Comparative Effectiveness Research of Robotic Surgeries for Cancer Treatment

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Objectives

- Scientific challenges of comparing robotic versus traditional oncological surgical approaches
- Focus on most mature robotic series and comparisons – radical prostatectomy
- Discuss randomized trials in bladder and colon cancer

The complexities of comparative effectiveness research on devices: the case of robotic-assisted surgery for prostate cancer

Journal of Comparative Effectiveness Research

Sheldon Greenfield*[1] & William Sohn[1]

"...three levels of variance need to be partitioned when a device is introduced: the effectiveness of the procedure, the quality of the operator and the quality of the device itself."

Effectiveness of the Procedure

ORIGINAL ARTICLE

Radical Prostatectomy or Watchful Waiting in Early Prostate Cancer

Anna Bill-Axelson, M.D., Ph.D., Lars Holmberg, M.D., Ph.D., Hans Garmo, Ph.D., Jennifer R. Rider, Sc.D., Kimmo Taari, M.D., Ph.D., Christer Busch, M.D., Ph.D., Stig Nordling, M.D., Ph.D., Michael Häggman, M.D., Ph.D., Swen-Olof Andersson, M.D., Ph.D., Anders Spångberg, M.D., Ph.D., Ove Andrén, M.D., Ph.D., Juni Palmgren, Ph.D., Gunnar Steineck, M.D., Ph.D., Hans-Olov Adami, M.D., Ph.D., and Jan-Erik Johansson, M.D., Ph.D.

Table 1. Cumulative Incidence, Absolute Risk Reduction, and Relative Risk of Death from Any Cause, Death from Prostate Cancer, and Development of Distant Metastases at 18 Years of Follow-up.*

End Point	Cumulative Incidence				Absolute Risk Reduction with Radical Prostatectomy	Relative Risk with Radical Prostatectomy (95% CI)	P Value
	Radical Prostatectomy (N=347)		Watchful Waiting (N=348)				
	no. of events	*% (95% CI)*	*no. of events*	*% (95% CI)*	*percentage points (95% CI)*		
Death from any cause							
All	200	56.1 (50.9 to 62.0)	247	68.9 (63.8 to 74.3)	12.7 (5.1 to 20.3)	0.71 (0.59 to 0.86)	<0.001
Age							
<65 yr	69	40.0 (32.7 to 49.0)	112	65.6 (58.2 to 73.9)	25.5 (14.3 to 36.8)	0.50 (0.37 to 0.68)	<0.001
≥65 yr	131	69.8 (63.1 to 77.4)	135	71.7 (64.9 to 79.3)	1.9 (–8.2 to 12.0)	0.92 (0.73 to 1.18)	0.52
Tumor risk							
Low	51	43.4 (34.8 to 54.1)	85	59.1 (50.7 to 68.8)	15.6 (2.5 to 28.8)	0.57 (0.40 to 0.81)	0.002
Intermediate	87	57.1 (49.0 to 66.4)	95	72.5 (64.5 to 81.6)	15.5 (3.3 to 27.6)	0.71 (0.53 to 0.95)	0.02
High	62	73.3 (63.8 to 84.2)	67	78.8 (69.7 to 89.2)	5.6 (–8.5 to 19.6)	0.84 (0.60 to 1.19)	0.34
Death from prostate cancer							
All	63	17.7 (14.0 to 22.4)	99	28.7 (24.2 to 34.2)	11.0 (4.5 to 17.5)	0.56 (0.41 to 0.77)	0.001
Age							
<65 yr	31	18.3 (13.1 to 25.7)	58	34.1 (27.3 to 42.5)	15.8 (6.0 to 25.5)	0.45 (0.29 to 0.69)	0.002
≥65 yr	32	17.3 (12.5 to 24.0)	41	23.9 (18.2 to 31.5)	6.6 (–2.1 to 15.2)	0.75 (0.47 to 1.19)	0.19
Tumor risk							
Low	11	10.2 (5.8 to 18.0)	20	14.0 (9.1 to 21.5)	3.8 (–4.6 to 12.2)	0.54 (0.26 to 1.13)	0.17
Intermediate	24	15.1 (10.2 to 22.2)	50	39.3 (31.3 to 49.3)	24.2 (13.6 to 34.9)	0.38 (0.23 to 0.62)	<0.001
High	28	33.1 (24.0 to 45.7)	29	35.7 (26.3 to 48.5)	2.6 (–12.7 to 17.8)	0.87 (0.52 to 1.46)	0.84

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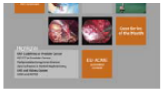
	no. of events	*% (95% CI)*	*no. of events*	*% (95% CI)*	*percentage points (95% CI)*		
Distant metastases							
All	89	26.1 (21.7 to 31.4)	138	38.3 (33.4 to 44.0)	12.2 (5.1 to 19.3)	0.57 (0.44 to 0.75)	<0.001
Age							
<65 yr	45	28.7 (22.2 to 37.1)	76	44.5 (37.3 to 53.0)	15.8 (5.1 to 26.6)	0.49 (0.34 to 0.71)	<0.001
≥65 yr	44	23.8 (18.4 to 30.9)	62	32.7 (26.4 to 40.5)	8.9 (–0.5 to 18.3)	0.68 (0.46 to 1.00)	0.04
Tumor risk							
Low	15	13.6 (8.4 to 21.9)	35	24.2 (17.8 to 33.0)	10.6 (0.7 to 20.6)	0.40 (0.21 to 0.73)	0.006
Intermediate	37	25.0 (18.8 to 33.3)	59	44.9 (36.9 to 54.7)	19.9 (8.5 to 31.3)	0.49 (0.32 to 0.74)	<0.001
High	37	45.9 (35.8 to 58.8)	44	50.8 (40.6 to 63.5)	4.9 (–11.2 to 21.0)	0.81 (0.52 to 1.26)	0.39
Androgen-deprivation therapy							
All	145	42.5 (37.5 to 48.1)	235	67.4 (62.6 to 72.6)	25.0 (17.7 to 32.3)	0.49 (0.39 to 0.60)	<0.001
Age							
<65 yr	68	44.2 (36.9 to 53.0)	122	72.6 (66.0 to 79.8)	28.4 (17.8 to 38.9)	0.39 (0.29 to 0.52)	<0.001
≥65 yr	77	40.9 (34.4 to 48.7)	113	62.8 (56.0 to 70.4)	21.8 (11.7 to 32.0)	0.60 (0.45 to 0.80)	<0.001
Tumor risk							
Low	32	27.9 (20.7 to 37.6)	63	47.9 (39.9 to 57.5)	20.1 (8.0 to 32.1)	0.45 (0.29 to 0.69)	0.001
Intermediate	65	44.9 (37.4 to 54.0)	98	73.6 (66.3 to 81.7)	28.6 (17.3 to 40.0)	0.45 (0.33 to 0.62)	<0.001
High	48	59.3 (49.3 to 71.2)	74	88.1 (81.2 to 95.6)	28.8 (15.8 to 41.9)	0.45 (0.31 to 0.65)	<0.001

European Association of Urology



Platinum Priority – Prostate Cancer
Editorial by Patrick J. Bastian on pp. 323–324 of this issue

Cancer Control and Functional Outcomes After Radical Prostatectomy as Markers of Surgical Quality: Analysis of Heterogeneity Between Surgeons at a Single Cancer Center

Andrew Vickers [a,], Caroline Savage [a], Fernando Bianco [b], John Mulhall [c], Jaspreet Sandhu [c], Bertrand Guillonneau [c], Angel Cronin [d], Peter Scardino [c]*

