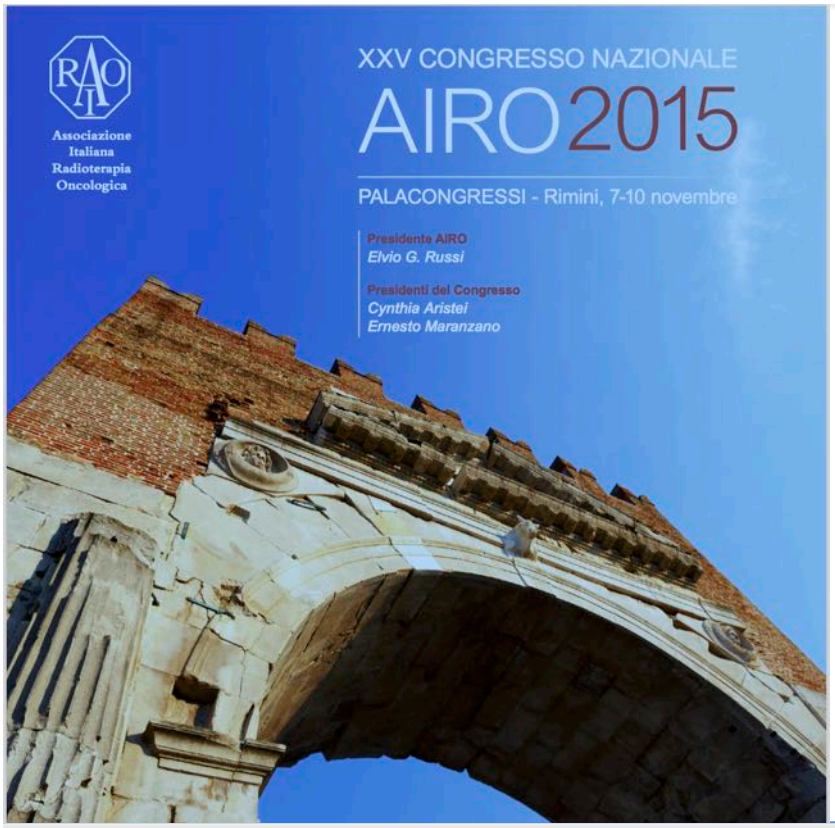


WORKSHOP

Intensificazione dei trattamenti neoadiuvanti nel carcinoma del retto e fattori predittivi di risposta

Cosa i pazienti si aspettano dall'intensificazione del trattamento

Maria Antonietta Gambacorta

Cattedra di Radioterapia

Università Cattolica del Sacro Cuore

Policlinico Agostino Gemelli
Università Cattolica del Sacro Cuore

Gemelli ART
Advanced Radiation Therapy

DICHIARAZIONE

Relatore: Maria Antonietta Gambacorta

Come da nuova regolamentazione della Commissione Nazionale per la Formazione Continua del Ministero della Salute, è richiesta la trasparenza delle fonti di finanziamento e dei rapporti con soggetti portatori di interessi commerciali in campo sanitario.

- Posizione di dipendente in aziende con interessi commerciali in campo sanitario **(NIENTE DA DICHIARARE)**
- Consulenza ad aziende con interessi commerciali in campo sanitario **(NIENTE DA DICHIARARE)**
- Fondi per la ricerca da aziende con interessi commerciali in campo sanitario **(NIENTE DA DICHIARARE)**
- Partecipazione ad Advisory Board **(NIENTE DA DICHIARARE)**
- Titolarietà di brevetti in compartecipazione ad aziende con interessi commerciali in campo sanitario **(NIENTE DA DICHIARARE)**
- Partecipazioni azionarie in aziende con interessi commerciali in campo sanitario **(NIENTE DA DICHIARARE)**
- Altro

