

Kolonkarzinom

Kontroversen der minimal invasiven Therapie

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www.magendarm-zentrum.ch

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Goldstandard

- Weniger postoperative Schmerzen
- Weniger Arbeitsausfall
- Weniger Verwachsungen
- Kürzere Hospitalisationszeit
- Weniger Wundinfektionen
- Kleinerer Schnitt

Anteil laparoskopische Kolonchirurgie

	Australien	27.5%
	DE	17%
	Frankreich	35%
	Holland	40%
	Spanien	21%
	Schweden	5%
	UK	25%
	USA	27.4%

Zeitraum 2007/2008

Robinson Ann Surg Oncol 2011 (18):1412-1418
 Schwab Colorectal Dis 2009 11(3):318-22
 Thompson Med J Aust 2011 194(9):443-7

Beispiel:

	2005	2007
gutartige Kolon	25.2%	27.4%
maligne Kolon	4.7%	6.7%

n= 240'446 Patienten

Robinson Ann Surg Oncol 2011 (18):1412-1418

Study Design

- elektive Sigmaresektionen; Divertikulitis
- n= 54 (LAP); n= 51 (O=)
- "blinded"* (Patienten/Pflege) 4 Tage
- Messgrößen:
 - Zufriedenheit range: 0-10 (very poor- excellent)
 - Kosmetik range: 0-10 (very poor- excellent)
 - GIQLI Fragebogen
 - Reoperationen: Ileus/Narbenhernien

* opaque wound dressing

Gervaz 2011 Surg Endosc 25:3373-3378

Resultate

	LAP (n=54)	OP (n=51)
Zufriedenheit (0-10)	9	9
Kosmetik (0-10)	9	8
GIQLI	110 (61-134)	115 (57-144)
Narbenhernien	12.9%*	9.8%
Kosten	11'606 SFr	12'138 SFr

* 4 Mediane Laparotomien (Konversionen; explorative Laparotomie)

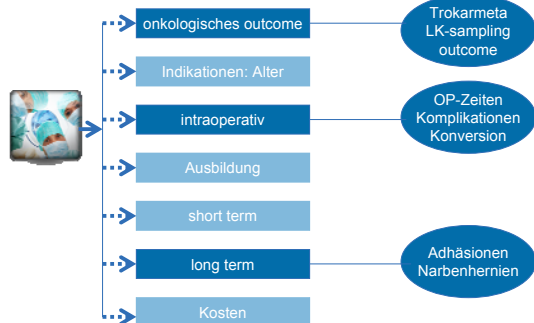
Gervaz 2011 Surg Endosc 25:3373-3378

Schlussfolgerung

- The benefits of laparoscopy are restricted to cosmetic, and it is fair to say that the magnitude of this benefit is smaller than anticipated

Gervaz 2011 Surg Endosc 25:3373-3378

KONTROVERSEN



Minimal invasiver Zugang

- keine Beeinträchtigung des onkologischen Resultates
- Prinzipien der onkologischen Chirurgie müssen respektiert werden

Technik: onkologische Prinzipien

- En-bloc- Resektion Tumor/ Lymphabflussgebiet
- „no-touch-isolation“ Technik:
 - Zentrale Gefäßligatur (Arterie/Vene)
 - Ligatur Marginalarterien und Darmlumen
 - Reinigung mit zytotoxischen Substanzen

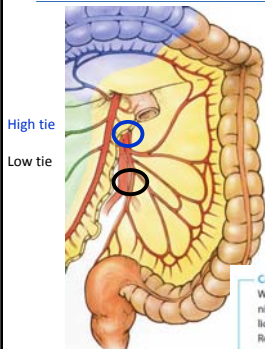


Turnbull 1967 Ann Surg 166:420-427
Wiggers 1988 Br J Surg 85:409-415

Nicht evidenced based!

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Zentrale Ligatur



- **Kein Effekt:**
Bacon 1966 Bull Soc Int Chir
Pezim 1984 Ann Surg 200:729
Surtees 1990 Br J Surg 77:618-21
- **Günstiger Effekt:**
Slanetz 1997 Dis CR 40:1205-18
N= 2409
5 y:
Dukes B 73.9% vs 84%
Dukes C 49% vs 58.6%
Kanemitsu 2006 BJS 93:609-615

Cave
Während die sog. «High-tie-Ligatur» deshalb onkologisch nicht zwingend erforderlich ist, ist sie ggf. technisch erforderlich zur Mobilisation des linken Hemikolons für die spätere Rekonstruktion.

