Minimally Invasive Esophagectomy

Inderpal (Netu) S. Sarkaria, MD, FACS

Vice Chairman, Clinical Affairs
Director, Robotic Thoracic Surgery
Co-Director, Esophageal and Lung Surgery Institute

Duke Masters Course, September 2017
Disclosures

Intuitive Surgical – Education/Speaking
Standard Esophagectomy?

- Transthoracic vs Transhiatal?
- Neck vs Chest Anastomosis?
- Gastric vs Colonic vs Jejunal Conduit?
- Minimally Invasive vs Open?
- Robotic vs “Standard” MIS?
An individual surgeon’s approach to GEJ cancer is determined by:

- Religion, belief, faith
- Training
- Mentors
- Anecdotal experience
- Evidence
My Background & Mentors

- General Surgery: New York Hospital – Cornell
- Thoracic Surgical Oncology: MSKCC
- Cardiac Surgery: New York Hospital – Cornell
- Minimally Invasive Esophageal Surgery: UPMC
- Attending Surgeon, Thoracic Service: MSKCC
- Attending Surgeon, Thoracic Service: UPMC
Esophagectomy: Transhiatal vs Transthoracic

- Randomized trial of Transhiatal vs. Transthoracic approach

- 5-year survival: Transthoracic en bloc 39% vs Transhiatal 27%

- Morbidity increased after transthoracic
  - ICU 6 days vs 2
  - LOS 19 days vs 15
  - Mortality 5 vs 2 patients

- Median survival: Transthoracic en bloc 2.0 years vs 1.8 years after transhiatal (p=0.38)

Hulscher et al. NEJM 2002;347(21):1662-69
The Impact of Complications on Outcomes after Resection for Esophageal and Gastroesophageal Junction Carcinoma

Nabil P Rizk, MD, Peter B Bach, MD, Deborah Schrag, MD, Manjit S Bains, MD, FACS, Alan D Turnbull, MD, FACS, Martin Karpeh, MD, FACS, Murray F Brennan, MD, FACS, Valerie W Rusch, MD, FACS

Transhiatal Esophagectomy
Average 10-15 nodes

Ivor Lewis Esophagectomy
Average 20-30 nodes

Courtesy of Dr. Manjit Bains, MSKCC
En Bloc Esophagectomy

Standard

En bloc
World Esophageal Cancer Consortium Analysis: RFS Analysis for pN+M0 5-Year Survival

Ann Surg 2010; 251:46–50
Ivor Lewis vs Transhiatal: Post CRT

*All patients received pre-operative chemo-radiation

Data Courtesy Dr. Nabil Rizk, MSKCC, 2014
Survival if 1-8 Nodes Positive: MSKCC

Transthoracic Approach Improved Survival

\[ P=0.05 \]
Why a Thoracotomy?

TRANSTHORACIC
Aggressive operation
More complications
Better long-term outcome

TRANSHIATAL
Conservative operation
Fewer complications
Worse long-term outcome
Same Operation...
...Smaller Incisions

Open Esophagectomy vs Minimally Invasive Esophagectomy?
U. Pittsburgh MIE Experience

- Luketich 1996-2011
  - Ivor Lewis & McKeown (3-hole)
  - 1011 patients (960 for cancer)
  - Conversion - 5%
  - LOS (mean) - 8 days
  - Mortality - 1.7%
  - Anastomotic leak - 5%
  - Median LN - 21
  - Comparable survival

Prospective MIE Trial: ECOG E2202

- Phase II Multicenter Study of MIE: 106 enrolled pts from 16 institutions
  - 99 underwent MIE (Adenocarcinoma 88 pts, HGD 11 pts)

- 30 day mortality 2%

- Anastomotic leak 7.8%

- Mean ICU stay 2 days

- Median LN count 20

- Stage specific survival similar to open

Traditional Invasive vs Minimally Invasive Esophagectomy (TIME-trial)

- Prospective randomized study-Europe
  - Holland, Spain, Italy (6 credentialed centers)

- Primary end-point; respiratory complications

- Secondary end-points;
  - Operative (duration, EBL, conversion)
  - Oncologic outcomes

- Sample-size 48 patients each group
  - Estimated respiratory events 57% OE/29%MIE

