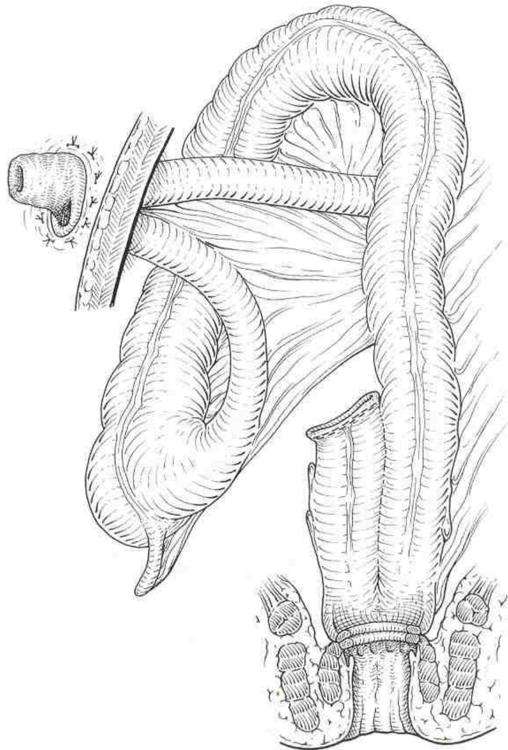
PROCARE
Defunctioning stoma and leak rate after TME



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PROJECT ON CANCER OF THE RECTUM

www.kankerregister.org

Penninckx Freddy, Beirens Koen

on behalf of PROCARE

no disclosures

FUNDING
for training (review) and registration
Stichting tegen Kanker (2006-2007)
RIZIV / INAMI (2007 – 2012)

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Aim

- clinical anastomotic leak (AL) rate after TME
- risk adjusted variability between centres

- AL-related in hospital mortality and Length of Stay
- With versus without primary defunctioning stoma (DS)

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Patients and Methods

- 1912 patients
- Elective TME + colo-anal reconstruction
- invasive rectum adca up to 15 cm
- 1/2006 – 3/2011

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AL definition and grading

International Study Group of Rectal Cancer

Surgery 2010, 147: 339-51

- defect at the anastomotic site, incl. suture and staple lines of neorectal reservoir, pelvic abscess close to the anastomosis and rectovaginal fistula
- Grade A: no change in management ('radiological')
- **Grade B: therapeutic intervention, no relaparotomy**
- **Grade C: requiring relaparotomy**

- ***Early AL: before discharge after primary surgery***
- *Late AL: diagnosed after discharge*

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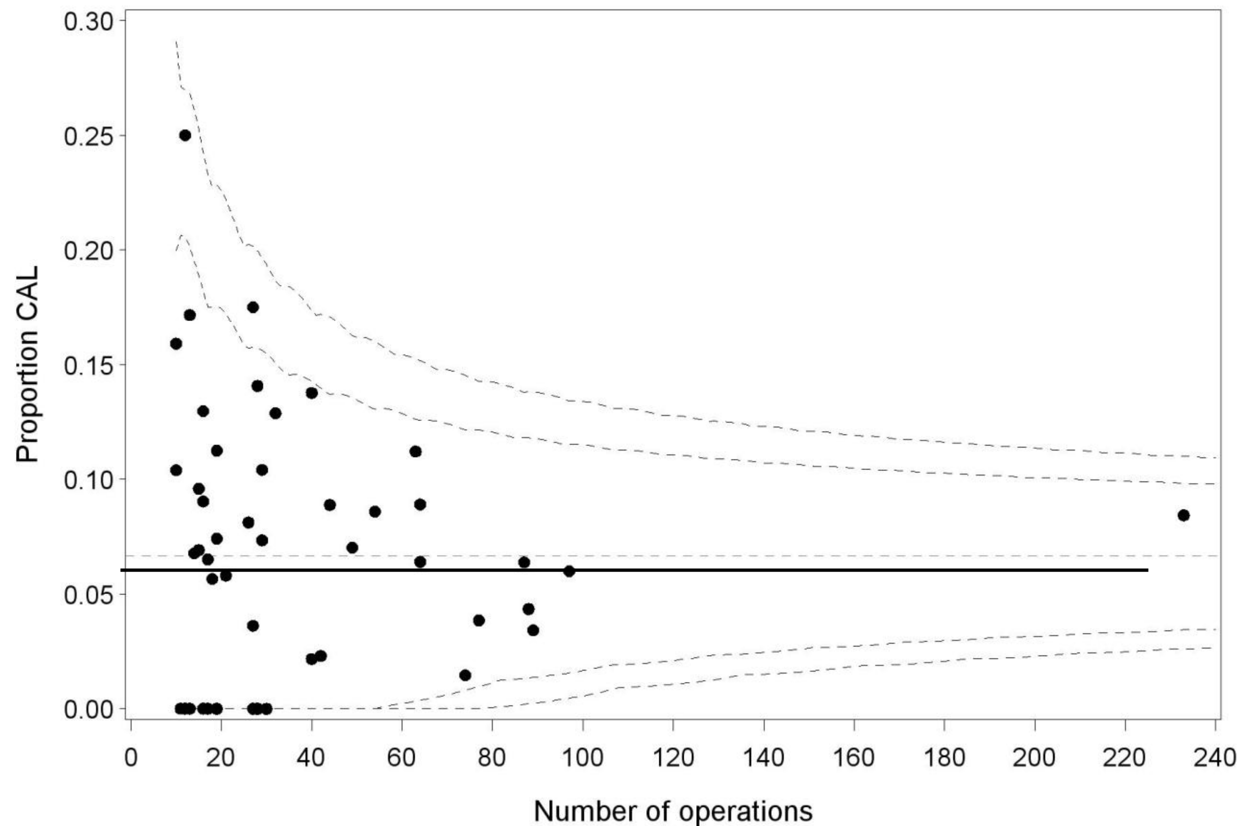
Risk-adjusted early clinical leaks grade B and C after SSO around the overall rate

