Wait A Minute: Do We Really Need to Operate on Almost Every Rotator Cuff?

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Speaker Disclosure

Disclosure Information
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- Elsevier - Book Royalties
- DJO – Royalties for Sling

Rotator Cuff Tear Treatment

- Do we really know what works best?
- We think we know what works best?
- Why do we do what we do?

Dogma

- How Medicine was Practiced from Hippocrates until now
- Apprenticeship
- Why do I practice the way I do?
  - Because Hawkins did it
  - Because Neer did it
  - Because Codman did it.

Bloodletting

- One of the most enduring and popular medical practices in history.
- Originated by Greeks used until 19th century
- Four Humours: Blood, Phlegm, Yellow Bile, Black Bile get out of balance
- Contributed to Death of George Washington

Thanks to Jed Kuhn, MD at Vanderbilt Univ. in Nashville Tennessee for many of the Slides and thoughts on this topic
Evidence Based Medicine

- Use DATA, not DOGMA
- Empowers young physicians
- Implies we should:
  - Question the things we do and find data to support our practice patterns
  - Avoid adopting new technologies until there is data to support their use.

Case Scenario

- 72 yo female with Painful Shoulder
  - No history of injury
  - Night pain
  - Crepitus
  - Limits Gardening, Swimming
  - Exam Full Painful ROM
  - MRI

What would you do and why?

- How many would:
  - Offer Surgery?
  - Offer Physical Therapy?
  - Offer Injection?

- IS THERE DATA ON THE BEST APPROACH?
- Is there a consensus on the best approach?

Geographic Variation

- Wide Geographic Variation for Cuff Repairs in USA
  - Mississippi 9/100,000 Medicare pts
  - Idaho 65/100,000 Medicare pts
  - Michigan 27/100,000 Medicare pts

Vitale et al. Geographic variations in the rates of operative procedures involving the shoulder, including total shoulder replacement, humeral head replacement and rotator cuff repair. JBJS; 1999;81-A(6):763-771

Do Surgeons Agree on Approach?

- Survey of AAOS with 49% response rate
- Four Hypothetical Cases
- Significant variation in decision making and lack of clinical agreement regarding role of surgery vs nonoperative care and effectiveness of treatments

Dunn et al. Variation in orthopaedic surgeons’ perceptions about the indications for rotator cuff surgery. JBJS;2005;87-A(9):1978-84
Systematic Reviews
Indications for Surgery

Hypothesis: indications for surgery in literature are poorly described
- 86 Papers Reviewed
- Patient Characteristics and Indications not described in most
  - Limitations in ADL (31%)
  - Failure of Nonoperative Tx (52%)
  - Duration of Nonoperative Tx (26%)
  - Night Pain (16%)


Systematic Reviews
Indications for Surgery

• Level IV Review
• Results
  - Age and Gender should not impact decision
  - Acute tears may benefit from early surgery
  - Weakness or Functional Disability may have worse outcomes with nonoperative treatment

Oh et al. Indications for Rotator Cuff Repair: A systematic review. CORR 2007; 455:52-63

The Best Evidence Suggests

• Acute Tears Should be Repaired
• Weakness is an Indication for Rotator Cuff Repair

Oh et al. Indications for Rotator Cuff Repair: A systematic review. CORR 2007; 455:52-63

Question

• What is the Best Way to Treat the Patient WITHOUT AN INJURY Who:
  - Has Pain
  - Has an MRI with a Cuff Tear
  - What are the indications for surgery?
  - Should these patients be managed non-operatively?

Is the Cuff the Issue?

Subjective
• Patient Complaints?
  - Pain
  - Trouble Sleeping
  - Function (pain)
  - Weakness (pain)

Does SUBJECTIVE = OBJECTIVE?

Objective
• Surgeon Findings?
  - Full Thickness Cuff Tear

Is the Cuff the Issue?

• Assumption #1:
  "The patients subjective complaints are directly related to my objective findings."
  • Surgeon Bias
  • This is likely NOT the case
Is the Cuff the Issue?

- Pain is Slippery
- Surveys have been misled tying pain to objective data before...
  - Black Disk
  - Acromion
  - TFCC Tears
  - FAI?

Is the Cuff the Issue?

- Is it possible that the patients complaints of PAIN are not originating from the easily seen objective findings of an MRI documented cuff tear?