TIME Trial Results

- MIE – decreased pulmonary complications
  - 1st two weeks 29% vs. 9%
  - In-hospital 34% vs. 12%
- Similar anastomotic leak (7% vs. 12%)
- Improved short-term QOL
  - Pain
  - Talking
- Shorter hospital stay
- Similar mortality (2%-3%)
MIE Quality of Life

- Quality of Life decreases significantly in first 6 months after esophagectomy
  - Recovery in most aspects by one year

- MIE shows preservation of QOL comparable to open surgery
  - Dysphagia
  - Reflux
  - Dyspnea
  - Diarrhea

- No rigorous comparisons MIE vs. open

Luketich et al. Ann Surgery 2003;238:486-95
Taguchi et al. Surg Endoscopy 2003;17:1445-50
Minimally Invasive Esophagectomy Provides Equivalent Survival to Open Esophagectomy: An Analysis of the National Cancer Database

Brian Mitzman, MD,* Waseem Lutfi, BS,† Chi-Hsiung Wang, PhD,‡ Seth Krantz, MD,§ John A. Howington, MD,§ and Ki-Wan Kim, MD‡

- Increase in MIE utilization 27%→36%
  - 3-year study period (2010 – 2012)
- Propensity matched OE vs MIE
  - 977 patients each cohort
- MIE improved LN (16.3 vs 14.5)
- No Difference post-op/quality metrics
  - pStage (pT), upstaging, margins, LOS (14 days), readmission (6.5%)
  - Mortality: 30-day (3%), 90-day (7%)
  - Median Survival (mths): OE 49, MIE 47
Comparison of Short-Term Outcomes Between Open and Minimally Invasive Esophagectomy for Esophageal Cancer Using a Nationwide Database in Japan

Hiroya Takeuchi, MD, PhD1-3, Hiroaki Miyata, PhD2-5, Soji Ozawa, MD, PhD3, Harushi Udagawa, MD3, Harushi Osugi, MD, PhD3, Hisahiro Matsubara, MD, PhD3, Hiroyuki Konno, MD, PhD4, Yasuyuki Seto, MD, PhD4, and Yuko Kitagawa, MD, PhD1,3

- Propensity matched (3515 each cohort), NCD 2011-2012
- MIE (total thoracoscopic/laparoscopic or hybrid)
  - Longer OR time (526 v 461), less EBL (442 v 608)
  - Decreased 48h vent (9% v 11%), atelectasis, superficial SSI
  - Increased RLN palsy (8% vs 10%)
  - 30-day reoperation rate higher (7% v 5%)
- No difference
  - 30-day mortality (1%), Op mortality (2%-3%), Leak (12%-13%)
- RCT JCOG 1409 Initiated
  - MIE v OE short-term and OS stage I-III

Bottom Line: MIE

• Comparable
  – Oncologic resection, survival, long-term QOL
  – Morbidity and mortality

• Improved or decreased
  – Hospital stay
  – ICU days
  – Respiratory complications
  – Wound complications
Robotic Assisted Minimally Invasive Esophagectomy (RAMIE)
Why Robotic over Standard MIS?

- Stable, controlled video
- Articulated instruments
- Motion scaling
- Immobile fulcrum
- Self-assist or control assistant
- Shorten learning curve?

IMPROVED CONTROL OVER CONDUCT OF OPERATION

MSKCC Esophageal

- 87 (67%) RAMIE
MSKCC Robotic Trends

- **2002-2013: Open vs Standard MIS/VATS vs Robotic**
  - Lobectomy 3%→22%, Esophagectomy 13%→39%, Thymectomy 20%→47%
**RAMIE Procedure**

- Robotic-assisted laparoscopy and thoracoscopy
  - Two-surgeon console, Two dedicated attendings
- Abdominal hiatal and esophagogastric mobilization
- Retrogastric lymph node dissection
- Gastric-emptying procedure (optional)
- Gastric conduit formation
- Feeding jejunostomy (laparoscopic)
- Thoracic en-bloc esophageal mobilization and lymph node dissection
- End to side anastomosis
  - Intra-thoracic robotic-assisted circular stapled (Ivor Lewis)
  - Neck handsewn (McKeown)
RAMIE Port Placement - Abdomen

