

Azienda Ospedaliero Universitaria Pisana Dipartimento di Gastroenterologia e Malattie Infettive U.O. Chirurgia Generale Direttore: Dott. Piero Buccianti



Collaborazione:



6° Edizione del Corso CHIRURGIA LAPAROSCOPICA DELLA PARETE ADDOMINALE

7-8-9 OTTOBRE • PISA

Johnson Johnson MEDICAL S.P.A.



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6° Edizione del Corso CHIRURGIA LAPAROSCOPICA DELLA PARETE ADDOMINALE 7-8-9 OTTOBRE • PISA



U.O. Chirurgia Generale Ospedale "Campostaggia" Poggibonsi Primario Dott. Alessandro BIANCHI



EBM DELL'ERNIA OMBELICALE

Dott. Massimo RANALLI



inda Ospedaliere Universitaria Pisa Dipartimento di Gastroenterologia e Malattie Infective E.O. Chirergia Gonerale Direttore: Dott. Piera Baccianti





"It is unwise to be too sure of one's own wisdom. It is healthy to be reminded that

the strongest might weaken and the wisest might err."

Mahatma Gandhi



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The conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research

Sackett D, 1996

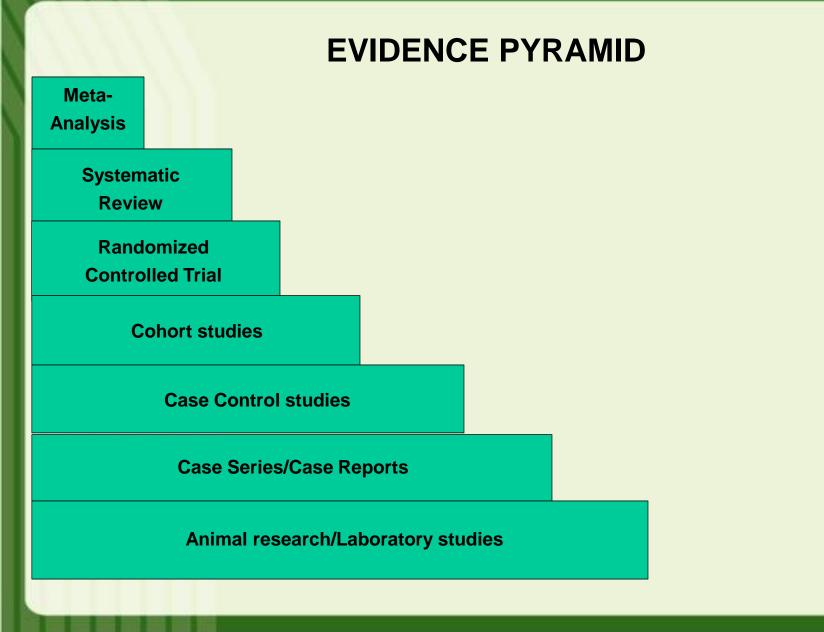


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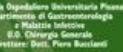




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"ventral hernia": 8494 articoli

"umbilical hernia": 3327 articoli

"ventral hernia" (2004-2014): 2431 articoli

"umbilical hernia" (2004-2014): 1058 articoli

"umbilical hernia" RCTs (2004-2014): 27 articoli

"umbilical hernia" RCTs + adult (2004-2014): 19 articoli

"umbilical hernia" RCTs + adult + "title" (2004-2014): 6 articoli



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Devo ricordarmi di ringraziare Antonio di questa stupenda relazione



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NR6/CA

Surg Endosc DOI 10.1007/s00464-013-3170-6

GUIDELINES

Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society (IEHS)—Part 1

R. Bittner · J. Bingener-Casey · U. Dietz · M. Fabian · G. S. Ferzli · R. H. Fortelny · F. Köckerling · J. Kukleta · K. LeBlanc · D. Lomanto · M. C. Misra · V. K. Bansal ·

S. Morales-Conde · B. Ramshaw · W. Reinpold · S. Rim · M. Rohr · R. Schrittwieser ·

Th. Simon · M. Smietanski · B. Stechemesser · M. Timoney · P. Chowbey

Level The level of complexity and variability for ventral/incisional 4 hernia patients and repair techniques is high.

Level The degree of complexity is growing higher at an increasing 5 rate of change. The techniques and outcomes, therefore, cannot be considered comparable using current methods of analysis due to the many complex ever-changing variables as well as the relationships between variables, which are not controllable.

