Navigating the Dichotomies Between Literature and Your Clinical Practice

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Disclosures
- No relevant conflicts related to this presentation
Are we evidence based “wanna be’s”?
Some historical examples dichotomy
A strategy

Dichotomy

When what I am doing is in conflict with the current literature.
Historical Example
Endoscopic Vein Harvest

Endoscopic saphenous vein harvest

Sources: Cola JJ. Cardiac Surgery in the Adult, 4th Edition.
www.heart.surgery.com
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Endoscopic versus Open Vein-Graft Harvesting in Coronary-Artery Bypass Surgery
Renato D. Lopes, M.D., Ph.D., Gail E. Hafl ey, M.S., Keith B. Allen, M.D., E. Bruce Ferguson, M.D., Eric D. Peterson, M.D., M.P.H., Robert A. Harrington, M.D., Rajendra H. Mehta, M.D., C. Michael Gibson, M.D., Michael J. Mack, M.D., Nicholas T. Kouchnour, M.D., Robert M. Califf, M.D., and John H. Alexander, M.D., M.H.S.
Table 1. Randomized controlled trials comparing endoscopic and open vein harvesting technique.

<table>
<thead>
<tr>
<th>First author, publication year, (Ref)</th>
<th>Study period</th>
<th>No. of patients</th>
<th>Follow-up duration</th>
<th>Wound infection</th>
<th>NIWHD</th>
<th>30 day-mortality</th>
<th>Graft patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Au, 2008, (13)</td>
<td>2005-2006</td>
<td>120</td>
<td>30 days</td>
<td>O/VH = EVH</td>
<td>O/VH = EVH</td>
<td>O/VH = EVH</td>
<td>NM</td>
</tr>
<tr>
<td>Schultz, 2006, (14)</td>
<td>2003-2004</td>
<td>200</td>
<td>30 days</td>
<td>O/VH = EVH</td>
<td>O/VH = EVH</td>
<td>O/VH = EVH</td>
<td>NM</td>
</tr>
<tr>
<td>Yun, 2005, (15)</td>
<td>2000-2002</td>
<td>200</td>
<td>6 months</td>
<td>O/VH &gt; EVH</td>
<td>O/VH = EVH</td>
<td>O/VH = EVH</td>
<td>NM</td>
</tr>
<tr>
<td>Allen, 2003, (17)</td>
<td>1998</td>
<td>112</td>
<td>5 years</td>
<td>O/VH &gt; EVH</td>
<td>O/VH = EVH</td>
<td>O/VH = EVH</td>
<td>NM</td>
</tr>
<tr>
<td>Bonde, 2002, (18)</td>
<td>2000</td>
<td>60</td>
<td>30 days</td>
<td>O/VH &gt; EVH</td>
<td>O/VH = EVH</td>
<td>O/VH = EVH</td>
<td>NM</td>
</tr>
<tr>
<td>Schurr, 2002, (19)</td>
<td>2002</td>
<td>140</td>
<td>30 days &amp; 3 months</td>
<td>O/VH &gt; EVH</td>
<td>O/VH = EVH</td>
<td>O/VH = EVH</td>
<td>NM</td>
</tr>
<tr>
<td>Kiail, 2002, (20)</td>
<td>1997-1998</td>
<td>144</td>
<td>6-8 weeks</td>
<td>O/VH &gt; EVH</td>
<td>O/VH = EVH</td>
<td>O/VH = EVH</td>
<td>NM</td>
</tr>
<tr>
<td>Hayward, 1999, (21)</td>
<td>1997</td>
<td>100</td>
<td>Hospital discharge, 3 weeks, 6 weeks</td>
<td>O/VH = EVH</td>
<td>O/VH = EVH</td>
<td>O/VH = EVH</td>
<td>NM</td>
</tr>
</tbody>
</table>

EVH, endoscopic vein harvesting; OVH, open vein harvesting; NA, not available; NIWHD, non-infective wound healing disturbances; NM, not measured.

Table 3. Major Adverse Cardiac Events at 3 Years of Follow-up, According to Vein-Graft Harvesting Technique.