- Supine with arms 45 degrees
- Reverse Trendelenburg
- CO2 insufflation
- 9-10 cm between ports

- 5mm, lateral subcostal
  Liver Retractor

- 5mm, costal reflection
  Robotic Assistant
  Schertl grasper

- 8mm, 23 cm from xiphoid
  Robotic “Left Hand”
  Fenestrated Bipolar

- 8mm, 13cm from xiphoid
  Robotic “Right Hand”
  Ultrasonic Shears

- 12-15mm
  Bedside Assistant
  Suction, Retraction, Stapler

- Umbilicus, 12mm
  Robotic Camera
  23 cm from xiphoid
RAMIE Port Placement - Chest

- Standard lateral VATS position with flexion
- CO2 insufflation
- 9-10 cm between robotic port sites (avoid arm collisions)

8mm, 9th or 10th ICS, Robotic “Left Hand” Fenestrated Bipolar

12mm, over diaphragm Bedside Assistant, Suction, Linear stapler

3rd ICS, 5mm, Robotic 3rd arm (assistant), Schertl atraumatic grasper

5th ICS, 8mm, Robotic “Right Hand” Ultrasonic Shears

8th ICS, 12 mm, Robotic Camera

Trajectory of robotic cart center column over shoulder
RAMIE Room Setup
Hiatal Dissection
Retrogastric Dissection
Gastric Mobilization

:35; :55
Robotic Pyloroplasty

:30; 1:00; 2:25; 3:00
RAMIE Conduit Formation: Standard and Robotic Staplers

**Standard Hand Held**

**Robotic**
RAMIE - Replaced Left Hepatic Artery
:30; 1:00; 1:10; 1:45
Esophageal Mobilization
Subcarinal/Airway Dissection
Anastomosis I
Robotic EEA Anvil Placement

19 Oct 2009
RAMIE Anastomosis

Actual

Simulated Training
Anastomosis II

:35; :45;
Fluorescence & PET Imaging

- Fluorescence angiography
- Tumor localization
  - NIFI
  - PET
  - Raman Spectroscopy

Sarkaria et al. Innovations 2014
Holland et al. Mol Imaging 2011, vol 10:177-86 (MSKCC)
MIE/RAMIE Pitfalls & Challenges

- Airway injury
  - Consider energy device carefully

- Greater curve visualization

- Conduit formation

- Traverse of conduit

- Trocar placement & Arm collisions

- Anastomosis creation

First 21 patients: 3 (14%) airway fistulas → 1 mortality at 70 days

“While four-arm RAMIE may offer advantages over standard MIE, its adoption in a structured program, with critical evaluation of adverse events and subsequent adjustment of technique, is paramount to maximize patient safety, minimize complications and improve the conduct of the operation early in the learning curve. Particular consideration should be given to prevention of airway complications.”

RAMIE: Outcomes & Learning Curve

- Initial 45 patients: MSKCC
- No intra-operative complications
- Median EBL 300cc (range 100-700cc)
- Median LN count 21 (range 10-56)
- Median time: 468 min (range 283-807 min)
  - First 5 cases: 600min (range 468-643 min)
  - Last 5 cases: 297min (range 283-374 min)
- Median LOS 10 days (range 7-70 days)
  - Last 5 cases: 9 days (range 7-9 days)
- 81% complete (R0) resection rate