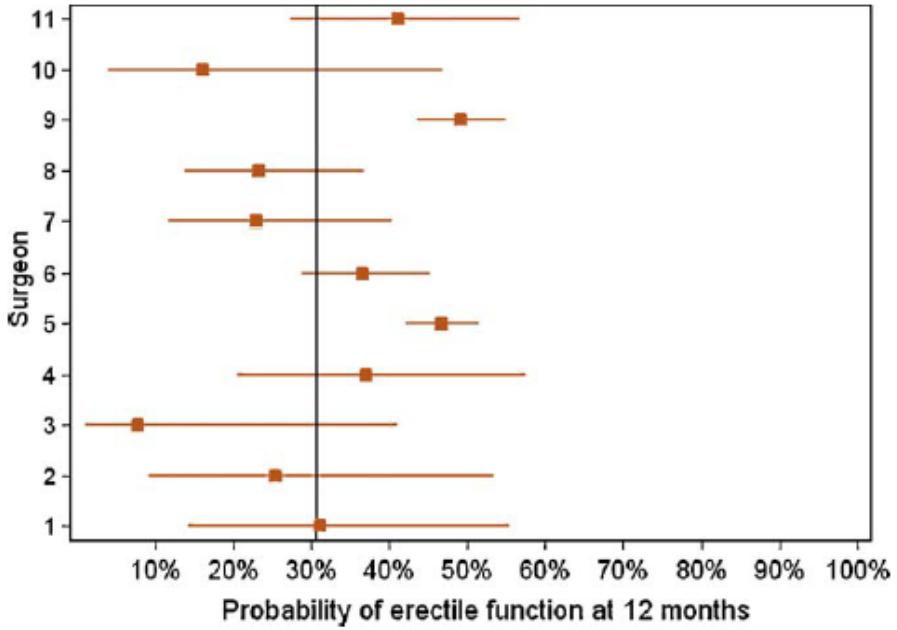


Fig. 1 – Forest plot for probability of erectile function (erectile rigidity score of 1 or 2) at 1 yr. The proportions are for a patient with the mean level of all covariates. The vertical line represents the mean adjusted proportion of patients with erectile function at 1 yr for all surgeons.

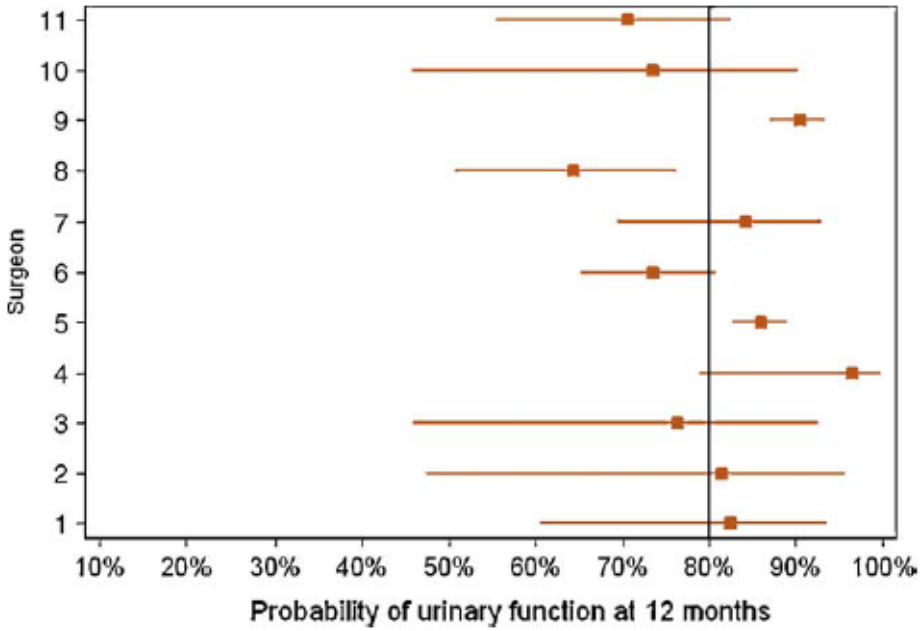


Fig. 2 – Forest plot for probability of full continence (urinary control score of 1 [no pads]) at 1 yr. The proportions are for a patient with the mean level of all covariates. The vertical line represents the mean adjusted proportion of patients who were continent at 1 yr for all surgeons.

Quality of the Operator: Learning Curves for Robotic Assisted Radical Prostatectomy

- threshold for significantly decreasing complication rates is 150 cases (Ou YC, BJU 2011)
- Over 1600 cases required to reduce positive surgical margins to <10% (Sooriakumaran P, Min Urol Nef 2011)
- Operative times began to plateau at 750 cases (Sooriakumaran P, Min Urol Nef 2011)
- Preservation of Sexual Function plateaus at 1400 cases (Alemozaffar M, Euro Urol 2012)

Quality of the Device
Robotic Surgery Platform

- 3 dimensional vision
- 7 degrees of wristed motion
- Ergonomic advantages for the surgeon
- Absence of fulcrum effect

Global robotic experience and the type of surgical system impact the types of robotic malfunctions and their clinical consequences: an FDA MAUDE review

BJUI
BJU INTERNATIONAL

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TABLE 1
Total number of FDA MAUDE reports per year from 2002 to 2009

Year	Total number of reports	Approximate number of cases	dVS	dV
2003	82	N/A	0	82
2004	114 (1.14%)	10 000	0	114
2005	140 (0.64%)	22 000	0	140
2006	188 (0.42%)	44 000	11	177
2007	544 (0.75%)	73 000	319	211
2008	703 (0.61%)	115 000	571	125
2009	137 (0.08%)	171 000	89	26
Total	1914	435 000	991	878

TABLE 3 Effect of robotic system an outcomes following device malfunction

	dV	dVS	*P*
Conversions (%)	Open 10 (1.2) Lap 163 (19.3)	Open 10 (1.0) Lap 75 (7.7)	<0.001
Aborted procedures (%)	30 (3.6)	22 (2.3)	0.093
Procedure delay	Minor 14 (1.7) Major 17 (2.0)	Minor 28 (2.9) Major 29 (3.0)	0.099
Injury (%)	30 (3.5)	57 (5.9)	0.021
Death	4	19	0.002

Population-Based Comparative Effectiveness Studies

Comparative Effectiveness of Minimally Invasive vs Open Radical Prostatectomy

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Michael J. Barry, MD
Anthony V. D'Amico, MD, PhD
Aaron C. Weinberg, MD
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Context Minimally invasive radical prostatectomy (MIRP) has diffused rapidly despite limited data on outcomes and greater costs compared with open retropubic radical prostatectomy (RRP).

Objective To determine the comparative effectiveness of MIRP vs RRP.

Design, Setting, and Patients Population-based observational cohort study using US Surveillance, Epidemiology, and End Results Medicare linked data from 2003 through 2007. We identified men with prostate cancer who underwent MIRP (n=1938) vs RRP (n=6899).

Main Outcome Measures We compared postoperative 30-day complications, anastomotic stricture 31 to 365 days postoperatively, long-term incontinence and erectile dysfunction more than 18 months postoperatively, and postoperative use of additional cancer therapies, a surrogate for cancer control.

Results Among men undergoing prostatectomy, use of MIRP increased from 9.2% (95% confidence interval [CI], 8.1%-10.5%) in 2003 to 43.2% (95% CI, 39.6%-46.9%) in 2006-2007. Men undergoing MIRP vs RRP were more likely to be recorded as Asian (6.1% vs 3.2%), less likely to be recorded as black (6.2% vs 7.8%) or Hispanic (5.6% vs 7.9%), and more likely to live in areas with at least 90% high school graduation rates (50.2% vs 41.0%) and with median incomes of at least $60 000 (35.8% vs 21.5%) (all $P<.001$). In propensity score–adjusted analyses, MIRP vs RRP was associated with shorter length of stay (median, 2.0 vs 3.0 days; $P<.001$) and lower rates of blood transfusions (2.7% vs 20.8%; $P<.001$), postoperative respiratory complications (4.3% vs 6.6%; $P=.004$), miscellaneous surgical complications (4.3% vs 5.6%; $P=.03$), and anastomotic stricture (5.8% vs 14.0%; $P<.001$). However, MIRP vs RRP was associated with an increased risk of genitourinary complications (4.7% vs 2.1%; $P=.001$) and diagnoses of incontinence (15.9 vs 12.2 per 100 person-years; $P=.02$) and erectile dysfunction (26.8 vs 19.2 per 100 person-years; $P=.009$). Rates of use of additional cancer therapies did not differ by surgical procedure (8.2 vs 6.9 per 100 person-years; $P=.35$).

