Open or Laparoscopic Repair of Ventral Incisional Hernias

Kamal Itani, M.D., FACS

Chief of surgery, Boston VAHCS

Professor of Surgery, Boston and Harvard Universities

Associate Chief of Surgery,

Boston Medical Center and Brigham and Women's Hospital

ACS Spring Meeting, April 17, 2005

Open or Laparoscopic?

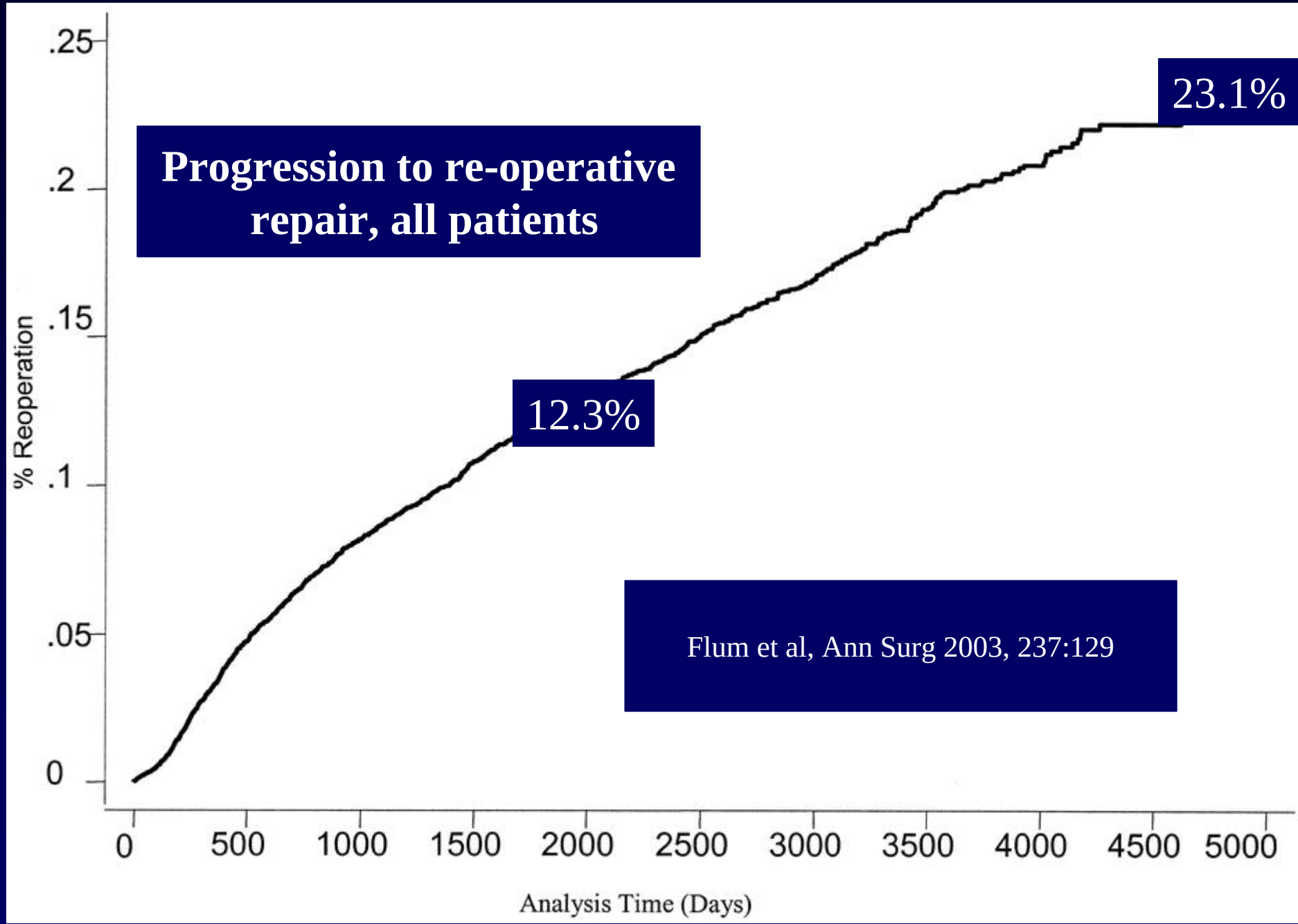
Open or Laparoscopic?

