The evidence of robotic surgery

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What is evidence?

SHOW ME THE EVIDENCE!
<table>
<thead>
<tr>
<th>Level</th>
<th>Intervention 1</th>
<th>Diagnostic accuracy 2</th>
<th>Prognosis</th>
<th>Aetiology 3</th>
<th>Screening Intervention</th>
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</thead>
<tbody>
<tr>
<td>I</td>
<td>A systematic review of level II studies</td>
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<tr>
<td>II</td>
<td>A randomised controlled trial</td>
<td>A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive persons with a defined clinical presentation</td>
<td>A prospective cohort study</td>
<td>A prospective cohort study</td>
<td>A randomised controlled trial</td>
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<tr>
<td>III-1</td>
<td>A pseudorandomised controlled trial (i.e. alternate allocation or some other method)</td>
<td>A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation</td>
<td>All or none</td>
<td>All or none</td>
<td>A pseudorandomised controlled trial (i.e. alternate allocation or some other method)</td>
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<tr>
<td>III-2</td>
<td>A comparative study with concurrent controls: • Non-randomised, experimental trial • Cohort study • Case-control study • Interrupted time series with a control group</td>
<td>A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence</td>
<td>Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial</td>
<td>A retrospective cohort study</td>
<td>A comparative study with concurrent controls: • Non-randomised, experimental trial • Cohort study • Case-control study</td>
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<td>III-3</td>
<td>A comparative study without concurrent controls: • Historical control study • Two or more single arm study • Interrupted time series without a parallel control group</td>
<td>Diagnostic case-control study</td>
<td>A retrospective cohort study</td>
<td>A case-control study</td>
<td>A comparative study without concurrent controls: • Historical control study • Two or more single arm study</td>
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<tr>
<td>IV</td>
<td>Case series with either post-test or pre-test/post-test outcomes</td>
<td>Study of diagnostic yield (no reference standard)</td>
<td>Case series, or cohort study of persons at different stages of disease</td>
<td>A cross-sectional study or case series</td>
<td>Case series</td>
</tr>
</tbody>
</table>
Robotic prostate surgery: keyhole to the future

At first glance, the da Vinci appears like a man-made praying mantis. It comprises a surgeon console, a patient-side cart with four interactive robotic arms and offers 10-times three-dimensional visual magnification.

When urologist Justin Vass scrubs in for surgery, he and his team are not alone.

Robotic surgery – the future?
Robotic surgery is becoming much more common, but is it the best way to carry out operations?
Lucy Cormack reports. WARNING: Medical procedures.
A prospective comparison of radical retropubic and robot-assisted prostatectomy: experience in one institution.

Tewari 2003

n= 300

Comparable operating time

In the robotic arm (n=100)
  - Significantly less blood loss
  - Shorter hospital stay
  - Less positive surgical margin
  - Achieve continence more quickly
  - Return to erectile function & return to intercourse more quickly
Robot-assisted laparoscopic prostatectomy versus open radical retropubic prostatectomy: early outcomes from a randomised controlled phase 3 study.

The Lancet. Yaxley 2016

- n=308
- No difference in functional outcome @ 12 weeks
  - Continence
  - Erectile
- No difference in positive surgical margin
- Follow up for 2 years
A meta-analysis of robotic vs. conventional mitral valve surgery. Cao 2015

- Degenerative mitral valve disease

- 7 studies (n=1964)
- Robotics - 953 patients
- Sternotomy - 1,011 patients

- Stroke and reoperation were not statistically different
- The lengths of hospitalization & ICU stay were not significantly different
- Both surgical techniques appeared to achieve satisfactory echocardiographic outcomes
- No Major Benefit at this point in time
Colorectal

• case series & comparative studies- favourable outcomes for robotic-assisted rectal cancer surgery
  o may reduce the length of stay, blood loss, and conversion rates

• Baik 2008
  o Robotic tumor-specific mesorectal excision of rectal cancer: short-term outcome of a pilot randomized trial
    • robotic vs laparoscopic low anterior resection for rectal cancer
  o n= 36
  o No significant difference in operating time, haemoglobin change and conversion rate

