia	0.290	0.005	0.445	0.001	$R^2 = 0.37, P < 0.001$
	Stenosis	0.172	0.100	0.223	0.085	
	Age at RPC	0.24	0.023	0.304	0.021	

QOL, quality of life; RPC, restorative proctocolectomy.

CONCLUSION: The predictors of negative outcome after construction of a diverting loop ileostomy after RPC were urgent surgery, use of standard rod, the distance of the stoma site from the umbilicus, parastomal herniae and the older age of patients.

#### role of body image after restorative proctocolectomy

### Body image, cosmesis, quality of life, and functional outcome of hand-assisted laparoscopic versus open restorative proctocolectomy: long-term results of a randomized trial

S. W. Polle,<sup>1</sup> M. S. Dunker,<sup>1</sup> J. F. M. Slors,<sup>1</sup> M. A. Sprangers,<sup>2</sup> M. A. Cuesta,<sup>3</sup> D. J. Gouma,<sup>1</sup> W. A. Bemelman<sup>1</sup>

Table 1. Characteristics of the 53 patients completing the 1-year questionnaires after laparoscopic (LRP) versus open restorative proctocolectomy (ORP)

$\mathrm{RP}\ (n\ =\ 26)$	ORP (n = 27)	P Valu
:20	13:14	0.057 <sup>a</sup>
2.6 (19–59)	37.5 (18-62)	$0.012^{b}$
7:9	17:10	0.854 <sup>a</sup>
	0	
	1	
	2	
	20 2.6 (19–59)	2.6 (19–59) 37.5 (18–62) 7:9 17:10



<sup>a</sup> Pearson's chi-square

•

<sup>b</sup> Mann–Whitney U test





Surg Endosc (2007) 21: 1301-1307 DOI: 10.1007/s00464-007-9294-9

role of body image after restorative proctocolectomy

Body image, cosmesis, quality of life, and functional outcome of hand-assisted laparoscopic versus open restorative proctocolectomy: long-term results of a randomized trial DOI: 10.1007/s00464-007-9294-9

S. W. Polle,<sup>1</sup> M. S. Dunker,<sup>1</sup> J. F. M. Slors,<sup>1</sup> M. A. Sprangers,<sup>2</sup> M. A. Cuesta,<sup>3</sup> D. J. Gouma,<sup>1</sup> W. A. Bemelman<sup>1</sup>



Fig. 2. Results of the BIQ in female patients according to surgical approach (ORP versus LRP).

Fig. 3. Results of the BIQ after open restorative proctocolectomy according to gender.

In female patients body image score and cosmesis socre were significantly different according the surgical approach while in male patients there was not any difference



# • CONCLUSION: Quality of life after restorative proctocolectomy for ulcerative colitis

- RPC patients in a long-term follow-up reach and maintain a HRQL similar to those of remission/mild UC patients.
- the difference of the interpretation of the same HRQL can be attributed to the different discriminant ability of the questionnaires
- English version of the PIBDQL questionnaire has good test-retest reliability, internal consistency and construct validity.
- female patients reported a significantly higher rate of pouch complication and these worse functional results reflected on English PIBDQL scores
- CD patients experience a worse long-term HRQL than UC or FAP patients even when their functional results are good I RPC should be avoided.
- IC diagnosis is not a significant predictor of HRQL and the complication rate and the functional results were equivalent in IC and UC patients.
- technical details of stoma formation can make a major difference to the patient
- In female patients body image score and cosmesis socre were significantly different according the surgical approach while in male patients there was not any difference

PART 3. Quality of life after surgery for Crohn's disease

- 1. Health related quality of life after ileo-colonic resection for Crohn's disease: long-term results.
- 1. Predicting quality of life after intestinal surgery for Crohn's disease

1. Quality of life as outcome measure laparoscopic resection vs infliximab therapy





•



#### Original Article

#### Azienda Ospedale Università di Padova

### Health-Related Quality of Life after Ileocolonic Resection for Crohn's Disease: Long-term Results

Marco Scarpa, MD\* Cesare Ruffolo, MD\* Renata D'Incà, MD<sup>\*</sup> Teresa Filosa, MD\* Eugenia Bertin, MS\* Stefania Ferraro, MD\* Lino Polese, MD\* Alessandro Martin, MD<sup>\*</sup> Giacomo C. Sturniolo, MD<sup>\*</sup> Mauro Frego, MD\* Davide F. D'Amico, MD\* and Imerio Angriman, MD\*