Preoperative RT in rectal Ca: the downside of the coin

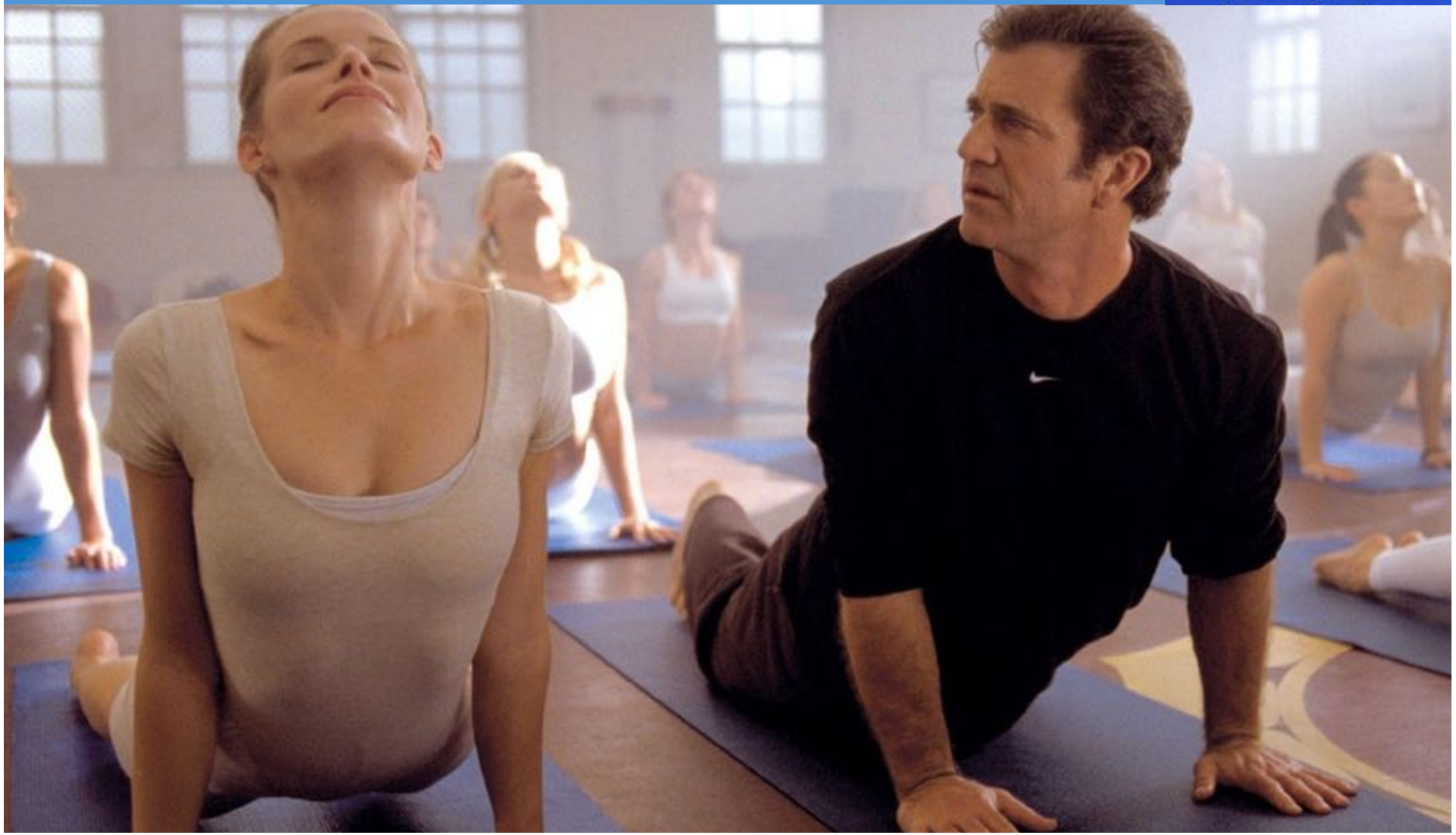
Preop Radiotherapy is the **STANDARD of CARE**

➢ Local control	6% advantage
➢ Overall survival	no benefit
➢ Bowel dysfuntion	20% disadvantage
➢ Sexual dysfunction	10% disadvantage
➢ Second tumor	5% disadvantage

Preop Radiotherapy has a CONTRVERSIAL ROLE!!

Shared Decision Making (SDM)

What Women Want



Shared Decision Making:

is the patient really involved?

Radiotherapyin Rectal Cancer: Shared Decision Making

Radiotherapy and Oncology xxx (2015) xxx–xxx

Contents lists available at ScienceDirect

Radiotherapy and Oncology

journal homepage: www.thegreenjournal.com

Original article

Considering patient values and treatment preferences enhances patient involvement in rectal cancer treatment decision making

Marleen Kunneman [a], Corrie A.M. Marijnen [b], Monique C.M. Baas-Thijssen [a], Yvette M. van der Linden [b], Tom Rozema [c], Karin Muller [d], Elisabeth D. Geijsen [e], Anne M. Stiggelbout [a], Arwen H. Pieterse [a,*]

[a] *Leiden University Medical Center, Department of Medical Decision Making;* [b] *Leiden University Medical Center, Department of Radiotherapy;* [c] *Verbeeten Institute, Tilburg;* [d] *Radiotherapy Group Deventer; and* [e] *Amsterdam Medical Center, Department of Radiation Oncology, The Netherlands*

Radiotherapyin Rectal Cancer: Shared Decision Making

Patients' point of view

Perceived decisional role[b]	
Patient made the decision	4 (7)
Patient made the decision after considering the radiation oncologist's opinion	13 (22)
Radiation oncologist and patient made the decision together	22 (37)
Radiation oncologist made the decision after considering the patient's opinion	12 (20)
Radiation oncologist made the decision	9 (15)

85%

ROs' point of view

In deciding about PRT, the radiation oncologists explicitly indicated to consider patients' values in 1/90 consultations (1%), patients' treatment preferences in 10/90 consultations (11%), or both in 5/90 consultations (6%).