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Anzahl Lymphknoten

- Prognostischer Faktor ≈ 14
- mindestens 14 LK entfernen
- Intergroup Trial INT-0089:
 - Je mehr LK befallen Überleben \downarrow (p=0.0001)
 - pN0; je mehr LK entfernt Überleben \uparrow (p=0.0001)
- 12 LK = > 90% accuracy in staging (Guidelines 2000)

Le Voyer 2003 J Clin Oncol 21:2912-9
Wong 2005 Arch Surg 140:881-887
Nelson JNCI 2001 93:583-596

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Entfernte Lymphknoten

TABLE 2. Intraoperative outcomes of 1721 elective colon and rectal cancer resections

	Colon		p
	Open (n = 742)	Laparoscopic (n = 434)	
Operating time (min)	150.9 ± 52.4	175.0 ± 61.2	<0.0001
Hemoglobin drop (g/L) ^a	16.2 ± 14.7	15.1 ± 14.4	0.28
Units blood transfused	0.7 ± 1.7	0.4 ± 1.2	0.003
Closest mucosal margin (mm)	57.2 ± 26.6	54.8 ± 23.7	0.34
Closest radial margin (mm)	24.9 ± 27.2	21.0 ± 14.4	0.74
No. of nodes examined	18.2 ± 10.0	17.4 ± 8.8	0.38
Conversion to open ^b		6.5%	

Unless otherwise stated, values are presented as mean ± SD.
^aLowest hemoglobin within 3 days of operation.
^bWhere incision was made longer than intended.

McKay Dis Col Rec 2012;55:42-50

Trokarmetastasen

- Wexner 1995: 6.3% (1.5-21%) [BJS 1995;82:295](#)
- AM Society Colon&Rectal Surgeons- nur im Rahmen prospektiver Datenerfassung
- 16 Serien (1993-2000): Inzidenz < 1% bei n=1737 Patienten
- Allardyce 0.85% / 1769 Patienten
- COST: 0.5%

Wexner BJS 1995;82:295-8
 Zmora Surg Endosc 2001;15:788-93
 Allardyce Aust N Z J Surg 1999;69:479-84
 COST NEJM 2004;350:2050-9

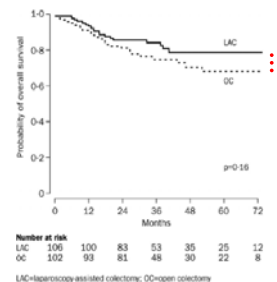


4 RCT mit Langzeitresultaten (3-5 Jahre)

Author	Start	End	Patienten n goal / anal	journal
M. J. Curet et al (Albuquerque)	1993	1995	43	Surg Endosc 2000
A. Lacy et al (Barcelona)	1993	1998	250 / 219	Lancet 2002
S. Araujo et al (Sao Paulo)	1997	2000	28	Rev.Hosp.Clin 2003
K. L. Leung et al (Hong-Kong)	1993	2002	? / 403	Lancet 2004
H. Nelson et al (COST) (USA)	1994	2001	1200 / 872	N Engl J Med 2004
(CLASICC) (UK)	1996	2002	1000 / 749	BJS 2010
(COLOR)(NL,Sk)	1997	2003	1500 / 1082	Lancet 2005

Onkologisch

- Lacy 2000 Lancet
- Einzelzentrum
- N= 219
- Nur Kolon (>15cm)
- Survival:
 - Unterschied Stadium III



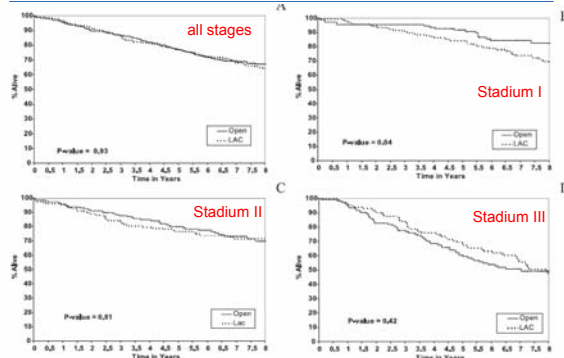
Lacy Lancet 2002;359:2224-29 16

Onkologisch

- COST (USA); n=872; 1994-2011
- Multizenter: 48 Kliniken, 66 Chirurgen
- Kolonkarzinom
- 5 Jahres Überlebensraten