(Inflamm Bowel Dis 2007;13:000-000)

#### Aim: To identify the possible predictors of quality of life after ileo-colonic resection

TABLE 1A. Patient Characteristics: Preoperative, Operative, and Postoperative Predictors CD Patients PIBDQL CD Patients CGQL Mean (95% CI) Mean (95% CI) Demographic and past medical history Number of patients 96 63 41/23 Male/female ratio 66/30 29.9 (27.1-32.7) 31.3 (27.6-34.9) Age at disease onset (years) Age at operation (years) 38.1 (35.3-40.9) 38.8 (35.1-42.6) Age at inclusion in study (years) 43.5 (40.6-46.4) 43.9 (40.0-47.8) Disease duration before operation (months) 109.9 (89.9-130.0) 108.8 (85.6-131.9) Recurrent CD/first operation ratio 27/69 15/4814/829/54 Fistulizing CD/obstructing CD ratio Reocolonic resection 17/69 11/52Laparoscopy/laparotomy 60/36 38/25 Stapled anastomosis/hand-sewn 18/78 8/55 End-to-side anastomosis/side-to-side anastomosis Duration of operation (minutes) 208.1 (189.3-226.9) 218.2 (191.9-244.4) Days to first bowel movement 3.8 (3.4-4.1) 3.9 (3.5-4.3) Postoperative hospital stay (days) 9.4 (8.7-10.0) 9.4 (8.7-10.2) 10 8 Intestinal complications (patients) 8 Surgical complications (patients) 4 Follow-up 47.1 (40.7-53.5) 43.7 (36.6-50.9) Duration (months) Symptom recurrence (patients) 22 12 16 8 Hospital admission (patients) Surgical recurrence (reoperation) 6 5



#### Original Article

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### **Methods**

cross sectional study

- CDAI: disease activity
- CGQL: generic HRQL
- **PIBDQ**: disease specific HRQL

TABLE 2. Scores (with 95% CIs) of PIBDQL and CGQL Functions in Patients Who Underwent Operations and in Healthy Controls

	CD Patients	Healthy Controls
PIBDQL		
Number of patients	63	81
Intestinal symptoms	4.1 (3.2-5.0)*	1.9 (1.4-2.3)
Systemic symptoms	4.3 (3.4-5.2)*	2.9 (2.2-3.5)
Emotional function	5.5 (4.3-6.7)*	3.1 (2.5-3.8)
Social function	2.0 (1.3-2.6)*	0.4 (0.1-0.7)
Total PIBDQL score	15.9 (12.9-18.9)*	8.3 (6.6-9.9)
CGQL		
Number of patients	96	69
Current quality of life	7.8 (7.5-8.2)	8.1 (7.9-8.4)
Current quality of health	7.7 (7.4-8.1)*	8.2 (8.0-8.4)
Current energy level	7.7 (7.3-8.1)	7.6 (7.3–7.9)
Total CGQL score	7.8 (7.5-8.1)	8.0 (7.8-8.2)

\*P < 0.01 versus controls; \*P < 0.05 versus controls.



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FIGURE 1. (A) CGQL scores according to the number of daily bowel movements. (B) CGQL scores according to the CDAI score. (Q PIBOQL scores according to the number of daily bowel movements. (D) PIBDQL scores according to the CDAI score. All differences for CGQL and PIBOQL scores were significant (P < 0.05), and all values are shown with their respective standard deviations (IS, intestinal symptoms; SS, systemic symptoms; EF, emotional function; SF, social function).



# What Is Current Knowledge

- Long-term HRQL after surgery for Crohn's disease is controversial
- Predictors for HRQL after surgery for Crohn's disease are unclear

# What Is New Here

- Generic and disease-specific questionnaires give different results
- HRQL should be analyzed with both type of questionnaires
- Disease activity is the main predictor of HRQL in CD after surgery

#### Azienda Ospedale Università di Padova

#### Intestinal Surgery for Crohn's Disease: Predictors of Recovery, Quality of Life, and Costs

Marco Scarpa · Cesare Ruffolo · Domenico Bassi · Riccardo Boetto · Renata D'Incà · Andrea Buda · Giacomo C. Sturniolo · Imerio Angriman