18%

Kunneman M, Marijnen CAM et al Radiother Oncol 2015 in press

Shared Decision Making:

Patient and Doctor

Do we have same expectations?

Benefit and Harms

patients' and oncologists' treatment preferences

British Journal of Cancer (2007) 97, 717 – 724

www.bjcancer.com

Benefit from preoperative radiotherapy in rectal cancer treatment: disease-free patients' and oncologists' preferences

AH Pieterse*[,1], AM Stiggelbout[1], MCM Baas-Thijssen[1], CJH van de Velde[2] and CAM Marijnen[3,4]

[1]Department of Medical Decision Making, University Medical Center Leiden, Leiden, the Netherlands; [2]Department of Surgery, University Medical Center Leiden, Leiden, the Netherlands; [3]Department of Radiotherapy, Netherlands Cancer Institute, Amsterdam, the Netherlands; [4]Department of Clinical Oncology, University Medical Center Leiden, Leiden, the Netherlands

Benefit and Harms

patients' and oncologists' treatment preferences

66 DFS patients
60 oncologists (25 surgical, 26 radiation, 10 medical)
Interviewed

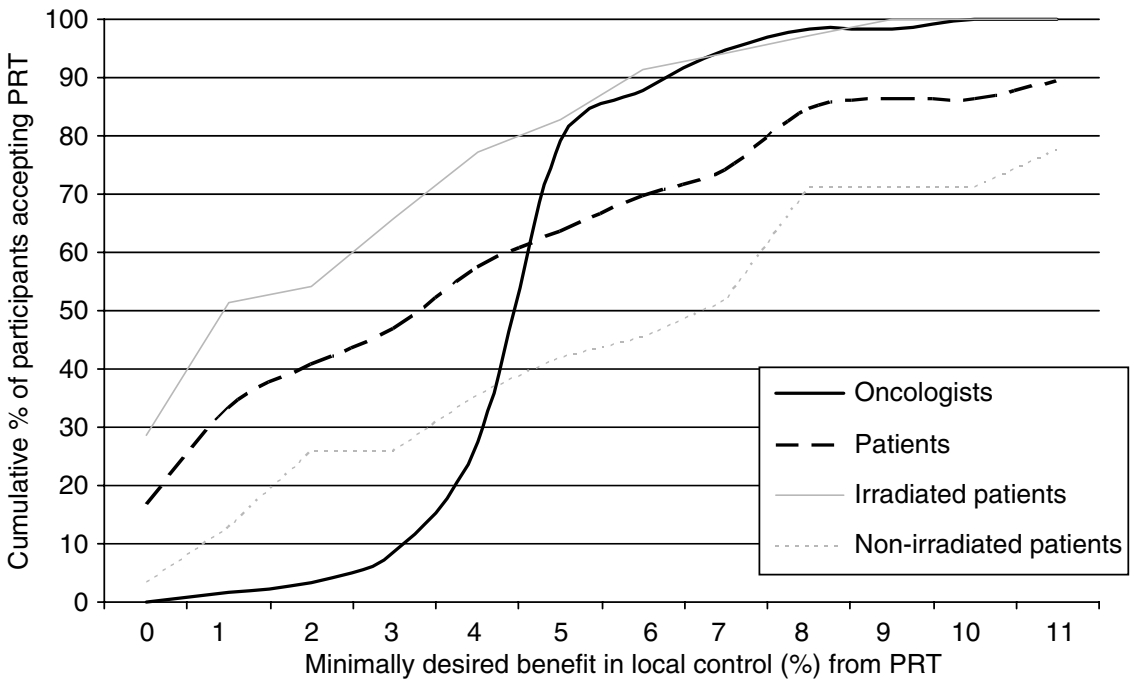
1. **Minimally desired benefit** from preop RT

2. **Relative importance of treatment oucomes** in **determining treatment outcome preference**:
   OS, LC, faecal incontinence, sex problems

Pieterse AH, Marijnen CAM et al Br J Can 2007

Minimally desired benefit from RT

patients' and oncologists' treatment preferences



Patients:

average **4.4%**

RT 2.6% vs **S** 5.1% p<0.001

Oncologists:

average **5%**

RO: 4.7%

MO: 5%

SO: 5.3%

p: n.s.