Grade C	Due to the increasing pace of change and the complexity of ventral/incisional hernia patients and techniques, use of
	traditional human subjects clinical research, evidence- based methods and guidelines in health care should be considered a starting point rather than a goal.
Grade C	The application of principles of complex adaptive systems science, particularly real-world clinical quality- improvement methods, likely will be required to improve the value of care (e.g., quality outcomes measures, satisfaction, patient experience, costs) for the patient with a ventral/incisional hernia.

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Surg Endosc DOI 10.1007/s00464-013-3170-6



GUIDELINES

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A new field of medicine is forming, referred to as complex adaptive systems research [8]. Complex adaptive systems describe any biologic organism (e.g., the human body) and any grouping of biologic organisms (e.g., our health care system). Research conducted to generate evidence based on the study of complex adaptive systems includes clinical quality improvement methods, participatory research (sometimes led by patients and family members), and documentation of data throughout the entire cycle of patient care including psychosocial and other nontraditional outcomes measures. This field recognizes that humans likely belong to many subgroups that must be identified for better prediction of outcomes and improvement of value. These subgroups may be based on genetics, environment, disease states, age, sex, and the like.





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Laparoscopic repair of primary and incisional ventral hernias: the differences must be acknowledged

A prospective cohort analysis of 1,088 consecutive patients

Vincent M. A. Stirler · Ernst J. P. Schoenmaeckers · Robbert J. de Haas · Johan T. F. J. Raymakers · Srdjan Rakic

(IVH group $(n = 426)$	PVH group $(n = 662)$	P value
Mean age at operation (years)	54.99 ± 13.85	51.27 ± 13.47	<0.001
Gender: n (%)			
Male	195 (45.77)	460 (69.49)	< 0.001
Female	231 (54.22)	202 (30.51)	
Mean ASA classification	1.92 ± 0.72	1.68 ± 0.70	<0.001
Hernia location: n (%)	Midline: 255 (59.86)	Umbilical: 456	(68.88)
	Trocar site: 68 (15.96)	Epigastric: 170	(25.68)
	Subcostal: 36 (8.45)	Spigelian: 35 (5	5.29)
	Lumbar: 18 (4.23)	Lumbar: 1 (0.1	5)
	Transverse: 19 (4.46)		
	Pfannenstiel: 7 (1.69)		
	McBurney: 23 (5.56)		

Surg Endosc 2013

				$ \land $
	Pooled data ($n = 1,088$) $n (\%)^{a}$	IVH group ($n = 426$) n (%)	PVH group $(n = 662) n (\%)$	P value ^b
Open introduction	159 (15.07)	143 (36.11)	16 (2.43)	<0.001
Mean no. of trocars	2.86 ± 0.78	3.16 ± 0.73	2.40 ± 0.61	< 0.001
Adhesiolysis	307 (29.10)	301 (76.01)	6 (0.91)	< 0.001
Conversion to open procedure	33 (3.03)	30 (7.04)	3 (0.45)	< 0.001
Mean hernia size (cm ²)	9.86 ± 22.36	23.04 ± 33.00	2.41 ± 3.77	<0.001
Mesh size $(cm^2)^c$	213.16 ± 154.35	322.94 ± 199.00	148.79 ± 58.26	<0.001
Double-crown fixation ^c	728 (69.00)	276 (69.70)	452 (68.59)	0.724
Median no. of tacks ^c	34.58 ± 21.28	52.15 ± 26.46	28.13 ± 14.54	<0.001
Length of procedure (min) ^c	53.73 ± 33.70	72.56 ± 42.79	42.27 ± 19.14	<0.001
Hospital stay (days) ^c	3.33 ± 3.99	4.53 ± 5.79	2.43 ± 1.00	<0.001
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IVH incisional ventral hernia, PVH primary ventral hernia

^a Pooled data are combined data of IVH and PVH

^b Comparison of the IVH and PVH groups

^c Converted patients are excluded

IVH incisional ventral hernia, PVH primary ventral hernia, ASA American Society of Anaesthesiologists



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Laparoscopic repair of primary and incisional ventral hernias: the differences must be acknowledged

A prospective cohort analysis of 1,088 consecutive patients

Vincent M. A. Stirler · Ernst J. P. Schoenmaeckers · Robbert J. de Haas · Johan T. F. J. Raymakers · Srdjan Rakic