Conclusion Men undergoing MIRP vs RRP experienced shorter length of stay, fewer respiratory and miscellaneous surgical complications and strictures, and similar postoperative use of additional cancer therapies but experienced more genitourinary complications, incontinence, and erectile dysfunction.

JAMA. 2009;302(14):1557-1564 www.jama.com

Following the description of consistently reproducible advantages of minimally invasive radical prostatectomy (MIRP) with and without robotic assistance in 2000-2001,[1,2] use of MIRP has surged.[3,4] In particular, use of robotic-assisted MIRP increased from 1% to 40% of all radical prostatectomies from 2001 to 2006.[5,6] Many patients intuitively perceive minimally invasive approaches to reduce complications compared with conventional open operations and prefer minimally invasive procedures because of smaller incisions requiring less analgesics and shorter hospital stays, even at greater cost.[7]

Moreover, the widespread direct-to-consumer advertising and marketed benefits of robotic-assisted MIRP in the United States may promote publication bias against studies that detail challenges and suboptimal outcomes early in the MIRP learning curve.[8] Until com-

Table 3. Propensity Model–Adjusted Outcomes by Surgical Approach[a]

Outcomes	MIRP	RRP	MIRP vs RRP, Ratio (95% Confidence Interval)[b]	*P* Value
Length of stay, median (IQR)[c]	2 (1-2)	3 (2-4)	0.67 (0.58-0.72)	<.001
Heterologous blood transfusion, %	2.7	20.8	0.11 (0.06-0.17)	<.001
30-Day complications, %				
Overall	22.2	23.2	0.95 (0.77-1.16)	.58
Cardiac	2.4	2.9	0.81 (0.49-1.33)	.37
Respiratory	4.3	6.6	0.63 (0.46-0.87)	.004
Genitourinary	4.7	2.1	2.28 (1.61-3.22)	.001
Wound	2	1.9	1.05 (0.61-1.82)	.86
Vascular	3.4	3.9	0.86 (0.55-1.35)	.50
Miscellaneous medical	10	8.5	1.19 (0.89-1.6)	.26
Miscellaneous surgical	4.3	5.6	0.75 (0.56-0.99)	.03
Death	0.1	0.2	0.31 (0.07-1.28)	.05
Anastomotic stricture, %[d]	5.8	14.0	0.38 (0.28-0.52)	<.001
Incontinence per 100 person-years[e]				
Diagnosis	15.9	12.2	1.3 (1.05-1.61)	.02
Procedures	7.8	8.9	0.87 (0.69-1.1)	.24
Erectile dysfunction per 100 person-years[e]				
Diagnosis	26.8	19.2	1.40 (1.14-1.72)	.009
Procedure	2.3	2.2	1.05 (0.74-1.51)	.78
Additional cancer therapy per 100 person-years				
Overall	8.2	6.9	1.19 (0.84-1.69)	.35
Radiation	5.1	4.9	1.05 (0.84-1.32)	.67
Hormone	5.3	3.7	1.42 (0.88-2.32)	.21

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Temporal National Trends of Minimally Invasive and Retropubic Radical Prostatectomy Outcomes from 2003 to 2007: Results from the 100% Medicare Sample

Keith J. Kowalczyk[a], *Jesse M. Levy*[b], *Craig F. Caplan*[b], *Stuart R. Lipsitz*[c], *Hua-yin Yu*[d], *Xiangmei Gu*[c], *Jim C. Hu*[c,d,*]

Table 4 – Comparison of overall complications of minimally invasive radical prostatectomy and retropubic radical prostatectomy from 2003 to 2007

	MIRP $n = 19\,594$	RRP $n = 58\,638$	*p* value
Mean length of stay, d, plus or minus standard deviation *n* (%)	2.0 ± 0.1	4.2 ± 0.1	<0.001
Any perioperative complication	3836 (19.6)	17 369 (29.8)	<0.001
Cardiac	431 (2.2)	2756 (4.7)	<0.001
Genitourinary	933 (4.8)	4068 (6.9)	<0.001
Miscellaneous medical	1721 (8.8)	7360 (12.6)	<0.001
Miscellaneous surgical	816 (4.2)	3498 (6.0)	<0.001
Respiratory	808 (4.1)	5535 (9.4)	<0.001
Vascular	520 (2.7)	2529 (4.3)	<0.001
Wound	349 (1.8)	2294 (3.9)	<0.001
Death	30 (0.2)	367 (0.6)	<0.001
Perioperative blood transfusion	502 (2.6)	10 135 (17.3)	<0.001
Cystography utilization	7194 (36.7)	6468 (11.0)	<0.001
	MIRP $n = 11\,108$	RRP $n = 45\,277$	*p* value
Late complications			
Anastomotic stricture	333 (3.0)	4225 (9.3)	<0.001
Ureteral complications	58 (0.5)	610 (1.3)	<0.001
Rectourethral fistula	39 (0.4)	159 (0.4)	0.999
Lymphocele	146 (1.3)	1003 (2.2)	<0.001
Surgical intervention for incontinence	30 (0.3)	132 (0.3)	0.734

MIRP = minimally invasive radical prostatectomy; RRP = retropubic radical prostatectomy.

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Utilization of Pharmacotherapy for Erectile Dysfunction Following Treatment for Prostate Cancer

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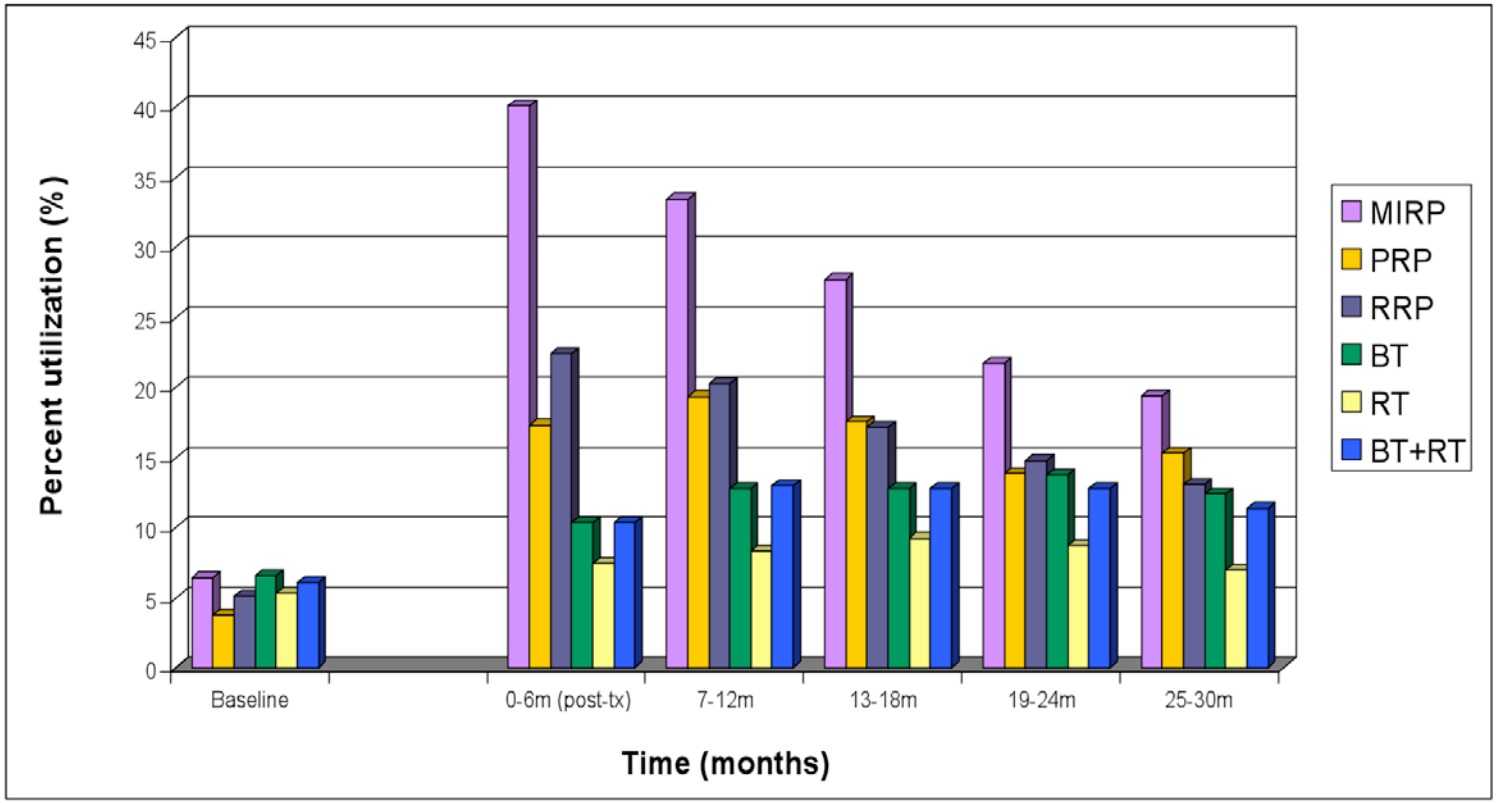

