Apical Prolapse: the Laparoscopic Approach

Marie Fidela R. Paraiso, M.D.
Professor of Surgery
Head, Section of Urogynecology and Reconstructive Pelvic Surgery
The OBGYN and Women’s Health Institute
Cleveland, OH
USA
Disclosures

- Ethicon Women’s Health and Urology
Women Should Have a Choice

- They should be empowered to choose minimally invasive surgery
Conventional Laparoscopic Versus Robotic-Assisted Laparoscopic Sacrocolpoproxy: A Randomized Controlled Trial

MFR Paraiso, CCG Chen, JE Jelovsek, A Frick, MD Barber
Obstetrics, Gynecology, and Women’s Health Institute
Section of Urogynecology and Reconstructive Pelvic Surgery
Cleveland, OH

Obstet Gynecol 2011;118:1005-13
2011 Roy Pitkin Award
AUGS and AAGL Awards 2010
Disclosures

- MFR Paraiso: Coloplast Corporation
- CCG Chen: None
- JE Jelovsek: None
- A Frick: None
- MD Barber: None
Objective

- Despite wide adoption of robotic-assisted laparoscopy in the US, there are currently no RCTs in the gynecologic literature comparing robotic versus conventional laparoscopic procedures.
- The objective of this study is to compare robotic-assisted (RASC) versus traditional laparoscopic sacrocolpopexy (LSC) with operative time as the primary outcome.
Methods

- **Inclusion criteria**
  - Post-hysterectomy vaginal apex prolapse at POPQ stages 2-4
  - > 21 years of age
  - Desires laparoscopic surgical management

- **Exclusion criteria**
  - General anesthesia contraindicated
  - History of prior sacrocolpopexy
  - Suspicious adnexal masses or other factors that may increase risk of pelvic malignancy
  - History of pelvic inflammatory disease
  - Morbid obesity (BMI ≥ 40)
  - History of prior or concomitant need of rectopexy for rectal prolapse
Methods

- Structured Urogynecologic history, physical examination including POPQ staging, urodynamic testing if indicated
- Validated questionnaires at baseline and follow-up
  - PFDI-20, PFIQ-7, PISQ-12 and EQ-5D at 6 months
  - Functional status was assessed using the Activity Assessment Scale (AAS) at weeks 1, 2, and 4 and 6 months
  - Pain was assessed using Visual Analogue Scales (VAS) weekly for 6 weeks
- Subjects were randomized in a 1:1 ratio to one of two treatment groups (LSC or RASC)
  - Randomization stratified by surgeon
  - Randomization at time of surgical scheduling
Methods: Trocar Placement

**Conventional Laparoscopic Sacrocolpopexy**

- 5-12 mm port
- 5 mm port

**Robotic-assisted Laparoscopic Sacrocolpopexy**

- 5-12 mm port
- 8 mm robotic port

**Key Anatomical Landmarks**
- Superficial epigastric artery
- Inferior epigastric artery
- Rectus muscle
- External iliac artery
- Superficial circumflex artery

*Images courtesy of CCF ©2010*
Technique and Central Docking
A priori, we determined that 32 subjects in each group were needed to detect a difference of 30 minutes or more in operating time between LSC versus RASC with 90% power and a significance level of .05.

The primary and secondary measures were analyzed according to the original treatment assignment (intent to treat).

Patient Allocation

Enrolled and randomized n=76

Allocated to LSC n=37
- Withdrew prior to surgery n=5
- Did not qualify (n=1)
- Personal choice (n=4)

Allocated to RASC n=39
- Withdrew prior to surgery n=4
- Did not qualify (n=3)
- Personal choice (n=1)

Received to LSC n=32
- Convert to laparotomy (n=1)
- or vaginal approach (n=1)

Follow-up:
- 6 Weeks, n=28
- 6 Months, n=24

Received RASC n=35
- Convert to laparotomy (n=1)
- or laparoscopy (n=2)