• No Cochrane systematic review
Gynaecology

- Benign gynaecology
- Urogynaecology
- Gynaecological oncology
Literature search

- Embase
- Pubmed
- Medline
- Cochrane database

Keywords:
- robotic surgery, gynaecology, safety, outcome, cost-effectiveness, endometriosis, sacrocolpopexy, prolapse, myomectomy, hysterectomy, ovarian cancer, endometrial cancer, cervical cancer
Results

• 846 references since 2005 (FDA approval)
• 2 Cochrane reviews
• 6 RCTs
Laparoscopic Compared With Robotic Sacrocolpopexy for Vaginal Prolapse

Paraiso et al 2011
A Randomized Controlled Trial

- 78 patients randomised
- Longer operating time for the robotic-assisted approach: 67 min difference
- Cost difference $1936
- Significant higher postoperative pain at rest & with activity during week 3 to week 5 post-op
- No significant differences between groups in functional activity, bowel and bladder symptoms, quality of life, anatomic vaginal support, complications
Why do patients experience more pain after robotic sacrocolpopexy?

- Additional operating ports
- Larger size ports
- Different location of the robotic trocars
- Longer operating time
- Robotic manipulation of the trocars rather than manual manipulation
Robotic compared with conventional laparoscopic hysterectomy: a randomized controlled trial.

Sarlos 2012

• n= 95
• 2 surgeons with prior expertise in conventional laparoscopy
• Longer operating time for the robotic-assisted approach: 31 min
• No differences in blood loss or surgical complication
• No difference in post-op analgesic use or return to normal activities, length of stay
  o Greater improvement in post-op Quality of life 6 weeks following robotic hysterectomy
A randomized trial comparing conventional and robotically assisted total laparoscopic hysterectomy

Paraiso et al 2013

• 53 patients randomised
• No significant differences between groups in estimated blood loss, pre-op and post-op haematocrit change and length of stay
• Very few complication
• Significantly longer operating time for the robotic-assisted approach: 77 min

• Criticism of the trial: the authors were more experienced at laparoscopy than robotics
3 more RCTs

Robot-assisted surgery in gynaecology
Hongqian Liu et al

- 6 RCTs
- n= 517 women
- 4 studies evaluated Robot-assisted surgery for hysterectomy
  - 371 women
- 2 studies evaluated Robot-assisted surgery for sacrocolpopexy
  - 146 women
• uncertain as to whether robotic assisted surgery or conventional laparoscopic surgery has lower intraoperative and postoperative complication rates because of the imprecision of the effect and inconsistency among studies when they are used for hysterectomy and sacrocolpopexy
• procedures take longer
• may be associated with a shorter hospital stay following robotic hysterectomy- 7 hours
Cochrane 2015

Surgical approach to hysterectomy for benign gynaecological disease
Johanna WM Aarts et al

• Robotic-assisted hysterectomy versus LH
  ○ Paraiso 2013 & Sarlos 2012

Conclusion
“Single-port laparoscopic hysterectomy and Robotic Hysterectomy should either be abandoned or further evaluated since there is a lack of evidence of any benefit over conventional laparoscopic hysterectomy.”
Comparison of Robotic and Laparoscopic Hysterectomy for Benign Gynecologic Disease

Rosero 2013

Cohort of 7,788 patients undergoing robotic-assisted hysterectomy, compared to a cohort of propensity matching 7,788 patients undergoing conventional laparoscopic hysterectomy

- Median length of stay was 1 day in robotic arm
- Laparoscopic hysterectomy group: more blood transfusion
  - in contrast with findings from previous RCTs
  - need for blood transfusion may not have been recognized previously because of their rarity

- Robotic-assisted hysterectomy group:
  - More post-op pulmonary complication
    - Longer operating time (range from 26 to 72 minutes longer)
    - Steep trendelenburg
- Cost: US$2,489 higher per patient undergoing robotic-assisted hysterectomy (~ $14 million more)
Is robotic hysterectomy better for “difficult patients” in the hands on “high volume surgeons”?