Pieterse AH, Marijnen CAM et al Br J Can 2007

Relative importance of treatment outcomes

oncologists' *treatment preferences*

Radiation Oncologists: **LOCAL CONTROL**

(RO 35 vs SO 28; p=0.02 vs MO: 24; p= 0.04)

Medical Oncologists: **SURVIVAL**

(MO 28 vs SO 17 vs; p= 0.05)

Surgical Oncologists: **SEXUAL ACTIVITY**

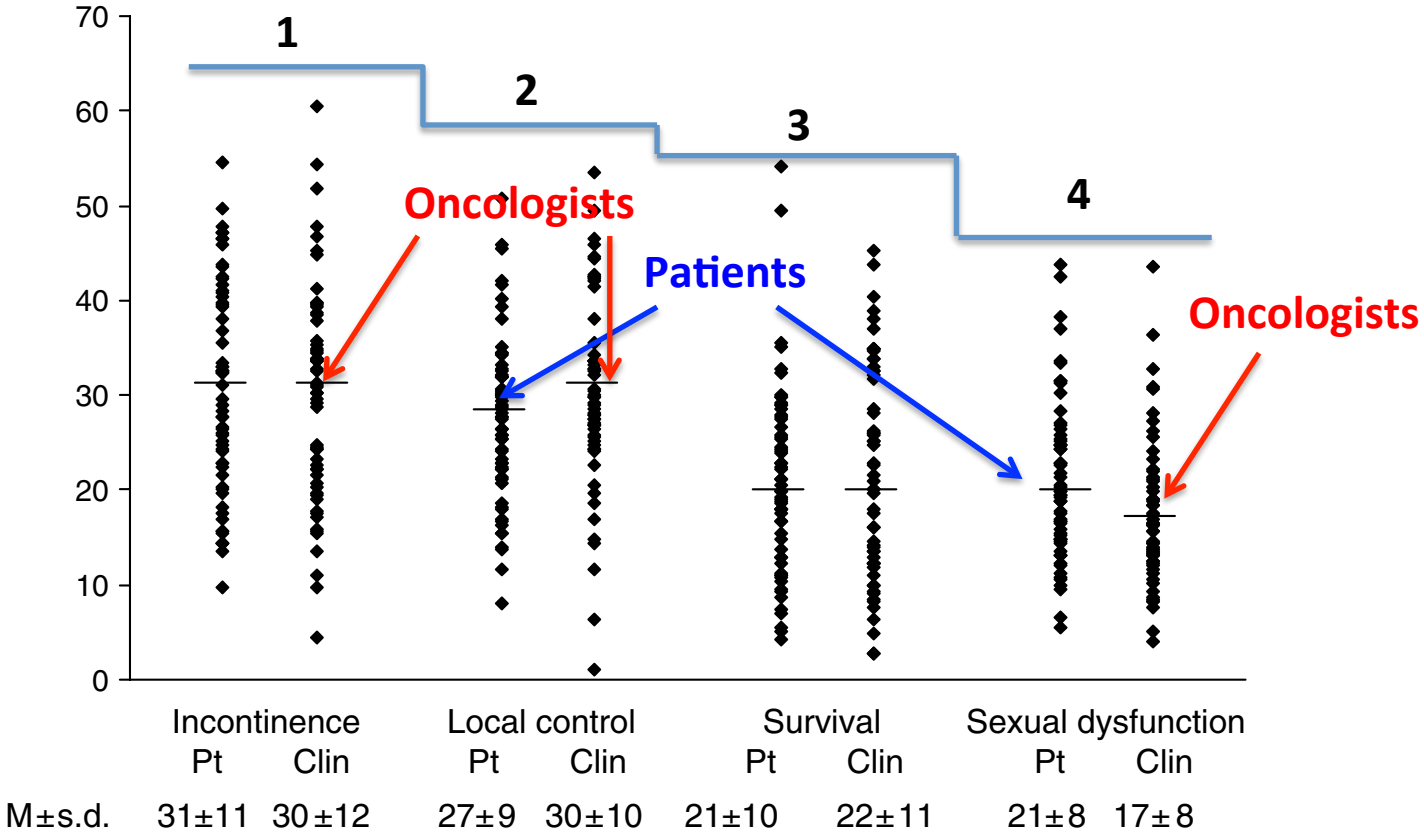
(SO 20 vs RO 14 vs; p= 0.02)

All males!!