	Pooled data $(n = 1,055)$ $n (\%)^{a}$	IVH group (<i>n</i> = 396) <i>n</i> (%)	PVH group $(n = 659)$ n (%)	P value ^b
Early complications			AS 28	
Bleeding	4 (0.38)	2 (0.51)	2 (0.30)	0.604
Prolonged ileus	10 (0.95)	5 (1.26)	5 (0.76)	0.308
Wound infection	1 (0.09)	1 (0.25)	0 (0.00)	0.196
Mortality (not specific to LR)	3 (0.28)	3 (0.76)	0 (0.00)	0.025
Unrecognized bowel lesion (diagnosed postoperatively)	3 (0.28)	3 (0.76)	0 (0.00)	0.025
Late complications				
Pain followed by reoperation (removal of fixation)	8 (0.76)	4 (1.01)	4 (0.61)	0.463
Bulging of mesh	13 (1.23)	8 (2.02)	5 (0.76)	0.071
Trocar-site hernia	15 (1.42)	12 (3.03)	3 (0.46)	0.001
Recurrent hernia	32 (3.03)	23 (5.81)	9 (1.37)	< 0.001
Clinically relevant chronic seroma	5 (0.47)	3 (0.76)	2 (0.30)	0.297
Total complications, Clavien grade ≥ 3	104 (9.86)	74 (18.69)	30 (4.55)	< 0.001

Converted patients are excluded

IVH incisional ventral hernia, PVH primary ventral hernia, LR laparoscopic repair

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^a Pooled data are combined data of IVH and PVH

^b Comparison of the IVH and PVH groups

The results of the current study demonstrate important differences in all aspects related to LR of IVH and PVH, from patient characteristics to complexity and risks of procedure to intra- and postoperative complications to late outcome. Surgeons in their "learning curve" of acquiring skills for performance of LR must be aware of these differences and respect them. Using "pooled data" evidently leads to inexact preoperative counseling of patients and may seriously call into question the correctness of the acquired informed consent. Clearly, the practice of pooling these two entities together should come to an end.





Uso routinario di TC e/o RM per la diagnosi di ernia ombelicale

Nessun lavoro specifico pubblicato

Guidelines of IEHS

Level The evidence for the use of CT/MRI in the daily routine is 5 insufficient. In some cases, especially those involving posttraumatic hernias, obese patients, large hernias with loss of domain, or special rare entities such as lumbar hernias, a CT scan or MRI can be helpful. Grade In special cases, such as those involving posttraumatic D hernias, rare entities such as lumbar hernias or Spieghelian hernias, and connections with obesity, a CT scan or MRI may be considered.



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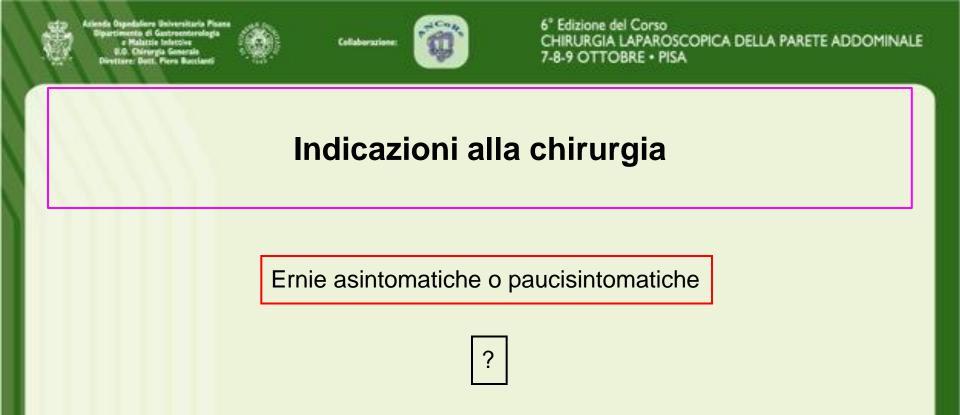




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Indicazioni alla chirurgia





Lauscher et al.: Development of a clinical trial to determine whether watchful waiting is an acceptable alternative to surgical repair for patients with oligosymptomatic incisional hernia: study protocol for a randomized controlled trial. Trials 2012 13:14.

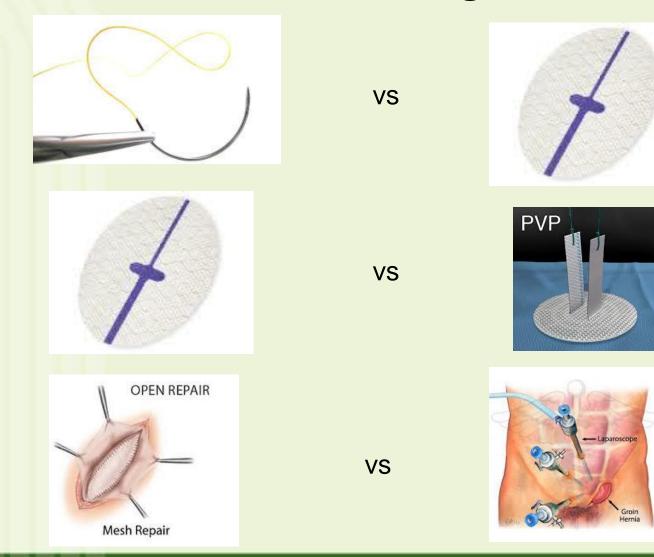


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Tecnica chirurgica



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VS



IEHS Guidelines: 45 articoli rilevanti

Level Suture herniorrhaphy is the simplest procedure among the open repair techniques.

