

11th Meeting of the EAU Robotic Urology Section

17-19 September 2014

Amsterdam, The Netherlands



European Association of Urology



## Complications in robotic surgery

# Review of the literature RALP, RAPN and RARC







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## Agenda

- The importance of reporting surgical complications
- How to report surgical complications
- Complications according to the literature
  - RALP (330 articles)
  - RAPN (97 articles)
  - RARC (26 articles)
- Conclusion





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## The importance of reporting surgical complications

- Complications surrogate marker of quality in surgery
- Standardized reporting of complications could improve:
  - Patient care
  - Scientific quality of papers
  - Comparison of data
- Combined Outcome Measures Score (COMS)





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# How to report surgical complications, recommendations from EAU

available at www.sciencedirect.com journal homepage: www.europeanurology.com





#### Guidelines

Reporting and Grading of Complications After Urologic Surgical Procedures: An ad hoc EAU Guidelines Panel Assessment and Recommendations

Dionysios Mitropoulos a, \*, Walter Artibani b, Markus Graefen c, Mesut Remzi d, Morgan Rouprêt c, Michael Truss f





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- Define the method of accruing data:
   retrospective \_ prospective \_, through:
   chart review \_ telephone interview \_ face-to-face interview \_ other \_
- Define who collected the data: medical doctor \_ nurse \_ data manager \_ other \_ and whether he or she was involved in the treatment: yes \_ no \_
- 3. Indicate the duration of follow-up: 30 d \_ 60 d \_ 90 d \_ >90 d \_
- 4. Include outpatient information
- 5. Include mortality data and causes of death
- 6. Include definitions of complications
- 7. Define procedure-specific complications
- 8. Report intraoperative and postoperative complications separately
- Use a severity grading system for postoperative complications (avoiding the distinction minor/major); Clavien-Dindo system is recommended
- Postoperative complications should be presented in a table either by grade or by complication type (specific grades should always be provided; grouping is not accepted)
- 11. Include risk factors

ASA score \_ Charlson score \_ ECOG \_ other \_

- 12. Include readmissions and causes
- 13. Include reoperations, types and causes
- 14. Include the percentage of patients lost to follow-up

eal



Grades

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## Clavien Dindo grading system

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-	Any deviation from the normal postoperative course without the need for pharmacologic treatment or surgical, endoscopic, and radiologic interventions. Acceptable therapeutic regimens are drugs such as antiemetics, antipyretics, analgesics, diuretics, and electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.
1	Requiring pharmacologic treatment with drugs other than those allowed for grade 1 complications. Blood transfusions and total parenteral nutrition are also included.
III	Requiring surgical, endoscopic, or radiologic intervention.
Illa	Intervention not under general anaesthesia.
шь	Intervention under general anaesthesia.
IV	Life-threatening complication (including central nervous system complications: brain haemorrhage, ischaemic stroke, subarachnoid bleeding, but excluding transient ischaemic attacks) requiring intermediate care/intensive care unit management.
IVa	Single-organ dysfunction (including dialysis).
IVb	Multiorgan dysfunction,
٧	Death of a patient.

Definitions





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# **Complications after RARP**







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Platinum Priority - Review - Prostate Cancer Editorial by XXX on pp. x-y of this issue

Positive Surgical Margin and Perioperative Complication Rates of Primary Surgical Treatments for Prostate Cancer: A Systematic Review and Meta-Analysis Comparing Retropubic, Laparoscopic, and Robotic Prostatectomy

Ashutosh Tewari <sup>a,\*</sup>, Prasanna Sooriakumaran <sup>a,b</sup>, Daniel A. Bloch <sup>c</sup>, Usha Seshadri-Kreaden <sup>d</sup>, April E. Hebert <sup>d</sup>, Peter Wiklund <sup>b</sup>

- Largest meta analysis in RALP
- 400 articles
- 47 comparative studies of ORP and RALP





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## **Peri-operative outcomes**

RALP had significantly lower rates of:

- Estimates blood loss (adjusted difference 563 ml)
- Blood transfusion rates
- Length of stay in hospital





