Robotic-Assisted Surgery for Esophageal Cancer: Analysis of Short & Long-Term Outcomes

Presenters: Paul Shekelle, MD, PhD, Michael Mederos, MD, and Mark Girgis, MD
Co-authors: Michael de Virgilio, BS; Rivfka Shenoy, MD, MS; Linda Ye, MD; Selene S. Mak, PhD, MPH; Meron Begashaw, MPH; Marika S. Booth, MS; and Melinda Maggard-Gibbons, MD

April 27, 2021
VA Evidence Synthesis Program overview

- Established in 2007
- Provides tailored, timely, and accurate evidence syntheses of VA-relevant, Veteran-focused healthcare topics. These reports help:
  - Develop clinical policies informed by evidence;
  - Implement effective services and support VA clinical practice guidelines and performance measures; and
  - Set the direction for future research to address gaps in clinical knowledge.

- Four ESP Centers across the US:
  - Directors are VA clinicians, recognized leaders in the field of evidence synthesis, and have close ties to the AHRQ Evidence-based Practice Center Program and Cochrane Collaboration

- ESP Coordinating Center in Portland:
  - Manages national program operations and interfaces with stakeholders
  - Produces rapid products to inform more urgent policy and program decisions

To ensure responsiveness to the needs of decision-makers, the program is governed by a Steering Committee comprised of health system leadership and researchers.

The program solicits nominations for review topics several times a year via the program website.
The review team developed the report’s scope, study questions, and methodology in consultation with the Operational Partners, ESP Coordinating Center, and technical expert panel (TEP). The authors gratefully acknowledge Roberta Shanman, Jon Bergman, and the following individuals for their contributions:

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Department of Veterans Affairs

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Former National Director of Surgery  
Department of Veterans Affairs

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This report is based on research conducted by the Evidence Synthesis Program (ESP) Center located at the **West Los Angeles VA Medical Center, Los Angeles, CA**, funded by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development. The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (e.g., employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.
Robotic-Assisted Surgery for Esophageal Cancer: Analysis of Short & Long-Term Outcomes

March 2021

Full-length report available on ESP website:
http://www.hsrdr.research.va.gov/publications/esp/reports.cfm
Esophageal Cancer Awareness Month

- Esophageal cancer makes up 1% of all cancer diagnoses in the U.S.
- About 19,260 patients will be diagnosed in 2021
- About 15,530 esophageal cancer-related deaths
- 20% 5-year survival

American Cancer Society; 2021 Cancer Statistics
• Nine-fold increase in robot-assisted minimally invasive esophagectomy (RAMIE) from 2009-2016

• Open esophagectomy and thoraco-laparoscopic esophagectomy are the most common approaches. It is unclear how RAMIE compares to these other techniques.

Seto (2017); Ann Gastroenterol Surg
Caution When Using Robotically-Assisted Surgical Devices in Women's Health including Mastectomy and Other Cancer-Related Surgeries: FDA Safety Communication

• Benefits and risks are not established, and long-term clinical and oncologic outcomes are questioned

• Robotic platform requires economic investment and unclear whether improvements in outcomes outweigh costs (cost-effectiveness questions remain).
Key questions

1) What is the clinical effectiveness of robotic-assisted esophagectomy compared to open or thoracoscopic/laparoscopic esophagectomy for cancer?

2) What is the cost-effectiveness of robotic-assisted esophagectomy compared to open or thoracoscopic/laparoscopic esophagectomy for cancer?
Selection of Studies

390 Titles

146 Abstracts

45 Full texts

244 References

101 References

23 References

Clinical outcomes: 20
Clinical outcomes and cost: 1

Cost only: 1

19 observational studies
2 randomized trials

Intervention: 1
Comparison: 66
Systematic review: 7
Review/editorial: 19
Protocol: 8

Intervention: 6
Comparison: 3
Sample size: 1
Not original research: 1
Duplicate: 11
Unavailable: 1

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2) What is the **cost-effectiveness** of robotic-assisted esophagectomy compared to open or thoracoscopic/laparoscopic esophagectomy for cancer?
# Outcomes of Interest

## Intra-operative
- Operative time
- Estimated blood loss (EBL)
- Lymph node harvest

## Short-term
- Anastomotic leak
- Recurrent laryngeal nerve (RLN) palsy
- Pulmonary complications
- Total complications
- Length of stay**
- 90-day mortality