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
23.1%
12.3%
Flum et al, Ann Surg 2003, 237:129
% Reoperation
.25
.2
.15
.1
.05
0
0
500
1000
1500
2000
2500
3000
3500
4000
4500
5000
Analysis Time (Days)

Recurrence and Mean F/U
Laparoscopic Repair

Name	Year	N	Rec(%)	F/U-months
Franklin	2004	384	2.9	47.1
LeBlanc	2003	200	6.5	36
Bower	2003	100	2.0	6.5
Eid	2003	23	0	13
Heniford	2003	850	4.7	20.2
Raftopoulos	2002	50	2.0	NR
Ben-Haim	2002	100	2.0	19
Berger	2002	150	3.0	15
Aura	2002	86	7.0	37
Parker	2002	50	0	41
Birgisson	2001	64	0	1-35
Total		2057	3.8	27

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

Cobb WS, Kercher KW Henniford BT: Surg Clin N Am 85 (2005) 91-103

"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

Short Term Outcomes of Laparoscopic and Open Ventral Hernia Repair- A Meta-Analysis

Goodney et al Arch surg 2002;137:1161

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	LAPAROSCOPIC VIH
12%	4%
80% POWER, X = 0.05	TOTAL = 488 PATIENTS

COMPLICATIONS – OPEN VENTRAL HERNIA REPAIR

Author	No of Pts.	Bowel Injury	Seroma	Suture Pain	Infection	Hema-toma	Skin Necrosis	Cellulitis	Ileus/ Bowel Obst.	Other	Total
Park	49	2	1	2	3	5				5	18 (36.7%)
Carbajo	30		20		3	6	1	2		3	35 (11.6%)
DeMaria	18	1	4		2				2	4	13 (72.2%)
Holzman	16				1				1	1	3 (18.8%)
Chari	14	1							1		2 (14.3%)
Salameh	35		2		7				6	4	19 (54.2%)
Termuder	50				6	2			1		9 (18%)
Bauer	98	3	5		9						17 (17.3%)
Ramshaw	174	2			5			2	9	12	30 (17.2%)
White	99	5	21		16	1					43 (63.4%)
McLanahan	106	2	1	5	7	1	3	6		5	30 (28.3%)
Anthony	29	2	2		3					5	10 (34.51%)
TOTAL	718	16	56	7	62	15	4	10	20	39	229 (32%)

COMPLICATIONS – LAPARASCOPIC VENTRAL HERNIA REPAIR

Author	No of Pts.	Bowel Injury	Ser-oma	Suture Pain	Infection	Hema toma	Trocar Hernia	Trocar Cellulitis	Ileus/ Bowel Obst.	Other	Total
Heniford	407	5	8	8	4	3	0	5	9	10	52 (12.8%)
Toy	144		23		5	2			3	1	34 (23.6%)
Heniford	100	3	3	2				2	2	2	14 (14%)
Carbajo	30		4			1	1				6 (20%)
De Maria	21	1	9		1				1		12 (57%)
Holzman	21				1				4	1	6 (28.6%)
Park	56		2	2	2				3	1	10 (17.8%)
Chari	14	2									2 (14.3%)
Reiter	49				1		1				2 (4.1%)
Salameh*	1	3		2					5	4	15 (60%)
Ramshaw	79	3	2					2	3	5	15 (19%)
TOTAL	946	15 (9%)	54 (32.2 %)	12 (7.8%)	16 (10.5%)	6 (4%)	2 (1.3%)	9 (5.4%)	30 (18%)	24 (14.3%)	168 (17.8%)

*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)