<table>
<thead>
<tr>
<th>Event</th>
<th>Total (N=3000)</th>
<th>Open Harvesting (N=1247)</th>
<th>Endoscopic Harvesting (N=1753)</th>
<th>Hazard Ratio with Endoscopic Harvesting (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death, myocardial infarction, or revascularization</td>
<td></td>
<td></td>
<td></td>
<td>1.22 (1.01–1.47)</td>
<td>0.04</td>
</tr>
<tr>
<td>No. of events</td>
<td>564</td>
<td>214</td>
<td>350</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kaplan–Meier estimate of 3-year event rate (%)‡</td>
<td></td>
<td></td>
<td></td>
<td>19.0 (17.4–20.2)</td>
<td></td>
</tr>
<tr>
<td>Death or myocardial infarction</td>
<td></td>
<td></td>
<td></td>
<td>1.38 (1.07–1.77)</td>
<td>0.01</td>
</tr>
<tr>
<td>No. of events</td>
<td>235</td>
<td>93</td>
<td>162</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kaplan–Meier estimate of 3-year event rate (%)‡</td>
<td></td>
<td></td>
<td></td>
<td>8.6 (7.6–9.3)</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td></td>
<td></td>
<td></td>
<td>1.52 (1.13–2.04)</td>
<td>0.005</td>
</tr>
<tr>
<td>No. of events</td>
<td>199</td>
<td>71</td>
<td>128</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kaplan–Meier estimate of 3-year event rate (%)‡</td>
<td></td>
<td></td>
<td></td>
<td>6.7 (5.8–7.4)</td>
<td></td>
</tr>
</tbody>
</table>

CONCLUSIONS

Endoscopic vein-graft harvesting is independently associated with vein-graft failure and adverse clinical outcomes. Randomized clinical trials are needed to further evaluate the safety and effectiveness of this harvesting technique.
Is Endoscopic Vein Harvest associated with poor outcome in the NNE? Analysis

- 8,780 consecutive first-time isol cabg
  - 8 institutions in Northern New England
  - Repeat revascularization within 4-years of index procedure
  - Survival within 4-years of index procedure

Letter to the Editor. Lawrence J. Dacey, John H. Braxton, Donald S. Likosky.

Letter to the Editor. Lawrence J. Dacey.
Oct – Nov 2009
New England Journal of Medicine

“Our experience suggests that the risk of an in-hospital myocardial infarction, the need for repeat revascularization, and long-term mortality are not affected by the vein-harvesting approach during isolated CABG surgery.”

ARS #1

Modified ultrafiltration (MUF) is used at my center as a blood conservation strategy for adult cardiac operations.

- 1. True
- 2. False
Preoperative identification of high-risk patients (advanced age, preoperative anemia, small body size, etc.) should be performed, and all available preoperative and perioperative measures of blood conservation should be undertaken in this group as they account for the majority of blood products transfused.

( Class I Level of evidence A)

- **Use of modified ultrafiltration (MUF) is indicated or blood conservation and reducing postoperative blood loss in adult cardiac operations using CPB.**

  (Class I Level of evidence A).

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**Boodhwanni- Meta-Analysis**
10 RCT 1004 pts.

![Graph showing pooled effect blood loss](image)
The Use of Modified Ultrafiltration to Reduce Morbidity After Cardiopulmonary Bypass: Proposal for a Pilot Study

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Introduction and Significance
Hemodilution occurs in patients undergoing cardiac surgery with cardiopulmonary bypass (CPB). Patients that present for surgery with anemia or low red cell mass are at higher risk for blood transfusions, organ failure, or excessive postoperative bleeding. Mitigating postoperative hemodilution (blood diluted with an electrolyte solution) in cardiac surgical patients at the completion of cardiopulmonary bypass (CPB) has implications regarding the continuation of postoperative care.

Inclusion Criteria:
- Adult cardiac surgery patients ≥18 yrs
- Body surface area less than or equal to 1.7 meters squared.
- All adult cardiac surgery procedures (valve, coronary revascularization, aortic)
- Primary Endpoint-
  Post-operative chest catheter drainage (4, 6, 8 and 24 hours)
Demographic Measures and Secondary Outcomes

- Procedure
- Age
- Sex
- HT and Wt (daily Wt)
  - Pump time
  - OR I & O (anes, perf)
  - ICU I & O
  - Blood Products
- Blood product use
- TEG parameters
- Extubation Time
- Bleeding Complications
- AKI rate
- A-A gradient

Patients

- Male/Female= 0/10
- BSA = 1.57m² (1.37-1.71m²)
- Age = 69 (52-83)
Procedures

Procedures-Male/Female= 0/10
BSA = 1.57m² (1.37-1.71m²)
Age = 69 (52-83)

2 -CABG
2 -CABG + AVR
2 -CABG + AVR + MVR
2 -AVR + Conduit
1 -MVR
1 -MVR + PVR

Pump time  140 (+/-39) min

Change in HCT

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Pre-MUF</th>
<th>Post-MUF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in HCT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>33</td>
<td>22</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>28-42</td>
<td>18-26</td>
<td>18-32</td>
</tr>
</tbody>
</table>

MUF Volume removed- 1247ml (1000-1400)
### Primary Outcome

**Chest Drainage**

<table>
<thead>
<tr>
<th></th>
<th>4hr</th>
<th>6hr</th>
<th>8hr</th>
<th>24hr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median</td>
<td>355</td>
<td>405</td>
<td>445</td>
<td>695</td>
</tr>
</tbody>
</table>

