Open or Laparoscopic Repair of Ventral Incisional Hernias

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Open or Laparoscopic?
Open or Laparoscopic?

Wantz et al: JACS 1999;189:635-637
Short Term Outcomes of Laparoscopic and Open Ventral Hernia Repair- A Meta-Analysis  
Goodney et al Arch surg 2002;137:1161

- Comparison of laparoscopic and open ventral hernia repair; 83 studies 8 included
- Main outcome measures: complications, operative time, length of hospital stay
- Conclusion: ”Laparoscopic ventral hernia offers lower complication rates and shorter length of stay than open repair. However, randomized controlled trials and studies with long term follow-up are needed to confirm these findings and to assess long term rates of hernia recurrence”
Progression to re-operative repair, all patients

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European Society Of Hernia Surgery

Rives-Stoppa-Wantz repair considered “standard”

Recurrence rate 15% (1989) Stoppa 368 patients
1.4% (1998) Stoppa 604 patients
1.9% (2001) Wantz 766 patients
Laparoscopic repair of incisional hernias

“The authors believe that the time for prospective, randomized studies comparing laparoscopic with open ventral hernia repair has passed. With the numerous cases touting low rates of mesh infection and recurrence with the minimally invasive approach, it would be difficult and potentially unethical to recruit patients for such a study”
Open Vs. Laparoscopic Ventral Incisional Hernia Trial

UNETHICAL?

- Bowel injury
- Seroma
- Ileus, bowel obstruction
- Trocar site complications
- Hematoma
- Pain
- Health related quality of life measures
- Cost and cost effectiveness
- Other postoperative complications
Open Vs. Laparoscopic Ventral Incisional Hernia Trial

Unresolved Issues

- Personal case series- Dedicated laparoscopic surgeons
- Small prospective trials
- Poor reporting of complications (no definitions)
- No standardized techniques (mesh, fixation, overlap)
- Comparison to a variety of open techniques
- Pain
- HRQL is not equivalent to discharge from the hospital and return to work
- Etc…. 
• **Horton:** “If surgeons wished to retain their academic reputation, they must find imaginative ways to collaborate with epidemiologists to improve the design of the case series and to plan randomized trials.”

• **Greenwell:** “I should like to shame surgeons out of comic opera performances which they suppose are statistics of operations.”

• **Spodick:** “The repeated reporting of biased data from uncontrolled or poorly controlled trials, giving an illusion of success due to sheer quantity but that a thousand zeros look impressive on paper, but they still amount to zero.”

Lancet, 1996;347:984-985
Conclusion:”Laparoscopic ventral hernia offers lower complication rates and shorter length of stay than open repair. However, randomized controlled trials and studies with long term follow-up are needed to confirm these findings and to assess long term rates of hernia recurrence”
END POINTS

RECURRENCE

OPEN VIH
12%

80% POWER, X = 0.05

LAPAROSCOPIC VIH
4%

TOTAL = 488 PATIENTS
## COMPLICATIONS – OPEN VENTRAL HERNIA REPAIR

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<th>Author</th>
<th>No of Pts.</th>
<th>Bowel Injury</th>
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<th>Suture Pain</th>
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# COMPLICATIONS – LAPARASCOPIC VENTRAL HERNIA REPAIR

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<td>24 (14.3%)</td>
<td>168 (17.8%)</td>
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*PI’s series from Houston VAMC
Sample Size

Complication  Open 32%  Laparoscopic 17%
Meaningful difference 15%  Power 80%
TOTAL 282 Patients
Drop out rate 10%  314 Patients

3 Centers  39 Patients/year/center
3 – 4 patients/month/center
Participating Centers

• Dallas: George Sarosi MD (PI)
• Houston: David Berger MD (PI)
• Little Rock: Larry Kim MD (PI)
Primary Hypothesis

Laparoscopic repair of VIHs is associated with fewer complications at 8 weeks than the open repair.
END POINTS

Secondary Hypothesis

There is a difference between the two surgical techniques with respect to the following outcomes:

- Health related quality of life
- Post operative pain
- Time to return to normal activities
- Patient satisfaction
- One and two year recurrence rates
Chevrel Combination Fascia And Mesh Repair
Chevrel Combination Fascia And Mesh Repair
DESIGN OF TRIAL

FIGURE 1 - DESIGN OF TRIAL
Patient Presents with Ventral Incisional Hernia

Referred to Coordinator

Agrees to participate

No

Yes

Eligible?

