Adult Spinal Deformity
Surgical Complications and Classification

9th Annual UCSF Practical Course in Advanced Spinal Techniques

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I have no financial interest with any company regarding this subject

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Introduction

- Surgical intervention can have a significant impact
- Complications can be significant

Introduction

Deformity Surgery
- Considered to have higher risks
- Perioperative complications are frequent (up to 40%)
What is a complication?

- **com·pli·ca·tion**
  - noun ˌkäm-plə-ˈkä.shən: something that makes something harder to understand, explain, or deal with
  - medical: a disease or condition that happens in addition to another disease or condition: a problem that makes a disease or condition more dangerous or harder to treat

INTRODUCTION

- Glassman et al
  - major and minor complications did not adversely affect the improvement found in the HRQOL measures
  - except for deterioration in the SF-12 for major complications.
  - Theorized that outcome instruments were not sensitive enough to detect a difference
  - Perioperative complications may not have a continued impact at one year.

What is a complication?

Does it matter?

What is a complication?

- Physician and patient dependent
Informed Consent

Despite ranking the consent process as important, patient recall was only 41% immediately after discussion and video reinforcement. Recall subsequently declined to 20% at 6 months post-operatively.

Surgical Strategy

Adult Spinal Deformity Patients Recall Fewer Than 50% of the Risks Discussed in the Informed Consent Process Preoperatively and the Recall Rate Worsens Significantly in the Postoperative Period.
Complication Category | Period 1 (<6wks) | Period 2 (>6wks) | Total
--- | --- | --- | ---
Surgical Implant | 3/8 (3.8) | 11/59 (24.1) | 14/67 (27.8)
Radiographic Error | 4/10 (4.8) | 25/42 (23.0) | 29/52 (27.8)
Neurologic | 21/24 (15.5) | 16/20 (12.4) | 37/44 (27.8)
Operative | 41/32 (25.1) | 0/1 (0.3) | 41/33 (25.4)
Cardiopulmonary | 31/20 (17.5) | 1/3 (1.4) | 32/23 (18.9)
Infection | 11/20 (10.7) | 5/7 (4.1) | 16/27 (14.8)
Gastrointestinal | 24/1 (8.6) | 0/0 (0) | 24/1 (8.6)
Wound (excluding infection) | 3/7 (3.4) | 0/5 (1.7) | 3/12 (5.2)
Vascular | 4/0 (1.4) | 1/0 (0.3) | 5/0 (1.7)
Musculoskeletal | 0/0 (0) | 3/0 (1.0) | 3/0 (1.0)
Renal | 1/2 (1.0) | 0/0 (0) | 1/2 (1.0)
Other | 2/1 (1.0) | 0/0 (0) | 2/1 (1.0)
Total (minor/major) | 270 (145/125) | 199 (62/137) | 469 (207/262)
Mean # complications/patient (minor/major) | 0.93 (0.50/0.43) | 0.68 (0.21/0.47) | 1.61 (0.71/0.90)
Number of patients affected (%) | 150 (51.5) | 124 (42.6) | 203 (69.8)

Results: 246 patients with 2 year follow-up.
Can We Develop A Better Complication Score?

- We rely on AE/Minor/Major determination
  - No consensus
  - Severity of complication may be biased
- Can a less biased score better predict HRQoL outcomes?

Canadian (SAVES)

- Have led the way with the development of an intervention severity score
  - Use a scale from I-IV to determine severity (or grades 1-6)
  - Also assign a Length Of Stay modifier
  - Do not have specific score for neurology, readmission or reoperation
  - How we obtain the information is critical

CMS

- Increased interest in complications and when they occur
- All complications that occur within 30 days from the operation
- All readmission/reoperations that occur within 90 days
- May have significant impact with bundling of payments

AO Spine/Scoli-Risk-1

- Gathers info for non-neurologic complications
- Granular information regarding neurologic injury
- Defines the neurologic injury
  - (cord, motor, sensory, incontinence etc...)
  - Level of injury
- Describes timing, intervention, and outcome
Do Complications Effect HRQoL?