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## Intra- and peri-operative complication rates

### RALP had significantly lower rates of:

- Ureteral injury (1.5% vs 0.1%)

- DVT (1% vs 0.3%)

- Anastomotic leakage (10% vs 3.5%)

- Wound infection (2.8% vs 0.7%)

– Hematoma (1.6% vs 0.7%)

- Lymphocele (10% vs 3.5%)

## RALP had significantly higher rates of:

- Bowel injury (0% vs 0.09%)

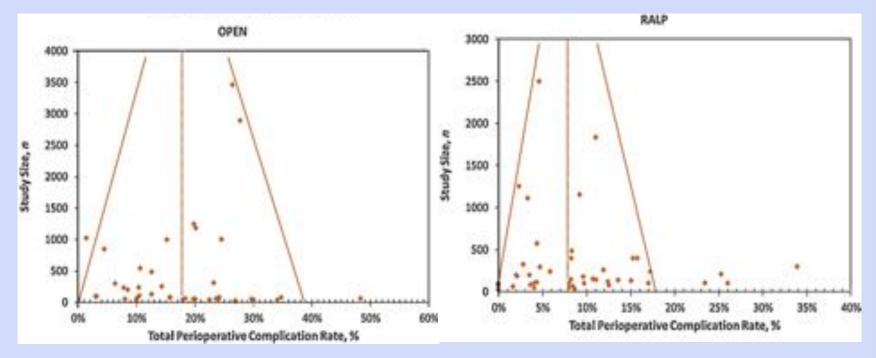




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## Total peri-operative complication rate



Tewari A, et al. Positive Surgical Margin and Perioperative Complication Rates of Primary Surgical Treatments for Prostate Cancer: A Systematic Review and Meta-Analysis Comparing Retropubic, Laparoscopic, and Robotic Prostatectomy. Eur Urol (2012)



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## **Complications after RAPN**







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Practice Patterns and Outcomes of Open and Minimally Invasive Partial Nephrectomy Since the Introduction of Robotic Partial Nephrectomy: Results from the Nationwide Inpatient Sample

Khurshid R. Ghani,\*,† Shyam Sukumar,† Jesse D. Sammon, Craig G. Rogers,‡ Quoc-Dien Trinh‡ and Mani Menon

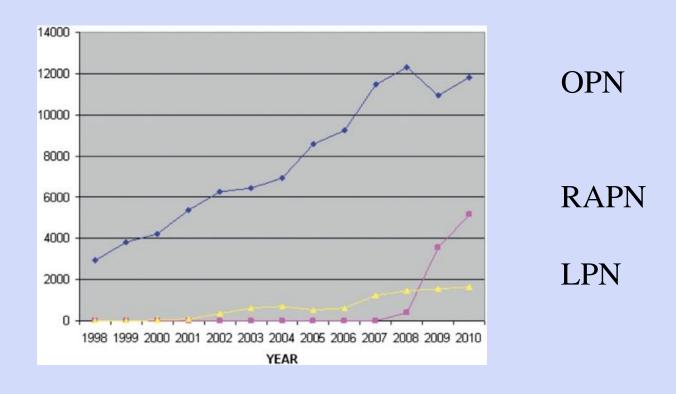
- Data from NIS (Nationwide Inpatient Sample)
- Oct 2008 Dec 2010
- Renal cell carcinoma
  - without metastatic disease
  - >18 years
- 38 000 partial nephrectomies





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Total number of partial nephrectomies per year in NIS





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	OPN	RAPN	LPN	p Value RAPN vs OPN
Overall complication rate	30.5%	22.1%	24.9%	<0.001
Intraoperative complication rate	5.3%	3.7%	3.5%	0.014
Blood transfusion rate	10.6%	5.8%	7.1%	<0.001
pLOS	34.8%	23.6%	29.4%	<0.001
Excessive hospital charges (>75 <sup>th</sup> percentile)	25.0%	23.6%	29.4%	<0.001



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# A multicentre matched-pair analysis comparing robot-assisted versus open partial nephrectomy