J Sex Med 2010

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Platinum Priority – Prostate Cancer
Editorial by Thomas E. Ahlering on pp. 226–227 of this issue

Urinary Incontinence and Erectile Dysfunction After Robotic Versus Open Radical Prostatectomy: A Prospective, Controlled, Nonrandomised Trial

Eva Haglind [a,], Stefan Carlsson [b], Johan Stranne [c], Anna Wallerstedt [b], Ulrica Wilderäng [d], Thordis Thorsteinsdottir [d,e], Mikael Lagerkvist [f], Jan-Erik Damber [c], Anders Bjartell [g], Jonas Hugosson [c], Peter Wiklund [b], Gunnar Steineck [d,h], on behalf of the LAPPRO steering committee [†]*

Table 2 – Erectile dysfunction compared between open and robot-assisted laparoscopic surgery using various definitions and as reported by patients 12 mo after surgery

Definition of erectile dysfunction	Open surgery, *n* (%)	Robot-assisted surgery, *n* (%)	Adjusted A, OR (95% CI) **	Adjusted B, OR (95% CI) †	Adjusted C, OR (95% CI) ‡
IIEF score §	531 (75)	1200 (70)	0.80 (0.64–1.00)	0.79 (0.63–1.00)	0.73 (0.58–0.93)
IIEF-5 score # at 12 mo ≤16	570 (81)	1311 (78)	0.86 (0.68–1.09)	0.75 (0.58–0.96)	0.75 (0.58–0.97)
IIEF-5 score # at 12 mo ≤21	654 (93)	1508 (90)	0.71 (0.50–0.99)	0.61 (0.42–0.88)	0.61 (0.42–0.88)
Penile stiffness less than half of the time	574 (81)	1323 (77)	0.81 (0.64–1.03)	0.75 (0.59–0.96)	0.75 (0.58–0.97)
No spontaneous morning erection	664 (93)	1522 (89)	0.59 (0.42–0.82)	0.52 (0.36–0.76)	0.50 (0.35–0.74)
Erectile dysfunction, combined variable ¤	561 (79)	1282 (75)	0.80 (0.64–1.00)	0.74 (0.59–0.95)	0.75 (0.58–0.96)

For all definitions of ED, OR ranged from 0.59 to 0.86 and significantly favored Robotic versus Open

Evidence of Superior Quality of Life after Robotic Prostatectomy: Results from a Population-Based Analysis

Brock O'Neil*, Tatsuki Koyama, JoAnn Rudd, Nashville, TN, Albertsen Peter, Farmington, CT, Cooperberg Matthew, San Francisco, CA, Michael Goodman, Atlanta, GA, Sheldon Greenfield, Irvine, CA, Ann Hamilton, Los Angeles, CA, Karen Hoffman, Houston, TX, Richard Hoffman, Albuquerque, NM, Sherrie Kaplan, Irvine, CA, Janet Stanford, Seattle, WA, Antionette Stroup, New Brunswick, NJ, Xiao-Cheng Wu, New Orleans, LA, Matthew Resnick, Daniel Barocas, David Penson, Nashville, TN

1505 RRP vs. 933 RARP

	Urinary Function RALP vs. Open Difference in EPIC (95% CI)	Sexual Function RALP vs. Open Difference in EPIC (95% CI)
6 months	3.8 (1.1 - 6.4)	10.2 (7.5 – 12.9)
12 months	1.2 (1.3 – 3.7)	10.3 (7.5 – 13.1)

“This population-based study using validated and reliable QOL tools suggests benefit of RALP”

European Association of Urology

Platinum Priority – Prostate Cancer

Editorial by R. Jeffrey Karnes, Steven Joniau, Michael L. Blute and Hendrik Van Poppel on pp. 673–675 of this issue

Comparative Effectiveness of Robot-assisted Versus Open Radical Prostatectomy Cancer Control

Jim C. Hu [a,], Giorgio Gandaglia [b,c], Pierre I. Karakiewicz [b,g], Paul L. Nguyen [d], Quoc-Dien Trinh [e], Ya-Chen Tina Shih [f], Firas Abdollah [b,g], Karim Chamie [a], Jonathan L. Wright [h], Patricia A. Ganz [i], Maxine Sun [b]*

Table 2 – Unadjusted rate of positive surgical margins by clinical stage, pathological stage, and the D'Amico risk classification for open versus robot-assisted radical prostatectomy in the post-propensity based cohort

	ORP, no. (%)	RARP, no. (%)	RARP vs ORP OR (95% CI)*	*p*
Overall	1010 (18.3)	752 (13.6)	0.70 (0.66–0.75)	<0.001
Clinical stage				
≤T1c (*n* = 6770)	594 (17.9)	483 (14.0)	0.73 (0.67–0.79)	<0.001
T2a/b (*n* = 3226)	308 (18.3)	205 (13.3)	0.67 (0.57–0.79)	<0.001
≥T2c (*n* = 1052)	108 (20.7)	64 (12.1)	0.59 (0.40–0.88)	0.009
Pathologic stage				
pT2 (*n* = 9156)	676 (14.6)	466 (10.3)	0.66 (0.62–0.71)	<0.001
pT3a (*n* = 1892)	334 (37.2)	286 (28.8)	0.73 (0.63–0.85)	<0.001
Risk groups				
Low (*n* = 2314)	109 (9.2)	90 (8.0)	0.89 (0.71–1.12)	0.321
Intermediate (*n* = 4333)	420 (21.0)	351 (15.0)	0.66 (0.59–0.75)	<0.001
High (*n* = 4401)	481 (20.6)	311 (15.1)	0.70 (0.63–0.77)	<0.001

CI = confidence interval; OR = odds ratio; ORP = open radical prostatectomy; RARP = robot-assisted radical prostatectomy.

* Overall multivariable model adjusted for age at diagnosis, race, marital status, population density, socioeconomic status, baseline comorbidities, clinical stage (except in stratified analyses), Gleason score, preoperative prostate-specific antigen, region, as well as clustering of surgeons and year of surgery.