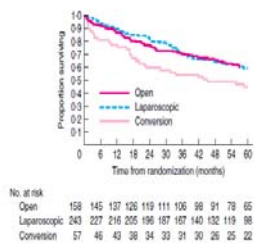
Fleishman Ann Surg 2007; 246:655-664

COST (5- J-Überleben)



Onkologisch

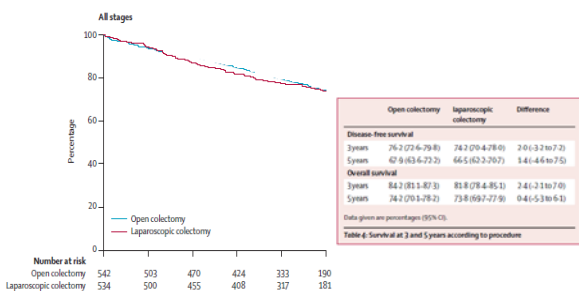
- CLASICC (UK) BJS 2010;97:1638-1645
- n=794 (413 Kolon Ca); 27 centers, 32 surgeons (1996-2002)
- 5-year survival vergleichbar
- Port site Metastasen 2.4%
- Konversion (25% Kolon): schlechteres overall aber nicht disease free survival



Onkologisch

- COLOR Lancet Oncol 2009;10:44-52
- n=1'248 Kolon-Ca (621 offen; 627 laparoskopisch); 29 europ. Zentren, (1997-2003)
- 3-year survival vergleichbar (overall 81.8% (L); 84.2% (O))

COLOR



Alter

- retrospektive Analyse; n=592;

	No. of complications				P*
	Open resection	Intention to treat	Laparoscopic resection		
			Completed		
All patients	270 of 298	205 of 204	147 of 201		<0.001
Age < 70 years	118 of 148	78 of 100	50 of 103		0.008
Age > 70 years	180 of 152	127 of 174	94 of 148		<0.001

*Fisher's exact test.

Allardyce BJS 2010;97:86-91

Alter

- randomisierte Studie; n=535; 37,5% > 70

Alter	n	Morbidität		Hospit.	
		offen	laparoskop	offen	laparoskop
< 70	334	23.9%	15.1%	10.6 Tage	9.1 Tage
> 70	201	37.5%	20.2%	13 Tage	9.5 Tage

Frasson Dis Colon Rectum 2008;51:296-300

Alter

- Analyse > 65j. Patienten mit Kolon Ca
 - nicht randomisiert
 - prospektive Datenerfassung
 - American College of Surgeons
- n= 2113 laparoskopisch
- n= 3801 offen

Ann Surg 2011;253:508-514

Ann Surg 2011;253:508-514

	offen (n=3801)	laparoskopisch (n=2113)	p
Hospitalisation	8.7 Tage	6.7 Tage	< 0.005
Revisionseingriff	5.7%	5.1%	0.31
Morbidität	25.4%	16.1%	< 0.005
Mortalität	3.7%	2.1%	< 0.005

operativ

OP- Zeiten

Trial	n= L vs O	laparoskopisch (min)	offen (min)
COLOR 2005	627/621	145	115
Law 2007	401/255	162	115
Kennedy 2011	2113/3801	145	130
Lacy 2002	111/108	142	118
COST 2004	435/428	150	95