Vincenzo Ficarra<sup>1</sup>, Andrea Minervini<sup>2</sup>, Alessandro Antonelli<sup>3</sup>, Sam Bhayani<sup>4</sup>, Giorgio Guazzoni<sup>5</sup>, Nicola Longo<sup>6</sup>, Giuseppe Martorana<sup>7</sup>, Giuseppe Morgia<sup>8</sup>, Alexander Mottrie<sup>9</sup>, James Porter<sup>10</sup>, Claudio Simeone<sup>3</sup>, Gianni Vittori<sup>2</sup>, Filiberto Zattoni<sup>11</sup> and Marco Carini<sup>2</sup>

- Retrospective, multicenter, matched-pair analysis
- Comparing RAPN and OPN
- Matching 1:1, 200 patients in each arm
  - OPN
    - PN for suspected cT1 renal tumour
    - Jan 2009 Jan 2011
    - 19 centers
  - RAPN
    - 4 high volume centers





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	RAPN N=200	OPN N=200	P
Artery clamping	90%	69%	<0.001
Median WIT, min	18	15	<0.001
Median OR time, min	120	127	0.19
Median (IQR)Hospital stay, days	6 (5-6)	7 (6-8)	0.014
Median EBL, mL	100	150	<0.001
Transfusion rate	10.5%	10.0%	0.78



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		RAPN N=200	OPN N=200	P
Postoperative overall complications		14%	21.5%	0.027
Clavien grade:				
	1-2	9.5%	17%	0.03
	3	4%	3.5%	0.34
	4	0.5%	1%	-
PSM		5.7%	5.5%	0.98
Mean decline o months (mL/min		16.4	16.6	0.28



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#### **Conclusion**

- ORN
  - Less renal artery clamping
  - Shorter WIT
- RAPN
  - Less postoperative complications
  - Shorter hospital stay
- No significant differences in
  - Functional outcome at 3 months
  - PSM





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## **Complications after RARC**







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Platinum Priority – Bladder Cancer Editorial by Declan G. Murphy and Paul Anderson on pp. 742–743 of this issue

#### Oncologic, Functional, and Complications Outcomes of Robot-assisted Radical Cystectomy with Totally Intracorporeal Neobladder Diversion

Stavros I. Tyritzis<sup>a</sup>, Abolfazl Hosseini<sup>a</sup>, Justin Collins<sup>a</sup>, Tommy Nyberg<sup>b</sup>, Martin N. Jonsson<sup>a</sup>, Oscar Laurin<sup>a</sup>, Dinyar Khazaeli<sup>a</sup>, Christofer Adding<sup>a</sup>, Martin Schumacher<sup>a</sup>, N. Peter Wiklund<sup>a</sup>.

- 70 consecutive patients
- Recruitment Dec 2003 Oct 2012
- Intracorporeal neobladder
- 2 surgeons

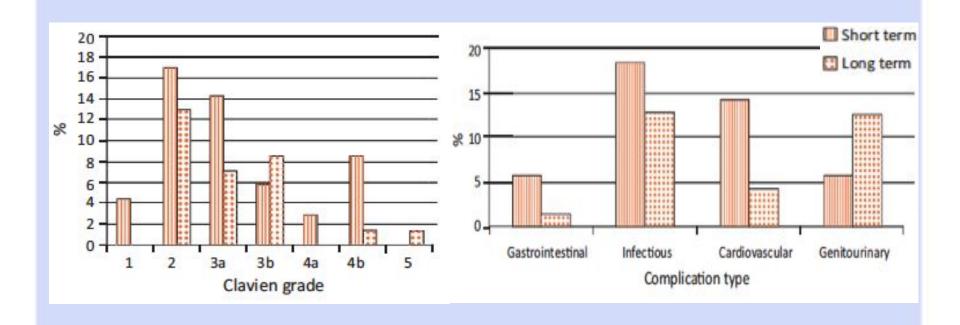




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## **Short- and long-term complications**