<table>
<thead>
<tr>
<th>Demographic/Datapoint</th>
<th>Overall</th>
<th>1st 1/3rd</th>
<th>2nd 1/3rd</th>
<th>3rd 1/3rd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>45</td>
<td>15</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Mean age</td>
<td>62 (37-83)</td>
<td>62</td>
<td>60</td>
<td>62</td>
</tr>
<tr>
<td>Male</td>
<td>75%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>84%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Induction chemoradiation</td>
<td>73%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ivor-Lewis</td>
<td>75%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete resection (R0)</td>
<td>81%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median estimated blood loss</td>
<td>250 cc (50-700)</td>
<td>350</td>
<td>300</td>
<td>200</td>
</tr>
<tr>
<td>Median lymph nodes</td>
<td>21 (10-56)</td>
<td>21</td>
<td>19</td>
<td>24</td>
</tr>
<tr>
<td>Conversion to open surgery</td>
<td>24%</td>
<td>33%</td>
<td>13%</td>
<td>7%</td>
</tr>
<tr>
<td>Last 5 cases</td>
<td>0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median operative time</td>
<td>468 min (283-807)</td>
<td>603</td>
<td>452</td>
<td>373</td>
</tr>
<tr>
<td>Last 5 cases</td>
<td>297 min (283-374)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median length of stay</td>
<td>10 days (7-70)</td>
<td>10</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>Last 5 cases</td>
<td>9 days (7-9)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complications (CTCAE v3.0)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade II</td>
<td>12/45 (27%)</td>
<td>40%</td>
<td>20%</td>
<td>20%</td>
</tr>
<tr>
<td>Grade III-V</td>
<td>8/45 (17%)</td>
<td>33%</td>
<td>27%</td>
<td>0%</td>
</tr>
<tr>
<td>Grade V (death)</td>
<td>1/45 (2.2%)</td>
<td>7%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Anastomotic leak &gt;= Grade II</td>
<td>4/45 (9%)</td>
<td>13%</td>
<td>0%</td>
<td>7%</td>
</tr>
</tbody>
</table>

Sarkaria et al. SSAT/DDW 2014, Chicago, IL
RAMIE Learning Curve

- 30-35 cases to obtain median 400-500 min
  - Experienced surgeons
  - Unvarying team

Sarkaria et al. SSAT/DDW 2014, Chicago, IL
Attaining Proficiency in Robotic-Assisted Minimally Invasive Esophagectomy While Maximizing Safety During Procedure Development

Inderpal S. Sarkaria, MD, Nabil P. Rizk, MD, Rachel Grosser, BA, Debra Goldman, MA, David J. Finley, MD, Amanda Ghanie, BA, Camelia S. Sima, MD, Manjit S. Bains, MD, Prasad S. Adusumilli, MD, Valerie W. Rusch, MD, and David R. Jones, MD

- 100 Patients, MSKCC
- No intra-operative complications
- Median EBL 250cc (range 20-700cc)
- Median LN count 24 (range 10-56)
- Median time: 379 min (range 275-807 min)
- Median LOS 9 days (range 4-70 days)
- 89% complete (R0) resection rate
- 0% 30-day mortality
- 1% 90-day mortality
Attaining Proficiency in Robotic-Assisted Minimally Invasive Esophagectomy While Maximizing Safety During Procedure Development

Inderpal S. Sarkaria, MD, Nabil P. Rizk, MD, Rachel Grosser, BA, Debra Goldman, MA, David J. Finley, MD, Amanda Ghanie, BA, Camelia S. Sima, MD, Manjit S. Bains, MD, Prasad S. Adusumilli, MD, Valerie W. Rusch, MD, and David R. Jones, MD

- **Learning Curve***
  - 30-50 Cases
    - EBL
    - Op Time (400-500 min)
    - LN Harvest
    - LOS

- **Experienced Surgeons**
- **Consistent Team**

*Experienced Surgeons

*Consistent Team

---

*Sarkaria et al. SSAT/DDW 2014, Chicago, IL*
# UPMC Robotic Thoracic Experience

\[ n = 314 \]

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Esophageal/Foregut</strong></td>
<td></td>
</tr>
<tr>
<td>Esophagectomy</td>
<td>33</td>
</tr>
<tr>
<td>Hiatal Hernia/Anti-Reflux</td>
<td>62</td>
</tr>
<tr>
<td>Heller Myotomy</td>
<td>12</td>
</tr>
<tr>
<td><strong>Pulmonary</strong></td>
<td></td>
</tr>
<tr>
<td>Lobectomy</td>
<td>72</td>
</tr>
<tr>
<td>Segmentectomy</td>
<td>11</td>
</tr>
<tr>
<td>Wedge Resection</td>
<td>34</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
</tr>
<tr>
<td><strong>Mediastinal</strong></td>
<td></td>
</tr>
<tr>
<td>Anterior</td>
<td>53</td>
</tr>
<tr>
<td>Posterior</td>
<td>10</td>
</tr>
<tr>
<td>Other</td>
<td>24</td>
</tr>
</tbody>
</table>
Robotic assisted minimally invasive esophagectomy (RAMIE): the University of Pittsburgh Medical Center initial experience

