ERUS 2014
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Complications in robotic surgery

Review of the literature
RALP, RAPN and RARC

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Karolinska University Hospital Stockholm, Sweden
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
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)
How to report surgical complications, recommendations from EAU

Guidelines

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

Dionysios Mitropoulos, Walter Artibani, Markus Graefen, Mesut Remzi, Morgan Roupret, Michael Truss
1. Define the method of accruing data:
   retrospective _ prospective _, through:
   chart review _ telephone interview _ face-to-face interview _ other _
2. 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
9. Use a severity grading system for postoperative complications (avoiding the distinction minor/major); Clavien-Dindo system is recommended
10. 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
### Clavien Dindo grading system

<table>
<thead>
<tr>
<th>Grades</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>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.</td>
</tr>
<tr>
<td>II</td>
<td>Requiring pharmacologic treatment with drugs other than those allowed for grade 1 complications. Blood transfusions and total parenteral nutrition are also included.</td>
</tr>
<tr>
<td>III</td>
<td>Requiring surgical, endoscopic, or radiologic intervention.</td>
</tr>
<tr>
<td>IIIa</td>
<td>Intervention not under general anaesthesia.</td>
</tr>
<tr>
<td>IIIb</td>
<td>Intervention under general anaesthesia.</td>
</tr>
<tr>
<td>IV</td>
<td>Life-threatening complication (including central nervous system complications: brain hemorrhage, ischaemic stroke, subarachnoid bleeding, but excluding transient ischaemic attacks) requiring intermediate care/intensive care unit management.</td>
</tr>
<tr>
<td>IVa</td>
<td>Single-organ dysfunction (including dialysis).</td>
</tr>
<tr>
<td>IVb</td>
<td>Multiorgan dysfunction.</td>
</tr>
<tr>
<td>V</td>
<td>Death of a patient.</td>
</tr>
</tbody>
</table>
Complications after RARP
• Largest meta analysis in RALP
• 400 articles
• 47 comparative studies of ORP and RALP
Peri-operative outcomes

RALP had significantly lower rates of:

- Estimates blood loss (adjusted difference 563 ml)
- Blood transfusion rates
- Length of stay in hospital
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%)
Total peri-operative complication rate

Complications after RAPN
Data from NIS (Nationwide Inpatient Sample)

Oct 2008 – Dec 2010

Renal cell carcinoma
  • without metastatic disease
  • >18 years

38 000 partial nephrectomies
Total number of partial nephrectomies per year in NIS

- OPN
- RAPN
- LPN
<table>
<thead>
<tr>
<th></th>
<th>OPN</th>
<th>RAPN</th>
<th>LPN</th>
<th>p Value RAPN vs OPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall complication rate</td>
<td>30.5%</td>
<td>22.1%</td>
<td>24.9%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Intraoperative complication rate</td>
<td>5.3%</td>
<td>3.7%</td>
<td>3.5%</td>
<td>0.014</td>
</tr>
<tr>
<td>Blood transfusion rate</td>
<td>10.6%</td>
<td>5.8%</td>
<td>7.1%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>pLOS</td>
<td>34.8%</td>
<td>23.6%</td>
<td>29.4%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Excessive hospital charges (&gt;75th percentile)</td>
<td>25.0%</td>
<td>23.6%</td>
<td>29.4%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
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
<table>
<thead>
<tr>
<th></th>
<th>RAPN N=200</th>
<th>OPN N=200</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artery clamping</td>
<td>90%</td>
<td>69%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Median WIT, min</td>
<td>18</td>
<td>15</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Median OR time, min</td>
<td>120</td>
<td>127</td>
<td>0.19</td>
</tr>
<tr>
<td>Median (IQR)Hospital stay, days</td>
<td>6 (5-6)</td>
<td>7 (6-8)</td>
<td>0.014</td>
</tr>
<tr>
<td>Median EBL, mL</td>
<td>100</td>
<td>150</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Transfusion rate</td>
<td>10.5%</td>
<td>10.0%</td>
<td>0.78</td>
</tr>
<tr>
<td></td>
<td>RAPN N=200</td>
<td>OPN N=200</td>
<td>P</td>
</tr>
<tr>
<td>--------------------------</td>
<td>------------</td>
<td>-----------</td>
<td>-----</td>
</tr>
<tr>
<td>Postoperative overall complications</td>
<td>14%</td>
<td>21.5%</td>
<td>0.027</td>
</tr>
<tr>
<td>Clavien grade:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-2</td>
<td>9.5%</td>
<td>17%</td>
<td>0.03</td>
</tr>
<tr>
<td>3</td>
<td>4%</td>
<td>3.5%</td>
<td>0.34</td>
</tr>
<tr>
<td>4</td>
<td>0.5%</td>
<td>1%</td>
<td>-</td>
</tr>
<tr>
<td>PSM</td>
<td>5.7%</td>
<td>5.5%</td>
<td>0.98</td>
</tr>
<tr>
<td>Mean decline of eGFR at 3 months (mL/min)</td>
<td>16.4</td>
<td>16.6</td>
<td>0.28</td>
</tr>
</tbody>
</table>
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
Complications after RARC
• 70 consecutive patients
• Recruitment Dec 2003 – Oct 2012
• Intracorporeal neobladder
• 2 surgeons
Short- and long-term complications
Early complications < 30 days

A Randomized Trial of Robot-Assisted Laparoscopic Radical Cystectomy


- 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
Complication rates


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

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
Thank you

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