adjusted for gender, age (>60 yr), ASA 3 or more, BMI > 25



Colorectal Dis 2011, submitted

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Early clinical anastomotic leak rate
(grade B + C)

NO DS	DS
10.2 %	4.3 %

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Early AL grade B and C related morbidity and mortality

	AL if no DS 74/729	AL if DS 51/1183	
Re-operation rate for leak	93%*	78%	**No leak 1787**
Length of Stay	**33.4 d**	**30.4 d**	**14.7 d**
Mortality	**8.1%°**	**0%**	**1.1%**
	4.8%*		

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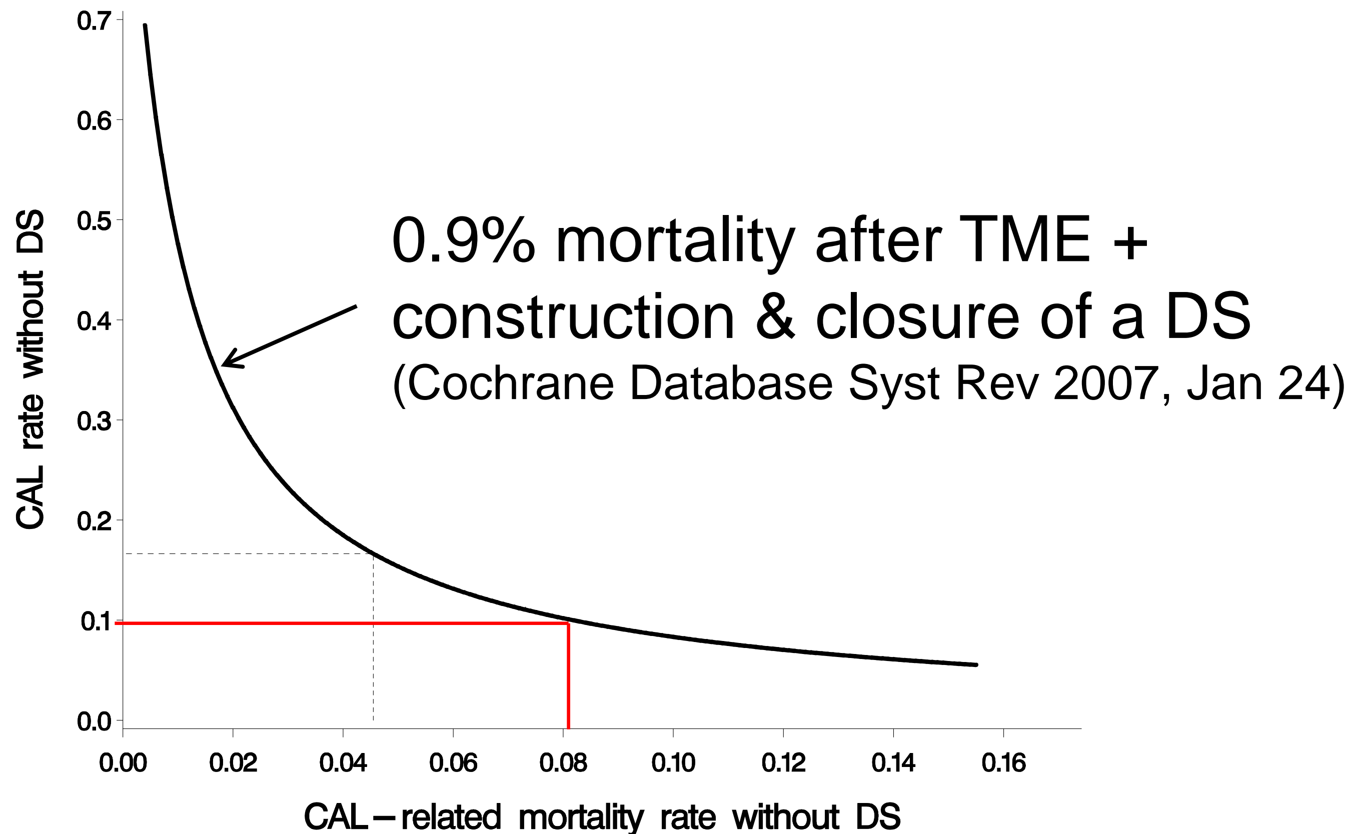
Mortality risk and clinical anastomotic leak
Limits of avoiding a primary defunctioning stoma