Survival after Robotic Assisted versus Open Radical Prostatectomy: National Comparative Effectiveness study

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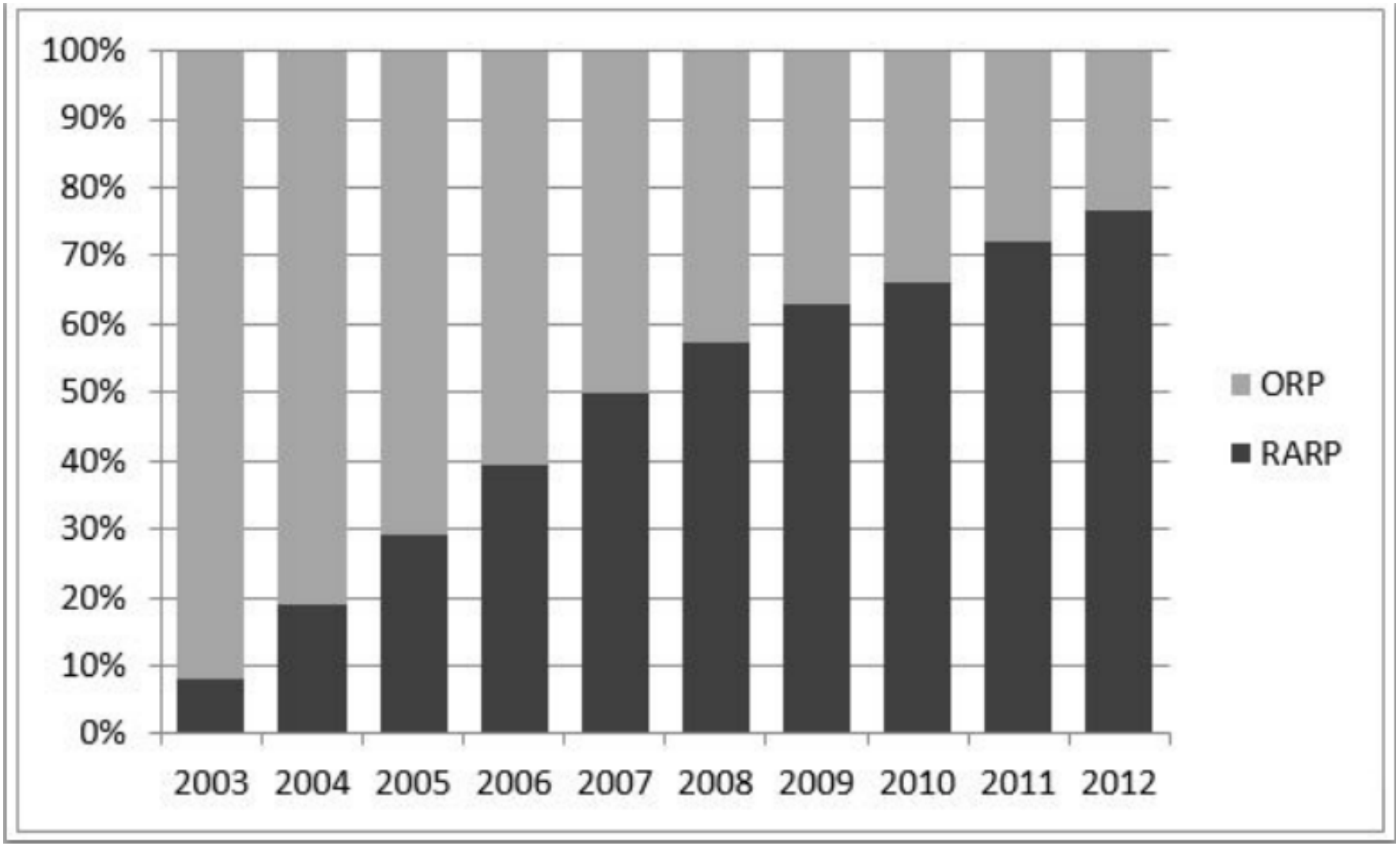
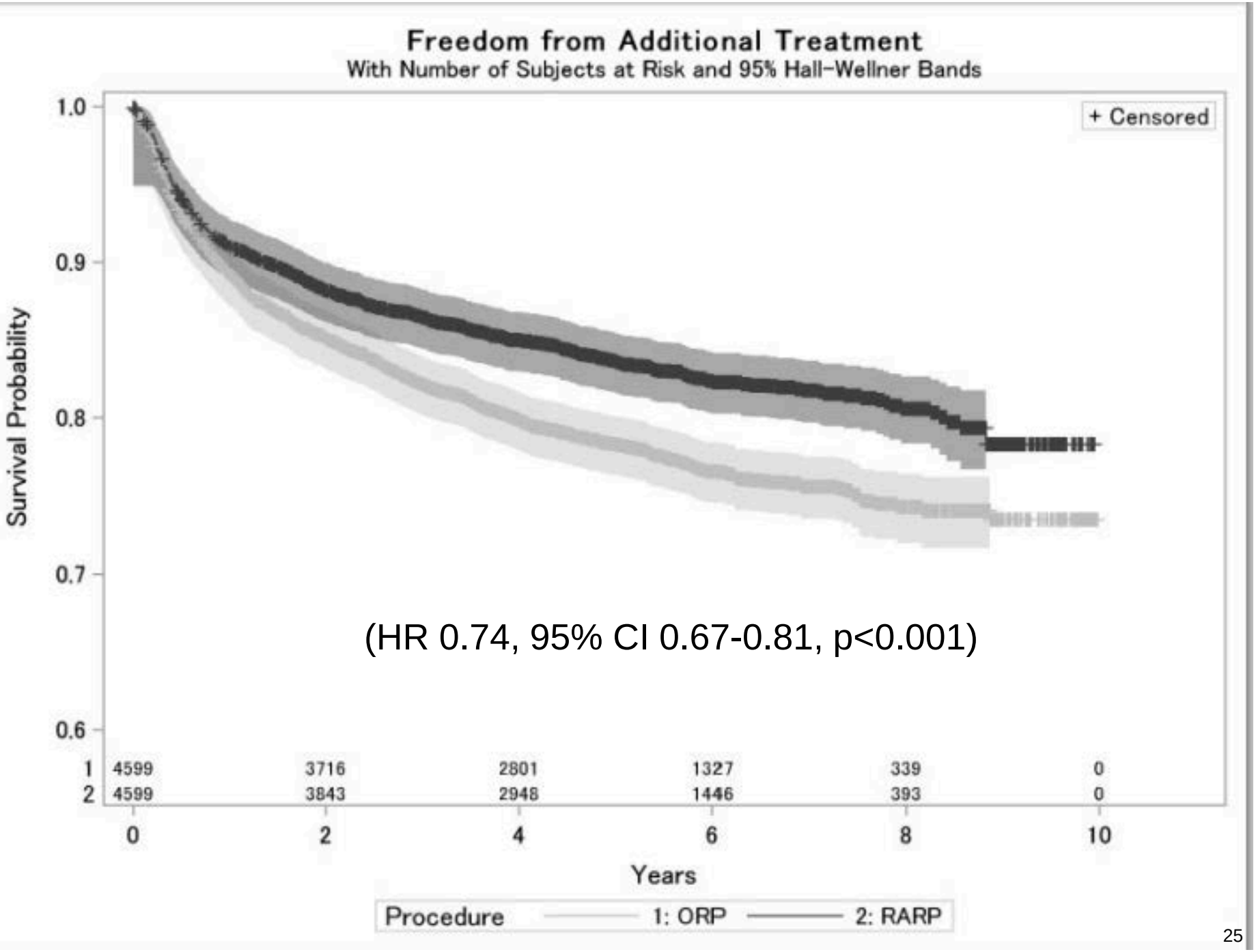
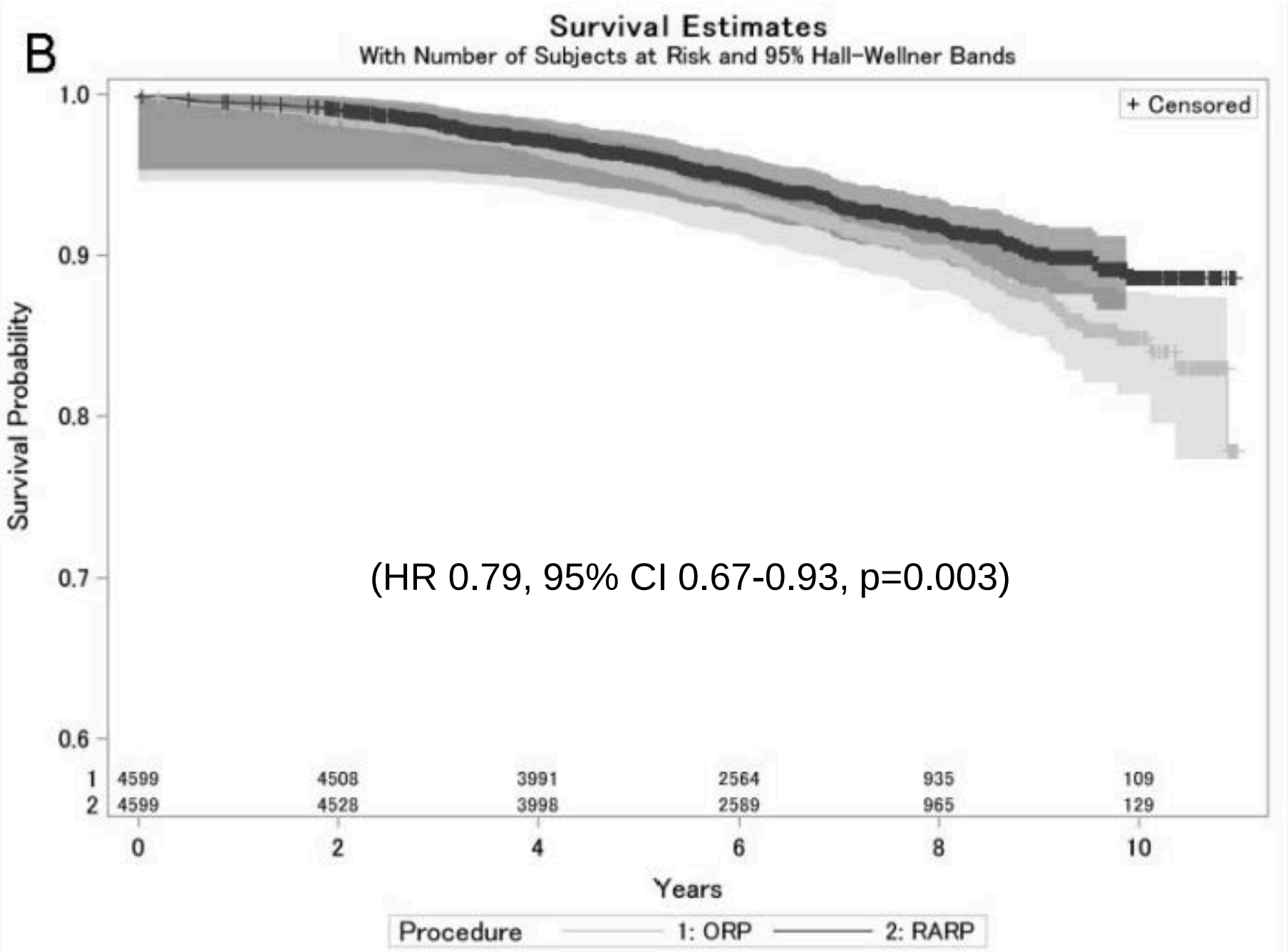
Current Utilization

