*Consensus statement*

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# The E.A.E.S Consensus Development Conferences on laparoscopic cholecystectomy, appendectomy, and hernia repair

## Consensus statements — September 1994

**The Educational Committee of the European Association for Endoscopic Surgery and other interventional techniques (E.A.E.S.).**
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**Abstract.** Under the mandate of the Educational Committee of the European Association of Endoscopic Surgery (E.A.E.S.), three consensus development conferences (CDCs) were performed in order to assess the current status of the endoscopic surgical approaches for the treatment of cholelithiasis, appendicitis, and inguinal hernia. Consensus panels for the different disease states (10–13 members each) selected by the education committee on the basis of members' clinical expertise, academic activity, community influence, and geographical location weighed the evidence on the basis of published results according to the criteria for technology assessment: feasibility, efficacy, effectiveness, economy. Draft statements were prepared, discussed by the panels, and presented at plenary sessions of the 2nd European Congress of the E.A.E.S. in Madrid September 15–17, 1994. Following discussions final consensus statements were formulated to provide specific answers for each topic to a minimum of the following questions:

1. What stage of technological development is the endoscopic surgical procedure at (in September 1994)?
2. Is endoscopic surgery safe and feasible?
3. Is it beneficial to the patients?
4. Who should undergo endoscopic surgery?
5. What are the training recommendations?

Laparoscopic cholecystectomy is the procedure of choice for symptomatic cholelithiasis. Laparoscopic appendectomy is presently at the efficacy stage of development, because most of the data on feasibility and safety originate from centers with special interest in endoscopic surgery: it is not yet the gold standard for acute appendicitis. Endoscopic hernia repair is presently a feasible alternative for conventional hernia repair if performed by experienced endoscopic surgeons. It appears to be efficacious in the short-term. The full text of the consensus panel's statements is given in this publication.

**Key words:** Consensus development conferences — Laparoscopic cholecystectomy — Laparoscopic appendectomy — Laparoscopic inguinal hernia repair

In the history of surgery, probably no other surgical development had such a dramatic and pivotal impact on surgery worldwide as endoscopic surgery. There is indeed no field in surgery which is not affected by endoscopic surgery. However, experience with this "new" tool has shown serious limitations and dangers of endoscopic surgical procedures, especially in less-experienced hands. Furthermore, it is not sufficient to demonstrate that an endoscopic surgical approach is feasible and safe; it must also be ascertained that the specific technique has a real benefit for the patients. Large international societies such as the European Association for Endoscopic Surgery (E.A.E.S.) have the responsibility to provide a forum for discussion of new developments and to provide guidelines on the best practice in the different fields based on the current state of knowledge. For this reason, the Educational Committee of the E.A.E.S. decided to perform con-

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sensus development conferences (CDCs) to assess the current status of endoscopic surgical approaches for treatment of cholelithiasis, appendicitis, and inguinal hernia. These topics were chosen because of: (1) importance in terms of prevalence and economy, (2) multidisciplinary interest, (3) scientific controversy, and (4) the existence of sufficient research data for evaluation. The second international European Congress of the E.A.E.S., in Madrid, September 15–17, 1994, was chosen as a forum for these consensus development conferences. The method, the same for all three CDCs, and the specific results given as answers to previously posed questions are presented in this comprehensive article.

## Methods

At their annual meeting in November 1993, the Educational Committee of th E.A.E.S. decided to perform three consensus development conferences (CDCs) on the topics mentioned. The second European Congress of the E.A.E.S. in September in Madrid should be the forum for a public session to discuss the final consensus statements. The Cologne group (Chairmen: H. Troidl, E. Neugebauer) was authorized to organize the CDCs according to general guidelines in format and conduct (see editorial, this issue of *Surgical Endoscopy*). The procedure chosen was the following:

A small group of panelists (10–13 members for each conference) was nominated by the Educational Committee of the E.A.E.S. Criteria for selection were (1) clinical expertise in the field of endoscopic surgery, (2) academic activity, (3) community influence, and (4) geographical location. Two chairpersons were determined and all of them (panelists and chairpersons) were asked to provide written agreements to participate. Four months prior to the conferences, each panelist got (i) a table with guidelines to use to estimate the strength of evidence in the literature for the specific endoscopical procedure, and (ii) a table with the description of the levels of technology assessment (TA) according to Mosteller (1985)[1]. Each panelist was asked to indicate what level of development, in his opinion, the endoscopic procedure had attained in general and was given (iii) a table with specific parameters of TA, relevant to the endoscopic procedure under assessment. In this table, the panelists were asked to indicate the status of the endoscopic procedure in comparison with conventional open procedures. The panelists' view must have been supported by evidence in the literature—a reference list was mandatory for each item in this table (always Table 1 in the results section of each CDC). Each panelist was given (iv) a list of relevant specific questions pertaining to each procedure (questions on indication, technical aspects, training, etc.). The panelists were asked to provide brief answers with references. Guidelines for response were given and the panelists were asked to send their initial evaluations back to the conference organizers 2 months prior to the conference. The next step was to compile and to analyze the initial evaluation of the panelists and to prepare provisional consensus statements and tables for each topic by the conference organizers. These drafts were then posted to each panelist prior to the Madrid panel meetings. At this time point, a complete list of the whole panel group was released to each panelist. In a 2-h session of each panel in Madrid, all statements and tables were discussed and modified if necessary under the leadership of the chairperson selected. When full agreement could not be obtained, the consensus was formulated on majority agreement. The consensus results of each panel were presented at the same day to the participants of the second European Congress of the E.A.E.S. in topic-related plenary sessions by one of the chairpersons. Following discussion final consensus statements were formulated by the panel. The full text of the statements is given below.

[1] Mosteller F. (1985) *Assessing Medical Technologies*, National Academic Press, Washington D.C.

# 1. Results of E.A.E.S. Consensus Development Conference on Laparoscopic Cholecystectomy

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Panelists: A. Cuschieri, Department of Surgery, University of Dundee, Ninewells Hospital 1 Dundee, Great Britain; T. C. Dupont, Jefe del Opto de Cirugia, Hospital Universitario Virgen del Rocio, Sevilla, Spain; M. Garcia-Caballero, Department of Surgery, Medical Faculty, Malaga, Spain; J. F. Gigot, Department de Chirurgie Digestive, St. Luc Hospital, Bruxelles, Belgique; H. Glise, Department of Surgery, Norra Älsborgs, Länssjukhus-NAL, Trollhättan, Sweden; C. Liguory, CMC Alma, Paris, France; M. Morino, Surgical Clinic, University of Torino, Torino Italy; M. Rothmund, Department of Surgery, University of Marburg, Marburg, Germany.

### *Literature list with rating*

All literature submitted by the panelists as supportive evidence for their evaluation was compiled and rated (Table 2). Only papers of grade I and above were considered. The consensus statements were based on these published results.

### *Question 1. What stage of technological development is laparoscopic cholecystectomy (LC) at (in Sept. 1994)?*

The definitions for the stages in technological development follow the recommendations of the Committee for Evaluating Medical Technologies in Clinical Use. The panel's evaluation as to the attainment of each technological stage by laparoscopic cholecystectomy, together with the strength of evidence in the literature, is presented in Table 3.

LC is the procedure of choice for symptomatic uncomplicated cholelithiasis. As it is not possible to conduct randomized trials on LC vs open surgery anymore, it is important for all surgeons to audit continually the results of LC. Results of analyses on its cost effectiveness and cost benefits are dependent on the health-care system. Open cholecystectomy remains the standard for comparison.