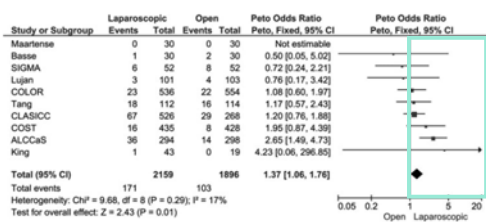
Intraoperative Komplikationen

- 10 RCT
- 4055 Patienten
 - 2159 laparoskopisch
 - 1896 offen

Sammour Ann Surg 2011;253:35-43

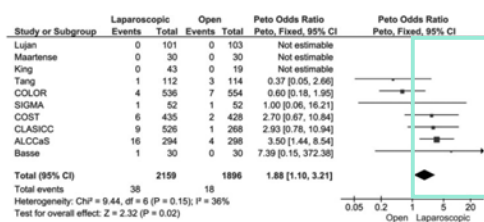
Intraoperative Komplikationen

- Gesamtkomplikationsrate



Intraoperative Komplikationen

- Darmverletzungen



Konversionsraten

Trial	n=	
CLASSIC	749	17%
COST*	872	21%
COLOR	627	17%
Dara Int J Colorectal Dis 2011	202	6.9%
Belizon Surg Endosc 2006	143	19.6%
Gonzales Dis Colon Rectum 2005	498	23%

* stabil über ganze Zeitperiode 1994-2011

Konversion

- kein Nachteil:
 - n=498; 23%
 - Konversionsgruppe = offene Gruppe bzgl. outcome (OP Zeit; Blutverlust; Hospitalisationsdauer usw.)

Gonzalez Dis Colon Rectum 2005;49:197-204

Konversion

- Nachteil:
 - n = 1685; multizenter
 - 5.2%

Complications	Postoperative Complications		P Value
	Conversion (n = 86)	No Conversion (n = 1,572)	
Overall	38.4	20.9	<0.05
Transit problems	9.3	3	<0.05
Ileus, no operation	2.3	0.4	<0.05
Ileus, operation	4.65	0.7	<0.05
Anastomotic leak, no operation	7	1.9	<0.05
Anastomotic leak, operation	4.65	1.6	<0.05
Cardiopulmonary	5.8	2.4	0.063*
Pneumonia	4.65	2.5	0.278*
Resit failure	3.5	0.3	<0.05
Hematoma, abscess	4.65	2.9	0.318*
Urinary tract infection	7	5.1	0.448*
Peritonitis	2.3	0.8	<0.05
Others	10.5	5.7	0.068*

Marusch Dis Colon Rectum 2001;44:207-216

Konversion

- Nachteil:
 - n = 143
 - 19.6%

Table 4. Outcome of converted colectomies compared to open and laparoscopic colectomies

Morbidity *ANOVA, p < 0.0001	Converted n = 28 (5%)	Open n = 28 (5%)	Laparoscopic n = 115 (5%)
Wound Infection*	9 (32.1)*	3 (10.7)	2 (1.7)
Incisional Hernia*	8 (28.5)*	2 (7.1)	7 (6.0)
Anastomotic Leak*	2 (7.1)*	0 (0)	1 (0.8)
Postoperative bleeding	0 (0)	1 (3.5)	2 (1.7)
Small bowel obstruction	0 (0)	0 (0)	2 (1.7)
Enterotomy	1 (3.5)	0 (0)	0 (0)
Fascitis	1 (3.5)	0 (0)	1 (0.8)
Mortality	1 (3.5)	0 (0)	3 (2.6)

Belizon Surg Endosc 2006;20:947-951

Konversion - onkologisches outcome

- Dt. Multizenterstudie
- overall survival:
 - OR 74.8%
 - LR-p 81.3%
 - LR-c 65.6%

kein signif. Unterschied!
- aber: Stadium II mit Konversion:
 - OR: 80.5%; LR-p 92.5%; **LR-c 43.3%**

Ptok EJSO 2009;35:1273-1279

Risikofaktoren für Komplikationen

- n=1316
- Multivarianzanalyse
- Faktoren:
 - Alter > 75
 - Malignom
 - Männer
 - ASA > III
 - Erfahrung

intraoperative Komplikationen

postoperative Komplikationen

Kirchhoff Ann Surg 2008;248:259-265

Ausbildung

- Learning curve
- Teaching offene Chirurgie
- wer macht die schwierigen offenen Eingriffe
- Superspezialisierung:
 - SILS
 - NOTES

Fallzahl – lap. Kolonchirurgie

	Low < 5/year	Medium 5-10/year	High > 10/year	p
Op Zeit (min)	240	210	188	< 0.001
Konversion (%)	24	24	9	< 0.001
Komplikationen N=	48/161	29/186	34/189	< 0.001
Hospitalisat. Tage	8	7	6	< 0.001
Lymphknoten				0.006

COLOR (2005) Surg Endosc 19:687-92

Ausbildung in laparoskopischer Kolonchir.