Suture repair is associated with a high recurrence rate.

Suture repair is accomplished in a shorter operative time than mesh repair.

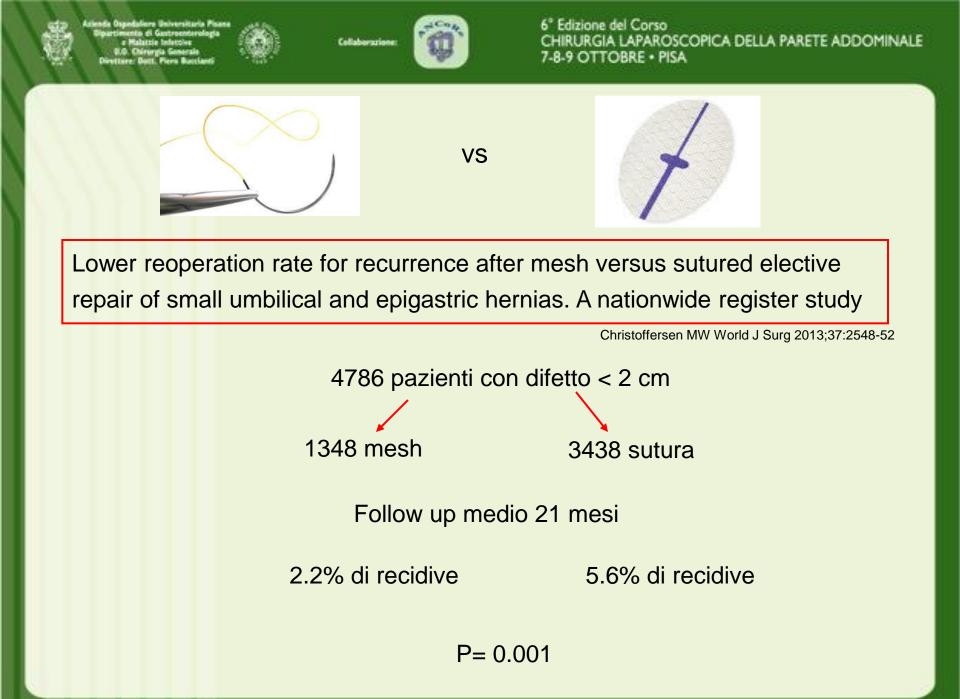
Mesh repair reduces the recurrence rate significantly compared with suture repair.

Mesh repair seems to be a safe method even in the presence of nonviable bowel loops in an incarcerated umbilical hernia.

Wound complication rates can be slightly higher in mesh repair or similar in the two groups.

- Level 3 Independent risk factors for recurrence of small hernias are not clearly defined. Hernia size, BMI, or wound infection in one study, and smoking, obesity, size of hernia, type of repair, and COPD in another study do not seem to predict recurrence in small hernia repair.
- Level 4 Not every "small hernia" requires mesh repair. Suture repair of hernias smaller than 2 cm shows an acceptable recurrence rate and low wound morbidity.
- Level 5 Despite the existing evidence, suture repair still is very popular in the surgical community

Grade A	For repair of primary defects larger than 2 cm or recurrent hernias of any size, mesh repair should be considered as the first choice.
Grade C	Suture repair should be used only for very small primary defects of the abdominal wall in the absence of any possible recurrence risk factors.
Grade D	In terms of recurrence, the available evidence is sufficiently strong to recommend that all defects of the abdominal wall, whether inguinal, incisional, or umbilical hernias, and of whatever size should be repaired with the use of prosthetic mesh.

