Evidence-Base Medicine Conference

Pediatric Inguinal Hernia: Laparoscopic Versus Open Surgery

住院醫師 蘇家弘

指導醫師 張鈺堂

Patient Profile

- Chart No: 19958427
- Name:殷x孝
- Gender: male
- Age: 11 year-old
- Date of admission: 98/2/4

Case summary

- This 11 year-old boy was generally well-being before.
- left palpable groin mass was noted by the family one year ago
- The mass characterized as: about 2 x 2 cm in size, elastic, movable, painless, and reducible manually
- PE: reducible left groin mass near the pubic tubercle with soft consistency.
- Positive silk glove sign

Case summary

- Impression: left inguinal hernia
- Operation: laparoscopic herniorrhaphy

EBM五大步驟

- Asking a answerable question
- Tracking down the best evidence
- Critical appraisal
- Integrating the appraisal with clinical expertise and patients' preference
- Auditing performance and evaluation

Systematic Reviews and Meta-analyses
Randomized Controlled Double Blind Studies
Cohort Studies
Case Control Studies
Case Series
Case Reports
Ideas, Editorials, Opinions
Animal research
In vitro ('test tube') research

Asking a answerable question

- Laparoscopic Versus Open Herniorrhaphy: Which way to go ?

The role of laparoscopic surgery in pediatric inguinal hernia repair

Laparoscopic Versus Open Herniorrhaphy

PICO model

Patient	Pediatric inguinal hernia
Intervention	Laparoscopic herniorrhaphy
Comparison	Open herniorrhaphy
Outcome	Operative time, length of hospital stay, post operative pain, complication rate and cost

Acquire

- Key words: Pediatric inguinal hernia，Laparoscopic，Open surgery
- Database:
  - Cochrane library: 0
  - UpToDate: 0
  - EBMR: Cochrane Central Register of Controlled Trials: 0
  - EBM Reviews: 0
  - PubMed: 3

Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)

Level	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR† validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval‡)	Individual inception cohort study with > 80% follow-up; CDR† validated in a single population	Validating** cohort study with good††† reference standards; or CDR† tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts††	All or none case-series	Absolute better-value or worse-value analyses ††††
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level >2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level >2 economic studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split-sample§§§ only	Exploratory** cohort study with good†††reference standards; CDR† after derivation, or validated only on split-sample§§§ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study		Non-consecutive study; or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies***)	Case-control study, poor or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

Searching Results

- Prospective, randomized, single-center, single-blind comparison of laparoscopic vs open repair of pediatric inguinal hernia

  Surg Endosc (2005) 19: 927–932
- Minimal access surgery of pediatric inguinal hernias: a review

  Surg Endosc (2008) 22:1751–1762
- One-Trocar Laparoscopic Transperitoneal Closure of Inguinal Hernia in Children

  World J Surg (2008) 32:2459–2463

Prospective, randomized, single-center, single-blind comparison of laparoscopic vs open repair of pediatric inguinal hernia

K. L. Chan, W. C. Hui, P. K. H. Tam

Surg Endosc (2005) 19: 927–932

Background

- The repair of indirect inguinal hernia (IH) is one of the most common pediatric surgical procedures, and open surgery (OS) is the standard treatment.
- The aim of this study was to determine whether the recently developed laparoscopic repair (LR) of IH is superior to OS.

Methods

- Between February 2003 and February 2004, we randomly assigned 83 consecutive IH patients at our institution into OS and LR groups.
- Two pain scales, the children and Infants Postoperative Pain were used to assess postoperative pain.
- Acetaminophen (15 mg/kg/dose every 6 h) was given at a fixed pain score. Analgesic doses were compared.
- Parents also provided assessments of their childrens recovery and wound appearance.

Endpoints

- The primary goal of the study was to differentiate the two groups in terms of use of acetaminophen analgesia.
- The secondary goals were to compare the two groups in terms of the recovery and wound appearance scores given by the parents
- The operative time, and the time to full recovery.

Costs of the consumables used in the two types of operation were also compared.

Results (1)

- Randomization was successful, and the two groups were similar in baseline characteristics

Table 3. Baseline characteristics of 83 pediatric patients undergoing open or laparoscopic (Lap) hernia repair

	Open (n = 42)	Lap (n = 41)	p value
Age (mo)	46 ± 34.2	56 ± 45.67	0.254
No of patients aged ≤ 3 yr	20	19	0.663
Sex	33 boys, 9 girls	34 boys, 7 girls	0.782
Side of hernia	Left (17), right (23) bilateral (2)	Left (17), right (23), bilateral (1)	0.89
Fantanyl (μg/kg/min	0.0563 ± 0.022	0.0670 ± 0.038	0.136
Follow-up (mo)	11.786 ± 2.545	12.207 ± 2.83	0.478

Results (2)

Table 4. Operative, postoperative analgesic, recovery and complication data for 83 patients undergoing open or laparoscopic (LAP) hernia repair

