May 20th, 10:00 AM

Patient Reported Outcomes in Arthritis, TJR, and Physical Activity Research

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Patient Reported Outcomes in Arthritis, TJR, and Physical Activity Research

UMMS CCTS Retreat
5.20.16

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University of Massachusetts Medical School
Disclosure

• I have no actual or potential conflict of interest in relation to this program/presentation.

• Current research funding:
  – PCORI
  – AHRQ
  – NIH/NIAMS
  – Zimmer Biomet, Inc.
Today’s Goals

1. Why collect PROs in clinic and research?
2. What are PROs? What do we learn from them?
3. PRO/physical activity translational research in OA and TJR at UMMS.

Note: OA/TJR as example; principles apply to other chronic conditions.
OA patients choose TJR to relieve pain, improve function

OA is the most common disabling condition among US adults; affects more than 2/3 of adults over 65 years.

• Knee and hip OA pain limits mobility
• Total Joint Replacement is the most common and costly procedure in Medicare budget;
• Use among patients <65 is escalating (now 48% of total)
• >1 million procedures each year in US
New paradigm: patient-reported outcomes as primary TJR endpoint

“When he [the surgeon] saw the PRO survey, he saw how my function was, how bad it was….” Patient, age 72, TKR, PA

Beyond Joint Implant Registries
A Patient-Centered Research Consortium for Comparative Effectiveness in Total Joint Replacement

Peter J. Franklin, MD, MCH, MRA
David C. Ayres, MD

Despite the proper effectiveness of total joint replacements (TJR) surgery in relieving pain and improving function, TJR outcomes have come under intense public scrutiny in recent years. The 2015 report of the annual survey “Joint Replacements: a patient’s perspective” showed 30 percent of patients who had undergone knee or hip joint replacements reported pain, while 50 percent reported limitations in their daily activities. In contrast, joint replacements performed for arthritis or traumatic injury are generally well tolerated, with high levels of satisfaction and pain relief.

The New Paradigm

In the past, joint replacement surgery was considered a last resort for patients with severe joint pain and disability. However, with the advent of new technologies and surgical techniques, joint replacement surgery is now being performed more frequently and with better outcomes. The new paradigm focuses on patient-reported outcomes (PROs), which are measures of patient function, pain, and quality of life. PROs are increasingly being used as outcomes measures in clinical trials, registries, and quality improvement initiatives.

The FORCENJR Approach

The FORCENJR registry is a prospective, observational registry that collects data on patients undergoing joint replacement surgery. The registry includes patients from over 1,000 hospitals across the United States, and data is collected at multiple time points, including pre-surgery, post-surgery, and long-term follow-up. The registry is designed to capture a wide range of outcomes, including patient-reported outcomes, clinical outcomes, and costs.

The registry is open to all hospitals and surgeons who perform joint replacement surgery, and data is collected using a standardized electronic data collection system. The registry is supported by the National Institutes of Health and the Agency for Healthcare Research and Quality.

The registry has several key features:

-Prospective collection of data
-Standardized data collection
-Real-time data analysis
-Programmatic evaluation of outcomes

The registry is designed to provide valuable information to surgeons, policymakers, and patients, and to improve the quality of care for patients undergoing joint replacement surgery.
FORCE-TJR: platform for TJR outcomes monitoring

Competitive Application: $12 million AHRQ P50 award
Department of Orthopedics and Physical Rehabilitation
University of Massachusetts Medical School (2011-14)
Supplemental grants (AHRQ, PCORI, FDA, NIH)

1. Develop a comprehensive TJR registry with sustainable data infrastructure for comprehensive TJR outcome monitoring and feedback to providers.
   – UMass is the TJR data coordinating center for the next 20+ years

2. UMass TJR research team conducting comparative effectiveness research in TJR quality and outcomes.
   – Participating on CMS expert panels and national TJR leadership groups
FORCE-TJR: National Cohort of 28,000 patients, >200 Surgeons, 28 States

- 75% of surgeons are community-based
- Fellowship-trained, general orthopedic surgeons
- High and low volume surgeons/hospitals; urban and rural hospitals

- Diverse patients and settings for first 25,000+ patients define NATIONAL NORMS on Pre- and Post- PROs for immediate benchmarking
- Patients <65 years and Medicare
FORCE-TJR: collected across TJR Care Cycle
>28,000 patients

<table>
<thead>
<tr>
<th>Patient Surgeon</th>
<th>Hospital</th>
<th>Direct to Patient (validate EHR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before Surgery</td>
<td>Surgery</td>
<td>30 -90 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Annual</td>
</tr>
<tr>
<td>• PRO Global: VR12 HOOS/KOOS</td>
<td>• PRO Pain</td>
<td>• PRO Global: VR12 HOOS/KOOS</td>
</tr>
<tr>
<td>• CLINICAL RISKS</td>
<td>• CLINICAL Implant Operative Notes</td>
<td>• CLINICAL Complication (if any)</td>
</tr>
<tr>
<td>Medical &amp; MSK risks Demographic</td>
<td></td>
<td>• CLINICAL Complication (if any)</td>
</tr>
<tr>
<td></td>
<td>• CLINICAL Readmission Complication (if any)</td>
<td>Revision</td>
</tr>
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</tbody>
</table>

**CMS DATA**

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PROs completed:

WEB-based
- In Office
- From Home
- On PC or Tablet
(Scannable Paper option)

85% complete Pre and Post-TJR
2. Patient reported outcome measures

• PROs: "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.” NQF

• PROs: two major groups

1. **Global** health status: physical, mental, and social well-being.