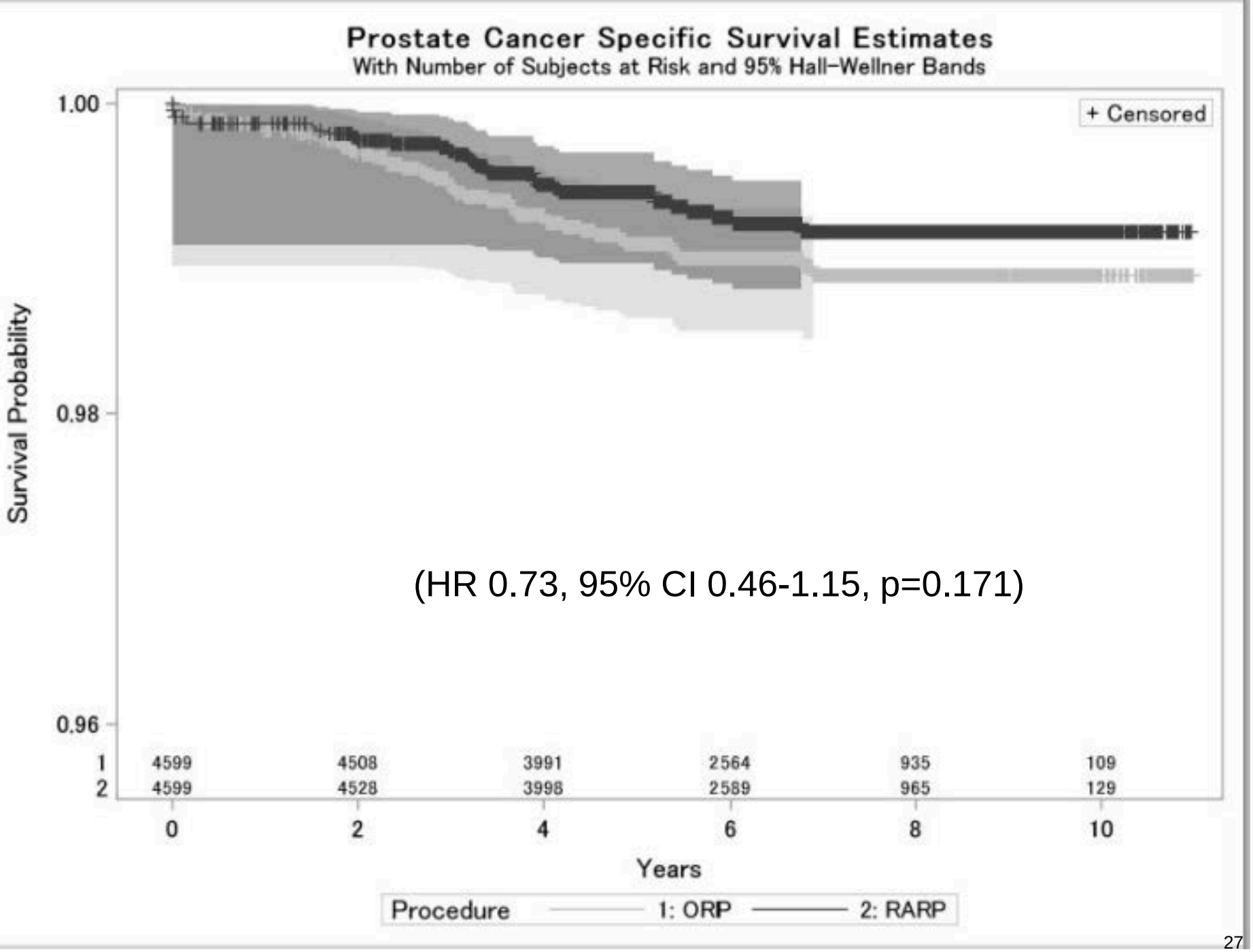


SEER-Medicare


Freedom from Additional Treatment
With Number of Subjects at Risk and 95% Hall-Wellner Bands
+ Censored
Survival Probability
1.0
0.9
0.8
0.7
0.6
(HR 0.74, 95% CI 0.67-0.81, p<0.001)
1 4599 3716 2801 1327 339 0
2 4599 3843 2948 1446 393 0
0 2 4 6 8 10
Years
Procedure 1: ORP 2: RARP



(HR 0.79, 95% CI 0.67-0.93, p=0.003)


Prostate Cancer Specific Survival Estimates
With Number of Subjects at Risk and 95% Hall-Wellner Bands
+ Censored
1.00
0.98
0.96
Survival Probability
(HR 0.73, 95% CI 0.46-1.15, p=0.171)
1 4599 4508 3991 2564 935 109
2 4599 4528 3998 2589 965 129
0 2 4 6 8 10
Years
Procedure 1: ORP 2: RARP

