EFFECTS OF REVISION SURGERY ON GRADE OF ADVERSE LOCAL TISSUE REACTION FOLLOWING RECALL OF A MODULAR HIP IMPLANT

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BACKGROUND

• In vivo metal hypersensitivity may occur after total hip arthroplasty (THA).
• Recall of the Stryker Rejuvenate modular hip implant (July 2012) highlights our uncertainty regarding causes of device metal corrosion/fretting & adverse local tissue reaction (ALTR).1,4
• Corrosion & fretting likely occur at the cobalt-chromium neck & titanium stem interface.1 Metal particles irritate local tissues, causing a gradation of problems (or grades of ALTR; Table 1).

STUDY OBJECTIVES

1. To describe the population of AHC patients who underwent THA with the recalled Stryker Rejuvenate hip implant.
2. To describe associations between (a) patient/hip characteristics, (b) receipt of total hip revision (THRev) surgery, & (c) grade of ALTR (or implant failure).
3. To quantify the effect of THRev on ALTR grade in patients who underwent THA with the Stryker Rejuvenate hip implant.

METHODS

• Conducted a prospective observational study of patients who underwent THA by a single AHC orthopedic surgeon.
• After recall, patients were asked to visit every 3-6 months for lab work, imaging, & device assessment.
• As needed & desired, some patients underwent THRev.
• Used repeated-measures logistic regression to examine THRev effect on odds of ALTR.
• In regression model, THRev & lab results (Co, Cr, CRP, ESR) were time-variant; THRev effect was adjusted by patient/hip characteristics, medications, & labs. RESULTS

• 154 hips (of 145 patients) underwent THA with Stryker implant during 2009-2012 & received follow-up assessment; 77 hips were revised during 2012-2016.
• Table 2: Patients (hips) were of median age 62 years (range 32-90), nearly all White, & mostly female & obese.
• Tables 2 & 3: THRev was less likely to be performed in older hips but more likely in hips with symptoms & higher grade of ALTR.
• Figure 1: Comparison of ALTR grade, lab levels, & symptoms/complications ("problems") in revised hips post-THRev vs pre-THRev showed marked improvement.
• Figure 2: Odds of ALTR were strongly associated with THRev; abnormal grade was 9 times more likely in non-revised hips.
• Figure 2: Odds of ALTR also increased with symptoms (e.g., pain, younger age, increased Co concentration, & time since the original THA with Stryker implant).

Table 1. Adverse Local Tissue Reaction Grades

<table>
<thead>
<tr>
<th>ALTR Grade</th>
<th>Description</th>
<th>Characteristic</th>
<th>All Hips</th>
<th>N=154</th>
<th>No THRev</th>
<th>N=77</th>
<th>THRev</th>
<th>N=77</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Joint tissues &amp; fluids; no ALTR</td>
<td>N=154</td>
<td>3 (2.0)</td>
<td>2 (2.6)</td>
<td>1 (1.3)</td>
<td>0.56</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal</td>
<td>ALTR present; accumulation of fluids, putting increased pressure on surrounding tissues</td>
<td>N=154</td>
<td>65 (41)</td>
<td>35 (45)</td>
<td>28 (36)</td>
<td>0.25</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal</td>
<td>ALTR present; marginal fluid accumulation by an increasingly thick fibrous tissue, causing ascavular response in nearby tissues</td>
<td>N=154</td>
<td>40 (26)</td>
<td>26 (34)</td>
<td>14 (18)</td>
<td>0.03</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal</td>
<td>ALTR present; formation of pseudo tumors that cause local &amp; distal problems, e.g., compression of tissues, arteries, veins, &amp; nerves</td>
<td>N=154</td>
<td>16 (10)</td>
<td>9 (12)</td>
<td>7 (9.3)</td>
<td>0.60</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal</td>
<td>ALTR present; destruction of the abductor mechanism of the hip, which can lead to profound weakness &amp; dislocation of the hip</td>
<td>N=154</td>
<td>82 (53)</td>
<td>46 (60)</td>
<td>36 (47)</td>
<td>0.11</td>
<td></td>
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</tbody>
</table>

Table 2. Patient Characteristics at THA, n (%)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ALTR symptoms</th>
<th>No THRev</th>
<th>THRev</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALTR symptoms</td>
<td>94 (61)</td>
<td>17 (22)</td>
<td>77 (100)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Abnormal Co</td>
<td>147 (95)</td>
<td>75 (97)</td>
<td>72 (94)</td>
<td>0.25</td>
</tr>
<tr>
<td>Abnormal Cr</td>
<td>8 (5.2)</td>
<td>7 (9.1)</td>
<td>1 (1.3)</td>
<td>0.03</td>
</tr>
<tr>
<td>Abnormal CRP</td>
<td>56 (37)</td>
<td>31 (40)</td>
<td>25 (32)</td>
<td>0.31</td>
</tr>
<tr>
<td>Abnormal ESR</td>
<td>75 (49)</td>
<td>37 (48)</td>
<td>38 (49)</td>
<td>0.87</td>
</tr>
</tbody>
</table>

Figure 1. Percentage of Revised Hips by ALTR, Abnormal Labs, & Problems Pre- vs. Post-THRev

Figure 2. Odds Ratios Showing Effect Sizes in the Model of Odds of ALTR (Grades 1-4)

CONCLUSIONS

• Within AHC, patients who underwent THA with the recalled Stryker Rejuvenate hip implant device often experienced symptoms & showed varying grades of ALTR.
• In the short-term, THRev significantly reduced symptoms & had a restorative effect on hip health.
• We recommend THRev for all patients who received the Stryker Rejuvenate device, but especially younger patients & those with any sign of possible implant failure.


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