*Note: Median 24hr CT rate for our center 595ml*  
Pilot stopped surgeons not interested - too time consuming

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**Miniaturized CPB (MECC)** - a system with a low prime circuit and without a cardiotomy reservoir, in which suction lines are driven into the cell saver directly or into a vacuum bag reservoir. No blood–air contact... shed blood separation was strictly followed.
Mini CPB

I currently use a MICS at my center

1. True
2. False
I have tried a miniaturized (MECC) circuit at my center.

1. True
2. False

Objective: To investigate whether the use of miniaturized cardiopulmonary bypass translates into decreased morbidity and mortality in patients having cardiac surgery.

Methods: Independently conducted a systematic review and meta-analysis of data pooled from existing trials listed in PubMed and conference proceedings.
The 16 included trials included 1619 patients (803 to miniaturized CPB and 816 undergoing standard cardiac surgery. Most studies (13) on-pump CABG 1 studied patients having off-pump CABG and two studies AVR Procedures.

### Blood Loss (ml)

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>MECC Mean (SD)</th>
<th>MECC Mean (SD)</th>
<th>WMD (random)</th>
<th>95% CI</th>
<th>90% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frame</td>
<td>30 94.00 (59.00)</td>
<td>30 80.00 (58.00)</td>
<td>16.00</td>
<td>-15.38, 201.72</td>
<td></td>
</tr>
<tr>
<td>Rapado I</td>
<td>90 79.00 (66.70)</td>
<td>30 80.00 (59.00)</td>
<td>-3.60</td>
<td>-65.59, 15.40</td>
<td></td>
</tr>
<tr>
<td>Abdul-Khalim</td>
<td>30 65.00 (32.00)</td>
<td>30 59.00 (24.00)</td>
<td>5.00</td>
<td>-23.08, 92.05</td>
<td></td>
</tr>
<tr>
<td>Kressesen</td>
<td>30 63.00 (31.00)</td>
<td>30 63.00 (31.00)</td>
<td>-0.00</td>
<td>-0.04, 0.04</td>
<td></td>
</tr>
<tr>
<td>Rapado II</td>
<td>200 75.00 (66.40)</td>
<td>200 64.00 (60.40)</td>
<td>11.00</td>
<td>-15.04, 37.04</td>
<td></td>
</tr>
<tr>
<td>Castello</td>
<td>19 21.00 (43.00)</td>
<td>15 25.00 (51.00)</td>
<td>4.00</td>
<td>-14.45, 22.45</td>
<td></td>
</tr>
<tr>
<td>Hypoxia</td>
<td>25 227.00 (355.00)</td>
<td>26 204.00 (302.00)</td>
<td>-23.00</td>
<td>-494.38, 441.38</td>
<td></td>
</tr>
<tr>
<td>Vukadinović</td>
<td>75 218.00 (577.00)</td>
<td>75 470.00 (635.00)</td>
<td>-15.00</td>
<td>-548.19, 518.19</td>
<td></td>
</tr>
<tr>
<td>Speni</td>
<td>50 32.00 (23.00)</td>
<td>50 32.00 (23.00)</td>
<td>0.00</td>
<td>-0.05, 0.05</td>
<td></td>
</tr>
</tbody>
</table>

Total (95% CI): 548 ± 13.00

Test for heterogeneity: $\chi^2 = 32.62$, df = 8 ($P = 0.004$), $I^2 = 88.1$

Test for overall effect: $Z = 9.95$ ($P < 0.0001$)

*Figure 5.* Forest plot for blood loss (ml) comparing miniaturized cardiopulmonary bypass versus standard CPB. CI, confidence intervals; df, degrees of freedom; OR, odds ratio pooled estimates of blood loss mortality.
### Red Blood Cell Transfusions

**Review:** Minimal extra-corporeal circulation (MECC) versus cardio-pulmonary bypass (CPB) in cardiac surgery  
**Comparison:** MECC versus standard CPB  
**Outcomes:** Need for RBC transfusion