No

Yes

Consent to be Randomized

No

Yes

Listed Demographic Data

Open Repair

Laparoscopic Repair
Monitoring of trial

- Kick of meeting with review of protocol and standardization of operative techniques
- Experience of surgeons
- Random videotapes of all procedures
- Review of all operative notes
- Monthly conference call (Investigators)
- Biweekly conference call (nurse coordinators)
- Yearly site visits and as needed
- DSMB and end points committee (2 surgeons, 1 anesthesiologist, 1 biostatistician)
Time Frame

1. Implementation (2 mos) – 1/1/04 to 3/1/04

2. Patient intake and follow-up (32 mos) 3/1/04 to 10/31/07

3. Closeout (2 mos)  10/31/07 to 12/31/07

   Follow-up  8 weeks – 34 mos.
Inclusion Criteria

Patients will be eligible for enrollment into the study if they meet the following criteria:

- Are 18 years of age or older
- Have a diagnosis of VIH 9 – 225 cm² in size (3 x 3 cm to 15 x 15 cm)
- Give informed consent for randomization
- Have a negative pregnancy test
Exclusion Criteria

Patients will be excluded for the following reasons:

- Hernia cannot be detected on physical examination
- Primary ventral or umbilical hernias
- Small hernia defined as less than 9cm$^2$
- Giant hernia defined as > 225cm$^2$
- ASA class 4 or 5, or contraindications to general anesthesia
- Severe co-morbid conditions likely to limit survival to less than 2 years
- History of malignancy within the past 5 years except for non-melanoma skin cancer
Exclusion Criteria (cont)

- Cirrhosis with or without ascites
- Presence of bowel obstruction (partial or intermittent), strangulation, peritonitis or perforation
- Presence of local or systemic infection
- Participation in another clinical trial
- Emergency operation
- Prisoner
Accrual
2/1/2004-12/01/2004

Screened: 83.3% of target

Non Participation
29% primary hernia; 20% no consent; 17.5% ASA 4 or 5; 14% hernia size too small or too large
4 strata within each center:

First time VIH - BMI $< 35$ (68%)
First time VIH - BMI $\geq 35$ (13.3%)
Recurrent VIH - BMI $< 35$ (16%)
Recurrent VIH - BMI $\geq 35$ (2.7%)
Baseline characteristics (72 patients)

NO DIFFERENCE between groups:

68 patient characteristics
Operation (57 patients)

- 34 open and 23 laparoscopic
- Operating time
  Open: 125 min; Lap 161 min
- Defect size: 9.0 X 6.4 cm; 71.9 cm²
- Mesh size
  Open 10.1x12.5 cm; Lap 14.5X 16.3
Primary End Points – Intraoperative Complications

- Bleeding (EBL) with or without transfusion
  - <25cc: 61.4%
  - 25-150 cc: 36.8%
  - 151-500 cc: 1.8%

- Injury to bowel (serosal only: repaired or not repaired, transmural: repaired via hernia incision, requires celiotomy to repair)
  - 1 patient
Primary End Points – Intraoperative Complications

- Injury to bladder (does not enter lumen; full thickness repaired through hernia incision); requires celiotomy to repair)
- Injury to vascular structure (including inferior epigastrics)
- Anesthetic complications
- Pneumothorax
- Other
END POINTS

Primary End Points – Intraoperative Complications

57 repairs, 2 complications

- One transmural bowel injury
- One subcutaneous emphysema
Primary End Points – Immediate and Early Postoperative Complications

- Hernia site infection:
  - Drainage only; not grossly infected
  - Cellulitis requiring antibiotics
  - Drainage of pus or I & D required.