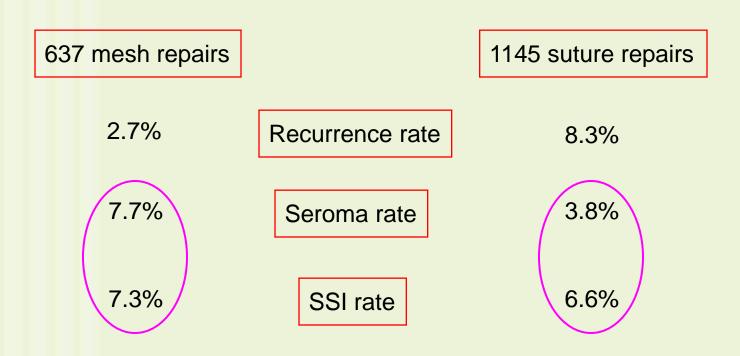


Comparison of outcomes of synthetic mesh vs suture repair of elective primary ventral herniorrhaphy: a systematic review and meta-analysis

Collaborazione:

Nguyen MT Jama Surg 2014;149(5):415-21

9 studies (RCT, case-control, cohort)

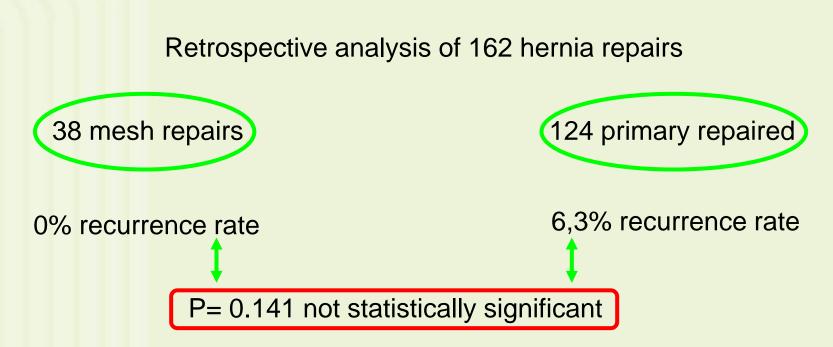






Long-term follow-up after elective adult umbilical hernia repair: low recurrence rates also after non mesh repairs

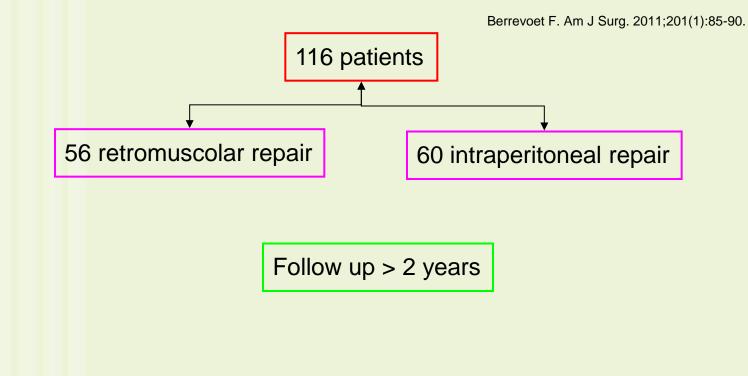
Dalenback J. Hernia 2013;17:493-97



Conclusion: AUH repair could be performed.....with low recurrence rates also after non-mesh repairs. A substantial cohort of patients will unnecessary be implanted with mesh.....that is 16 surplus meshes to prevent one recurrence....



Open intraperioneal versus retromuscolar mesh repair for umbilical hernia less than 3cm diameter



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Open intraperioneal versus retromuscolar mesh repair for umbilical hernia less than 3cm diameter

Berrevoet F. Am J Surg. 2011;201(1):85-90.

Table 2 Main outcome parameters					
	Group I (n = 56)		Group II ($n = 60$)		
Variable	Mean	SE	Mean	SE	Ρ
Mesh size (cm ²)	81.0	3.66	45.5	1.04	<.001
Operation time (min)	79.9	1.73	33.9	.74	<.001
Hospital stay (d)	3.8	.17	2.1	.07	<.001
Number of analgesics taken postoperatively	20.2	.81	12.8	.66	<.001
Visual analogue scale score					
Day 1	77.1	1.50	49.8	1.21	
Day 7	56.7	2.01	25.4	1.82	.003*
Day 21	23.63	2.18	3.3	.70	

*Between-groups difference evaluated with repeated-measures analysis of variance.

Collaborazione

Recurrence rate

3.6% mesh repair

8.3% intraperitoneal repair

Conclusion:However, possibly because of the less controllable mesh deployment, recurrence rates seem higher

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Ponten et al. BMC Surgery 2014, 14:33 http://www.biomedcentral.com/1471-2482/14/33



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STUDY PROTOCOL

Open Access



Mesh Or Patch for Hernia on Epigastric and Umbilical Sites (MORPHEUS trial): study protocol for a multi-centre patient blinded randomized controlled trial

Jeroen EH Ponten^{1*}, Bart JM Leenders^{2,6}, Jan A Charbon², Tanja Lettinga - van de Poll³, Jeroen Heemskerk⁴, Ingrid S Martijnse⁵, Joop LM Konsten⁶ and Simon W Nienhuijs¹