Table 1 Patients Characteristics

#### Patients characteristics

Patients operated on between 2007-2008	47
Gender: male/female	24 (51%)/23 (49%)
Age at operation (years)	38 (31-54)
Age at disease onset (years)	28 (19-44)
Disease duration (months)	79 (13-192)
Disease phenotype	
Fistulizing (patients)	11 (23%)
Obstructing (patients)	36 (77%)
Disease site	
Small bowel (patients)	38 (81%)
Large bowel (patients)	16 (34%)
Perianal (patients)	4 (9%)
Recurrent disease (patients)	9 (19%)
Operation (patients who had the procedure)	
Ileal/ileocolonic resection	32 (68%)
Colonic resection	16 (34%)
Ileostomy	6 (/13%)
Stricturoplasty	10 (21%)
Laparoscopy	25 (53%)
Duration of operation (minutes)	172 (120-225)
Outcome parameters	
First bowel movement	Third (first to sixth) post-operative day
Median post-operative stay	7 (5-20) days
Barthel's Index	
At admission	100 (0-100)
On the third postoperative day	45 (0-100)
At discharge	100 (30-100)
Complications	
Obstruction	3 (6%)
Anastomotic leak	2 (4%)
Re-operation	1 (2%)
Follow-up	
Median sick leave	30 (2-360) days
Harvey-Bradshaw Activity Index	3.5 (1-6.5)
Body image score	5 (5-8)
Cleveland Global Quality of Life score	7.7 (6.5-8.7)

J Gastrointest Surg (2009) 13:2128–2135 DOI 10.1007/s11605-009-1044-y

INTRODUCTION: The aim of this prospective study was to analyze the impact of different surgical techniques on patients undergoing intestinal surgery for Crohn's disease (CD) in terms of recovery, quality of life, and direct and indirect costs.

PATIENTS AND METHODS: Forty-seven consecutive patients admitted for intestinal surgery for CD were enrolled in this prospective study. Surgical procedures were evaluated as possible predictors of outcome in terms of disability status (Barthel's Index), quality of life (Cleveland Global Quality of Life score), body image, disease activity (Harvey-Bradshaw Activity Index), and costs (calculated in 2008 Euros). Univariate and multivariate analyses were performed. predicting quality of life after intestinal surgery for Crohn's disease



# Intestinal Surgery for Crohn's Disease: Predictors of Recovery, Quality of Life, and Costs

Marco Scarpa · Cesare Ruffolo · Domenico Bassi · Riccardo Boetto · Renata D'Incà · Andrea Buda · Giacomo C. Sturniolo · Imerio Angriman

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### Overall disability during hospital stay for surgery for Crohn's disease



Figure 1 Disability status after intestinal surgery for CD.

#### predicting quality of life after intestinal surgery for Crohn's disease



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#### Table 2 Surgical Techniques and Recovery Parameters

Surgical technique	Outcome measure	Yes: median (IQR)	No: median (IQR)	p level
Ileal resection	Discharge (days after operation)	7 (6–8)	9 (7–10)	0.038
	Sick leave duration (days)	30 (18-53)	45 (30-83)	0.063
Colonic resection	Discharge (days after operation)	9 (7–12)	7 (6–8)	0.025
	Barthel Index at discharge	100 (90-100)	100 (100-100)	0.016
Stricturoplasty	First bowel movement (days)	4 (3–5)	3 (2-4)	0.042
Laparoscopy	Discharge (days after operation)	7 (6-8)	8 (7-10)	0.001
	Body Image score	6 (5-8)	5 (0-7)	0.072
Ileostomy	Discharge (days after operation)	11 (8–16)	7 (6–9)	0.015
	Barthel Index at third post-operative day	3 (0-25)	45 (25-70)	0.020
	Barthel Index at discharge	93 (58–100)	100 (100-100)	0.048
	Sick leave duration (days)	71 (48–98)	30 (20-60)	0.071