European Association of Urology

Platinum Priority – Collaborative Review – Prostate Cancer

Editorial by Suzanne Biehn Stewart, Shelby D. Reed and Judd W. Moul on pp. 325–327 of this issue

Costs of Radical Prostatectomy for Prostate Cancer: A Systematic Review

Christian Bolenz[a,*], *Stephen J. Freedland*[b], *Brent K. Hollenbeck*[c], *Yair Lotan*[d], *William T. Lowrance*[e], *Joel B. Nelson*[f], *Jim C. Hu*[g]

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Table 1 – Studies reporting on direct costs of different approaches to radical prostatectomy

Study no.	Authors (study year)	Reference	Study design	RP approaches (no. of patients); direct costs[a]	Cost premium for MIRP[b] (%)	Comment
1	Guillonneau, Vallancien (2000)	18	Retrospective	**RRP (100); $6296**	**−$1238 (−25)**	First cost comparison between RP approaches
				LRP (120); $5058		
2	Benoit, Cohen (2001)	17	Retrospective	RRP (104); $5305[c]	n.a.	OR/surgical time and units of blood transfused were the main drivers of costs for RRP
3	Makhlouf et al. (2002)	20	Retrospective	RRP (29); $7476[c]	n.a.	Higher OR and surgical supply costs than [17]
4	Silverstein et al. (2004)	23	Retrospective	**RRP (123); $9757[d]**		Perineal RP was associated with lower costs when pelvic lymphadenectomy was not performed
				RPP (279); $7195[d]	n.a.	
5	Anderson et al. (2005)	16	Retrospective	RRP (67); $5253[c]		Main cost drivers for LRP were higher surgical supply costs and higher OR costs due to longer OR time
				LRP (30); $6760[c]	**$1507 (22)**	
6	Jayadevappa et al. (2005)	19	Prospective	RRP (40); $3384[c]	n.a.	Only prospective cost study; incremental costs of PCa within 1 yr postprostatectomy were considered
7	Mouraviev et al. (2007)	21	Retrospective	RRP (197); $5259[c]		First study comparing actual direct costs associated with RALP vs other approaches
				RPP (60); $5273[c]		
				RALP (137); $5386[c]	**$127 (2.4)**	
8	Bolenz et al. (2010)	6	Retrospective	RRP (161); $4437[d]		Largest direct comparison of costs for RRP, LRP, and RALP
				LRP (220); $5687[d]	**LRP: $1250 (22)**	
				RALP (262); $6752[d]	**RALP: $2315 (34)**	
9	Hohwü et al. (2011)	7	Retrospective	RRP (154); €3863[c]		Only study applying standardized health economic evaluation criteria; RALP was not found to be cost effective
				RALP (77); €8369[c]	**€4506 (54)**	
10	Rebuck et al. (2011)	22	Retrospective	RALP (200); $11 806[c] and $9258 (after modifications in OR processes)	n.a.	Highest OR and surgical supply costs; provides suggestions for cost savings when performing RALP
11	Tomaszewski et al. (2012)	24	Retrospective	RRP (n = 358); $4075[c]		Highest frequency of RP cases among studies on direct costs of RP
				RALP (n = 115); $6489[c]	**$2414 (37)**	

Bladder Cancer

Robotic Assisted Radical Cystectomy

European Association of Urology

Bladder Cancer

Comparative Analysis of Outcomes and Costs Following Open Radical Cystectomy Versus Robot-Assisted Laparoscopic Radical Cystectomy: Results From the US Nationwide Inpatient Sample

Hua-yin Yu [a], *Nathanael D. Hevelone* [b], *Stuart R. Lipsitz* [b], *Keith J. Kowalczyk* [c], *Paul L. Nguyen* [d], *Toni K. Choueiri* [e], *Adam S. Kibel* [a], *Jim C. Hu* [f,*]

[a] *Division of Urology, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA;* [b] *Center for Surgery and Public Health, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA;* [c] *Department of Urology, Georgetown University Hospital, Washington, DC, USA;* [d] *Department of Radiation Oncology, Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA, USA;* [e] *Department of Medicine, Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA, USA;* [f] *Institute of Urologic Oncology, Department of Urology, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA, USA*

	Adjusted		
Primary outcomes	Open	Robotic	*p* value
Categorical		%	
Deaths	2.5	0	<0.001
Inpatient complications	63.8	49.1	0.035
Blood transfusion	37.9	32.0	0.448
Parenteral nutrition	13.3	6.4	0.046
Routine discharge	28.2	19.4	0.099
Lymph node dissection	67.0	76.8	0.248
Continuous		Median (IQR)	
Length of stay, d	8 (7.8–8.2)	8 (7.2–8.8)	0.999
Costs, $	24 303 (23 265–25 341)	28 100 (25 015–31 185)	0.023

A Randomized Trial of Robot-Assisted Laparoscopic Radical Cystectomy

Bernard H. Bochner, M.D.
Daniel D. Sjoberg, M.A.
Vincent P. Laudone, M.D.
Memorial Sloan Kettering Cancer Center
New York, NY

Table 1. Outcomes after Radical Cystectomy in the Intention-to-Treat Analysis.*

Variable	Robot-Assisted Surgery (N=60)	Open Surgery (N=58)	Difference (95% CI)	P Value
Complication — no. of patients (%)				
Grade 2–5	37 (62)	38 (66)	−4 (−21 to 13)	0.66
Grade 3–5	13 (22)	12 (21)	1 (−14 to 16)	0.90
Operating-room time — min	456±82	329±77	127 (98 to 156)	<0.001
Length of stay in hospital — days	8±3	8±5	0 (−2 to 1)	0.53

* Plus–minus values are means ±SD. Differences between percentages are measured in percentage points. Complications were assessed according to a five-grade modified Clavien system (with grades ranging from 1 to 5 and higher grades indicating greater severity).[4] CI denotes confidence interval.

The Wall Street Journal

BUSINESS

Surgical Robot Fails to Show Advantages in Treating Bladder Cancer

Study Compares Intuitive Surgical's da Vinci Device to Traditional Surgery

By JOSEPH WALKER CONNECT

Updated July 23, 2014 7:10 p.m. ET

Robots like the da Vinci, pictured, are intended to make it easier to perform minimally invasive procedures.
The Star-News/Associated Press

Some doctors questioned the broader significance of the researchers' findings, noting the study was confined to one hospital and included a relatively small number of patients. The lack of benefit in favor of robotic surgery may be because surgeons performing the open procedures were more experienced than the surgeons performing the robotic procedures, said Jim Hu, director of minimally invasive and robotic surgery at the University of California, Los Angeles.