Olugbenga T. Okusanya*, Inderpal S. Sarkaria*, Nicholas R. Hess, Katie S. Nason, Manuel Villa Sanchez, Ryan M. Levy, Arjun Pennathur, James D. Luketich

Table 3 Comparative outcomes of minimally invasive esophagectomy (MIE) and robotic assisted minimally invasive esophagectomy (RAMIE)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Lukotich 2012, MIE</th>
<th>Sarkaria 2013, RAMIE</th>
<th>Current study 2017, RAMIE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient number</td>
<td>1,011</td>
<td>21</td>
<td>25</td>
</tr>
<tr>
<td>Age, median</td>
<td>64</td>
<td>62</td>
<td>67</td>
</tr>
<tr>
<td>Histology, n [%]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>727 [76]</td>
<td>18 [85]</td>
<td>18 [72]</td>
</tr>
<tr>
<td>Median operative time, minutes</td>
<td>NR</td>
<td>566</td>
<td>661</td>
</tr>
<tr>
<td>Median estimated blood loss, mL</td>
<td>NR</td>
<td>307</td>
<td>250</td>
</tr>
<tr>
<td>Adequacy of cancer resection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative margins, n [%]</td>
<td>939 [98]</td>
<td>17 [81]</td>
<td>24 [96]</td>
</tr>
<tr>
<td>Median lymph nodes examined</td>
<td>19</td>
<td>20</td>
<td>26</td>
</tr>
<tr>
<td>Median hospital length of stay, days</td>
<td>8</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Anastomotic leak, n [%]</td>
<td>26 [5]</td>
<td>2 (0.6)</td>
<td>1 [4]</td>
</tr>
<tr>
<td>30-day mortality, n [%]</td>
<td>17 [1.7]</td>
<td>0 [0]</td>
<td>0 [0]</td>
</tr>
</tbody>
</table>

• Equivalent Demographics
• Equivalent Leak Rate
• Equivalent Mortality  
  • 0% 90-day
• Improved Lymph Node Harvest?
Quality of Life Outcomes: MIE & Open Esophagectomy

- Better assessment of short and long term QOL needed
- Prospective trial, 150 patients expected accrual

- Primary Endpoint: Quality of Life Assessment
  - FACT-E
  - Brief Pain Inventory

- Secondary Endpoint: surgical outcomes
  - Morbidity
  - Survival
  - Oncologic outcomes
## MSKCC MIE QOL Early Results: Demographics

### Descriptive Statistics

<table>
<thead>
<tr>
<th>Procedure</th>
<th>OE</th>
<th>MIE</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median</td>
<td>62</td>
<td>60</td>
<td>0.11</td>
</tr>
<tr>
<td>IQR</td>
<td>(57-70)</td>
<td>(54-67)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Octogenarian</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>80</td>
<td>97.56</td>
<td>54</td>
<td>98.18</td>
<td>1.00</td>
</tr>
<tr>
<td>Yes</td>
<td>2</td>
<td>2.44</td>
<td>1</td>
<td>1.82</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Induction Treatment</th>
<th>No</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>14</td>
<td>17.07</td>
<td>14</td>
<td>25.45</td>
<td>0.28</td>
</tr>
<tr>
<td>Yes</td>
<td>68</td>
<td>82.93</td>
<td>41</td>
<td>74.55</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ASA</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>10</td>
<td>12.2</td>
<td>8</td>
<td>14.55</td>
<td>0.58</td>
</tr>
<tr>
<td>3</td>
<td>66</td>
<td>80.49</td>
<td>45</td>
<td>81.82</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>6</td>
<td>7.32</td>
<td>2</td>
<td>3.64</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>17</td>
<td>20.73</td>
<td>11</td>
<td>20</td>
<td>0.22</td>
</tr>
<tr>
<td>1</td>
<td>16</td>
<td>19.51</td>
<td>19</td>
<td>34.55</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>27</td>
<td>32.93</td>
<td>12</td>
<td>21.82</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>22</td>
<td>26.83</td>
<td>13</td>
<td>23.64</td>
<td></td>
</tr>
</tbody>
</table>
MIE QOL Early Results: Brief Pain Inventory

Decreased Short-Term Pain & Interference

Data Analysis: Debra Goldman, M.S. & Camelia Sima, M.D., M.S.