#### predicting quality of life after intestinal surgery for Crohn's disease



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	Kendall's $\tau$	p value	Multiple regression $\beta$	p value
Sick leave duration				
Ileal resection	0.261	0.025	0.045	0.803
Stoma creation	-0.300	0.010	0.026	0.883
Physical burden of job	0.468	0.000	0.403	0.028
$R^2 = 0.16$				
Body Image questionnaire				
Laparoscopic-assisted approach	0.234	0.020	0.331	0.036
Ileal resection	-0.254	0.012	-0.149	0.331
Harvey-Bradshaw Activity Index	0.296	0.011	0.426	0.006
$R^2 = 0.33$				
Cleveland Global Quality of Life scor	e			
Harvey-Bradshaw Activity Index	-0.420	0.000	-0.258	0.123
Obstruction	-0.238	0.041	-0.089	0.580
Barthel 's Index at admission	0.290	0.018	0.381	0.026
$R^2 = 0.26$				



# Intestinal Surgery for Crohn's Disease: Predictors of Recovery, Quality of Life, and Costs

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# CONCLUSIONS:

- laparoscopy →
- stoma creation →
- stricturoplasty  $\rightarrow$
- a shorter postoperative length of stay
- a long and expensive postoperative hospital stay
- a slower recovery of bowel function.



# Surg Endosc. 1998 Nov;12(11):1334-40. doi: 10.1007/s004649900851. Cosmesis and body image after laparoscopic-assisted and open ileocolic resection for Crohn's disease.

#### Dunker MS(1), Stiggelbout AM, van Hogezand RA, Ringers J, Griffioen G, Bemelman WA.

BACKGROUND: The objectives of this study were to evaluate body image, cosmetic results, and quality of life in patients with Crohn's disease of the terminal ileum who had either laparoscopic-assisted or open ileocolic resection, and to determine how patients experienced the pre- and postoperative periods after both procedures.

METHODS: Thirty-four patients participated: 11 patients after open resection (OR), 11 patients after laparoscopic-assisted resection (LR), and 12 patients without resection (WR). Retrospectively, the patients filled out several questionnaires pertaining to body image, hospital experiences, and quality of life. One-way analysis of variance, Student's t-tests, and Pearson's correlation were used for statistical analysis.

RESULTS: The cosmetic score was significantly higher in the LR than in the OR group (p < 0.01). Body image correlated strongly with cosmesis and with quality of life. The hospital experiences of the laparoscopic and open groups were similar.

CONCLUSIONS: Laparoscopic surgery was associated with better cosmesis than open surgery. Patients do not experience laparoscopic surgery any differently from open surgery.

#### quality of life as an outcome measure in RCT

#### Laparoscopic ileocaecal resection versus infliximab for terminal ileitis in Crohn's disease: a randomised controlled, open-label, multicentre trial Lancet Gastroenterol Hepatol

2017: 2:785-92

Cyriel Y Ponsioen, E Joline de Groof, Emma J Eshuis, Tjibbe J Gardenbroek, Patrick M M Bossuyt, Ailsa Hart, Janindra Warusavitarne, Christianne J Buskens, Ad A van Bodegraven, Menno A Brink, Esther C J Consten, Bart A van Wagensveld, Marno C M Rijk, Rogier M P H Crolla, Casper G Noomen, Alexander P J Houdijk, Rosalie C Mallant, Maarten Boom, Willem A Marsman, Hein B Stockmann, Bregje Mol, A Jeroen de Groof, Pieter C Stokkers, Geert R D'Haens, Willem A Bemelman, on behalf of the LIR!C study group\*

- The primary outcome was quality of life on the ٠ Inflammatory Bowel Disease Questionnaire (IBDQ) at 12 months.
- Secondary outcomes were general quality of life, ٠ measured by the Short Form-36 (SF-36) health survey and its physical and mental component subscales, days unable to participate in social life, days on sick leave, morbidity (additional procedures and hospital admissions), and body image and cosmesis.

	Infliximab (n=70)	Laparoscopic ileocaeca resection (n=73)
Men	21 (30%)	26 (36%)
Women	49 (70%)	47 (64%)
Age at randomisation, years	26-5 (21-0-37-5)	28-0 (23-0-41-0)
Age at diagnosis, years	23-0 (19-0-34-0)	25.0 (20-0-37-8)
Disease duration at randomisation, months	14-0 (6-0-30-0)	12-5 (4-3-39-5)
Length of diseased ileum at imaging at randomisation, cm	11-5 (8-8-20-0)	13-0 (8-8-25-0)
Body-mass index, kg/m²	23-3 (0-5)	24.2 (0.6)
Smokers*	30/67 (45%)	21/67 (31%)
Family history of inflammatory bowel disease*	9/60 (15%)	14/61 (23%)
Perianal fistulas ever*†	10/69 (14%)	2/73 (3%)
Abdominal fistulas ever*	2/68 (3%)	3/73 (4%)
Medical therapy at time of randomisation		
Prednisolone	28 (40%)	40 (55%)
Budesonide	24 (34%)	19 (26%)
Mesalazine	5 (7%)	3 (4%)
Thiopurines	49 (70%)	47 (64%)
Methotrexate	6 (9%)	1(1%)