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>MECC</th>
<th>CPB</th>
<th>OR (fixed) 95% CI</th>
<th>OR (fixed) 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ramesh I</td>
<td>2/20</td>
<td>4/20</td>
<td>0.72 (0.46, 1.14)</td>
<td>0.26 (0.10, 0.67)</td>
</tr>
<tr>
<td>Dughi</td>
<td>2/10</td>
<td>8/20</td>
<td>0.35 (0.07, 1.72)</td>
<td>0.11 (0.01, 1.35)</td>
</tr>
<tr>
<td>Ramesh II</td>
<td>12/10</td>
<td>23/200</td>
<td>0.85 (0.57, 1.28)</td>
<td>0.06 (0.03, 1.07)</td>
</tr>
<tr>
<td>Hoffmann</td>
<td>1/17</td>
<td>1/50</td>
<td>0.23 (0.05, 1.11)</td>
<td>0.01 (0.00, 0.71)</td>
</tr>
<tr>
<td>Mezari</td>
<td>4/20</td>
<td>4/100</td>
<td>0.96 (0.06, 1.96)</td>
<td>0.42 (0.21, 0.85)</td>
</tr>
<tr>
<td>Mikaloff</td>
<td>1/10</td>
<td>7/50</td>
<td>0.47 (0.01, 1.80)</td>
<td>0.44 (0.21, 0.85)</td>
</tr>
<tr>
<td>Vetteran</td>
<td>1/10</td>
<td>1/25</td>
<td>0.89 (0.02, 3.66)</td>
<td>0.33 (0.01, 0.57)</td>
</tr>
<tr>
<td>Schubert</td>
<td>11/20</td>
<td>33/200</td>
<td>1.48 (0.52, 4.28)</td>
<td>1.48 (0.52, 4.28)</td>
</tr>
</tbody>
</table>

**Total (95% CI):** 4.5%  
**Total events:** 5 (MECC), 10 (CPB)  
**Test for heterogeneity:** Chi² = 5.20, df = 4 (P = 0.37), P = 0%  
**Test for overall effect:** Z = 2.57 (P = 0.01)

**FIGURE 1:** Forest plot for the risk of red blood cell transfusions comparing minimal extra-corporeal circulation versus control. CI, confidence intervals; df, degrees of freedom; OR, odds ratio pooled estimates of red blood cell transfusions.

### MECC Neurological Events

**Review:** Minimal extra-corporeal circulation (MECC) versus cardio-pulmonary bypass (CPB) in cardiac surgery  
**Comparison:** MECC versus standard CPB  
**Outcomes:** Neurologic events

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>MECC</th>
<th>CPB</th>
<th>OR (fixed) 95% CI</th>
<th>OR (fixed) 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ramesh I</td>
<td>2/20</td>
<td>7/50</td>
<td>0.26 (0.05, 1.30)</td>
<td>0.19 (0.01, 0.73)</td>
</tr>
<tr>
<td>Abdul-Rahman</td>
<td>0/30</td>
<td>1/10</td>
<td>0.04 (0.01, 0.87)</td>
<td>0.01 (0.00, 0.68)</td>
</tr>
<tr>
<td>Ramesh II</td>
<td>1/200</td>
<td>7/200</td>
<td>0.16 (0.02, 1.16)</td>
<td>0.16 (0.02, 1.16)</td>
</tr>
<tr>
<td>Hoffmann</td>
<td>1/25</td>
<td>0/50</td>
<td>No event</td>
<td>No event</td>
</tr>
<tr>
<td>Hyhrenga</td>
<td>0/25</td>
<td>0/24</td>
<td>No event</td>
<td>No event</td>
</tr>
<tr>
<td>Kaldorik</td>
<td>0/25</td>
<td>0/75</td>
<td>No event</td>
<td>No event</td>
</tr>
<tr>
<td>Strobel</td>
<td>0/30</td>
<td>2/50</td>
<td>0.19 (0.01, 0.94)</td>
<td>0.01 (0.00, 0.68)</td>
</tr>
<tr>
<td>Vetteran</td>
<td>0/20</td>
<td>1/25</td>
<td>0.32 (0.01, 0.75)</td>
<td>0.01 (0.00, 0.68)</td>
</tr>
<tr>
<td>Schubert</td>
<td>0/50</td>
<td>1/50</td>
<td>0.32 (0.01, 0.75)</td>
<td>0.01 (0.00, 0.68)</td>
</tr>
</tbody>
</table>

**Total (95% CI):** 5.1%  
**Total events:** 4 (MECC), 10 (CPB)  
**Test for heterogeneity:** Chi² = 0.30, df = 4 (P = 0.82), P = 0%  
**Test for overall effect:** Z = 2.87 (P = 0.004)

**FIGURE 3:** Forest plot for the risk of neurologic events comparing miniaturized cardiopulmonary bypass versus control. CI, confidence intervals; df, degrees of freedom; OR, odds ratio pooled estimates of neurologic events.
Solon the Law Giver
Athenian Statesman
(born c. 630 BCE—died c. 560 BCE)

“It is a crime for any citizen to shrink from Controversy”

How do we improve quality?

Generalizable Scientific Evidence + Context + Best Possible Care

- Published Guidelines
- RCTs
- Measurement of your system
- Registry
- Or just measure something
- Intelligent Action!