- n= 37 Studien;
- N=751 mentored cases

TABLE 1. Comparison of Pooled Weighted Outcomes of Mentored and Expert Series

Parameter	Mentored*	Experts*	P-value [†]
Conversions	0.13 (0.10-0.17)	0.10 (0.77-0.13)	0.2853
Complications	0.20 (0.16-0.24)	0.25 (0.19-0.31)	0.4933
Anastomotic leak	0.03 (0.01-0.06)	0.04 (0.02-0.08)	0.3682
Mortality	0.02 (0.01-0.04)	0.02 (0.01-0.02)	0.5680

*Pooled mean rates, random effects model (95% confidence intervals).
†Mixed effect model (method of moments).

Miskovic Ann Surg 2010; 252:943-951

case load und laparoskopische Resektionen

- Einfluss Case Load Chirurg /Spital
- US Daten
- n= 55'949 Patienten
- jährlicher case load an Sigmaresektionen für Divertikulitis
- 5 Gruppen (1-3;4-6,7-10;11-15;>15)

Weber Arch Surg 2007;142:253-259

Arch Surg 2007

Table 1. Characteristics of 28 742 Patients by Surgeon Volume and 55 949 Patients by Hospital Volume

Patient Characteristics by Health Care Provider Volume	Volume Group 1	Volume Group 2	Volume Group 3	Volume Group 4	Volume Group 5
Surgeon volume, procedures ^a	5-3	4-6	7-10	11-15	>15
Patients, No.	18 559	7543	2229	411	223
Age, mean ± SD, y	61.1 ± 14.6	61.5 ± 14.4	61.7 ± 14.3	62.9 ± 13.5	58.2 ± 13.9
Female, %	35.5	36.5	36.5	32.3	32.8
Days index score, mean ± SD ^b	1.9 ± 4.1	1.8 ± 4.0	1.7 ± 3.8	1.7 ± 3.9	1.1 ± 2.7
Location and teaching status of hospital, %					
Rural	14.6	12.9	10.8	6.8	9.9
Urban nonteaching	56.6	61.0	59.8	66.6	54.2
Urban teaching	28.8	26.1	29.4	26.6	35.9
Time of surgery, %					
Elective	40.6	48.2	51.3	65.9	78.9
Non-elective	56.3	50.0	47.1	34.1	21.1
Missing	3.1	1.8	1.6	0	0
Median yearly income, \$, %					
1-25 000	19.2	18.2	18.2	15.1	12.1
25 001-35 000	35.8	35.4	35.8	38.9	32.3
>35 001	40.9	43.9	42.9	42.1	53.8
Missing	4.2	4.6	5.1	3.9	1.8
Laparoscopic procedures, %	8.8	9.7	9.3	7.8	28.9

"high volume" Chirurg: 8.8 x grössere Chance für laparoskopischen Eingriff

Schwierigkeitsgrad

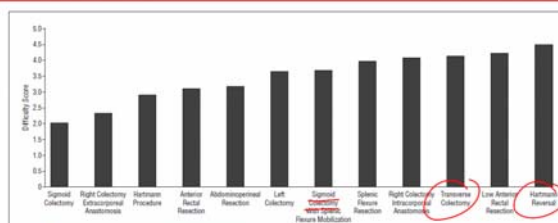


Figure 1. Overall difficulty scores for each of the 12 tested procedures.

Umfrage bei 35 erfahrenen Laparoskopieuren

Jamali Arch Surg 2008;143:762-767

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UK

lAPCO National Training Programme for Laparoscopic Colorectal Surgery



www.lapco.nhs.uk

Welcome to LAPCO

National Training Programme for Laparoscopic Colorectal Surgery

National Training Programme - Updates

Since April 2020 a total of over 1,000 Global Assessment Score (GAS) forms from Lapco theatre training sessions have been uploaded to the web site. A total of 180 Consultants are scheduled to complete their training with Lapco. Of this total 27% have already been successfully signed off, and a further 20% have been asked to undertake their sign off assessment. The remaining 53% of trainees are still in training who are expected to be asked to sign off in 2021/2022. In addition, there are now 63 registered trainers in our 11 national training centres coordinated from 30 separate NHS Trusts in England. This takes the total number of trainers and trainees involved with the programme to 213, which represents over one third of the total number of Colorectal Consultants in England.