- Trocar Site Infection
  - Drainage only; not grossly infected
  - Cellulitis requiring antibiotics
  - Drainage of pus or I & D required.
Primary End Points – Immediate and early post-operative complications

- Intra-abdominal abscess or fluid collection
  - Antibiotic Tx only
  - Percutaneous drainage
  - Operative drainage

- Ileus or bowel obstruction
  - 3-5 days NPO
  - greater than 5 days NPO
  - Operative management

- Seroma
  - Self limited
  - Aspiration <50cc fluid
  - Aspiration > 50cc fluid
Primary End Points – Immediate and Early Postoperative Complications

- **Wound Hematoma**
  - Bruising, ecchymosis
  - Moderate swelling
  - Requiring transfusion

- **Intra-abdominal Bleeding**
  - Mild (<500cc) or Hgb drop <5
  - >500cc but not requiring transfusion or Hgb drop >5
  - Requiring transfusion
Primary End Points – Immediate and Early Postoperative Complications (cont)

- Trocar Hernia
  - Found by physical exam or radiologic study, reducible
  - Noticed by patient, reducible
  - Incarcerated or strangulated

- Skin necrosis
  - Bedside or no debridement
  - Debridement in OR
  - Requires skin graft or flap

- Other
Is there a need for a secondary operation
If yes, was mesh removed?
Primary End Points – Other Complications

- Intraoperative or post operative hypertension requiring pharmacologic therapy
- Myocardial ischemia manifested by intraoperative or postoperative ECG changes, hypotension, arrhythmia, oliguria (<15 ml/hr)
- Respiratory insufficiency occurring intraoperatively or in the immediate post-operative period requiring additional ventilatory support
Primary End Points – Other Complications

- Postoperative deep venous thrombosis documented by Doppler ultrasound or venogram
- Pulmonary embolism documented by high or intermediate probability V/Q scan or pulmonary arteriogram
- Malignant hyperthermia intraoperatively
- Anaphylactic drug reaction
- CVA (stroke)
- Coma
- Cardiac arrest
Primary End Points – Complications
57 patients- 21 post-op complications

- Hernia site infection: 1 drainage only, 1 cellulitis requiring antibiotics, 2 I&D
- Wound hematoma: 1 bruising
- Abscess: 1 Percutaneous drainage, 2 operative drainage
- Ileus: 1 reoperation
- Seroma: 2 self-limited, 1 aspiration>50 cc
- Skin necroses: 2 debridement in OR
Primary End Points – Complications
57 patients- 21 post-op complications

- Other
  - Topical burn due to betadine when placing foley
  - Post op mucus plug requiring intubation
  - Laceration to gumline
  - Wound separation
  - Skin excoriation from adhesive tape
  - Persistent drainage from drain site
Serious/Life-threatening complications

57 patients - 6 complications

- 2 sepsis
- 1 Urinary retention
- 3 others:
  - 1 operation to remove mesh
  - IV antibiotics for IV site cellulites
  - Omental infarction requiring second operation
Primary End Points – Long Term Complications (8 weeks)
25 patients – 7 complications

- Hernia site infection
  - 1 Drainage Only
  - 1 Incision and Drainage

- Abscess
  - 1 Operative Drainage

- Skin necrosis
  - 1 Required skin graft or flap

- Other
  - 1 hospital rehab, 1 hospitalized for wound care, 1 burning/sharp pain)
Secondary operations were required in 2 cases; mesh not removed

Primary End Points – Long Term Complications (8 weeks)
25 patients – 7 complications
Secondary End Points

- Pain: Baseline, Follow-up (normal activities, work, exercise, average pain at rest, how disturbing and worst pain)

- Functional status, HRQoL, Activities and Satisfaction with the care

- Recurrence: One at 2-weeks and one at 8-weeks
Analysis

- Analysis by intent to treat, i.e. the patients will be analyzed according to the group they were originally assigned.
- Crossovers (as a consequence of conversion of a laparoscopic to an open repair) are expected to occur in 1 – 2% of the cases.
Open Vs. Laparoscopic Ventral Incisional Hernia Repair

• Improve recruitment: Boston added as a site in August 2005)
• Design paper published: AJS, December 2004
• Consider re-applying to coop study program to convert to recurrence as end point