END POINTS

Primary Hypothesis

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

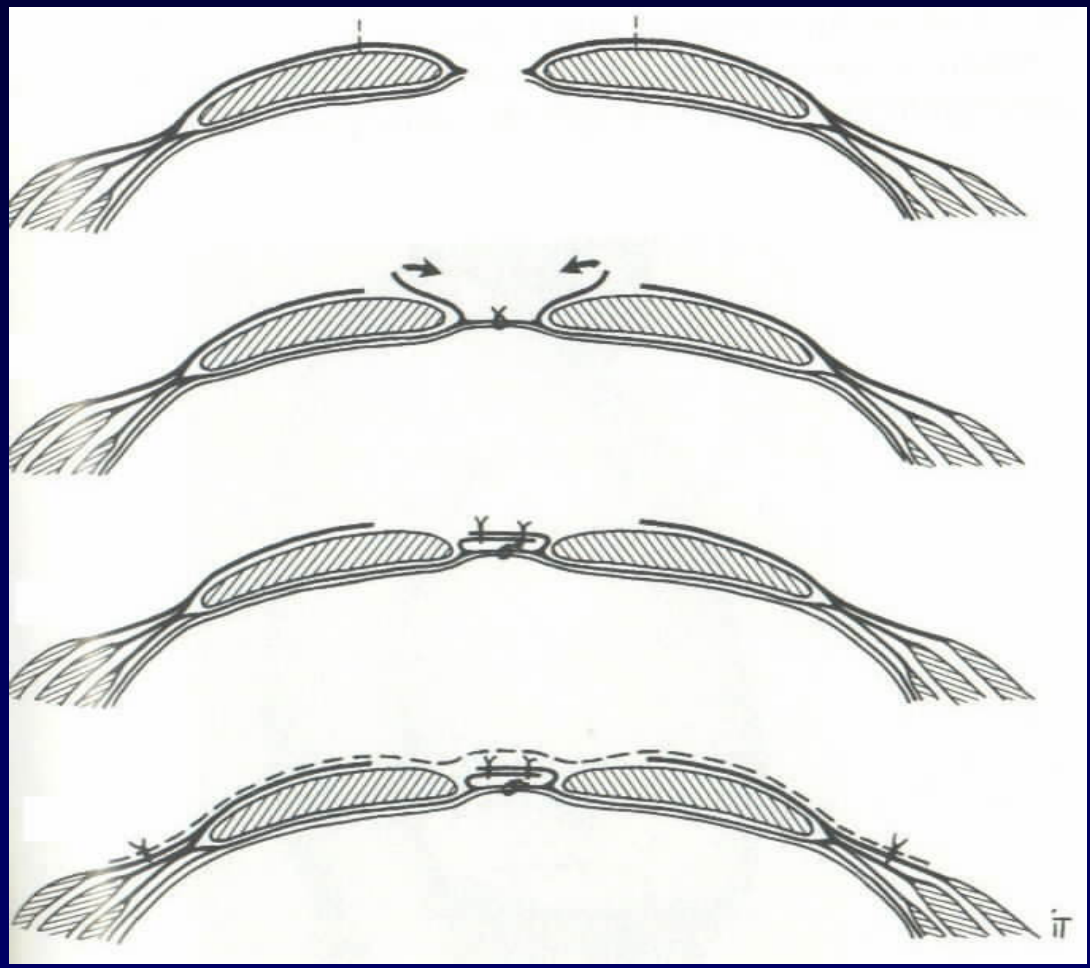
END POINTS

Secondary Hypothesis

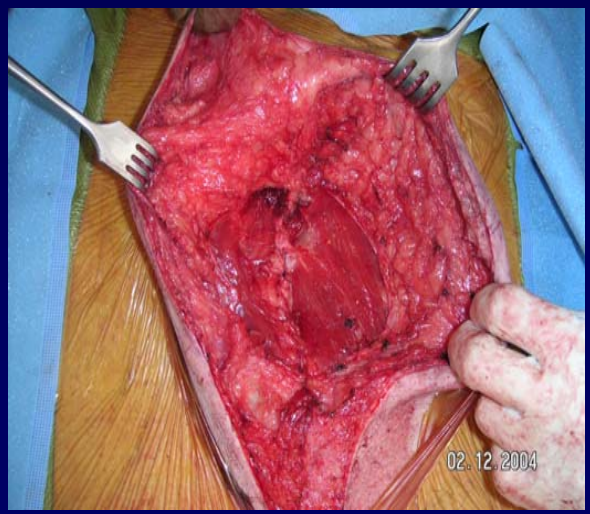
There is a difference between the two surgical techniques with respect to the following outcomes:

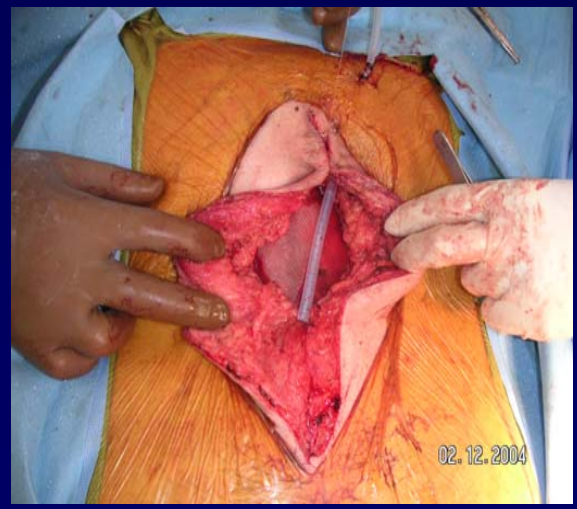
- **Health related quality of life**
- **Post operative pain**
- **Time to return to normal activities**
- **Patient satisfaction**
- **One and two year recurrence rates**