### *Question 2: Who should undergo LC?*

1. The indications for cholecystectomy remain unchanged. LC is indicated for patients who are able to tolerate general anesthesia without undue risk. It is also indicated in patients with calcified (porcelain) gallbladders.
2, Asymptomatic cholelithiases, in general, do not

**Table 1.** Evaluation of feasibility and efficacy parameters for laparoscopic cholecystectomy by the panelists before the final discussion

| Stages of technology Assessment | Definitely better | Probably better | Similar | Probably worse | Definitely worse | % of consensus[a] | Strength evidence 0–III |
|---|---|---|---|---|---|---|---|
| **Feasibility:** | | | | | | | |
| Safety (intra-op) | | | 2 | 5 | 1 | 75% | II |
| Operation time | | | 4 | 4 | | 50% | II |
| Postop complications | 1 | 3 | 4 | | | 50% | II |
| Mortality | 1 | 1 | 6 | | | 75% | II |
| **Efficacy:** | | | | | | | |
| Postoperative pain | 8 | | | | | 100% | II |
| Hospital stay | 8 | | | | | 100% | III |
| Return to normal activities | 8 | | | | | 100% | III |
| **Cosmesis** | 8 | | | | | 100% | II |
| **Overall assessment** | 5 | 3 | | | | 100% | II |

[a] Percentage of consensus was calculated by dividing the number of panelists who voted better (probably and definitely), similar, or worse (probably and definitely) by the total number of panelists who submitted their evaluation forms (8)
[b] Refer to Table 2 for definitions of grading system

warrant cholecystectomy. Most of the patients remain asymptomatic. It is also rare for complications to occur without symptoms appearing first. Patients with symptomless gallstones that should be followed up closely include:

i. Diabetics
ii. Those with sickle cell disease
iii. Children
iv. Those on long-term somatostatin
v. Those on immunosuppressive drugs

3. In the following conditions, LC is usually contraindicated.
   i. Generalized peritonitis
   ii. Septic shock from cholangitis
   iii. Severe acute pancreatitis
   iv. Cirrhosis with portal hypertension
   v. Severe coagulopathy that is not corrected
   vi. Cholecysto-enteric fistula
4. Extreme caution should be taken in the following groups of patients.
   i. Severe associated cardiorespiratory diseases
   ii. Previous upper abdominal surgery
   iii. Acute cholecystitis
   iv. Symptomatic cholecystitis in the second trimester of pregnancy

These cases should be performed only by an experienced team.

*Question 3: Is LC safe and feasible?*

1. The incidence of common bile duct injury is still slightly higher than open surgery. Vascular injury and bowel injury are specific to LC. This is due to surgeon inexperience, limitations of the two-dimensional view, lack of tactile sensation, and extension of indication to more difficult cases. Adequate training with close supervision and strict accredition is required.
2. Operation time is similar or longer than the open procedure.
3. Morbidity from wound complications and postoperative recovery period are reduced with LC.

**Table 2.** Ratings of published literature on laparoscopic cholecystectomy

| Study type | Strength of evidence | Ref. |
|---|---|---|
| Clinical randomized controlled studies with power and relevant clinical endpoints. | III | 5, 26, 30, 37 |
| Cohort studies with controls<br>Prospective, parallel controls<br>Prospective, historical controls<br>Case-control studies | II | 6, 16, 19, 23, 25, 27, 29, 34, 36, 43, 44, 49, 53, 54, 57, 59 |
| Cohort studies with literature controls<br>Analysis of databases<br>Reports of expert committees | I | 1–4, 7–15, 17, 18, 20–22, 24, 28, 31–33, 35, 38–42, 45–48, 50–52, 55, 56, 58, 60–65 |
| Case series without controls<br>Anecdotal reports<br>Belief | 0 | not evaluated |

**Table 3.** Evaluation of stage of technology attained and strength of evidence

| Stages in technology assessment[a] | Level attained/ strength of evidence[b] |
|---|---|
| 1. Feasibility<br>Technical performance, applicability, safety, complications, morbidity, mortality | III |
| 2. Efficacy<br>Benefit for the patient demonstrated in centers of excellence | III |
| 3. Effectiveness<br>Benefit for the patient under normal clinical conditions, i.e., good results reproducible with widespread application | II |
| 4. Costs<br>Benefit in terms of cost-effectiveness | I |
| 5. Gold standard | Yes |

[a] Mosteller F (1985) *Assessing Medical Technologies*. National Academy Press, Washington, D.C.
[b] Level attained, and if so, the strength of evidence in the literature as agreed upon by the panelists. Please refer to Table 2 for the definitions of the different grades