Data are n (%), n/N (%), median (IOR), or mean (SD). \*Denominator shows the number of patients for whom the parameter was known. †One patient in the resection group had an active perianal fistula at the time of randomisation (stratification was done for current perianal fistulas)

Table 1: Demographic and clinical baseline characteristics





#### quality of life as an outcome measure in RCT

#### Azienda Ospedale Università di Padova

# Laparoscopic ileocaecal resection versus infliximab for terminal ileitis in Crohn's disease: a randomised controlled, open-label, multicentre trial

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- the mean IBDQ score at 12 months was 178-1 (95% CI 171-1–185-0) in the resection group versus 172-0 (164-3–179-6) in the infliximab group (mean difference 6-1 points, 95% CI -4-2 to 16-4; p=0-25).
- the mean SF-36 total score was 112.1 (95% Cl 108.0–116.2) in the resection group versus 106.5 (102.1–110.9) in the infliximab group (mean difference 5.6, 95% Cl –0.4 to 11.6),
- the mean physical component score was 47.7 (45.7–49.7) versus 44.6 (42.5–46.8; mean difference 3.1, 4.2 to 6.0),
- the mean mental component score was 49.5 (47.0–52.1) versus 46.1 (43.3–48.9; mean difference 3.5. –0.3 to 7.3).
- Body-image scale mean scores in the patients who had resection were 16.0 (95% CI 15.2–16.8) at baseline versus 17.8 (17.1–18.4) at 12 months
- 6. cosmetic scale mean scores were 17.6 (16.6– 18.6) versus 18.6 (17.6–19.6).





# Laparoscopic ileocaecal resection versus infliximab for terminal ileitis in Crohn's disease: a randomised controlled, open-label, multicentre trial

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	resection (n=73)
15 (21%)	13 (18%)
7.0 (3.0–11.0)	5·0 (3·5–10·0)
122	149
0	2 (3%)
0	17.0
6.8 (3.2)	6·5 (3·8)
473	471
	7·0 (3·0–11·0) 122 0 0 6·8 (3·2)

Data are n (%), median (IQR), or mean (SD) unless otherwise stated. All patients had at least one scheduled admission for either infliximab infusions or surgery. \*No SD is available for the mean number of days spent in an intensive care unit because only two patients were admitted.

Table 2: Unscheduled and scheduled admissions

 $\rightarrow$  Laparoscopic resection in patients with limited (diseased terminal ileum <40 cm), non-stricturing, ileocaecal Crohn's disease in whom conventional therapy has failed could be considered a reasonable alternative to infliximab therapy.
# CONCLUSION: Quality of life after ileo-colonic resection for Crohn's disease

- Crohn's disease current disease activity is the main predictor of quality of life after ileocolonic resection.
- Side-to-side configuration of the ileo-colonic anastomosis seem to delay re-operation both by decreasing the local factor involved in recurrence or, more probably, by reducing obstruction symptoms.
- Laparoscopy was associated with a shorter postoperative length of stay; stoma creation was associated with a long and expensive postoperative hospital stay, and stricturoplasty was associated with a slower recovery of bowel function.
- Quality of life can be an effective outcome measure in RCT
- Body-image and cosmetic scale scores in the patients who had resection are similar to patients who have infliximab

PART 4. Quality of life after ileostomy in colorectal surgery

- 1. Body profile and Health-related quality of life in stoma patients.
- 2. Assessment of body profile in stoma patients

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Lina Martins, Birgitte Dissing Andersen, Janice Colwell, Gillian Down, Louise Forest-Lalande, Svatava Novakova, Rosalind Probert, Chris Juul Hedegaard and Anne Steen Hansen

British Journal of Nursing, 2022, Vol 31, No 7







Lina Martins, Birgitte Dissing Andersen, Janice Colwell, Gillian Down, Louise Forest-Lalande, Svatava Novakova, Rosalind Probert, Chris Juul Hedegaard and Anne Steen Hansen