Follow-up:
- 6 Weeks, n=33
- 6 Months, n=30
## Surgical Data

<table>
<thead>
<tr>
<th>Procedure</th>
<th>LSC (n=32)</th>
<th>RASC (n=35)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other Procedure</td>
<td>25 (78)</td>
<td>29 (82)</td>
<td></td>
</tr>
<tr>
<td>Incontinence Surgery</td>
<td>22 (69)</td>
<td>25 (71)</td>
<td>1.0</td>
</tr>
<tr>
<td>Rectocele Repair</td>
<td>15 (47)</td>
<td>10 (29)</td>
<td>0.14</td>
</tr>
<tr>
<td>Adhesiolysis &gt;45 minutes</td>
<td>17 (53)</td>
<td>14 (40)</td>
<td>0.33</td>
</tr>
<tr>
<td>Convert to Other</td>
<td>2 (7)</td>
<td>3 (9)</td>
<td>1.0</td>
</tr>
</tbody>
</table>

*Approaches*
# Hospital Parameters

<table>
<thead>
<tr>
<th></th>
<th>LSC (n=32)</th>
<th>RASC (n=35)</th>
<th>Mean Difference (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sacrocolpopexy Time</td>
<td>161 ± 47</td>
<td>227 ± 47</td>
<td>67 (44-90)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Laparoscopic Suturing Time</td>
<td>67 ± 15</td>
<td>98 ± 22</td>
<td>31 (22-42)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Docking Time</td>
<td>n/a</td>
<td>14 ± 8</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Additional Procedure Time</td>
<td>43 ± 37</td>
<td>31 ± 30</td>
<td>-12 (-29-5)</td>
<td>.08</td>
</tr>
<tr>
<td>Total Case Time</td>
<td>198 ± 46</td>
<td>265 ± 50</td>
<td>68 (44-91)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Anesthesia Time</td>
<td>255 ± 52</td>
<td>321 ± 52</td>
<td>66 (41-92)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Room Time</td>
<td>283 ± 49</td>
<td>349 ± 51</td>
<td>66 (42-91)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Hospital Stay (hours)</td>
<td>34 ± 11</td>
<td>43 ± 37</td>
<td>10 (-4-23)</td>
<td>.07</td>
</tr>
</tbody>
</table>
Results

- There were no differences in intraoperative or postoperative complications between groups.

- LSC and RASC groups experienced significant improvement of anatomic outcomes and quality of life with no differences between groups at 6 months.

- Mean C point was 0 at baseline and was -9.5 and -9.0 cm, respectively at 6 months.
Pain at Rest

![Graph showing VAS 0-150mm for weeks 0 to 6. The LSC group is represented by orange bars, and the RASC group by blue bars. Stars indicate p < .05.](image)

* p < .05
Pain with Normal Activity

* p < .05

Week

VAS 0-150mm

LSC  RASC

* * * * *
Unpleasantness of Pain

![Chart showing the unpleasantness of pain over time with VAS scores from 0 to 150mm. The chart includes weeks 0 to 6, with LSC and RASC data points. Significant difference marked with * p < .05.](chart-image)
<table>
<thead>
<tr>
<th></th>
<th>LSC n=32</th>
<th>RASC n=35</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Narcotics</strong></td>
<td>4.5 (1-10.5)</td>
<td>5.5 (0-14.3)</td>
<td>.77</td>
</tr>
<tr>
<td><strong>NSAIDS</strong></td>
<td>9.5 (0-12.8)</td>
<td>19.5 (5-30)</td>
<td>.005</td>
</tr>
</tbody>
</table>

**Medication Requirement**
Strengths

- Randomized blinded clinical trial
- A qualified, experienced research nurse administered validated questionnaires at baseline and follow-up
- Follow-up POPQ exams were performed by a surgeon who was not the staff surgeon involved in the case
- Hospital parameters, anatomic and functional outcome, patient pain and activity were assessed
Limitations

- Small numbers in each group
- Length of follow-up
- External validity
- Lack of specialized robotic nursing teams who had been trained
- Lack of significant curriculum for residents and fellows
- Lack of reliable robotic support
One-way Analysis of RASC

Total Case Time by Case Number
Conclusion

- This is the first RCT comparing LSC to RASC, the only RCT in the gynecologic literature comparing robotic and conventional laparoscopy, and the largest RCT comparing both minimally invasive techniques in any surgical field to date.