Pre-peritoneal mesh
VS
PVP

Hernia related	Patient related	
In epigastric or (peri-) umbilical region	Age 18 years or older	
< 3 cm (2 fingers)	Capacity (comprehension, language ability and physical ability)	
Primary	No ascites	
Single hernia		

Primary endpoint: number of complications

Secondary endpoints: VDS pain score, VDS cosmetic score, operation duration, recurrence and costs











VS



Laparoscpic versus open umbilical hernia repair

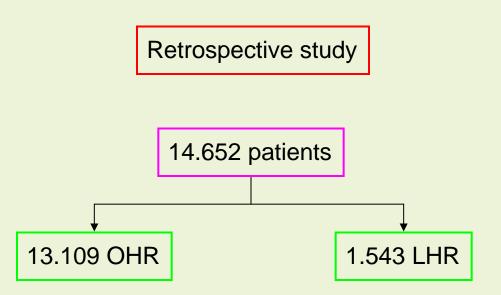
Gonzales R JSKS 2003;7:323-28

Table 2. Operative Results: Comparison Between Groups			
	Laparoscopic Group (n=32)	Primary Suture Repair Group (n=24)	Open Repair With Mesh (n=20)
Mesh Size (cm ₂) (range)	141 (32–400)	Not applicable	110 (20-144)*
Operating Time (min)	62±9	37±4	82±9*†
Estimated Blood Loss (cc)	21±5	15±3	32±5†
Postoperative Drains (%)	0	1 (4)	10 (50)*†
Postoperative Complications (%)	2 (6)	1 (4)	6 (30)*†
Length of Stay (hours)	27±3	20±2	91±53†
Return to Normal Activity (weeks)	3.1±0.5	4.3±0.6	7.7±0.3*†
Recurrences (%)	0	2 (8)	4 (20) *

Conclusions: laparoscopic umbilical hernia repair is a safe and effective technique......When compared with ORWM resulted in less use of postoperative drains, shorter RTNA, lower complication and recurrence rates.....PSR can be performed in patients with hernias smaller than 3 cm



Laparoscopic versus open elective repair of primary umbilical hernias: short-term outcomes from the American College of Surgeons National Surgery Quality Improvement Program
Cassie S Surg Endosc 2014;28:741-46



Conclusions: this study identified potential decreased total and wound morbidity associated with LHR.....at the expense of increased operative time, LOS, respiratory and cardiac complications.



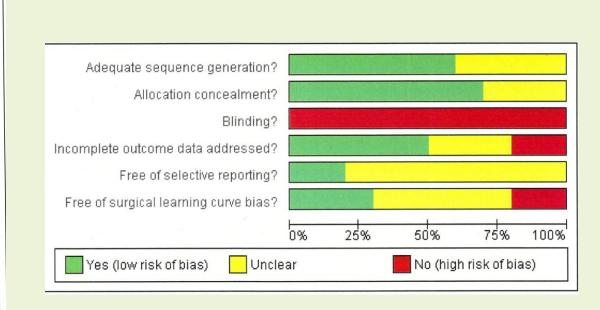


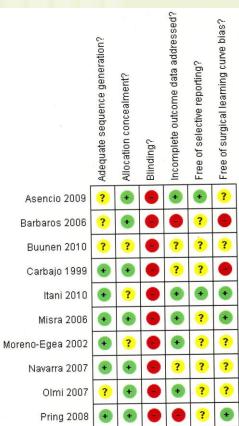


Laparoscopic versus open surgical techniques for ventral or incisional hernia repair

Sauerland S. The Cochrane Collaboration 2011

10 RCTs: 880 patients









Laparoscopic versus open surgical techniques for ventral or incisional hernia repair

Sauerland S. The Cochrane Collaboration 2011

Main results:

- 1. Not recurrence rate differences (follow up < 2 years)
- 2. Operative time too heterogeneous to be pooled
- 3. Intraoperative enterotomy slightly higher in LHR (5 cases vs 2 cases)
- 4. LHR **u**wound infection
- 5. LHR shortened hospital stay
- 6. Any difference in pain intensity
- 7. LHR 1 in-hospital costs



IEHS Guidelines: 17 articoli rilevanti

Recommendations

Grade B	Patients should be informed that LVHR for large hernia defects is feasible.
Grade B	Patients should be informed that LVHR for large hernias reduces the incidence of superficial SSIs compared with open repair.
Grade B	Patients should be informed that LVHR for large hernias is accompanied by less blood loss than open repair.
Grade B	Patients should be informed that LVHR for large hernias results in a shorter hospital stay than open repair.