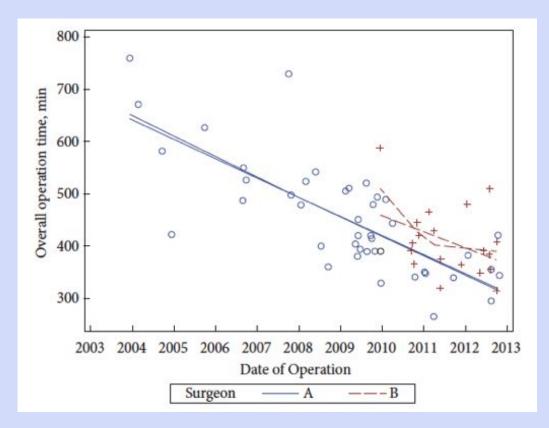




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#### **OR** time



Collins JW, Tyritzis S, Nyberg T, et al. Robot-assisted radical cystectomy (RARC) with intracorporeal neobladder - what is the effect of the learning curve on outcomes? BJU international 2014;113:100-7.





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## Early complications < 30 days

	Clavien classification (≤30 days)						Overall complication		
	None	T		Ma	ШЬ	IVa	IVb	rafe, % (% major)	
Surgeon A, #		10000							
Gp 1-10	3	1	3	1	1.	1.0	0	70 (30)	
Gp 11-20	8	1	0	0	0	0	1	20 (10)	
Gp 21-30	8	0	0	2	0	0	0	20 (20)	
Gp 31-40	7	0	0	1	2	0	0	30 (30)	
Gp 41-47	5	0	0	0	0	0	2	29 (29)	
Total, n (%)	31 (66)	2(4)	3 (6)	4 (9)	3 (6)	1(2)	3 (6)	44 (23)	
Surgeon B, #									
Gp 1-10	-4	0	1	2	1	100	1.0	60 (50)	
Gp 11-20	6	0	2	0	0	0	2	40 (20)	
Total, st (%)	10 (50)	0	3 (15)	2 (10)	1 (5)	1 (5)	3 (15)	50 (35)	

Collins JW, Tyritzis S, Nyberg T, et al. Robot-assisted radical cystectomy (RARC) with intracorporeal neobladder - what is the effect of the learning curve on outcomes? BJU international 2014;113:100-7.









## A Randomized Trial of Robot-Assisted Laparoscopic Radical Cystectomy

Bochner et al. N Engl J Med 2014; 371:389-390

- Recruitment March 2010 March 2013
- 118 patients (58 open, 60 robotic)
- Extra-corporeal urinary diversion in both approaches
- Randomization
  - Clinical Research Database (CRDB) at MSKCC
  - Stratifying
    - Age (<65 versus >=65)
    - ASA (1/2 versus 3/4) in randomly permuted blocks
- Not blinded





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## **Complication rates**

Variable	Robot-Assisted Surgery (N=60)			P Value
Complication — no. of pa	tients (%)			
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 — r	nin 456±82	329±77	127 (98 to 156)	< 0.00]
Length of stay in hospital	— days 8±3	8±5	0 (-2 to 1)	0.53

Bochner BH, Sjoberg DD, Laudone VP. A randomized trial of robot-assisted laparoscopic radical cystectomy. The New England journal of medicine 2014;371:389-90.





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#### **Conclusion**

- No large benefit of robotic techniques with respect to perioperative morbidity
- Results may not be generalizable to all clinical settings
- "Results highlight the need for randomized trials to inform the benefits and risks of new surgical technologies before widespread implementation"

Bochner BH, Sjoberg DD, Laudone VP. A randomized trial of robot-assisted laparoscopic radical cystectomy. The New England journal of medicine 2014;371:389-90.





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## Conclusion of complications in robotic surgery

- Data indicates some advantages compared to open surgery
- Comes down with experience
- Important to register complications
  - Not only oncological and functional outcomes
  - Most important to the patient?
- Qualify surgery: Combined Outcome Measures Score (COMS)
  - Including oncological, functional and complications
  - Time sensitive, should be measured at the same time





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## Thank you







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