Sarkaria et al. MSKCC IRB Protocol #12-003. QOL After MIE & Open Esophagectomy
MIE QOL Early Results: Peri-operative Outcomes

Current Analyses

- **RAMIE vs. OE**
  - Longer operative time
  - Less EBL
  - Decreased LOS (2 days)
  - Increased LN counts (25 v 22)

- **Equivalent R0 rate**
- **Improved QOL (FACT-E)**
- **Decreased ICU days**
- **Equivalent Readmissions**

<table>
<thead>
<tr>
<th>Peri-operative Variable</th>
<th>Summary Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Procedure</td>
</tr>
<tr>
<td></td>
<td>OE</td>
</tr>
<tr>
<td></td>
<td>Median 25th 75th</td>
</tr>
<tr>
<td>Operative Time (hrs)</td>
<td>5.37 4.57 6.53</td>
</tr>
<tr>
<td>Est. Blood Loss (mL)</td>
<td>350.00 200.00 500.00</td>
</tr>
<tr>
<td>Days of Hospitalization</td>
<td>11.00 10.00 14.00</td>
</tr>
</tbody>
</table>

Sarkaria et al. MSKCC IRB Protocol #12-003. QOL After MIE & Open Esophagectomy
MIE QOL Early Results: Complications

**RAMIE: Significantly Decreased Pulmonary and Infectious Complications**

<table>
<thead>
<tr>
<th>Complication Type</th>
<th>Descriptive Statistics</th>
<th></th>
<th>Procedure</th>
<th></th>
<th></th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>count</td>
<td>% of total</td>
<td>count</td>
<td>% of total</td>
<td></td>
</tr>
<tr>
<td>Any Complication</td>
<td></td>
<td>41</td>
<td>49.40</td>
<td>25</td>
<td>45.45</td>
<td>0.73</td>
</tr>
<tr>
<td>Respiratory Complication</td>
<td></td>
<td>24</td>
<td>28.92</td>
<td>11</td>
<td>20.00</td>
<td>0.32</td>
</tr>
<tr>
<td>Lung Infection</td>
<td></td>
<td>17</td>
<td>20.48</td>
<td>10</td>
<td>18.18</td>
<td>0.83</td>
</tr>
<tr>
<td>Uti</td>
<td></td>
<td>12</td>
<td>14.46</td>
<td>6</td>
<td>10.91</td>
<td>0.61</td>
</tr>
<tr>
<td>Thromboembolic</td>
<td></td>
<td>6</td>
<td>7.23</td>
<td>3</td>
<td>5.45</td>
<td>1.00</td>
</tr>
<tr>
<td>Esophageal Stenosis</td>
<td></td>
<td>2</td>
<td>2.41</td>
<td>4</td>
<td>7.27</td>
<td>0.22</td>
</tr>
<tr>
<td>Aspiration</td>
<td></td>
<td>3</td>
<td>3.61</td>
<td>0</td>
<td>0.00</td>
<td>0.28</td>
</tr>
<tr>
<td>Pleural Effusion</td>
<td></td>
<td>3</td>
<td>3.61</td>
<td>1</td>
<td>1.82</td>
<td>1.00</td>
</tr>
<tr>
<td>Pleural Infection</td>
<td></td>
<td>3</td>
<td>3.61</td>
<td>0</td>
<td>0.00</td>
<td>0.28</td>
</tr>
<tr>
<td>Recurrent laryngeal nerve palsy</td>
<td></td>
<td>0</td>
<td>0.00</td>
<td>3</td>
<td>5.45</td>
<td>0.06</td>
</tr>
<tr>
<td>Wound Infection</td>
<td></td>
<td>3</td>
<td>3.61</td>
<td>1</td>
<td>1.82</td>
<td>1.00</td>
</tr>
<tr>
<td>Dehydration</td>
<td></td>
<td>2</td>
<td>2.41</td>
<td>0</td>
<td>0.00</td>
<td>0.52</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td></td>
<td>2</td>
<td>2.41</td>
<td>1</td>
<td>1.82</td>
<td>1.00</td>
</tr>
</tbody>
</table>