- 355 pts prospectively enrolled in the ISSG multicenter study
- 202 met the inclusion criteria
- Mean age 57.4, levels fused 12
- Four groups identified:
  - No Complications N=84
  - Minor Complications N=87
  - Major Complications N=65
  - Both Major and Minor N=35

Baseline Pre-OP Demographics

- Factor that predicted 2-year SF-36PCS
  - Age (p < .001), ASA grade (p < .001)
  - Maximum preoperative Cobb angle (p = .007)
  - Number of three-column osteotomies (p = .049)
  - Type of neurologic complication (p = .068)
- Factors predictive of 2-year SRS-22R Total scores
  - Maximum preoperative Cobb angle (p = .001)
  - Number of serious adverse events (p = .071)

Operative Summary

- Similar distribution for Age, BMI, and ASA, as well as Pre-OP spinopelvic parameters.
- Sig lower Charlson Comorbidity Index for the no complication group.

Len of Stay (Days) & EBL & OR Time (min) & PSO/PVR & Osteotomy % & BMP % & Anterior % & Min & Maj & Both & p value

Levels Fused & 12.0 & 11.9 & 12.3 & 12.4 & 0.825
Osteotomy (%) & 75.1 & 55.4 & 73.0 & 72.6 & 0.097
PSO/PVR (%) & 23.9 & 21.4 & 24.7 & 25.7 & 0.413
BMP (%) & 87.7 & 87.7 & 89.8 & 90.1 & 0.001
Anterior (%) & 34.5 & 30.5 & 30.1 & 40.5 & 0.013
EBL (cc) & 1750 & 2381 & 2398 & 2786 & 0.008**
OR Time (min) & 415 & 494 & 517 & 523 & 0.008**
Length of Stay (Days) & 8.5 & 10.5 & 9.9 & 9.9 & 0.071

- Trend towards PSO for Major and BOTH complication groups
- No complication group also had the lowest percent of BMP anterior approach, EBL, and Time in the OR.
  - May be a surrogate for surgical complexity.
Baseline/1 Year HRQoL

<table>
<thead>
<tr>
<th></th>
<th>All Complication</th>
<th>No Complication</th>
<th>Major</th>
<th>Minor</th>
<th>Both</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline ODI</td>
<td>42.2</td>
<td>41.3</td>
<td>44.4</td>
<td>39.5</td>
<td>42.2</td>
<td>NS</td>
</tr>
<tr>
<td>1 year ODI</td>
<td>28.8</td>
<td>26.6</td>
<td>29.8</td>
<td>26.9</td>
<td>28.1</td>
<td>NS</td>
</tr>
<tr>
<td>Baseline PCS</td>
<td>30.9</td>
<td>29.2</td>
<td>31.1</td>
<td>29.9</td>
<td>31.8</td>
<td>NS</td>
</tr>
<tr>
<td>1 year PCS</td>
<td>19.1</td>
<td>18.6</td>
<td>19.0</td>
<td>18.6</td>
<td>19.2</td>
<td>NS</td>
</tr>
</tbody>
</table>

Significant improvement in All groups from Baseline to 1 year.

No differences between groups for any of the outcome measures, regardless of complication.

ISSG/AO/ESSG

- Working to develop a comprehensive score
- Using:
  - 1. Complication Category
  - 2. Intervention severity
  - 3. Complication Severity
  - 4. Neurologic severity
  - 5. Reoperation/readmission
  - 6. Resolution of complication
  - 7. Timing/Effect on LOS

Complication Grading System

<table>
<thead>
<tr>
<th>Complication Score</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity</td>
<td>A</td>
<td>E</td>
<td>M</td>
<td>J</td>
</tr>
<tr>
<td>Intervention</td>
<td>N</td>
<td>N</td>
<td>I</td>
<td>S</td>
</tr>
<tr>
<td>Neurologic G</td>
<td>S</td>
<td>W</td>
<td>B</td>
<td>S</td>
</tr>
<tr>
<td>Impact on Length of Stay</td>
<td>None</td>
<td>&lt;2 days</td>
<td>3-7 days</td>
<td>&gt;7 days</td>
</tr>
<tr>
<td>Reoperation Surgery</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Resolution</td>
<td>Resolved</td>
<td>Unresolved</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Timing</td>
<td>In-Hospital</td>
<td>Early Post-Op</td>
<td>Late Post-Op</td>
<td></td>
</tr>
</tbody>
</table>