Recommendations

For obese patients presenting with a ventral or incisional hernia, the laparoscopic approach is preferred because it
reduces the wound infection rate and complications.
For patients with a BMI of 35 kg/m ² or higher, laparoscopic ventral and incisional hernia repairs may be preferred.
In obese patients, the defect sizes are significantly larger, something that must be considered when the laparoscopic approach is advised.
For obese patients (BMI \ge 30 kg/m ²) with a defect size greater than 8–10 cm, there may be a need for additional technical steps (greater mesh fixation, more overlap, suture closure of the defect) when the laparoscopic approach is indicated.

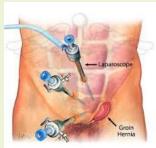


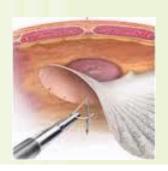
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Recommendations

Grade	Suture fixation alo	one or a combination with tacks should be
В	performed.	

- Grade The tacks-only fixation can be considered the technique of
- C choice, taking into account the increased risk of postoperative pain due to the number of devices and the need for an additional overlap of mesh (at least 5 cm) to prevent recurrence caused by shrinkage.
 - Additional glue fixation reduces the need for penetrating fixation devices and hence decreases postoperative pain and device-induced hernia.



Recommendations

The mesh used for laparoscopic repair of a ventral hernia Grade should overlap the hernia defect by at least 3 to 4 cm in В all directions For proper fixation and incorporation of the mesh dissection Grade of anatomic structures such as the falciform ligament, the С ligamentum teres and the prevesical fatty tissue should be done. A large overlap of the defect by mesh is necessary, with a minimum of 5 cm if the mesh is fixed without transfascial sutures. A larger overlap is recommended for larger hernias than the overlap used for small hernias. To avoid recurrences, the entire incisional scar should be covered by the mesh, even if the defect is overlapped 3 to 5 cm in all directions.



Fibrin sealant for mesh fixation in laparospcopic umbilical hernia repair: 1-year results of a randomized contolled double-blinded study

Eriksen JR Hernia 2013;17(4):511-4





Umbilical hernia defects 1.5-5 cm

40 patients enrolled

12 cm circular mesh

Fibrin sealant

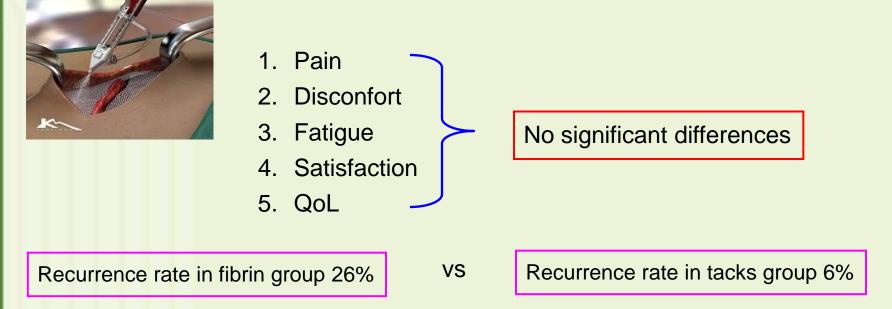
Tack fixation

Follow up 12 months



Fibrin sealant for mesh fixation in laparospcopic umbilical hernia repair: 1-year results of a randomized contolled double-blinded study

Eriksen JR Hernia 2013;17(4):511-4



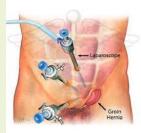
Conclusion: patients with larger hernia defects and fibrin sealant mesh fixation had higher recurrence rates than expected......The beneficial effects of mesh fixation with fibrin sealant.....warrant further studies on optimization of the surgical tecnique to prevent recurrence nda Ospedaliere Universitaria Pisane Dpartimento di Gastroenterologia e Malattie Infective E.O. Chirargia Generale Direttare: Dott, Piere Buccianti



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VS



IEHS Guidlines: 38 articles

Statements

Operating room time

The open and laparoscopic techniques do not differ Level 1A Some studies show longer and others shorter operating Level 1B room (OR) time for the laparoscopic technique. The results are inconclusive

Bowel injury

The laparoscopic approach carries a higher risk for Level 1A bowel injury

Seroma

The results are heterogeneous, showing no significant Level 1 A difference between the open and laparoscopic techniques

Wound infection

The laparoscopic approach has a significantly lower Level 1 A risk for wound infections

Recommendations

Laparoscopic repair is preferred because of a Grade A significantly reduced risk of surgical-site infection