Pieterse AH, Marijnen CAM et al Br J Can 2007

Relative importance of treatment outcomes

patients' *and* ***oncologists'*** *treatment preferences*



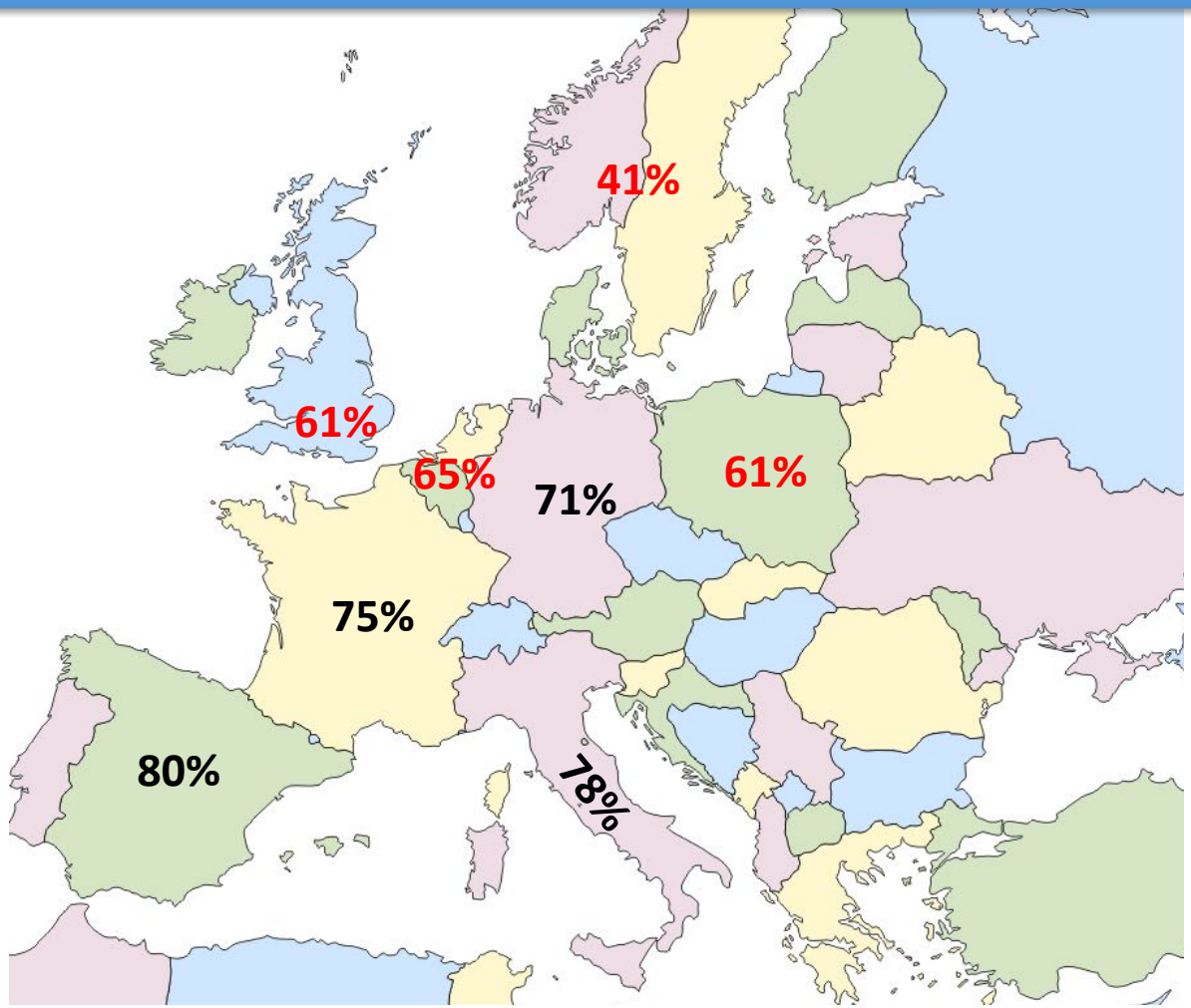
Pieterse AH, Marijnen CAM et al Br J Can 2007

Shared Decision Making:

May the sphincter preservation be preserved?

Has Sphincter Preservation the same value in Europe?

Data from RCT



Dutch Trial

MRC Trial

Polish Trial

Scandinavian Trial

German Trial

French Trial

Spanish Trial

Sphincter Preservation

TREATMENT GOLDEN STANDARD
Short RT, Chemorad…

WORKING IN TEAM
Specialists' availability,
Leadership conflicts

TECHNICAL SKILL
Ultra-low TME, TEM, TATA…

RISK TOLERANCE
Definitive surgery trust,
Clinical trial support

REHABILITATION SUPPORT SERVICES

PATIENTS' REQUEST
Cultural and religions constraints

Does the patients request influences the surgeon?

Swedish Rectal Cancer Registry 1995-2005: 16 713 patients

AR: 7433 patients (44.5%); APR 3808 (22.8 %) and Hartmann: 1704 (10.2 %)

Socio-economic	AR	APR
Un-married	Least likely (OR 0.76, 0.64 to 0.88)	More likely (OR 1.21, 1.00 to 1.48)
University educated	Most likely (OR 1.30, 1.04 to 1.62)	Less likely (OR 0.78, 0.63 to 0.98)
Highest income	More likely (OR 0.80, 0.85 and 0.86)	

Olsson LI Br J Surg *2010*

Does the patients request influences the surgeon?