- Let's look at DATA!

The Cuff is NOT the Issue

- US Population 2010=308.4 million
  - Over Age 60 = 57 million

The Cuff is NOT the Issue

- What proportion of people over age 60 have full thickness cuff tears?

<table>
<thead>
<tr>
<th>Group</th>
<th>Total Sample</th>
<th>Mean Age</th>
<th>F0% Prevalence</th>
<th>F0% Prevalence (%)</th>
<th>Total Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients</td>
<td>4629</td>
<td>69.3</td>
<td>12.7</td>
<td>10.4</td>
<td>23.1</td>
</tr>
<tr>
<td>Full thickness</td>
<td>2710</td>
<td>66.1</td>
<td>11.3</td>
<td>12.1</td>
<td>38.0</td>
</tr>
<tr>
<td>Deficiency asymptomatic</td>
<td>603</td>
<td>65.7</td>
<td>12.7</td>
<td>7.1</td>
<td>9.0</td>
</tr>
<tr>
<td>Ultrasound asymptomatic</td>
<td>105</td>
<td>56.7</td>
<td>12.7</td>
<td>5.7</td>
<td>4.1</td>
</tr>
<tr>
<td>MRI asymptomatic</td>
<td>271</td>
<td>56.4</td>
<td>19.3</td>
<td>15.9</td>
<td>29.2</td>
</tr>
<tr>
<td>MRI symptomatic</td>
<td>490</td>
<td>64.6</td>
<td>40.6</td>
<td>8.0</td>
<td>40.4</td>
</tr>
</tbody>
</table>

The Cuff is NOT the Issue

- Let's be as conservative as possible
- Let's say 10% of U.S. Population over 60 have full thickness cuff tears (real number is likely more...)
- What does this mean?

The Cuff is NOT the Issue

- 10% of 57 million is 5.7 million
- So at minimum, 5.7 million of the U.S. populations have full thickness cuff tears.
- That is a lot of people....
**Perspective**

- The number of people with cuff tears is equal or greater than the population of most states!

**Number of Rotator Cuff Surgeries in USA each Year**

- Industry Estimates
  - 200,000-350,000/year
  - Includes Decompressions, Transfers, Debridements etc
  - Number of Rotator Cuff Repairs is a portion of this number
- Let’s be Generous and say 350,000 cuff repairs performed in USA/year

**The Cuff is NOT the Issue**

**Prevalence Data**

- What proportion of patients with full thickness cuff tears get surgery each year?
  - 350,000 surgeries/5,700,000 with tears
  - 6.1%
  - Number is Likely even less as we used conservative estimates!

**The Cuff is NOT the Issue**

- So...
  - If >93% of people with full thickness rotator cuff tears are not getting surgery....
  - Should we be operating on every cuff tear we see?????

**Is the Cuff Tear Responsible for our Patient’s Symptoms?**

<table>
<thead>
<tr>
<th>Author</th>
<th>Citation</th>
<th>N</th>
<th>% Healed</th>
<th>% Success / Satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>DeFranco</td>
<td>JBJS 2007</td>
<td>85 small/medium</td>
<td>60%</td>
<td>PENN Satisfaction Score not significantly different between failed and healed groups</td>
</tr>
<tr>
<td>Galatz</td>
<td>JBJS 2004</td>
<td>18 Large/ Massive</td>
<td>50%</td>
<td>100% were satisfied with surgery</td>
</tr>
<tr>
<td>Harryman</td>
<td>JBJS 1991</td>
<td>105</td>
<td>85%</td>
<td>86% of failed repairs satisfied</td>
</tr>
<tr>
<td>Kappl</td>
<td>JSH 2004</td>
<td>321-47 patients followed</td>
<td>55%</td>
<td>No difference in ASES, UCLA, or Constant scores comparing failures to healed</td>
</tr>
<tr>
<td>Oh</td>
<td>Arthrosc 2009</td>
<td>78</td>
<td>39%</td>
<td>No difference in ASES, Constant, SST, VAS, or Satisfaction comparing failures to healed</td>
</tr>
<tr>
<td>Bell</td>
<td>JBJS 2000</td>
<td>65</td>
<td>80%</td>
<td>Of those that failed, 85% were satisfied</td>
</tr>
</tbody>
</table>

- Objective Outcomes do not Correlate with Subjective Outcomes.....