Significant impact on ODI and PCS for readmission, reoperation and no complication resolution.
Application of the system

- Different components of the score could be used for different outcome metrics
- I.e.: LOS vs HRQoL

Complication Impact on LOS

- Univariate analysis identified factors that correlated with increase over predicted LOS:
  - cumulative complication severity (OR 1.23, p<0.001)
  - cumulative intervention severity (OR 1.15, p<0.0001)
  - number of complications (OR 1.26, p<0.02)

- Development of a model to predict hospital LOS based on complications
  - Actual LOS was significantly higher than predicted LOS (10.7 days vs 8.3 days, p<0.0001)

Impact on HRQoL at 2 years

- Minimum one complication had lower 2-yr improvements in HRQL
  - (SF-36: PCS 6.91 vs 9.48, p=0.012, and SRS-22r: 0.79 vs 0.95, p<0.03)

- Number of complications
  - (PCS: -0.1159, p=0.016, SRS: -0.0929, p=0.048)

Impact on HRQoL at 2 years

- Severity Score:
  - maximum severity score (PCS: -0.1157, p=0.016)
  - cumulative severity score (PCS: -0.1223, p=0.011, SRS: -0.1487, p=0.03)

- Intervention Score:
  - Maximum intervention score (PCS: -0.16, p=0.001, SRS: -0.125, p=0.008)
  - Cumulative Intervention Score (PCS: 0.1245, p=0.0098)

- Complication resolution:
  - resolved complication PCS: -2.22, p=0.048
  - unresolved complication PCS: -3.12, p=0.012
Spine Complication Classification

- A simple classification system with discrete data points
- A more comprehensive one with additional data points and subgroups that captures more granular data.
- Determining what data points need to be acquired is our first challenge

Complication Category

- Each complication receives a categorical letter and sub-letter to define its primary complication category
- Then each complication is stratified into the four complication modifiers:
  - neurologic
  - timing
  - intervention severity
  - resolution

Neurologic Sub Score
Validation

- Identification and classification of complications can be difficult, and simple categories will improve our ability to classify and quantify the impact of complications.

- Intrinsic surgeon bias may increase accuracy of reporting for some complications more than others
  - I.e better reporting of surgical vs medical complications

Methods

- **10 randomized cases** were sent to participants, and they were asked to identify the complications and complete a standardized data collection form.
- There were **34 events** that occurred:
  - 25 events with only one complication
  - 5 with 2 complications
  - 4 with 2 or more complications

Results

- **17 people filled out all questionnaires**:
  - 10 attending surgeons, 5 trainees, and 2 research coordinators.
- Overall accuracy
  - 87.4% high level (i.e. neurologic vs gastrointestinal vs cardiac etc.)
  - 75.7% with more granular data (i.e. motor deficit vs ileus vs MI etc).
- Accuracy for medical and surgical complications is similar
  - (87.6% vs 87.1% for high level, 77.4% vs 74.3% for detail).

Results

- Highest overall accurate rate
  - CVA, gastrointestinal and radiographic (above 94%)
- Lowest overall accurate rate
  - renal (44.3%), pulmonary (54.5%) cardiac (55%)
- Overall event accuracy (combination of complications occurring simultaneously) is 57.1%.
Results

- **Neurologic impairment** per event was accurate for 79.1%.
- **Intervention severity** is 79.6% accurate, with the highest rate for severe intervention (98.6%).
- **Resolution** was accurately reported for 70.3% of the events
  - 80.1% for Resolved
  - 42.9% for Unresolved

Conclusions

- Accurate reporting and gathering of complications is difficult to standardize.
- In this case based survey, complex complications were categorized accurately 87%, neuro deficits accurately 79%, intervention accuracy of 80% and resolution accuracy of 70%.
- Surgeons need to be actively involved in complication reporting to enhance accuracy.

Does this system help us?

- What is the effect / incidence of timing?
- What is the effect on HRQL?
- Can it predict LOS?

Background: Timing of complication

- The timing and impact of complications over time is important to understand for patients, payors and providers. While most medical and operative complications occur proximate to the index surgical intervention, complications may occur at any time point during the care of our adult spinal deformity patients.
- Understanding the timing of specific complications may be helpful to guide patients and surgeons. The impact of those complications on health outcomes at 2 years is also critically important.
584/732 patients met inclusion criteria (mean age 58.6 yrs, 78% female, mean BMI 27.5, mean CCI 1.64, mean ODI 43.0). 70.9% had at least one complication event over the 2-year period, with an average of 1.45 events per patient.