IEHS Guidlines: 65 articles

Statements

Level 1a	Laparoscopic incisional and ventral hernia repair (LIVHR) significantly reduces hospital stay compared with open repair
Level 1b	Hospital stays are comparable after suture fixation and tacks fixation
Level 2b	The hospital stay is significantly shorter after LIVHR than after open repair for patients with hernias larger than 15 cm
Level 3	The hospital stay is shorter after LIVHR for primary ventral hernia than after incisional hernia

Mesh Repair

Recommendations

Grade A Based on the shorter hospital stay, LIVHR is the preferred operative technique

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VS



IEHS Guidlines: 38 articles

Statements

Level 1a	The cost of surgery is higher for laparoscopic procedure, but a shorter hospital stay may make laparoscopic surgery more cost effective
Level 1b	Suture fixation is a cost-effective alternative to tacks fixation for small and medium-sized defects in anatomically accessible areas
	Open repair is nine times cheaper than laparoscopic repair
	A shorter hospital stay is likely to reduce the total direct hospital cost
Level 3	Laparoscopic repair is costlier than open repair in terms of hospital cost but has a decreased mean overall cost
Level 5	A self-adhering prosthesis may decrease the cost of these procedures

Recommendations

Grade A	Suture fixation in laparoscopic incisional hernia repair is recommended

Grade D	Laparoscopic incisional hernia repair can be
	recommended as a cost-effective repair

Statements

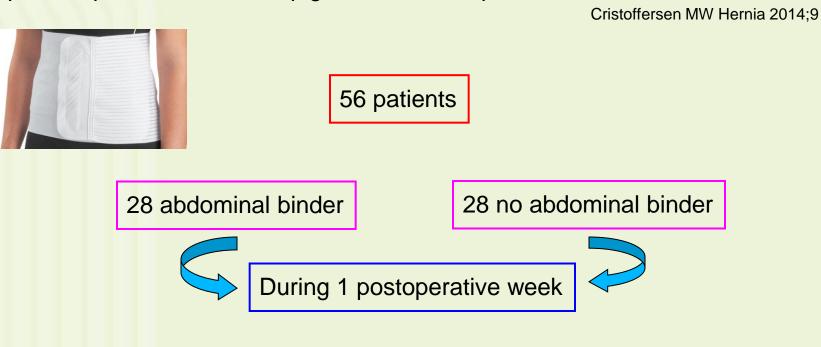
Level 1a	Quality of life (QOL) does not differ between open and laparoscopic repairs of incisional and ventral hernia
Level 1b	Use of absorbable sutures with tacks leads to better QOL than tacks with nonabsorbable sutures or tacks only
	The QOL does not differ between suture and tacks fixation in laparoscopic repair of incisional and ventral hernia
Level 2b	Laparoscopic repair leads to significant improvement in QOL compared with open repair
Level 4	Laparoscopic ventral hernia repair leads to a significant improvement in QOL experienced by the patient
	Patient satisfaction is higher after laparoscopic ventral hernia repair than after open repair
Level 5	Patients are satisfied cosmetically after suture fixation

Recommendations

Grade A Laparoscopic repair is recommended because it gives a OOL comparable with that of open repair



Randomized clinical trial on the postopeartive use of abdominal binder after laparoscopic umbilical and epigastric hernia repair.



Conclusions: there were no effects of an abdominal binder on pain, movement limitation, fatigue, seroma formation, general well-being, or QoL. However, most patients claimed a subjective beneficial effects of using abdominal binder



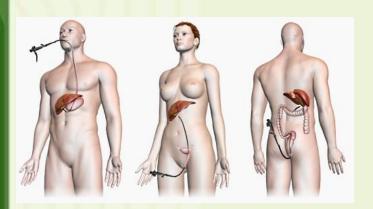
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Pure transvaginal umbilical hernia repair

Wood SG Surg Endosc 2013 Aug;27(8):2966



CONCLUSIONS: Our initial experience with transvaginal ventral hernia repair in humans suggests that this procedure is feasible and safe. This approach may improve cosmesis and decrease the risk of future ventral hernias. Potential cons may include a longer operative time, mesh infection and risk of visceral injury with a pure transvaginal approach. As transvaginal surgery evolves, techniques and devices will become increasingly refined to tackle these challenges.

Statements

Level 1	Mesh placement via NOTES is technically feasible but has a high infection rate
Level 4	The risk of infection is much higher than in open or laparoscopic transabdominal ventral hernia repair
	The vaginal wall seems to be a safer entry site compared to the gastric wall

Recommendations

Grade C Access and development of an effective delivery device (which eliminates the contamination of the mesh through a colonized route) is necessary before trials can be started in humans

Comparative studies are necessary to verify the feasibility and success rate of this new methodology



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