## Long-term
- Recurrence
- Cancer-free survival

**U.S. studies only**
**Included Studies**

- **RAMIE vs. VAMIE = 12**
  - RCT: 1
  - Propensity-matched: 8
  - Unmatched: 3

- **RAMIE vs. VAMIE and OE = 3**
  - Propensity-matched: 1
  - Unmatched: 2

- **RAMIE vs. OE = 6**
  - RCT: 1
  - Propensity-matched: 2
  - Unmatched: 3

- **RAMIE vs. VAMIE = 15**

- **RAMIE vs. OE = 9**
Intraoperative Outcomes – Operative Time

RAMIE vs. VAMIE
• RAMIE associated with longer operative time

RAMIE vs. OE
• RAMIE associated with longer operative time
Intraoperative Outcomes – EBL

RAMIE vs. VAMIE

• No difference in EBL

RAMIE vs. OE

• RAMIE associated with less EBL
Intraoperative Outcomes – LN Harvest

**RAMIE vs. VAMIE**
- RAMIE associated with larger lymph node harvest

**RAMIE vs. OE**
- RAMIE associated with larger lymph node harvest

**Legend**
- RCT
- Matched observational study
- Non-matched observational study
Short-term Outcomes

**RAMIE vs. VAMIE**
- No difference in anastomotic leak or RLN palsy

**RAMIE vs. OE**
- No difference in anastomotic leak or RLN palsy

- RCT
- Matched observational study
- Non-matched observational study
Short-term Outcomes cont.

**RAMIE vs. VAMIE**
- No difference in pulmonary or total complications

**RAMIE vs. OE**
- RAMIE associated with fewer pulmonary and total complications

---

- **RCT**
- **Matched observational study**
- **Non-matched observational study**
Short-term Outcomes cont.

**RAMIE vs. VAMIE**
- No difference in LOS

**RAMIE vs. OE**
- RAMIE may be associated with shorter LOS

---

**Graph Details**
- **RAMIE vs. VAMIE**: No significant difference in LOS.
- **RAMIE vs. OE**: RAMIE may be associated with shorter LOS.

- **Symbols**:
  - Green circle: RCT
  - Yellow square: Matched observational study
  - Yellow triangle: Non-matched observational study
Short-term Outcomes cont.

RAMIE vs. VAMIE
• No difference in mortality

RAMIE vs. OE
• No difference in mortality

RCT
Matched observational study
Non-matched observational study
Long-term Outcomes - Recurrence

**RAMIE vs. VAMIE**

- No difference in cancer recurrence

**RAMIE vs. OE**

- No difference in cancer recurrence

**Study Types**
- RCT
- Matched observational study
- Non-matched observational study
Long-term Outcomes – Cancer-free survival

RAMIE vs. VAMIE

- RAMIE may be associated with longer cancer-free survival

RAMIE vs. OE

- No difference in cancer-free survival
<table>
<thead>
<tr>
<th></th>
<th>RAMIE vs. VAMIE</th>
<th>RAMIE vs. Open</th>
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<td>Operative Time**</td>
<td>↑</td>
<td>↑</td>
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<tr>
<td>Lymph Node Harvest</td>
<td>↑</td>
<td>↑</td>
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<tr>
<td>EBL</td>
<td>=</td>
<td>↓</td>
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<tr>
<td>Anastomotic Leak</td>
<td>=</td>
<td>=</td>
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<tr>
<td>RLN Palsy</td>
<td>=</td>
<td>=</td>
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<tr>
<td>Pulmonary Complications</td>
<td>=</td>
<td>↓</td>
</tr>
<tr>
<td>Total Complications</td>
<td>=</td>
<td>↓</td>
</tr>
<tr>
<td>Length of Stay</td>
<td>=</td>
<td>↓</td>
</tr>
<tr>
<td>Mortality (90-day)</td>
<td>=</td>
<td>=</td>
</tr>
<tr>
<td>Recurrence</td>
<td>=</td>
<td>=</td>
</tr>
<tr>
<td>Cancer-free survival</td>
<td>↑(?)</td>
<td>=</td>
</tr>
</tbody>
</table>

**Significant heterogeneity across studies, suggesting differences in the measurement of this outcome**
Key questions

1) What is the **clinical effectiveness** of robotic-assisted esophagectomy compared to open or thoracoscopic/laparoscopic esophagectomy for cancer?