European Association of Urology

Platinum Priority – Bladder Cancer

Editorials by Urs E. Studer on pp. 1051–1052 of this issue and by Mihir M. Desai and Inderbir S. Gill on pp. 1053–1055 of this issue

Comparing Open Radical Cystectomy and Robot-assisted Laparoscopic Radical Cystectomy: A Randomized Clinical Trial

Bernard H. Bochner[a,], Guido Dalbagni[a], Daniel D. Sjoberg[b], Jonathan Silberstein[a,c], Gal E. Keren Paz[a], S. Machele Donat[a], Jonathan A. Coleman[a], Sheila Mathew[a], Andrew Vickers[b], Geoffrey C. Schnorr[b], Michael A. Feuerstein[a], Bruce Rapkin[d], Raul O. Parra[a], Harry W. Herr[a], Vincent P. Laudone[a]*

[a] *Urology Service, Department of Surgery, Memorial Sloan Kettering Cancer Center, New York, NY, USA;* [b] *Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY, USA;* [c] *Department of Urology, Tulane University School of Medicine, New Orleans, LA, USA;* [d] *Department of Epidemiology and Population Health, Albert Einstein College of Medicine, Bronx, NY, USA*

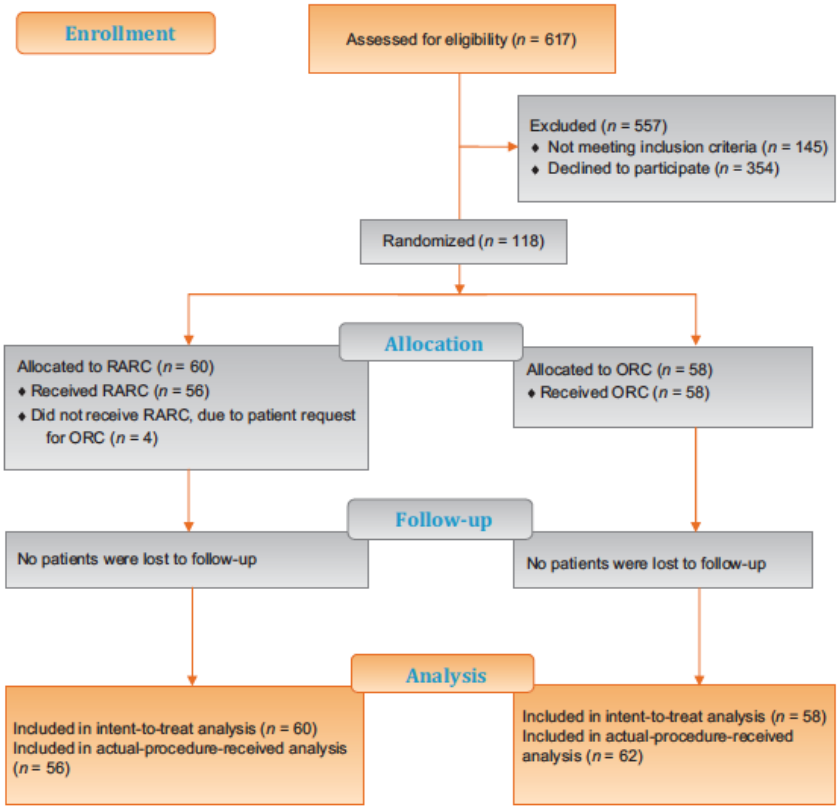

Table 2 – Outcomes after radical cystectomy

	Robotic	Open	Difference, %	95% CI for difference, %	*p* value
By randomization arm/intention-to-treat	*n* = 60	*n* = 58			
Grade 2–5 complication, *n* (%)	37 (62)	38 (66)	−3.9	−21 to 13	0.7
Grade 3–5 complication, *n* (%)	13 (22)	12 (21)	1.0	−14 to 16	0.9
Total number of grade 2–5 complications, mean (SD)	1.4 (1.80)	1.5 (1.66)	−0.2	−0.8 to 0.5	0.6
Total number of grade 3–5 complications, mean (SD)	0.3 (0.58)	0.3 (0.76)	0.0	−0.3 to 0.2	0.7
Any intraoperative complications, *n* (%)	3 (5.0)	3 (5.2)	−0.2	−8 to 8	>0.9
Operative room time, min, mean (SD)	456 (82)	329 (77)	127	98 to 156	<0.001
Estimated blood loss, ml, mean (SD)	516 (427)	676 (338)	−159	−300 to −19	0.027
Hospital length of stay, d, mean (SD)	8 (3)	8 (5)	0	−2 to 1	0.5
Positive surgical margin, *n* (%)	2 (3.3)	3 (5.2)	−1.8	−9 to 5	0.6
Subgroup of patients ≥T3, *n*/*n* (%)	2/17 (12)	3/19 (16)	−4.0	−26 to 18	0.7
Lymph node–positive patients, *n* (%)	10 (17)	9 (16)	1.1	−12 to 14	0.9
By type of surgery received	*n* = 56	*n* = 62			
Grade 2–5 complication, *n* (%)	35 (63)	40 (65)	−2.0	−19 to 15	0.8
Grade 3–5 complication, *n* (%)	12 (21)	13 (21)	0.5	−14 to 15	>0.9
Total number of grade 2–5 complications, mean (SD)	1.4 (1.85)	1.5 (1.63)	−0.1	−0.7 to 0.6	0.9
Total number of grade 3–5 complications, mean (SD)	0.3 (0.59)	0.3 (0.74)	0.0	−0.3 to 0.2	0.8
Any intraoperative complications, *n* (%)	3 (5.4)	3 (4.8)	0.5	−7 to 8	0.9
Operating room time, min, mean (SD)	464 (79)	330 (75)	134	106 to 162	<0.001
Estimated blood loss, ml, mean (SD)	500 (437)	681 (328)	−181	−321 to −41	0.012
Hospital length of stay, d, mean (SD)	8 (4)	8 (5)	0	−2 to 1	0.9
Positive surgical margin, *n* (%)	2 (3.6)	3 (4.8)	−1.3	−8 to 6	0.7
Subgroup of patients ≥T3, *n*/*n* (%)	2/16 (13)	3/20 (15)	−2.5	−25 to 20	0.8
Lymph node yield, mean (SD)					
Extended dissection	31.9 (12)	30.0 (12)	2.0	−3.8 to 7.8	0.5
Standard dissection	19.5 (10)	18.9 (10)	0.6	−6.2 to 7.5	0.5
Lymph node-positive patients, *n* (%)	10 (18)	9 (15)	3.3	−10 to 17	0.6

Table 5 – Cost comparison analysis of total adjusted operating room and inpatient-related costs by procedure received and type of urinary diversion [*]

Type of urinary diversion [†] and treatment arm	Patients, *n*	Average total cost		95% CI (Log $)	*p* value (difference >0)
		$	Log $		
Neobladder, robotic arm	30	19 231.26	9.84	9.77–9.92	–
Neobladder, open arm	35	15 311.00	9.61	9.54–9.69	
Difference	–	3920.26	0.23	0.13–0.33	$p < 0.0001$
Ileal conduit, robotic arm	26	18 388.19	9.80	9.72–9.87	–
Ileal conduit, open arm	24	16 648.58	9.64	9.50–9.79	
Difference	–	1739.61	0.16	0.001–0.317	$p < 0.05$

CI = confidence interval.

[*] Analysis includes actual procedure received by patients, not by intention to treat. We did not analyze the three patients who received continent cutaneous urinary diversion, as they were all in the open radical cystectomy arm.

[†] All urinary diversions were performed via an open surgical approach.

European Association of Urology

Platinum Priority – Editorial
Referring to the article published on pp. 1042–1050 of this issue

"The Devil Is in the Details": Randomized Trial of Robotic Versus Open Radical Cystectomy

Mihir M. Desai, Inderbir S. Gill *

Section of Robotic Surgery, Catherine and Joseph Aresty Department of Urology, USC Institute of Urology, Keck School of Medicine of USC, University of Southern California, Los Angeles, CA, USA

- The open RC surgeons at Memorial Sloan Kettering Cancer Center (MSKCC) have performed literally thousands of open RCs to date; however, the prior RC experience of MSKCC robotic surgeons is unclear

- How many robotic RCs had this team performed before starting this trial?

- Difference in the transfusion rate?

Rectal Cancer

ROLARR Study

- 1 to 1 randomization compared lap surgery to robotic surgery in rectal cancers
- Enrolled 471 patients across 29 centers in 10 countries
- Primary endpoint was conversion to open surgery

ROLARR Study

- Study surgeons on average had 3.6 times more experience with lap vs. robot
- Primary endpoint – conversion to open surgery
- Lap vs. robot conversion: 12.2% vs. 8.1% ($p = 0.158$)
- Lap vs. robot operative time: 260 vs. 300 min
- No difference in margin rate, lymph node yield, 30-day morbidity

Conclusion

- Comparisons of surgical devices and techniques must be made beyond training curves
- Sexual function and cancer control benefits for robotic assisted radical prostatectomy although more costly
- Although randomized controlled trials yet to show significant benefits