With only one complication, regardless of type, had worse final outcomes than no complications.
No complications:
- ODI (40 to 22, p=0.01)
- PCS (33.9 to 43.0, p=0.05)

One complication:
- ODI (45.8 to 30.5, p=0.05)
- PCS (30.6 to 38.0, p=0.05)

When we sub-analyze for type of complication, those that occur early have minimal effect, while those that occur later have a much more significant effect.

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Conclusion: Timing

- Complications occur over-time and can be predicted by type.
- Implant, radiographic and neurologic complications continue to occur over time, and need to be followed closely.
- Complication type is critical, and those complications that occur later, and increase over-time are more impactful for our patients at 2 years.
- Determining the relationship of the timing of complications and its impact to our patients is critical to understand.

LOS: Hypothesis

- Investigate the role of complications that occur during the initial hospitalization to predict LOS based on a novel classification that includes treatment severity.

LOS Parameters

- List of surgical parameters simplified for abstract analysis
  - Posterior length of fusion:
    - "short" versus "medium" versus "long" fusion
      - Threshold for short ≤ 5
      - Threshold for long > 13
    - Major osteo versus no
    - IBF versus no IBF
    - Primary versus revision
    - Stage yes/no
    - Posterior only vs combined

LOS: Distribution

- This parameter is not normally distributed
  - Kolmogorov-Smirnov p = 1.1737E-27
- Comparison with poison distribution
  - Kolmogorov-Smirnov p = 0.103964
LOS Demographics

- 494 patients included in the analysis
  - Mean age: 61 year
  - 72.8% female
  - 28.07 kg/m²
- Mean ASA grade was 2.44
  - 45.3% Grade 2
  - 45.7% Grade 3
- Mean number of levels fused posterior:
  - 11.6 +/- 3.9
- Mean number of levels fused using IBF:
  - 2.5 +/- 1.6
- 77.3% underwent some type of osteotomy
  - 26.1% underwent a major osteotomy (PSEO / VCR)
- 78.7% same day surgery

LOS by Intervention

- During the hospital stay
  - 65.1% of the maximum intervention where minor
  - 10.1% had at least one moderate intervention
  - 10.5% had at least one severe intervention
- Reop rate: 9.5%
- Number of events per patient between surgery and discharge
  - Mean Number events: 1.7 +/- 1.1

Multivariate Analysis

- 4 independent predictors identified
  - Group posterior fusion (short being reference)
    - Medium (p = 5.0798E-10)
    - Long (p = 8.7726E-12)
  - Major Osteo (No Major being reference)
    - Use of Major (p = 0.000096)
    - Stage (Same day being reference)
    - Stage (p = 0.005)
  - Intervention (No complication being reference)
    - No intervention (p = 0.002219)
    - Minor intervention (p = 0.033094)
    - Moderate intervention (p = 0.000006)
    - Severe intervention (p = 0.002730)

Predicators of LOS

- 3 parameters are significant independent predictor of LOS
  - Posterior fusion length group
  - Stage yes/no
  - Intervention
Conclusion: LOS

- LOS is correlated to in-hospital complications and to complication intervention severity.
- Surgical factors that affect LOS included length of fusion, major osteotomy or need for staged surgery.
- Increased invasiveness of complication treatment was identified by a novel complication severity assessment scale as the only non-surgical factor that independently predicted increased hospital LOS following ASD surgery.

Much left to understand

- Relationship of complication to HRQoL measure (i.e. timing)
  - Likely a correlation, and effect of complication weaken with time
  - Complication that has no effect now, but does later
- Cost of complication
  - May use scoring system
- Consensus for component score
  - AO Spine, ISSG, ESSG, Canadians, others...
- Development of a complication score

Conclusion

- Although surgical treatment for ASD can improve pain and disability, it is associated with high rates of complications.
- Many complications likely have minimal or no impact on ultimate patient outcome at 2 years
  - But may have impact on LOS, cost, recovery time
- No classification is currently able to predict LOS or HRQoL
- Can a comprehensive scores better classify complications for us and our patients?