**Major Complications by Common Terminology Criteria for Adverse Events v. 4.0**

<table>
<thead>
<tr>
<th>Complication Type</th>
<th>Descriptive Statistics</th>
<th></th>
<th>Procedure</th>
<th></th>
<th></th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anastomotic Leak</td>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>0.48</td>
</tr>
<tr>
<td>No Leak</td>
<td></td>
<td>76</td>
<td>91.57</td>
<td>52</td>
<td>94.55</td>
<td></td>
</tr>
<tr>
<td>Grade 1 Leak</td>
<td></td>
<td>1</td>
<td>1.20</td>
<td>1</td>
<td>1.82</td>
<td></td>
</tr>
<tr>
<td>Grade 2-4 Leak</td>
<td></td>
<td>6</td>
<td>7.23</td>
<td>2</td>
<td>3.64</td>
<td></td>
</tr>
</tbody>
</table>

**30-day & 90-day Mortality:**

- **OE:** 3%, 5%
- **RAMIE:** 0%, 0%

Sarkaria et al. MSKCC IRB Protocol #12-003. QOL After MIE & Open Esophagectomy
This paper describes the technique of robot-assisted minimally invasive esophagectomy. (RAMIE) Also, a systematic literature search was performed. Safety and feasibility of RAMIE was demonstrated in all reports. Short term oncologic results show radical resection rates of 77–100% and 18–43 lymph nodes harvested. RAMIE offers great visualization of the mediastinum and enables meticulous dissection in the mediastinum from diaphragm to thoracic inlet.

### TABLE II. Perioperative Statistics

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Cases (n)</th>
<th>Operation</th>
<th>Perioperative complications (n (%))</th>
<th>Blood loss (ml)</th>
<th>Total operative time (min)</th>
<th>Thoracic phase/Console (min)</th>
<th>Conversions (n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anderson</td>
<td>2007</td>
<td>9</td>
<td>TT/TH</td>
<td>0</td>
<td>350</td>
<td>482</td>
<td>NR</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Kermatineb</td>
<td>2007</td>
<td>10</td>
<td>TT</td>
<td>Bronchus injury 1 (7)</td>
<td>275</td>
<td>672</td>
<td>294</td>
<td>1 (7.1)</td>
</tr>
<tr>
<td>Galvani</td>
<td>2008</td>
<td>11</td>
<td>TH</td>
<td>0</td>
<td>54</td>
<td>267</td>
<td>NA</td>
<td>0</td>
</tr>
<tr>
<td>Kim</td>
<td>2010</td>
<td>12</td>
<td>TT</td>
<td>0</td>
<td>150</td>
<td>410</td>
<td>108.8</td>
<td>0</td>
</tr>
<tr>
<td>Boone</td>
<td>2011</td>
<td>6</td>
<td>TT</td>
<td>Bleeding 1 (2)</td>
<td>625</td>
<td>450</td>
<td>180</td>
<td>7 (15)</td>
</tr>
<tr>
<td>Puntambekar</td>
<td>2011</td>
<td>13</td>
<td>TT</td>
<td>NR</td>
<td>80</td>
<td>210</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>Sutherland</td>
<td>2011</td>
<td>14</td>
<td>TH</td>
<td>NR</td>
<td>97</td>
<td>312</td>
<td>NA</td>
<td>NR</td>
</tr>
<tr>
<td>Hernandez</td>
<td>2012</td>
<td>15</td>
<td>TT</td>
<td>NR</td>
<td>NR</td>
<td>442f</td>
<td>NR</td>
<td>0</td>
</tr>
<tr>
<td>Weckler</td>
<td>2012</td>
<td>16</td>
<td>TT</td>
<td>0</td>
<td>200</td>
<td>439</td>
<td>NR</td>
<td>0</td>
</tr>
<tr>
<td>Cerfolio</td>
<td>2013</td>
<td>17</td>
<td>TT</td>
<td>NR</td>
<td>60/75</td>
<td>367</td>
<td>NR</td>
<td>0</td>
</tr>
<tr>
<td>Dunnb</td>
<td>2013</td>
<td>18</td>
<td>TH</td>
<td>NR</td>
<td>97.2</td>
<td>311</td>
<td>NA</td>
<td>5 (12.5)</td>
</tr>
<tr>
<td>Sarkaria</td>
<td>2013</td>
<td>19</td>
<td>TT</td>
<td>NR</td>
<td>307</td>
<td>556</td>
<td>NR</td>
<td>2 (9.5)</td>
</tr>
<tr>
<td>Suda</td>
<td>2013</td>
<td>20</td>
<td>TT</td>
<td>NR</td>
<td>144.5</td>
<td>692.5</td>
<td>335.5</td>
<td>NR</td>
</tr>
<tr>
<td>Coker</td>
<td>2014</td>
<td>21</td>
<td>TH</td>
<td>0</td>
<td>100</td>
<td>231</td>
<td>NA</td>
<td>0</td>
</tr>
<tr>
<td>Kim</td>
<td>2014</td>
<td>22</td>
<td>TT</td>
<td>Bleeding 1 (3)</td>
<td>156.7</td>
<td>428.6f</td>
<td>186.7f</td>
<td>1 (2.5)</td>
</tr>
<tr>
<td>Truigeda</td>
<td>2014</td>
<td>23</td>
<td>TT</td>
<td>NR</td>
<td>75</td>
<td>NR</td>
<td>222</td>
<td>0</td>
</tr>
</tbody>
</table>