secondary DS
& closure
for all CALs



Colorectal Dis 2009, 11: 797-805

Early leaks after SSO in 48 teams (>10 pts) Surgical information on how to adjust practice

	P < 50 centres	P > 75 centres (12 centres)
Primary defunct. stoma	74%	45%
Mobilisation splenic flexure	90%	80%

Colorectal Dis 2011, submitted

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Conclusions

- Low overall AL
- No significant variability after benchmarking with adjustment for gender, ASA > 2, age and obesity
- AL (B,C) increases LoS and mortality
- Primary DS decreases early AL rate, and AL related re-operation rate, LoS and mortality (NS but 0% vs. 8.1%)
- Primary DS in 62%
- Primary DS (besides other surgical aspects) may be indicated to reduce variability and improve outcome

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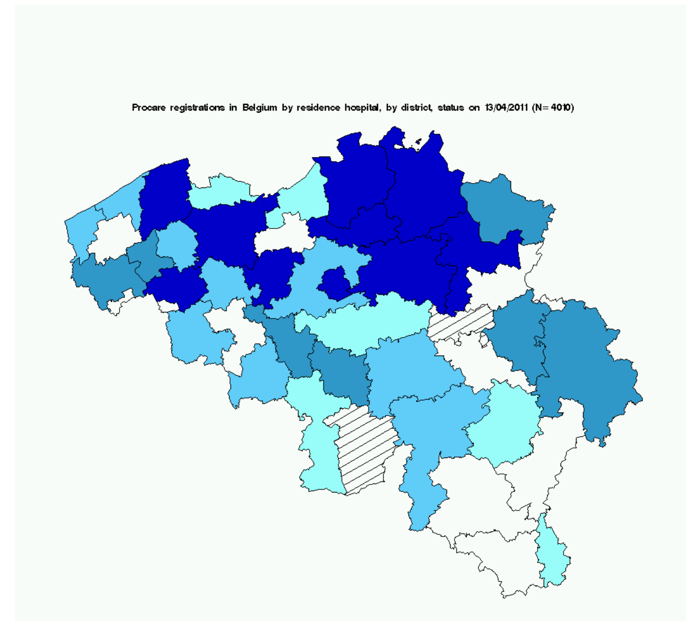
THANKS



Background

Factors independently associated with AL *

+	±
male gender	neoadjuvant RT or CRT
smoking	BMI
ASA >2	…/…
intra-oper. adverse events	
perioperative bleeding	
absence of defunct. stoma	

* in 3 multi- and 2 monocentric studies including > 1000 patients

Background
Meta-analysis DS versus no DS if no intra-operative adverse events

Cochrane Database of Systematic Reviews 2010, Issue 5 (Montedori et al)

	Risk Ratio
AL (B+C)	**0.33 (0.21 – 0.53)**
Reoperations	**0.28 (0.17 – 0.48)**
30 d mortality	0.58 (0.14 – 2.33)

Early AL grade B and C rate according to approach of reconstruction

	Global	No DS	DS	P-value*
Open	6.3%	9.9%	4.2%	<.001
Laparoscopic	7.4%	10.9%	4.7%	<.01

* for difference between no DS and DS

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Early AL grade B and C rate according to type of reconstruction

	N	Global	No DS	DS	P-value*
CAA straight	687	6.6%	7.2%	6.1%	.54
CAA coloplasty	64	6.3%	20%	2.0%	<.01
CAA side/end	455	7.7%	15.3%	3.4%	<.001
Colon pouch-AA	706	5.8%	9.6%	3.6%	<.001

* for difference between no DS and DS

How PROCARE became possible

- Belgian Foundation against Cancer (2006)
- **RIZIV/INAMI (2007-2012)**
- KCE (2007, 2008, 2011)

- Steering Group (all societies)
- **Participating professionals**
- **BCR**

RBSSurgery (BSCRS), BSSO, BGES
BSRadiotherapy – Oncology
BSPathology (Dig Path Club)
BSMOncology, BGDO
RBSRadiology
VVGE
SRBGE
BSGIEndoscopy
BPSA
FBCR

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