2) What is the **cost-effectiveness** of robotic-assisted esophagectomy compared to open or thoracoscopic/laparoscopic esophagectomy for cancer?
Cost-Effectiveness

- No studies evaluated cost-effectiveness
- 2 studies included some measure of cost

<table>
<thead>
<tr>
<th>Source</th>
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<th>VAMIE</th>
<th>Open</th>
<th>P-values</th>
<th>Notes</th>
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<tr>
<td>Chen, 2019</td>
<td>Total Expenses: $25,300 ± 9,000 (USD)</td>
<td>Total Expenses: $20,800 ± 9,000 (USD)</td>
<td>P=0.009</td>
<td></td>
<td>ICU and total length of stay were longer for RAMIE but did not reach significance</td>
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<tr>
<td></td>
<td>Expenses/Day: $1,700 ± 700 (USD)</td>
<td>Expenses/Day: $1,500 ± 400 (USD)</td>
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<td>P=0.028</td>
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<tr>
<td>Van Der Sluis, 2018</td>
<td>Mean cost: €34,892</td>
<td>Mean cost: €39,463</td>
<td></td>
<td>P=0.07</td>
<td>RAMIE had a shorter length of stay that did not reach significance</td>
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</table>
Overview of Findings

• RAMIE is associated with longer operative times and larger LN harvest compared with VAMIE and open esophagectomy

• Short term outcomes are similar between RAMIE and VAMIE

• RAMIE is associated with less EBL, pulmonary complications, and total complications compared with open esophagectomy

• Insufficient data to make conclusions about long-term outcomes and cost-effectiveness
Applicability of Findings to the VA Population

- No studies specific to VA populations.

- Applicability may depend on both similarity of the patients studied to VA and experience of surgical teams using the robot to VA surgical teams.

- Benefits for robotic approach may still be realized despite patient-level differences (VA patients greater burden of comorbidities), which will need to be confirmed in future studies.
Applicability of Findings to the VA Population

• Robotic systems in the VA increased from **43 to 95** from 2014 to 2019
Applicability of Findings to the VA Population

- Four-fold increase in robot-assisted thoracic surgery at the VA from 2014-2019

*Figure A.1. Robotic system utilization for surgical subspecialty procedures by calendar year.*
Research Gaps

• Need for randomized/well-designed studies evaluating **long-term oncologic outcomes**.

• There are several approaches/techniques to performing an esophagectomy, which is difficult to disentangle (e.g., McKeown, Ivor-Lewis, transhiatal).

• Regional variations in surgical practice, operative volume, and esophageal cancer epidemiology (SCC vs. adenocarcinoma).

• There is a need for high quality cost-effectiveness studies as well as a standardized method to assess cost (i.e., analytics, consistent definitions, accounting for upfront capital, staff training, etc.)
## Acknowledgements

### Our Team
- Paul Shekelle
- Melinda Maggard-Gibbons
- Mark Girgis
- Michael Mederos
- Michael de Virgilio
- Rivfka Shenoy
- Linda Ye
- Paul Toste
- Christopher Childers
- Selene Mak
- Meron Begashaw
- Marika Booth

### Operational Partners
- Mark Wilson
- William Gunnar

### Technical Expert Panel
- Rajeev Dhupar
- Nir Hofman
- James Maloney
- Daniel Wiener
Questions?

If you have further questions, please feel free to contact:

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Mark.Girgis@va.gov

Full-length report and cyberseminar available on ESP website:

http://www.hsrdr.research.va.gov/publications/esp/

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<table>
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<tr>
<th>Author, year</th>
<th>Surgical Approach</th>
<th>Technique</th>
<th>Abdomen</th>
<th>Chest</th>
<th>Anastomosis</th>
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<td>Chao 2017</td>
<td>RAMIE</td>
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<td>Laparoscopic</td>
<td>Robotic</td>
<td>Circular stapled; cervical</td>
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<td>McKeown</td>
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<td>Deng 2018</td>
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<td>He 2018</td>
<td>RAMIE</td>
<td>McKeown</td>
<td>Robotic</td>
<td>Robotic</td>
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<td>van der Sluis 2019</td>
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<td>Ivor Lewis</td>
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</table>

**Table:** Surgical Approach Techniques and Anastomosis Methodology

- **RAMIE:** Robotic-Assisted Minimally Invasive Esophageal Surgery
- **VAMIE:** Video-Assisted Minimally Invasive Esophageal Surgery
- **NR:** Not Reported
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<td>Thoracotomy</td>
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<td>Park 2016</td>
<td>RAMIE</td>
<td>90% McKeown 10% Ivor Lewis</td>
<td>58% robotic 42% open*</td>
<td>Robotic</td>
<td>90% cervical 10% thoracic</td>
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<td>VAMIE</td>
<td>81% McKeown 19% Ivor Lewis</td>
<td>49% laparoscopic 51% open*</td>
<td>Laparoscopic</td>
<td>81% cervical 19% thoracic</td>
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