**Systematic Review**

Does the Literature Confirm Superior Clinical Results in Radiographically Healed Rotator Cuff After Rotator Cuff Repair?

Mark A. Boxburgh, M.D., Shah I. Ali, M.D., D.W., Brian C. Cramer, M.D., Joseph A. Kosa, M.D., John T. Scully, M.D., David T. Ruby, M.D., Andrew A. Salo, M.D., Charles J. B. Harrison, M.D., Mike C. Evans, and Mark G. Yasko, M.D.

- Systematic Review Comparing Outcomes of Successful Repairs to Failed Repairs
  - Strength
  - Patient Reported Outcome
Do We Need to Operate on Every Cuff

**Strength**

- Measured a variety of methods in 8 reports
- 6/8 statistically significant difference
- 4/6 clinically significant difference (>5 kg or 20% constant score)

**Patient Reported Outcomes**

<table>
<thead>
<tr>
<th></th>
<th>Reported</th>
<th>Stat Sig</th>
<th>MCID</th>
<th>Clinically Significant?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>9/13</td>
<td>6/9</td>
<td>10%</td>
<td>1/9</td>
</tr>
<tr>
<td>ASES</td>
<td>3/13</td>
<td>0/3</td>
<td>NA</td>
<td>0/3</td>
</tr>
<tr>
<td>L’Insalata</td>
<td>1/13</td>
<td>0/1</td>
<td>NA</td>
<td>0/1</td>
</tr>
<tr>
<td>PENN</td>
<td>1/13</td>
<td>1/13</td>
<td>10%</td>
<td>0/13</td>
</tr>
<tr>
<td>VAS</td>
<td>3/13</td>
<td>1/3</td>
<td>10%</td>
<td>0/3</td>
</tr>
</tbody>
</table>

**Summary**

**Comparing Outcomes**

- Healed vs Failed Repairs
  - Strength is probably better when the repair heals
  - Constant score (25% strength) may be better when repair heals
  - Other outcomes NO DIFFERENCE!

**Non-Operatively Treated Rotator Cuff Tears**

- Many cuff tears are asymptomatic
- Most orthopaedic disease states have increased symptoms with increased severity of disease (e.g. osteoarthritis, GH instability, AC instability...) 

**Do Symptoms Correlate with Rotator Cuff Tear Severity?**

- Does pain correlate with rotator cuff tear severity?

**Results**

- No measure of pain correlated with any measure of rotator cuff tear severity
- Pain did correlate with
  - Comorbidities
  - Education level
  - Race

Dunn et al (MOON Shoulder), AAOS 2011
Do We Need to Operate on Every Cuff

Factors related to successful outcome of conservative treatment for rotator cuff tears


Success of Non-op Cuff Tear Tx

- Prospective cohort study
- 50 patients
- Avg age 60 (40-85)
- Mean duration of symptoms 2 years
- Standardized home-based physiotherapy x 3 mos
- 76% success rate (38/50 declined surgery at 3 mos)
- Rotator Quality of Life score most sig. predictor

Mohtadi et al

Is Nonoperative Treatment of Cuff Tears Effective?

- Multicenter Prospective Cohort
- 400 patients
- Avg. age 62 years
- Atraumatic Full Thickness Rotator Cuff Tears
- Treated with EBM Physical Therapy Program
- Followed at 6, 12 weeks and 1, 2 years

Effectiveness of Physical Therapy in Treating Atraumatic Full Thickness Rotator Cuff Tears. A Multi-Center Prospective Cohort Study

John E. Kuhn, MD, MS, Warren Dunn MD, MPH

Moon Shoulder Group:
- Keith Baumgarten MD, Julie Bishop MD, James Carey MD,
- Charles Cox MD, Brian Holloway MD, Grant Jones MD, Benjamin Ma MD, Robert Marx MD MSc, Eric McCarty MD, Matthew Smith MD, Edwin Spencer MD, Armando Vidal, MD, Brian Wolf MD MS, Rick Wright MD

2011 Neer Award

Is Nonoperative Treatment Effective?

Effectiveness of Physical Therapy in Treating Atraumatic Full Thickness Rotator Cuff Tears.