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Postoperativer Verlauf

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"short term" outcome

TABLE 3. Comparison of Postoperative Pain, Opiates Intake, and Ileus Between Groups

	Mean (SD), Median [Range]		P
	Laparoscopy Group	Open Group	
Pain on day 1, VAS	3.4 (2.0), 3 [0-10]	3.8 (2.0), 4 [0-10]	0.25
Pain on day 2, VAS	2.5 (1.6), 2 [0-6]	3.0 (1.8), 3 [0-7]	0.19
Pain on day 3, VAS	1.8 (1.2), 2 [0-5]	2.3 (1.9), 2 [0-8]	0.31
Pain on day 4, VAS	1.3 (1.4), 1 [0-5]	1.9 (1.5), 1 [0-6]	0.019
Maximal pain, VAS	3.9 (1.8), 4 [1-10]	4.5 (1.9), 5 [1-10]	0.055
Morphine (total dose) [MG]	8.9 (13.7), 7.5 [0-82.5]	16.8 (17.6), 10 [0-82.5]	0.006
Duration of ileus (flatus), [hours]	35.9 (14.2), 31 [15-70]	53.6 (18), 48 [20-118]	<0.001
Duration of ileus (bowel movement) [hours]	81.4 (31), 76 [31-163]	106.6 (24), 107 [53-175]	<0.001
Duration of surgery [min]	168 (37), 165 [90-285]	118 (28), 110 [70-210]	<0.001
Length of stay [d]	7.7 (9.7), 5 [4-69]	7.9 (2.6), 7 [5-17]	<0.001

Gervaz Ann Surg 2010;252:3-8

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Wundinfekte

Trial	n=	LO vs OR
Bilimoria J Gastrointest Surg 2008	837	9.1% vs 11.8%
COLOR 2005	1082	4% vs 3%
Law 2007	656	2% vs 2.2%
Lacy Lancet 2002	219	7.2% vs 16.7%
Kiran J Am Coll Surg 2010	3414/7565	9.5% vs 16.1%

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Hospitalisationsdauer

Trial	n=	Laparoskopisch (Tage)	offen (Tage)
COLOR 2005	536/546	8.2	9.3
Mc Kay 2012	434/742	7.0	10.0

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Fast Track Surgery

TABLE 3. Duration of Surgery, Transfusion, Hospitalization, and Readmissions in 60 Patients Randomized to Open or Laparoscopic Colonic Resection (* = P < 0.05 Between Groups)

	Open, N = 30	Laparoscopic, N = 30
Duration of surgery, min*	131.5 (79-234)	215.5 (100-363)
Intraoperative blood transfusion, mL*	0 (0-1200)	0 (0-0)
Postoperative blood transfusion, mL	0 (0-1200)	0 (0-1500)
Postoperative hospital stay days	Median 2 (2-5) [†] Mean 2.3	Median 2 (2-20) [‡] Mean 2.9
Readmission		
Pts.	8	6
Days	6 (1-11)	3 (2-9)
Total hospital stay ^{††}	Median 2 d Mean 3.9 d	Median 2 d Mean 3.8 d

*P < 0.05 between groups.
[†]The 2 patients who died at days 1 and 2 are not included.
[‡]One patient in the laparoscopic group had a cerebral infarction at day 2 and was transferred to the neurologic department at day 20, where he stayed for rehabilitation until day 155. Only the 20 days in the surgical department is counted in the calculation of total hospitalization.

short term: Mobilität; GI-Funktion; Schlafqualität; Morbidität usw
absolut vergleichbar

Basse Ann Surg 2005;241:416-423

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RANDOMIZED CONTROLLED TRIALS

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

A Randomized Clinical Trial (Lafa-study)

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 Michael F. Gerhards, MD, PhD,** Bart A. van Wogensveld, MD, PhD,†† Edwin S. van der Zaag, MD,‡‡
 Anna A.W. van Geloven, MD, PhD,§§ Mirjam A.G. Sprangers, PhD,¶¶ Miguel A. Cuesta, MD, PhD,*** and
 Willem A. Bemelman, MD, PhD,* on behalf of the collaborative Lafa study group*