	Open (n = 42)	Lap (n = 41)	p value
Bilateral hernias found at operation	2	13	0.006
Operative time (unilateral) (min)	18.38 ± 5.71	23.25 ± 6.26	0.001
Operative time (bilateral) min	39.08 ± 13.37	34.0 ± 6.26	0.623
Acetaminophen (dose)/patient	1.05 ± 1.248	0.54 ± 0.84	0.032
Time to resume feeding (h)	2.6 ± 1.298	3.09 ± 1.479	0.113
Time to discharge (h)	10.30 ± 4.92	10.66 ± 5.319	0.127
Time to resume full activity (h)	57.71 ± 27.478	48.21 ± 28.683	0.127
Recovery score	90.24 ± 6.044	95.37 ± 5.957	0.000
Wound score	84.29 ± 7.696	97.56 ± 5.376	0.000
Complications			
Hypertrophic scar	2	1	1.000
Transient hydrocele	0	1	0.494
Skin sensitivity to dressing	0	2	1.000
Postoperative vomiting	1	0	1.000
Stitch granuloma	1	0	1.000
Contralateral hernia	5	0	0.026

Results (3)

Table 5. Comparison of the costs of consumables (in US $) for 83 patients undergoing open or laparoscopic (LAP) hernia repair

	Cost	Open	Lap
Stitches			
Prolene	$3	—	1
Vicryl	$2	2	—
Monocryl	$6	1	1
Primipore dressing	$0.25	1	3
Sterile strip	$0.50	1	1
Marcaine (0.5%)	$5	1	1
Sterile cable cover	$3	—	1
Carbon dioxide (10 L)	$0.20	—	1
Antimist (1 ml)	$0.50	—	1
Total		$15.75	$18.95

Conclusions

- In pediatric patients with IH, the outcome of LR is superior to OS with regard to postoperative pain, recovery, and cosmesis.
- Laparoscopic hernia repair also enables the detection of contralateral hernias so that they can be repaired in the same operative setting.
- For unilateral repair, LR takes slightly more time than the open procedure, but there is no difference in the operative time for bilateral hernias.
- Finally, the cost of consumables is marginally higher for LR than for OS.

Appraisal – therapy study

Was the assignment of patients to treatments randomised?

What is best?	Where do I find the information?
Smaller trials may use an *independent* person (e.g, the hospital pharmacy) to "police" the randomization.	The ***Methods*** should tell you how patients were allocated to groups and whether or not randomisation was concealed.

This paper: Yes ☑ No ☐ Unclear ☐

Appraisal

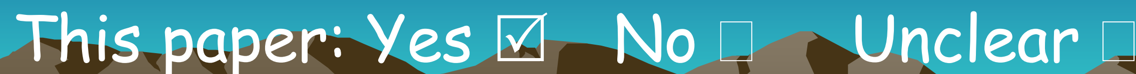
Were the groups <u>similar</u> at the start of the trial?

What is best?

If the randomisation process worked (that is, achieved comparable groups) the groups should be similar. The more similar the groups the better it is. There should be some indication of whether differences between groups are statistically significant (ie. p values).

Where do I find the information?

The ***Results*** should have a table of "Baseline Characteristics" comparing the randomized groups on a number of variables that could affect the outcome (ie. age, risk factors etc). If not, there may be a description of group similarity in the first paragraphs of the ***Results*** section.



This paper: Yes ☑ No □ Unclear □

Appraisal

Aside from the allocated treatment, were groups treated equally?

What is best?

Apart from the intervention the patients in the different groups should be treated the same, eg., additional treatments or tests.

Where do I find the information?

Look in the ***Methods*** section for the follow-up schedule, and permitted additional treatments, etc and in ***Results*** for actual use.

Appraisal

Were all patients who entered the trial accounted for? – and were they analysed in the groups to which they were randomised?

What is best?

Losses to follow-up should be minimal – preferably less than 20%. if few patients have the outcome of interest, then even small losses to follow-up can bias the results.

Where do I find the information?

The ***Results*** section should say how many patients were randomised (eg., Baseline Characteristics table) and how many patients were actually included in the analysis. You will need to read the results section to clarify the number for losses to follow-up.

This paper: Yes ☑ No ☐ Unclear ☐

Appraisal

Were measures <u>objective</u> or were the patients and clinicians kept "<u>blind</u>" to which treatment was being received?

What is best?

It is ideal if the study is 'double-blinded' – that is, both patients and investigators are unaware of treatment allocation. If the outcome is *objective* (eg., death) then blinding is less critical. If the outcome is *subjective* (eg., symptoms or function) then blinding of the outcome assessor is critical.

Where do I find the information?

First, look in the ***Methods*** section to see if there is some mention of masking of treatments, eg., placebos with the same appearance or sham therapy. Second, the ***Methods*** section should describe how the outcome was assessed and whether the assessor/s were aware of the patients' treatment.

External Validity / Applicability

- The outcome of LR is superior to OS with regard to postoperative pain, recovery, and cosmesis.
- It is recommended that laparoscopic herniorrhaphy should be used for pediatric inguinal hernia.

Thanks for your attention!