Multicentre analysis comparing robotic, open, laparoscopic, and vaginal hysterectomies performed by high-volume surgeons for benign indications

Lim 2016

- 2300 robotic-assisted
- 11,952 laparoscopic
- 9,745 abdominal
- 8,121 vaginal

- high-volume surgeons (≥60 prior procedures)
“difficult patients” in robotic group

- significantly higher rate of adhesive disease
- significantly higher rate of morbid obesity
- significantly higher rate of large uteri to other groups
Results

- The robotic-assisted cohort experienced
  - significantly fewer intraoperative complications than the abdominal ($P < 0.001$) and vaginal cohorts ($P < 0.001$)
  - significantly fewer postoperative complications compared with all the comparator cohorts ($P < 0.001$)

Conclusion:
When performed by gynecologic surgeons with relevant high-volume experience, robotic-assisted benign hysterectomy provided improved outcomes compared with abdominal, vaginal, and laparoscopic hysterectomy.
Conflict of interest

• Acknowledgments Intuitive Surgical Inc. provided funding for independent research and editorial support.
• Intuitive Surgical Inc. provided funding for the present study and editorial support.
Myomectomy and robotic surgery
Myomectomy

- Myomectomy is a more challenging procedure.
- Advincula 2004 and 2007: retrospective case-matched analysis of 58 patients who underwent robotic-assisted laparoscopic myomectomy vs open myomectomy.
- Robotic assisted myomectomy is associated with
  - decreased blood loss (195 ml vs 365 ml)
  - length of stay (1.48 days vs 3.62 days)
  - decreased complication (3 vs 14)
- Higher hospital charges for the robotic group: $17,000 more
Barakat 2011

• Retrospective study
• 575 patients
• Compared outcomes between robotic-assisted, conventional laparoscopic and open abdominal approaches.

• Robotic-assisted laparoscopic myomectomy: 
  decreased blood loss and length of stay - compared to open
• Between robotic-assisted and conventional laparoscopy: no significant difference in operating time
Myomectomy

- Robotic assisted vs laparoscopic and/or open myomectomy: systematic review and meta-analysis of the clinical evidence. Iavazzo 2016

- 9 comparative studies
- n= 2027
- 90 ml less blood loss in robotic vs open
- Nil significant difference between robotic and laparoscopic approach
- Increased operating time robotic arm
Comparative Effectiveness of Robotically Assisted Compared With Laparoscopic Adnexal Surgery for Benign Gynecologic Disease - Wright 2014

2009-2012 population based analysis
• n=87,514
• 502 hospitals
• robotically assisted oophorectomy had a higher rate of intraoperative complications
  o bladder injuries (0.6% compared with 0.3%, P<0.05)
  o ureteric injuries (1.7% compared with 0.4%, P<0.001)
    • Complications from surgeons gaining experience in new technology
    • Attempting more challenging cases
• no statistically significant difference in the transfusion rates
Endometriosis

- Robot-assisted versus conventional laparoscopic surgery in the treatment of advanced stage endometriosis: a meta-analysis.

- Chen 2016
  - two comparative clinical trials
  - No difference blood loss, complication, and hospital stay
  - Safe & efficient
  - Benefits remains uncertain
Robotic-assisted versus traditional laparoscopic surgery for endometrial cancer: A Randomized Controlled Trial


- Hysterectomy, bilateral salpingo-oophorectomy, and pelvic lymphadenectomy
- n= 99
- Less operating time comparing to laparoscopy
- Less conversion rate to laparotomy
  - 5 patient from laparoscopic group
  - Nil from robotic group
- No difference in number of lymph nodes harvested & complications
- Increased experience with robotic surgery
Cost effectiveness

- Biggest downside of robotic surgery
- 2015 to 2016 - *55 references* just on cost effectiveness

- Additional cost due to
  - The robot
  - Maintenance
  - Cost of disposable robotic instruments

- Not compensated by shorter hospital stay and optimal operating time
What have we learnt?

- Robotic surgery is more expensive
- However.....it is safe & comparable

- The evidence is still lacking in benign gynaecology
- It may, however, have a role in gynaecological oncology
Thank you!