Swedish Rectal Cancer Registry 1995-2005: 16 713 patients

AR: 7433 patients (44.5%); APR 3808 (22.8 %) and Hartmann: 1704 (10.2 %)

Socio-economic	AR	APR
Un-married	Least likely (OR 0.76, 0.64 to 0.88)	More likely (OR 1.21, 1.00 to 1.48)
University educated	Most likely (OR 1.30, 1.04 to 1.62)	Less likely (OR 0.78, 0.63 to 0.98)
Highest income	More likely (OR 0.80, 0.85 and 0.86)	

Olsson LI Br J Surg *2010*

Does the patients request influences the surgeon?

Swedish Rectal Cancer Registry 1995-2005: 16 713 patients

AR: 7433 patients (44.5%); APR 3808 (22.8 %) and Hartmann: 1704 (10.2 %)

Socio-economic	AR	APR
Un-married	Least likely (OR 0.76, 0.64 to 0.88)	More likely (OR 1.21, 1.00 to 1.48)
University educated	Most likely (OR 1.30, 1.04 to 1.62)	Less likely (OR 0.78, 0.63 to 0.98)
Highest income	More likely (OR 0.80, 0.85 and 0.86)	

Olsson LI Br J Surg *2010*

Has Sphincter Preservation the same value in Europe?
Data from RCT

	Sphinc Saving RT – RT+ %	
DUTCH trial	67 - 65	ns

	Sphinc Saving RT - RTCh %	
EORTC 22921	51 - 53	ns
FCCD 9203	52 - 53	ns
Polish Trial	57 - 52	ns
UCSC Trial	85 - 90	ns
ACCORD Trial	75 - 75	ns

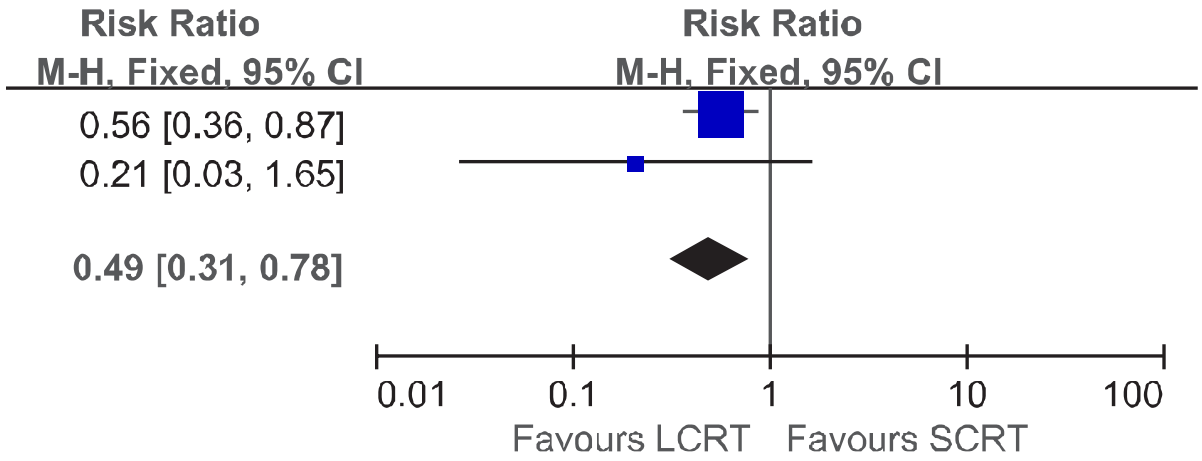
Van de Velde CJ – ECCO 13 - 2005

Bosset JF / Buiko K / Gerard JP – *NEJM, JCO,RO* – 2006

Valentini V – *IJROBP* – 2008

Gerard JP – *JCO* – 2010

SCRT delayed Surg vs LC-CRT delayed Surg



pCR rate

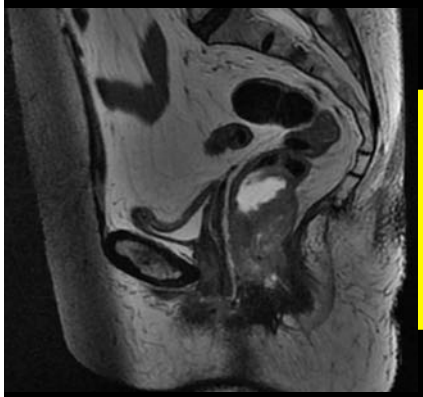
Shi-Xin Liu et al Asian Pac J Cancer Prev 2015

Shared Decision Making:

Can surgery be avoided?

