PD23-07  A MULTI-CENTER, PROSPECTIVE, RANDOMIZED, CONTROLLED STUDY TO EVALUATE THE SAFETY OF A VALVE-LESS TROCAR INSUFFLATION SYSTEM (AIRSEAL) VS. CONVENTIONAL INSUFFLATION FOR THE MANAGEMENT OF PNEUMOPERITONEUM DURING ROBOTIC PARTIAL NEPHRECTOMY

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Disclosures

• Intuitive Surgical
• C-SATS
• Ethicon
• VTI
• ConMed
Introduction

- Airseal (Valveless Trocar Insufflation) introduced in 2007
- Air barrier, no duckbill
- .01 micron filter
• Advantages
  – Stable pneumoperitoneum
  – Decrease in CO2 absorption
  – Able to suction without loss of pneumoperitoneum
  – Decrease in IAP -> decrease in pain

• Disadvantages
  – Masked Pneumothorax
  – Increase risk of SQE
  – Increase risk air embolism
Material Methods

Inclusion Criteria:
1. 18 to 80 years of age
2. Capable and willing to give informed consent
3. Acceptable candidate for an elective, non-emergent robotic partial nephrectomy

Exclusion Criteria:
1. Advanced renal or blood transfusion, if necessary
2. Active systemic or cutaneous infection or inflammation
3. Pre-existing immunodeficiency disorder and/or chronic use of systemic steroids
4. Uncontrolled diabetes mellitus
5. Known significant history of bleeding diathesis or coagulopathy, or Von Willebrand’s disease or current platelet count < 100,000 cells/mm³, baseline INR > 1.8, or fibrinogen level less than 140 mg/dL if received a fibrinolytic agent within prior 24 hours
6. Severe co-existing illnesses, any life expectancy of less than 30 days
7. Currently involved in any other investigational clinical studies
8. Significant anemia with a hemoglobin level less than 10 g/dL or a hematocrit less than 30%
9. Renal insufficiency (serum creatinine > 2.5 mg/dL)
10. Female who are pregnant, planning to become pregnant within 3 months of the procedure, or lactating
11. Extremes morbid obesity (BMI greater than 45 kg/m²) or undertweight (BMI less than 20 kg/m²)
12. Patients presenting with Anuria
Outcome Data

• Effectiveness endpoints:
  – maintenance of stable pneumoperitoneum as measured by fluctuations in intraabdominal pressure
  – insufflation time,
  – ease of anesthesia management,
  – recovery room time,
  – hospital discharge time

• Safety endpoint:
  – Insufflation device-related subcutaneous emphysema
  – Rate of pneumothorax, pneumomediastinum
  – Post-operative pain (general/shoulder) measured with Visual Analogue Scale
  – Complications.
Demographics

- 202 patients randomized 1:1:1
- No difference
  - Gender
  - Age
  - BMI

<table>
<thead>
<tr>
<th>Variable</th>
<th>AIS 12 mmHg</th>
<th>AIS 15 mmHg</th>
<th>C15 15 mmHg</th>
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<tbody>
<tr>
<td>Enrollment</td>
<td>67</td>
<td>67</td>
<td>68</td>
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<tr>
<td>Gender</td>
<td></td>
<td></td>
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<tr>
<td>Female</td>
<td>24 (34%)</td>
<td>25 (37%)</td>
<td>24 (35%)</td>
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<tr>
<td>Male</td>
<td>43 (66%)</td>
<td>42 (63%)</td>
<td>44 (65%)</td>
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<td>Mean age, y (± SD) [range]</td>
<td>60 (13.2)</td>
<td>60 (11.9)</td>
<td>60.1 (12.4)</td>
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<tr>
<td>Mean BMI (± SD) [range]</td>
<td>29.1 (6.0)</td>
<td>31.3 (5.6)</td>
<td>28.8 (5.6)</td>
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</tbody>
</table>
Effectiveness AIS vs. CIS

- Decrease Airway pressure
- Decrease end tidal CO2
- Maintain DBP
Safety AIS vs CIS

- AIS 12 – Shorter RRT
- AIS 12 – Decease SQE
- No difference in PTX
- No difference in PMS
- 2 Retro RPN need to convert CIS -> AIS
Effect of Retro vs Trans Approach

- Higher rate of SQE
- No difference in PTX
- No difference in PMS

<table>
<thead>
<tr>
<th>Approach</th>
<th>N</th>
<th>SCE</th>
<th>Rate</th>
<th>p-value*</th>
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<td>AIS 12 mmHg</td>
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<tr>
<td>Trans</td>
<td>35</td>
<td>1</td>
<td>3%</td>
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<tr>
<td>Retro</td>
<td>28</td>
<td>8</td>
<td>29%</td>
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<tr>
<td>AIS 15 mmHg</td>
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<td>Trans</td>
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<td>6</td>
<td>16%</td>
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<tr>
<td>Retro</td>
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<td>15</td>
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<td>CIS</td>
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<tr>
<td>Trans</td>
<td>44</td>
<td>12</td>
<td>27%</td>
<td>0.004</td>
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<tr>
<td>Retro</td>
<td>19</td>
<td>13</td>
<td>68%</td>
<td>0.004</td>
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</table>
Post-op Pain

• Using MMRM Analysis
  – Less shoulder pain with AIS
  – No difference in AIS 12 vs AIS 15

Combining over all time points by Mixed Model Repeated Measures (MMRM) Analysis

<table>
<thead>
<tr>
<th>Original Data</th>
<th>Using Ranks</th>
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<tr>
<td>Effect Estimate*</td>
<td>p-value**</td>
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<tr>
<td>AIS 12 mmHg vs CIS</td>
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<tr>
<td>AIS 15 mmHg vs CIS</td>
<td>-0.40</td>
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</table>
Summary

• Largest RCT comparing AIS vs CIS for RPN
• Airseal distinct efficacy advantages
  – Stable pneumoperitoneum
  – Decrease Airway pressure
  – Decrease end tidal CO2
  – Maintain DBP
Summary

• Distinct Safety Advantages
  – Shorter RRT
  – Decrease SQE
  – No difference in PTX or PSM
• Retro Approach higher rate SQE only
• Decrease in shoulder pain based on VAS
• No air embolism symptoms noted in any group