f: blood loss measured using intraperitoneal drains
Multi-institutional RAMIE Database

- Retrospective pooled database
- Identify challenges & pitfalls early in learning curve
- Identify & develop improved training paradigms
- Avoid recapitulation of avoidable morbidity with inception of new programs
- First abstract (n=260) submitted (UPMC & UAB)
Prospective RCT: RAMIE vs OE

Robot-assisted minimally invasive thoraco-laparoscopic esophagectomy versus open transthoracic esophagectomy for resectable esophageal cancer, a randomized controlled trial (ROBOT trial)

Pieter C van der Sluis, Jelle P Ruurda, Sylvia van der Horst, Roy JJ Verhage, Marc GH Besselink, Margriet JD Prins, Leonie Haverkamp, Carlo Schippers, Inne HM Borel Rinkes, Hans CA Joore, Fiebo JW ten Kate, Hendrik Koffijberg, Christiaan C Kroese, Maarten S van Leeuwen, Martijn PJK Lolkema, Onne Reerink, Marguerite El Schipper, Elles Steenhagen, Frank P Vleggaar, Emile E Voest, Peter D Siersema and Richard van Hillegersberg
RAMIE Conclusion

- RAMIE is clinically likely equivalent to standard MIE and an acceptable alternative

- Technical superiority: impact on outcomes unknown

- RAMIE may improve lymph node harvest
  - Long term outcomes required to assess impact

- Impact of adjunct technologies promising but unknown

- Impact of future platforms promising but unknown

- Cost considerations unknown
Thoracic CART – Basic & Advanced

- Didactic
- Advanced Simulation
- Proctored Cadaveric
- Ongoing Assessment
“Future” Platforms

- Multi-jointed “snake” robots
- Single-port entry
- Intraluminal endoscopic robots
- Advanced image overlay
  - Training & “rehearsal” surgery
  - Training
- Decreased footprint
- Procedure specific capabilities
- Decreasing costs
Bottom Line: Robotics

- Technology likely here to stay
  - Future improvements

- Improvements and cost reduction inevitable
  - Instrumentation
  - Energy sources
  - Market competition

- Ongoing evaluation of specific procedures
  - Morbidity & mortality
  - Cost/Benefit

- Credentialing/Certification
Thank You

Inderpal S. Sarkaria, MD

Vice Chairman, Clinical Affairs
Director, Robotic Thoracic Surgery
Co-Director, Esophageal & Lung Surgery Institute

Department of Cardiothoracic Surgery
University of Pittsburgh School of Medicine
University of Pittsburgh Medical Center