pCR: the good and the bad news

PRE

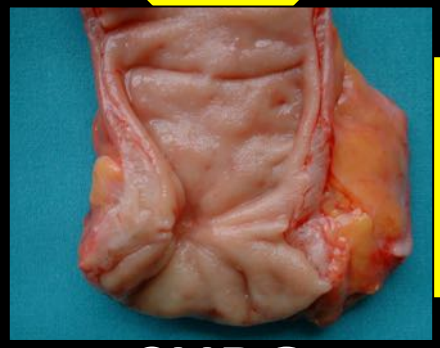


LC-CRT

POST

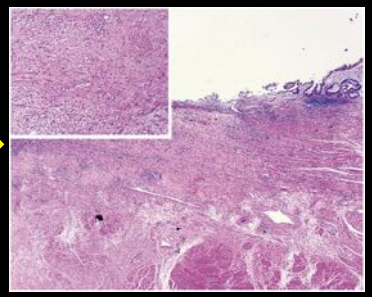
cCR

pCR



APR
sec Miles

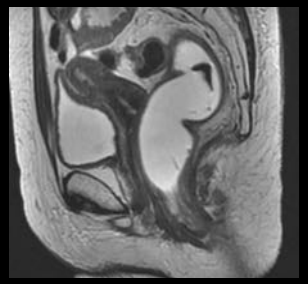
SURG

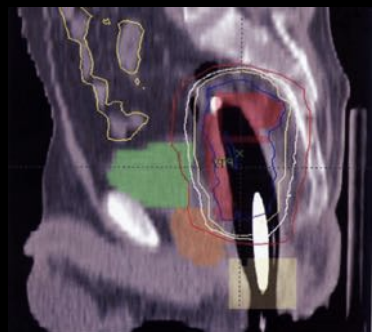


PATH

cCR: can we do LESS?

R
T
C
T





pCR: can we do MORE?

Br J Surg. 2015 Jun;102(7):853-60. doi: 10.1002/bjs.9809. Epub 2015 Apr 2.

Chemoradiation therapy for rectal cancer in the distal rectum followed b organ-sparing transanal endoscopic microsurgery (CARTS study).

Verseveld M[1], de Graaf EJ, Verhoef C, van Meerten E, Punt CJ, de Hingh IH, Nagtegaal ID, Nuyttens J Marijnen CA, de Wilt JH; CARTS Study Group.

Dis Colon Rectum. 2013 Dec;56(12):1349-56. doi: 10.1097/DCR.0b013e3182a2303e.

Local excision after preoperative chemoradiotherapy for rectal cancer: results of a multicenter phase II clinical trial.

Puccarelli S[1], De Paoli A, Guerrieri M, La Torre G, Maretto I, De Marchi F, Mantello G, Gambacorta MA, Canzonieri V, Nitti D, Valentini V, Coco C.

Hematol Oncol Clin North Am. 2015 Feb;29(1):135-51. doi: 10.1016/j.hoc.2014.09.004.

Nonoperative management of rectal cancer: identifying the ideal patients.

Habr-Gama A[1], São Julião GP[2], Perez RO[3].

J Contemp Brachytherapy. 2015 Apr;7(2):183-8. doi: 10.5114/jcb.2015.51402. Epub 2015 May 6.

High-dose-rate pre-operative endorectal brachytherapy for patients with rectal cancer.

Vuong T[1], Devic S[2].

Int J Radiat Oncol Biol Phys. 2012 Jun 1;83(2):e165-71. doi: 10.1016/j.ijrobp.2011.12.002.

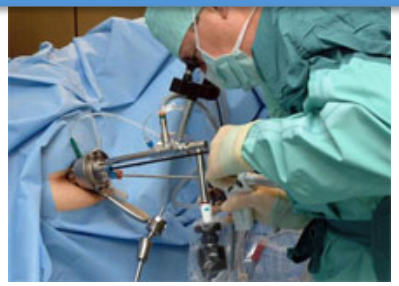
Correlation in rectal cancer between clinical tumor response after neoadjuvant radiotherapy and sphincter or organ preservation: 10-year results of the Lyon R 96-02 randomized trial.

Ortholan C[1], Romestaing P, Chapet O, Gerard JP.

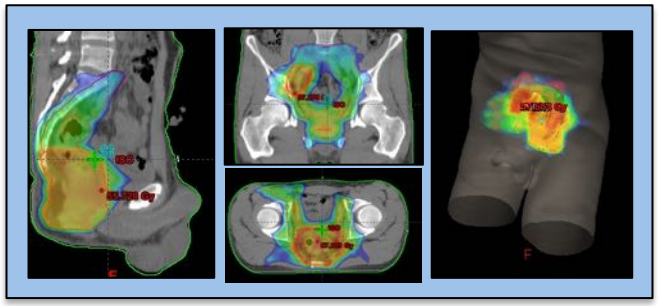
Surg Endosc. 2013 Aug;27(8):2860-7. doi: 10.1007/s00464-013-2842-6. Epub 2013 Feb 13.

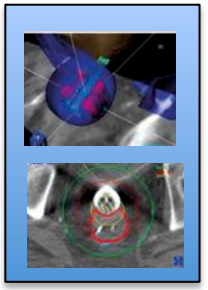
Transanal endoscopic microsurgery after neoadjuvant radiochemotherapy for locally advanced extraperitoneal rectal cancer: short-term morbidity and functional outcome.