Vlug Ann Surg 2011;254:868-875

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Resultate

TABLE 3. Postoperative Data

	1. Laparoscopy and Fast Track (n = 100)	2. Open and Fast Track (n = 93)	3. Laparoscopy and Standard care (n = 109)	4. Open and Standard care (n = 98)	P
Total hospital stay, median (IQR), days	5 (4-8)	7 (5-11)	6 (4.5-9.5)	7 (6-13)	<0.001*
Postoperative hospital stay, median (IQR), days	5 (4-7)	6 (4.5-10)	6 (4-8.5)	7 (6-10.5)	<0.001*
Days to fulfill discharge criteria, median (IQR)					
(1) Pain control with oral medication	2 (2-3)	2 (2-4)	3 (2-4)	3 (2-5)	
(2) Tolerate solid food	1 (1-2)	1 (1-3)	2 (1-3)	3 (2-5)	
(3) Absence of nausea	1 (1-3)	2 (1-5)	1 (1-3)	1 (1-4)	
(4a) Passage of first flatus	1 (1-2)	1 (1-3)	2 (1-3)	2 (1-3)	
(4b) Passage of first stool	2 (1-4)	3 (2-4)	3 (2-4)	4 (3-6)	
(5) Mobilization as preoperative	3 (2-5)	4 (3-7)	5 (4-7)	6 (5-8)	
(6) Acceptance of discharge	4 (3-6)	5.5 (4-9)	5.5 (4-8)	7 (5-12)	
In-hospital costs					
University hospitals, median (IQR, €)	10,594 (5461-16,763)	12,805 (6847-20,658)	11,967 (6222-17,039)	10,479 (6608-16,875)	0.56*
Teaching hospitals, median (IQR, €)	2768 (4873-8017)	5497 (4566-6513)	6228 (5780-6604)	3650 (4836-8003)	0.41*

*Statistical: Wilcoxon test/Groups individually tested by means, when appropriate.
 †Significant difference between LapFT and OpenFT (0.006) LapTT and LapStandard (0.026) LapFT and OpenStandard (0.000) LapStandard and OpenStandard (0.010).
 ‡Significant difference between LapFT and OpenFT (0.005) LapTT and LapStandard (0.020) LapTT and OpenStandard (0.000) OpenFT and OpenStandard (0.052) LapStandard and OpenStandard (0.004).

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Spätfolgen

- Narbenhernien/ Adhäsionen
- Datenlage bescheiden

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Narbenhernien

	laparoskopisch	offen
Gervaz Surg Endosc 2011	12.9%	9.8%
CLASICC BJS 2010	8.6%	9.2%
Braga 2005	4.7%	8.9%
Winslow 2002	24%	19%

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Postoperativer Ileus

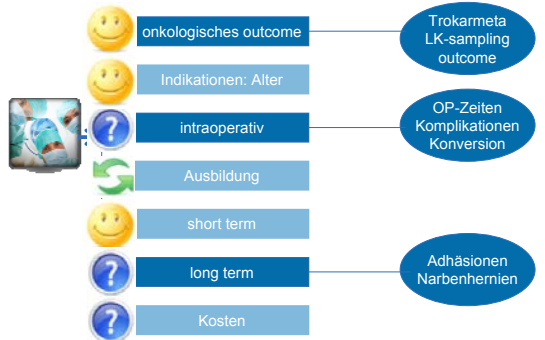
Referenz	n= Patienten	offen	laparoskopisch	p=follow-up
CLASICC BJS 2010	411	3.1%	2.5%	0.6/ 3 Jahre
Braga 2005	391	2.4%	1.1%	

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Kosten

n= Patienten	laparoskopisch	offen
Gervaz Surg Endosc 2011	105 11'606.- SFr	12'138.- SFr
Braga Ann Surg 2005	517 + 125 Euro + additional OR costs/instruments 1171	+ 1046 Euro complications/LOS
Janson BJS 2004	210 11660 £	9814 £

KONTROVERSEN



Take home

- onkologisch vergleichbar
- (L): mehr intraop. Probleme/ Konversionen (!)
- (L): ältere Patienten profitieren am meisten
- Ausbildung anspruchsvoller
- short term: Fasttrack wichtiger als Zugang
- longterm: ?
- beide Verfahren mit gutem Gewissen gleichwertig angewendet werden
- es gibt keinen Goldstandard!

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