- Robotic-assistance results in longer operating times (all parameters) and increased pain weeks 3 through 6 after sacrocolpopexy compared to the conventional laparoscopic approach.

- LSC and RASC had significant improvement in anatomic and functional outcomes but no difference between groups 6 months after surgery.
Show Me the Money

- Cost Minimalization of Robot vs Lsc vs Open ASC
  Judd et al. JMIG 2010;17(4):493
  - Baseline estimates time: 328 vs 269 vs 170 min
  - Existing case model cost: 8508 vs 7353 vs 5792
  - Robot = lsc at 149 minutes or if disposables for robot decreased to $2132 while lsc increased to $3413

- Robot-assisted vs Open ASC: A Cost Minimization Analysis
  - Time: 226 vs 221 min
  - Length of Stay: 1 vs 3.3 days
  - Base case analysis: Robot savings 10% ($10,178 vs $11,307)
# Results: Our RCT

<table>
<thead>
<tr>
<th>Costs</th>
<th>Laparoscopic</th>
<th>Robotic</th>
<th>Mean Difference (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td>11,383</td>
<td>13,050</td>
<td>1667 (448-2885)</td>
<td>.008</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>2696</td>
<td>2968</td>
<td>271 (-419-963)</td>
<td>.43</td>
</tr>
<tr>
<td>Postoperative</td>
<td>263</td>
<td>260</td>
<td>-3 (-100-94)</td>
<td>.95</td>
</tr>
<tr>
<td>Total</td>
<td>14,342</td>
<td>16,278</td>
<td>1936 (417-3454)</td>
<td>.01</td>
</tr>
</tbody>
</table>
Discussion

- Robotic-assistance is associated with $1936 of excess cost

- Including the cost of purchase and maintenance of the robot would add approximately $495 per case
Mounting evidence demonstrates feasibility and safety of robotic surgery in benign gynecology.

No data to support benefits for benign disease and which procedures will benefit most.

Procedures: hysterectomy, myomectomy, endometriosis, ovarian cystectomy, tubal reanastamosis, sacrocolpopexy, and vesicovaginal fistula.

This systematic review does not support the use of robotic surgery for women with benign gynaecological disease, particularly sacrocolpopexy and hysterectomy based on limited data.

Robotic surgery fails to show any superiority over laparoscopy for benign gynaecological disease.
Learning Curves with the Robot

- Novice can increase surgical efficiency and approach expert level in basic skills after 10 trials
  Judkins. Surg Endosc 2008 (Epub ahead print)

- Operative times significantly decrease after 20 cases of robotic hysterectomies and myomectomies

- Learning curves with regard to operative times in benign surgical procedures stabilized after 50 cases

- Learning curves with regard to robot set-up stabilized after 20 cases

- Docking times decreases after the first 20 cases
My Experience

- **Conventional Laparoscopy Benefits**
  - Minimal set up time
  - Haptic feedback
  - Ability to teach at bedside hands-on without a second console
  - Clearly decreased cost and OR time
  - Resident involvement early on as junior residents

- **Robotic-assisted Laparoscopy Drawbacks**
  - Greater set up time
  - Need for specialized robot teams (nurses+surgeons)
  - Need for dual consoles
  - Great cost of system and instrumentation
  - Electrosurgical instruments are not as smart as conventional
  - Decreased resident cases and involvement
  - Concern that this may be the next dilemma unless clear-cut credentialing and training

MRFAT and Aging Ergonomics: Double Edged Sword
How Do We Train the Next Generation?

- Assessing current trends in resident hysterectomy training  
  Burkett et al. FPMRS 2011;17(5):210

- Graduating residents report adequate numbers of vaginal and abdominal hysterectomies.

- Both residents and program directors report that graduating residents are not prepared to perform all types of hysterectomies.

- Both residents and program directors express concern that robotic surgery is negatively impacting surgical training.
The Evidence in Benign Gynecology

I am not anti-robot. I am pro-evidence

I want to empower women to choose minimally invasive surgery.

Women have that right.

“Robotic surgery makes advanced surgical procedures accessible to surgeons who do not have advanced video endoscopic training.”

We need more evidence to show proven benefit of robotic surgery!

Robotic platform companies should sponsor unrestricted grants.