British Journal of Nursing, 2022, Vol 31, No 7







### Stoma position by stoma type



Lina Martins, Birgitte Dissing Andersen, Janice Colwell, Gillian Down, Louise Forest-Lalande, Svatava Novakova. Rosalind Probert: Chris Iuul Hedegaard and Anne Steen Hansen Pritish Journal of Nursing, 2002, Vol. 24, N

British Journal of Nursing, 2022, Vol 31, No 7

d



### Stoma position by body profile







### Ospedale Universit di Padova

## Challenges faced by people with a stoma: peristomal body profile risk factors and leakage

Lina Martins, Birgitte Dissing Andersen, Janice Colwell, Gillian Down, Louise Forest-Lalande, Svatava Novakova, Rosalind Probert, Chris Juul Hedegaard and Anne Steen Hansen British Journal of Nursing, 2022, Vol 31, No 7 In both the overall population and the leakage subgroup, approximately one-third of the respondents (32% and 33%, respectively) had experienced a permanent change in shape (such as a bulge) in the area around the stoma or in the abdominal region over the previous 2 years. When split by stoma type, a slightly greater frequency of respondents with a colostomy than either an ileostomy or a urostomy experienced these peristomal body changes (P=0.0295; *Figure 3a*).

Frequency	Body changes experienced n (%)	Body changes not experienced n (%)	Comparison <i>P</i> -value	Don't know n (%)
Output under baseplate				
Daily/almost daily	106 (7.7)	122 (5.4)	0.0047	28 (5.0)
A couple of times per week	223 (16.3)	257 (11.3)	0.0000	74 (13.1)
About once per week	198 (14.5)	255 (11.2)	0.0043	70 (12.4)
2–3 times in the past month	276 (20.2)	444 (19.5)	0.6366	111 (19.6)
Once within the past month	300 (21.9)	619 (27.2)	0.0004	111 (19.6)
Never	250 (18.3)	554 (24.3)	0.0000	148 (26.2)
Don't know	15 (1.1)	25 (1.1)	1	23 (4.1)
Total responses	1368	2276		565
Leakage onto clothes				
At least once per week	161 (11.8)	147 (6.5)	0.0000	59 (10.4)
At least once per month	277 (20.2)	368 (16.2)	0.0020	98 (17.2)
At least once every 3 months	222 (16.2)	315 (13.8)	0.0535	76 (13.5)
At least once every 6 months	187 (13.7)	336 (14.8)	0.3800	57 (10.1)
At least once per year	126 (9.2)	269 (11.8)	0.0154	52 (9.2)
Less than once per year	185 (13.5)	360 (15.8)	0.0615	60 (10.6)
Never	200 (14.6)	453 (19.9)	0.0000	135 (23.9)
Don't know	10 (0.7)	28 (1.2)	0.1789	28 (5.0)
Total responses	1368	2276		565

Lina Martins, Birgitte Dissing Andersen, Janice Colwell, Gillian Down, Louise Forest-Lalande, Svatava Novakova, Rosalind Probert, Chris Juul Hedegaard and Anne Steen Hansen British Journal of Nursing, 2022, Vol 31, No 7

### a. Stoma type

### Output under baseplate



\* *P*<0.01 vs colostomy † *P*<0.0001 vs ileostomy

### Key

- Daily/almost daily
- A couple of times/week
- Once a week
- 2–3 times in previous week
- Once in previous month
- Never



	7%		10%*		12%		8%	
	15%		20%*				17%	
	11%		2070				100/*	
	14%		$16\%^{*}$		52%		19%*	
	11%		14%				15%	
	16%		10%		12%		13% <sup>†</sup>	
			14%		12%		14%	
	26%		15%*	4%-	8%		13%*	
Colostomy Ileostomy Jejunostomy Urostomy								

\* *P*<0.0001 vs colostomy † *P*<0.05 vs ileostomy

Key
At least once a week
At least once a month
At least once every 3 months
At least once every 6 months
At least once a year
Less than once a year
Never



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### b. Stoma shape

Output under baseplate



\* P<0.03 vs irregular

### Azienda Ospedale Università di Padova

### Leakage onto clothes

10%*		8%*		15%	
 19%*†		16%*			
 12%*§		15%		25%	
14%		14%*		18%	
 9%		12%*		9%	
 14%*		15%*		7%	
20%*	1	19%	1	9% 14%	
Oval		Round		Irregula	r
 14% <sup>*</sup> 20% <sup>*</sup>				7% 9% 14%	 i r