2. **Diagnosis-specific** patient reported symptoms, e.g., knee.
SF/VR12, SF36  (John Ware; Rand, 1980s)

• 2 major domains:
  Physical Health (PCS) and Emotional Health (MCS) (SF12, 36)
• 8 sub-domains (SF36)
  1. vitality
  2. general health perceptions
  3. physical functioning
  4. bodily pain
  5. physical role functioning
  6. emotional role functioning
  7. social role functioning
  8. mental health
• Secondary value: Poor emotional health is predictor of poor physical function (PCS) after TJR
PROMIS
http://www.nihpromis.org/

• Physical Function
  1. Physical function
  2. Pain (interference)
  3. Fatigue
  4. Sleep

• Emotional function
  1. Anxiety
  2. Depression

• Social Health

Limitation of Global Function Measure: Low back pain or contralateral knee/hip disease, COPD, etc. will influence global function.
These first questions are about your health now and your current daily activities. It is important that you give your best answer to all questions - including those questions that may not seem as relevant to you.

1. In general would you say your health is:

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very Good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

<table>
<thead>
<tr>
<th>MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</th>
<th>Limited A lot</th>
<th>Limited A little</th>
<th>Not Limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLIMBING SEVERAL flights of stairs</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

<table>
<thead>
<tr>
<th>ACCOMPLISHED LESS than you would like</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were limited in the KIND of work or other activities</td>
<td></td>
<td></td>
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</tbody>
</table>

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

<table>
<thead>
<tr>
<th>ACCOMPLISHED LESS than you would like</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did work or other activities LESS CAREFULLY THAN USUAL</td>
<td></td>
<td></td>
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<td></td>
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</tbody>
</table>
Disease-specific PRO

• Knee/Hip OA
  – WOMAC- broadly used in OA assessment
  – HOOS/KOOS (includes WOMAC); 42 items
  – Five Domains:
    1. Pain
    2. Activities of Daily Living
    3. Symptoms (stiffness)
    4. Sport
    5. QoL
• 42 items; attribute limitations to KNEE or HIP
• brief “knee/hip health” PRO; AHRQ (Gandek)
The following questions concern your **physical function**. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your surgical knee. It is important you answer all questions even if they may not seem relevant to you. If you were not able to do an activity listed, tell us how difficult it would be if you attempted to do the activity.

<table>
<thead>
<tr>
<th>Activity</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descending stairs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ascending stairs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rising from sitting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bending to floor/picking up an object</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Walking on a flat surface</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Getting in/out of car</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Going shopping</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Putting on socks/stockings</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rising from bed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taking off socks/stockings</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lying in bed (turning over, maintaining knee position)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting in/out of bath</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sitting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting on/off toilet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doing heavy domestic duties(moving heavy boxes, scrubbing floors, etc)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doing light domestic duties (cooking, dusting, etc)</td>
<td></td>
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</tbody>
</table>
FORCE-TJR Protocols for Successful PRO Capture integrated with Clinic

1. Flexible IT to interface with patients and clinicians; diverse settings with varied EMRs.
2. Operational procedures to track patient over time
   • Surgeon office to Hospital to Home
3. Risk-adjusted analyses with useful benchmarks based on representative patients and practices.

How Use PRO data in Clinic and Research?

Ease of PRO administration; APP (AHRQ Ancillary; WPI/UMMS Zheng)
Individual Patient Level

Computer collect/score:
1. Actionable
Real-time scored Function and Pain as “lab test”

2. Interpretable
Trended across visits
Pre/Post treatments
Norms (colors)

3. Surgeon/ Patient Review
Shared decisions
Risk factors
Tailored Individual Outcome Estimates

• PCORI; Franklin, Li, Zheng, Ayers
• 2016-2020 ($6.3 million)
• Refine individualized models; predicted outcomes and risks
• Deploy web-based assessment and reports
• Conduct cluster randomized trial among 40 surgeons to define impact on patient/surgeon shared decision making for knee/hip OA care, including TJR
Pre-TKR Function: Indicator of appropriateness/timing?

Site **Pre-TKR** Patient Profile:

- National Norm for Healthy = 50 (SD=10) Green arrow
- Site Median PCS = 32
- National Median PCS for TJR = 32 (2SD below healthy; Red arrow)
- Site 75th%ile PCS = 38
- National 75th%ile PCS = 39

*Patient selection matches national norms; >83% have PCS scores reflecting disability.*

*Patients in yellow (1SD): evaluate clinical circumstances warranting TJR.*
Implant Surveillance
FDA U01; Cornell/network of registries

- Understanding PRO/ pain as an indicator for under-performing implants at risk for revision.
- Supporting post-market surveillance
Activity (steps/day) post-TKR vary by risk factors; Association activity== functional gain?

<table>
<thead>
<tr>
<th></th>
<th>PRE-TKR steps/day</th>
<th>POST-TKR steps/day</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-TKR</td>
<td>6600</td>
<td>7690</td>
<td>1280</td>
</tr>
<tr>
<td>Male</td>
<td>7496</td>
<td>9051</td>
<td>1239</td>
</tr>
<tr>
<td>Female</td>
<td>6218</td>
<td>7150</td>
<td>901</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Predicted Post-TKR steps/day</th>
<th>95% CI</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>7131</td>
<td>6156</td>
<td>8107</td>
</tr>
<tr>
<td>Male</td>
<td>9259</td>
<td>7678</td>
<td>10841</td>
</tr>
<tr>
<td>Gender diff.</td>
<td>2128</td>
<td>228</td>
<td>4027</td>
</tr>
</tbody>
</table>
UMass Kinesiology/Orthopedics
Worcester Gait Lab

- Patterns of activity loss and gait in progression of OA? Improvement after TKR? THR?
- Mechanism of OA influence on gait/function?
- Correlation with PROs? What incremental information? What consistent?
- Which gait measures have clinical diagnostic or treatment value?