Chevrel Combination Fascia And Mesh Repair

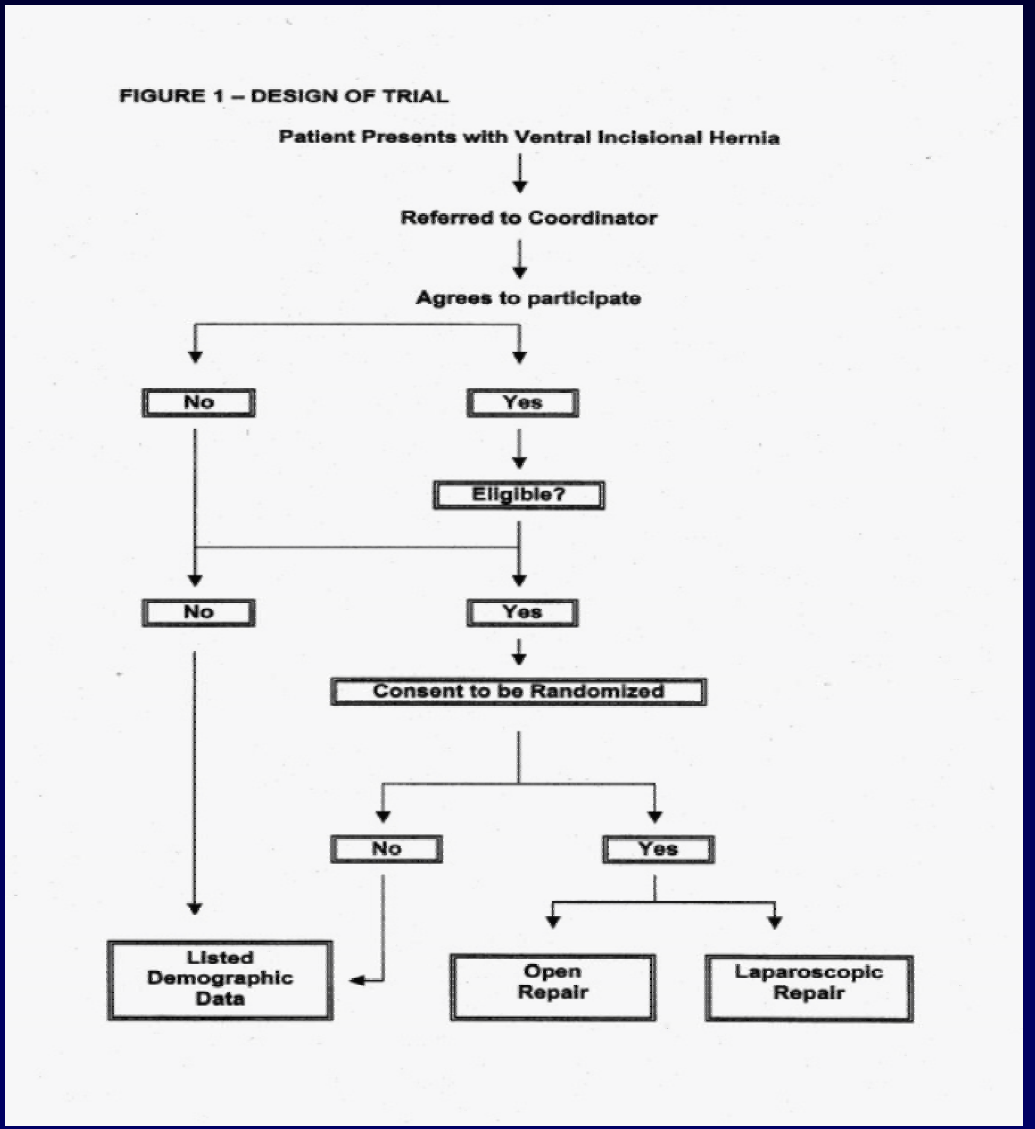


Chevrel Combination Fascia And Mesh Repair





DESIGN OF TRIAL



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 (2surgeons, 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 cm^2 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:

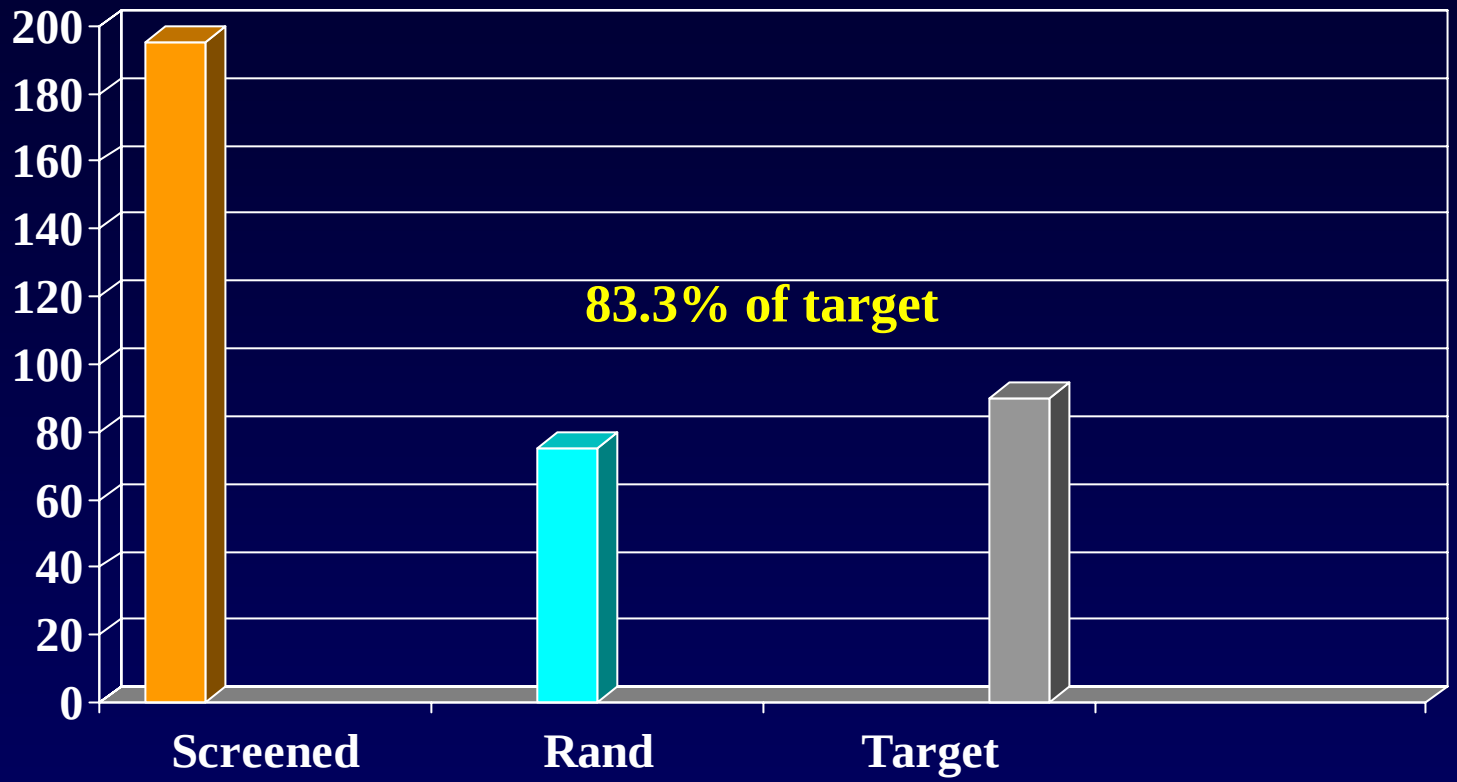
- Hernia cannot be detected on physical examination
- Primary ventral or umbilical hernias
- Small hernia defined as less than $9cm^2$
- Giant hernia defined as > $225cm^2$
- ASA class 4 or 5, or contraindications to general anesthesia
- Severe co morbid conditions likely to limit survival to less than 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



Non Participation

29% primary hernia; 20% no consent; 17.5% ASA 4or 5; 14% hernia size too small or too large

Stratification and Randomization

4 strata within each center:

- First time VIH - BMI < 35 (68%)
- First time VIH - BMI ≥ 35 (13.3%)
- Recurrent VIH - BMI < 35 (16%)
- Recurrent VIH - BMI ≥ 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

END POINTS

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

END POINTS

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

Primary End Points – Immediate and Early Postoperative Complications

- 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**
  - 1Operative Drainage
- **Skin necrosis**
  - 1 Required skin graft or flap
- **Other**
  - 1 hospital rehab, 1 hospitalized for wound care, 1 burning/sharp pain)

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

Secondary operations were required in 2 cases;mesh not removed

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 to coop study program to convert to recurrence as end point