\* P<0.05 vs irregular

† P=0.045 vs round

§ P=0.018 vs round

### Key

Daily/almost daily

A couple of times/week

Once a week

2–3 times in previous week

Once in previous month

Never

- At least once every 6 months
   At least once a year
- Less than once a year

At least once a week

At least once a month

At least once every 3 months

Key

### Azienda Ospedale Università di Padova

# Challenges faced by people with a stoma: peristomal body profile risk factors and leakage

Lina Martins, Birgitte Dissing Andersen, Janice Colwell, Gillian Down, Louise Forest-Lalande, Svatava Novakova. Rosalind Probert. Chris luul Hedegaard and Anne Steen Hansen British Journal of Nursing, 2022, Vol 31, No 7

### c. Stoma position

Output under baseplate



### \* P<0.03 vs protruding

### Key

- Daily/almost daily
- A couple of times/week
- Once a week
- 2–3 times in previous week
- Once in previous month
- Never

### Leakage onto clothes



\* P<0.02 vs. protruding

### Key

- At least once a week
- At least once a month
- At least once every 3 months
- At least once every 6 months
- At least once a year
- Less than once a year

### Never



Lina Martins, Birgitte Dissing Andersen, Janice Colwell, Gillian Down, Louise Forest-Lalande, Svatava Novakova. Rosalind Probert. Chris luul Hedegaard and Anne Steen Hansen British Journal of Nursing 2022 Vol 31 Novakova.

British Journal of Nursing, 2022, Vol 31, No 7

# 1

### a. Changes in the area around the stoma by stoma type

\* P=0.0295 vs not having a colostomy and not experiencing body changes † P=0.0157 vs not having a urostomy and experiencing body changes

Key

I fully agree

I disagree

I fully disagree

Neither agree nor disagree

I agree

18% 19% 21% 29% 21% 21% 22% 26% 20% 19% 18% 14% 23% 26% 24% 14% 14% 12% 12% 12% More often Have to change Feel less confident Made me change experience leakage stoma appliance stoma appliance to different stoma more often stays on body appliance

### b. Consequences of changes in the area around the stoma



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	No irregular	No irregularities (Group A)		Irregularities (Group B)		
Frequency	n	Percentage	n	Percentage	P-value	
Output under baseplate						
Daily/almost daily	137	4.7	119	9.0	<0.0001	
A couple of times per week	325	11.3	229	17.3	<0.0001	
About once per week	317	11.0	206	15.6	<0.0001	
2–3 times in the past month	560	19.4	271	20.5	0.404	
Once within the past month	734	25.4	296	22.4	0.0341	
Never	765	26.5	187	14.1	<0.0001	
Don't know	49	1.7	14	1.1	0.132	
Total responses	2887	100	1322	100		
Leakage onto clothes						
At least once per week	187	6.5	180	13.6	<0.0001	
At least once per month	425	14.7	318	24.1	<0.0001	
At least once every 3 months	400	13.9	213	16.1	0.0596	
At least once every 6 months	419	14.5	161	12.2	0.0430	
At least once per year	327	11.3	120	9.1	0.0310	
Less than once per year	454	15.7	151	11.4	0.0002	
Never	622	21.6	166	12.6	<0.0001	
Don't know	53	1.8	13	0.98	0.0442	
Total	2887	100	1322	100		

Data are presented for the subgroup of respondents who received leakage questions (n=4209) and reported no irregularities (n=2887) or superficial creases and/or deep folds (n=1322) around their stoma. Those who answered 'Don't know' to the question on whether they had skin irregularities (n=277) are not included above. Comparisons between the proportions of respondents in each group (A versus B) were made using Fisher's exact pairs test. Statistically significant *P* values are shown in **bold** 



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# **KEY POINTS**

- There remain many challenges that people living with a stoma face in their everyday lives and that impact on their quality of life
- People with a stoma commonly experience leakage of stomal effluents from under the baseplate of their stoma product and onto their clothes, which is usually associated with the individual's stoma characteristics and peristomal body profiles
- Optimal access to a stoma care nurse would enable the individual to receive the necessary guidance relevant for their specific needs and help to improve their quality of life