- 123 shoulders treated conservatively for > 3 mos
- Clinical improvement in 65 shoulder
- No improvement or worse in 58 shoulders (all went on to surgery)

Eric McCarty, MD
General Follow-up Protocol

• At follow up points (6 and 12 weeks) patients are asked:
  – Are you cured?
    • Future follow up by telephone and mail
    • Return if symptoms worsen
  – Are you better?
    • Continue PT to 12 weeks, then HEP and follow up by phone and mail
    • Return if symptoms worsen
  – Are you no better?
    • Arthroscopic RCR

Methods

Patient Data Collection

• T=0, 6 weeks, 12 Weeks, 1 Year, 2 years
• Demographic and Co-morbidities
• Outcome Scores
  • SF-12
  • ASES
  • WORC
  • SANE
  • Marx Activity Scale

Physician Data Collection

• T=0, 6 weeks, 12 weeks
• Physical Exam Data
  – ROM, Strength, Provocative Tests
• Imaging Data
  – Xrays
  – MRI Descriptors of Rotator Cuff

Results

Outcome of Treatment

<table>
<thead>
<tr>
<th></th>
<th>6 weeks</th>
<th>12 weeks</th>
<th>1 year</th>
<th>2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total/Outcome</td>
<td>377</td>
<td>336</td>
<td>254</td>
<td>136</td>
</tr>
<tr>
<td>No Data</td>
<td>16 (4%)</td>
<td>23 (7%)</td>
<td>2 (1%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>No Surgery</td>
<td>325 (86%)</td>
<td>293 (87%)</td>
<td>236 (93%)</td>
<td>133 (98%)</td>
</tr>
<tr>
<td>Surgery</td>
<td>36 (10%)</td>
<td>20 (6%)</td>
<td>16 (6%)</td>
<td>3 (2%)</td>
</tr>
</tbody>
</table>

Nonoperative Treatment of Rotator Cuff Tears

• Fewer than 10% of patients failed and went to surgery
• Most who went to surgery did so in first 6 weeks
• Results do not seem to worsen with time

Patient Outcome Measures After Nonoperative

<table>
<thead>
<tr>
<th>Assessment Tool</th>
<th>Baseline Scores</th>
<th>6 weeks</th>
<th>12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-12 MCS</td>
<td>40.26</td>
<td>40.57</td>
<td>40.84</td>
</tr>
<tr>
<td>SF-12 PCS</td>
<td>35.34</td>
<td>35.64</td>
<td>36.05</td>
</tr>
<tr>
<td>ASES Score</td>
<td>54.47</td>
<td>77.98</td>
<td>83.67</td>
</tr>
<tr>
<td>WORC Score</td>
<td>47.16</td>
<td>62.52</td>
<td>69.67</td>
</tr>
<tr>
<td>SANE Score</td>
<td>46.6</td>
<td>62.73</td>
<td>70.27</td>
</tr>
<tr>
<td>Marx Activity Scale</td>
<td>9.89</td>
<td>10.15</td>
<td>10.01</td>
</tr>
</tbody>
</table>

BOLD = p<0.0001, and Clinically Significant Differences
Conclusions

• Physical Therapy Program is Effective Nonoperative Treatment for Atraumatic Rotator Cuff Tears
  – Outcome Scores Improved over 12 Weeks
  – <15% of Patients Failed and Had Surgery

Conclusions

• Effectiveness of Physical Therapy is Revealed Early
  – Patients who Chose to have Surgery Generally Do So in the First 12 Weeks
  • After 12 Weeks Effectiveness Lasts 2 Years

What do we Make of This?

1.) The Cuff is NOT the Issue
• We repair less than 6% of all cuff Tears
• Results are Great in the Face of Surgical Failure
• There is NO correlation between severity of disease and pain

2.) Understand Your Bias
• Surgeons acknowledge pain, but look for OBJECTIVE sources because we fix anatomy
• With Cuff Tears, Patient Symptoms may have little to do with the Obvious Objective Finding.

3.) Don’t Make Claims without DATA!
• “Small Tears Always Get Bigger—Surgery can Prevent this!”
• “If we Don’t Fix this you may need a Reverse Shoulder Arthroplasty!”
4.) Patient Perception Rules
OR
You Can Sell Your Patients
Anything.....

Rotator Cuff Tears
Think about what you are doing and why

Thank You

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