Outpatient Instrumented Minimally Invasive Lumbar Fusion

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Lumbar Fusion – Traditionally Inpatient Surgery

• Trends in outpatient lumbar surgery
  • 4 to 13% of all lumbar surgery cases performed on an outpatient basis from 1994 to 1996
  • Outpatient procedures accounted for an increased 9% - 17% in 1997 – 2000
  • 90% of cases were discectomies and just below 1% - fusions

Gray et al, Spine 2006

Trends Are Changing

• Contributing Factors
  • Increasing health care cost
  • Development of less invasive surgical techniques
  • Advancements in anesthesia
  • Growing medical staff and surgeons’ confidence
  • Realization that hospitalizations increase the rate of complications
Minimally Invasive Surgery

• The size of incision is ONLY cosmetic
• What makes a clinically significant difference?
  • Tissue trauma and blood loss is minimized
  • Less epidural scarring
  • Postoperative pain is minimized
  • Hospital stay is minimized = outpatient surgeries
  • Decreased recovery time, but not at the expense of clinical outcomes

Changing Clinical Environment

• Hospital-acquired infections
  • Almost 100,000 deaths/year are caused by hospital acquired infections in the United States (The Association for Professionals in Infection Control and Epidemiology Economic Survey, 2009)
  • Antimicrobial resistance was found to be significantly higher for inpatients (Archibald et al, Clin Infect Dis, 1997)
  • A single non-compliant health care worker could cause a 73% – 238% increase in infections/month (Temime et al, Proc Natl Acad Sci USA, 2009)

Venous Thromboembolism

• A prospective cohort of almost 1 million middle-aged women was studied (Sweetland et al, BMJ, 2009)
  • A 7-fold increased risk after inpatient compared to outpatient surgeries in the first 6 weeks was found
  • Higher risk was associated with joint replacement or cancer surgeries, but hospital admission remained an important factor
Systematic Review

• A diverse group of outpatient surgeries was analyzed (Wu et al, Anesthesiology, 2002)

• Studies published from 1966 – 2000

• Patients complained:
  - Pain - 45%
  - Drowsiness - 42%
  - Fatigue - 21%
  - Dizziness - 18%
  - Nausea - 17%
  - Nonspecific headaches - 17%
  - Vomiting - 8%

• No critical or life-threatening problems were reported

• No infections, acute respiratory distress syndrome or thromboembolic complications were reported

Advantages vs. Disadvantages

• Prolonged hospital stays may better address such problems as:
  - Inadequate pain control
  - Urinary retention, constipation
  - Nausea, vomiting

• Disadvantages
  - Rising health care cost
  - Increased risk of infections
  - Pneumonia
  - Thromboembolic complications
  - UTIs

Patient “Home-Readiness”

• A total 500 patients were randomly selected that underwent various ambulatory surgeries (Chung, Anest Analg, 1995)

• The majority of patients were ready to be discharged
  - 82% after 2 hours
  - 96% after 3 hours

• The discharge delays were due to personal, non-medical reasons in 50% of the patients
Clinical Study

• Objectives
  • Analyze our results to determine if it is safe and effective to perform instrumented lumbar interbody fusion on an outpatient basis
  • Identify the need for prolonged observation for complications in the immediate postoperative period

Patients

• A total of 52 one-level TLIF surgeries with instrumentation were performed on an outpatient basis from 2003 – 2009
  • Ambulatory Surgery Center (ASC) = 27 patients
  • Hospital Outpatient Department (HOD) = 25 patients
  • The mean age was 49.8 years (range, 19 – 72)
  • M/F ratio 28:24

Methods

• Safety - complications
  • Discharge – 7 POD (0 - 7POD)
  • 7 days – 6 months (>7POD)
  • Hospital readmissions, visits to ED
  • UTI, pneumonia, thromboembolic complications

• Efficacy – pain relief
  • Pre- and postoperative VAS (0 – 100) scores were compared for lower back and extremity pain

• Follow-up – at least 6 months
• Surgeries
  • MI Tubular-Assisted Surgeries (MITS; n = 9)
  • Mini-open (n = 23)
  • Open (n = 20)
Surgical Technique

• Interspinous Process Fixation Systems
  • Less invasive than pedicle screw fixation
    • Smaller incision
    • No additional lateral exposure
  • Easy to implant
    • No fluoroscopic guidance required
    • No risk of neural injury
    • Feasible alternative to pedicle screw fixation

Rationale

• Pros
  • Pedicle screw fixation increases fusion rates
  • Stabilizes spine

• Cons
  • Increases complication rates (e.g. neural injury, need for re-operation)
  • Radiation exposure
  • Increased OR time

Interspinous Process System
Interspinous Process System

Surgical and Hospitalization Data
Effectiveness

Complications

<table>
<thead>
<tr>
<th></th>
<th>ASC (n = 27)</th>
<th>HOD (n = 25)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital readmissions [0-7 POD]</td>
<td>1 pain control #1</td>
<td>1 delirium tremens #3</td>
<td>3</td>
</tr>
<tr>
<td>Vists to ED (0-7 POD)</td>
<td>1 constipation #2</td>
<td>-</td>
<td>2</td>
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Other Complications (>7 POD)

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<tr>
<td>CSF leak</td>
<td>2 (#35/H and #8)</td>
<td>1 (#10)</td>
<td>3</td>
</tr>
<tr>
<td>Allograft malposition</td>
<td>1 (#45/H)</td>
<td>1 (#90/H)</td>
<td>2</td>
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<tr>
<td>Pedicle screw malposition</td>
<td>1 (#8/H)</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Pericarditis</td>
<td>1 (#14/H)</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>9 (33%)</td>
<td>3 (12%)</td>
<td>12 (23%)</td>
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Postoperative Complications According to Surgery Location (H - number of days after discharge; H – hospitalization was required)

Complications

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<tr>
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<th>Open (n=20)</th>
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<th>Mini-Open (n=23)</th>
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Cost Analysis

- Inpatient (Patel et al, J Spinal Disord Tech, 2008)
  - $45,184 incl. rhBMP-2
  - One-level TLIF surgeries
  - Average hospital stay – 3 days
  - Direct costs - OR time, inpatient room costs, nursing staff wages ($17,898)
  - Indirect costs – hospital overhead, maintenance, administration ($11,362)
- This study (ASC)
  - $18,420
  - $29,983 incl. the cost of implants and rhBMP-2

Conclusions

- Appropriate patient selection
  - Absence of significant comorbidities
  - Age
  - Adequate postoperative home care
- Time under anesthesia
- Blood loss
- Postoperative pain control

Conclusions

- This is the first study of it’s kind to evaluate outpatient instrumented lumbar fusion surgery

- Additional confirmation is needed, but these results strongly suggest 2 things:
  - That it is safe and efficacious to perform instrumented lumbar interbody fusions as outpatient procedures
  - There is significant cost savings associated with outpatient procedures as compared to inpatient
Questions?

“Helmet and chin straps were provided to patients as part of the decreased hospital length-of-stay initiative.”

[cartoon image]