Coco C[1], Rizzo G, Mattana C, Gambacorta MA, Verbo A, Barbaro B, Vecchio FM, Pafundi DP, Mastromarino MG, Valentini V.



Dose intensification



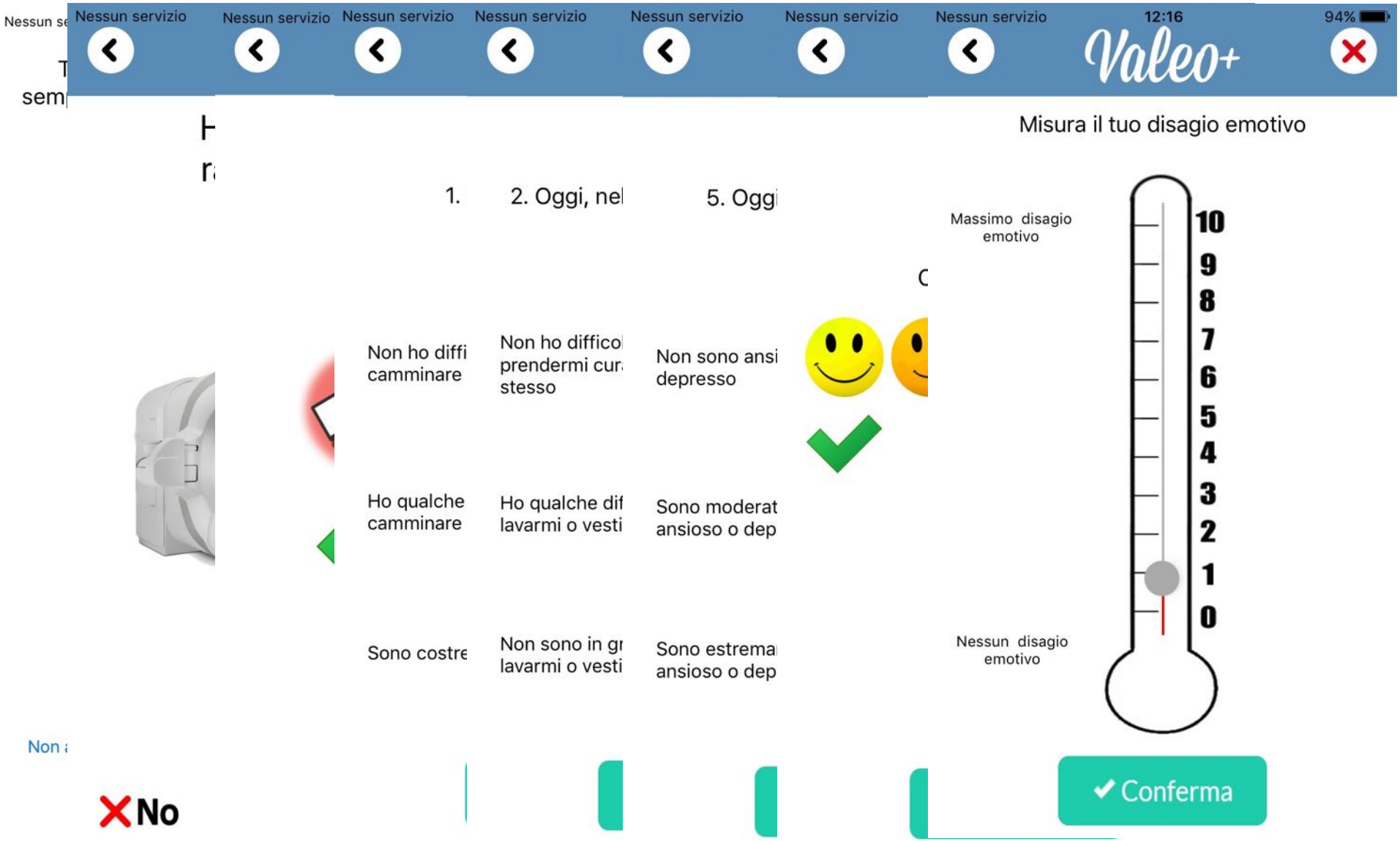


Shared Decision Making:

Is my oncologist always reacheable?

Valeo+ (VALuation Endorsed by Oncology Patient)

Valeo+ (VALuation Endorsed by Oncology Patient)



In conclusions

- Preop RT **Controversial Advantage**: **S**hared **D**ecision **M**aking

Cosa i pazienti si aspettano dall'intensificazione del trattamento?

- Patients **feel** themself **involved** > *increases outcomes*
- Consider **patient's values/preferences**: *incontinence >> LC!*
- **Sphincter preservation**: 'not objective' endpoint
- **Organ preservation**: open window
- Keep **in contact** with your patient: computerized systems