### Body profile assessment

### Using peristomal body profile assessment to improve leakage-related quality of life for individuals with an ostomy British Journal of Nursing, 2023, Vol 32, No 4

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### Table 3. Body profile of participants at the beginning of the study Form of the area around the ostomy (n=65)Inward 15 (23.1%) Outward 17 (26.2%) Regular 33 (50.8%) Form being uniform or variable (n=66) Uniform 30 (45.5%) Variable 36 (54.5%) Form of the area around the ostomy and being uniform or variable (n=65) Inward uniform 3 (4.6%) Inward variable 13 (20.0%) Outward uniform 11 (16.9%) Outward variable 5 (7.7%) Regular uniform 16 (24.6%) Regular variable 17 (26.2%) Soft or firm abdomen (n=67) Firm 14 (20.9%) Soft 53 (79.1%) Superficial creases or deep folds (n=59) Deep folds 13 (22.0%) Superficial creases 46 (78.0%) Location of the ostomy (n=65) Above bending line 9 (13.8%) At bending line 10 (15.4%) Below bending line 46 (70.8%) Position of the ostomy opening (n=66) Above skin surface 38 (57.6%) Below skin surface 6 (9.1%) 22 (33.3%) In level with skin surface

### Body profile assessment

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### **KEY POINTS**

- People with an ostomy have very different peristomal body profiles and an improper fitting between the ostomy area and the ostomy product(s) is one reason for leakage
- Stoma care nurses who took part in the study highly recommended the Body Assessment Tool as an objectively measure of peristomal body profile that offers a first step toward choosing the best-fitting ostomy product(s)
- Optimally fitting of ostomy product(s) reduced the number of leakages and increased the leakage-related quality of life



Table 5. Leakages occurring in the preceding 7 days and OLI scores (0–100) at the start and end of the study for population subgroups

at the start and end of the study for population subgroups							
	Beginning LS mean	End LS mean	Mean difference	P value			
Body profile							
Regular body profile (n=34)							
Number of leakages	5.5	2.4	-3.1	<0.001			
Emotional impact	63.2	81.8	18.6	<0.001			
Usual/social activity	76.4	88.4	12.1	0.010			
Coping/control	63.8	83.3	20.0	<0.001			
Outward body profile (n=17)							
Number of leakages	5.4	1.1	-4.3	<0.001			
Emotional impact	64.5	80.4	15.9	0.010			
Usual/social activity	75.3	84.6	9.2	0.173			
Coping/control	74.5	83.3	8.8	0.273			
Inward body profile (n=15)							
Number of leakages	8.3	1.6	-6.7	0.001			
Emotional impact	53.1	72.9	19.8	0.008			
Usual/social activity	86.2	90.6	4.4	0.434			
Coping/control	62.2	81.1	18.9	0.001			
Type of ostomy							
Colostomy (n=32)							
Number of leakages	4.8	1.5	-3.3	<0.001			
Emotional impact	69.7	86.8	17.1	<0.001			
Usual/social activity	79.8	91.9	12.1	0.033			
Coping/control	75.8	93.2	17.4	<0.001			
lleostomy (n=26)							
Number of leakages	6.7	2.5	-4.2	<0.001			
Emotional impact	52.4	67.9	15.5	0.003			
Usual/social activity	77.9	83.9	6.0	0.142			
Coping/control	56.3	69.9	13.6	0.009			



# Take home messages

- No difference in term of body image among total colectomy, right colectomy and left colectomy for cancer
   European Journal of Surgical Oncology 46 (2020) 1613–1619
- Better body image score in local excision than in TME for rectal cancer

*BJS* 2017; **104**: 138–147

• In female patients undergoing restorative proctocolectomy for ulcerative colitis, body image score and cosmesis score were significantly different according the surgical approach while in male patients there was not any difference

Surg Endosc (2007) 21: 1301–1307 DOI: 10.1007/s00464-007-9294-9

• The cosmetic score was significantly higher in the laparoscopuic ileocolonic resection than in open resection for Crohn's disease. Body image correlated strongly with cosmesis and with quality of life.

Surg Endosc. 1998 Nov;12(11):1334-40.

 Body-image scale and cosmetic scale mean scores in the patients who had ileocolonic resection for were similar to that of patients who had infliximab therapy

> Lancet Gastroenterol Hepatol 2017; 2: 785–92

# Thank you for your attention



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