4. Mortality risk is similar.
5. In pregnant women, the risk of $CO_2$ pneumoperitoneum on the fetus in the first trimester is not fully known. LC in the third trimester should be avoided as it is technically difficult and carries a risk of injuring the uterus. Only in the second trimester is LC relatively safe, but it should only be performed by experienced operators in severely symptomatic or complicated cholelithiasis.
6. For acute cholecystitis, publications of data on small numbers of patients by keen endoscopic surgeons have reported complication rates not more than routine LC, even when performed in the same admission. However, the true safety cannot be known until more data are available. The threshold for conversion should be low. Indications for conversion include:
   i. Unclear anatomy
   ii. Gangrenous, friable gallbladder that is difficult to handle
   iii. Bleeding
   iv. technical problems
   v. Unduly long operation time with no progress

*Question 4: Is it beneficial to the patients?*

1. LC leads to markedly less postoperative pain, shorter hospital stay, earlier return to normal activities, and better cosmesis.
2. In general, LC has a distinct advantage over open cholecystectomy.

*Question 5: How should common bile stones be managed?*

1. The optimal management of common bile duct stones (CBDS), which are present in 10–15% of patients, is not well defined. The common bile duct should be imaged in patients with a previous or present history of jaundice or pancreatitis, or abnormal liver function tests, or when ultrasonography reveals a dilated CBD. Either preoperative ERCP[2] or preoperative IV cholangiography (IVC) or intraoperative cholangiography (IOC) can be used to image the duct.
2. ERCP is the most reliable modality for confirming the presence of CBDS preoperatively in patients with abnormal biochemical or ultrasound findings. Endoscopic sphincterotomy (ES) and stone clearance is currently the established treatment for these patients, and is followed by LC. Studies are needed to compare the two-stage treatment (ERCP, ES + LC) with the single-stage laparaoscopic intervention (LC + laparoscopic removal of CBDS).
3. CBDS found on IOC[3] can be treated by (1) open exploration, (2) laparoscopic exploration, (3) intraoperative ERCP, (4) postoperative ERCP, (5) careful observation, depending on the expertise available. Open exploration remains the standard tech-

[2] Endoscopic retrograde cholangiopancreatography
[3] Intraoperative cholangiogram

nique. Laparoscopic techniques of exploration are under evaluation. Postoperative ERCP has the risk, albeit low, of failure.

*Question 6. What are the special technical aspects to be considered during LC?*

1. If problems are encountered during $CO_2$ insufflation with the Veress needle, the open technique should be used.
2. The junction between the cystic duct and the gallbladder must always be clearly defined. Dissection of the junction between the cystic duct and the CBD is not necessary. Dissection in this area, principally done to identify the CBD, is, however, associated with the risk of inadverent damage to the CBD itself.
3. Coagulation in Calot's triangle should be kept to a minimum. If needed, either bipolar or soft monopolar (<200 mV) coagulation is preferred.
4. Either metal clips (at least two) or locking clips are safe for securing the cystic artery and duct. In event of a large cystic duct, a ligature is safer.
5. The prevention of CBD damage by routine intraoperative cholangiogram (IOC) is not proven. However, IOC allows immediate detection of the injury and thus primary repair with better prognosis. IOC should be done when (1) anatomy is not well seen; (2) duct injury is suspected; (3) common bile duct stones are suspected. All surgeons should be trained to perform IOC.
6. To avoid injury to the CBD, the following principles should be adhered to:
   i. Unambiguously identify the structures in Calot's triangle
   ii. Avoid unnecessary coagulation
   iii. Dissect starting from the gallbladder–cystic duct junction
   iv. Perform IOC when the anatomy is not clear
   v. Convert to open surgery when in doubt
7. Drainage is usually not required.
8. Suturing of trocar sites 10 mm or more is recommended especially when such a site has been dilated or extended for extraction of the gallbladder.

*Question 7. What are the training recommendations for LC?*

Refer to E.A.E.S. guidelines published in *Surgical Endoscopy* 1994;8:721–722.

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(Grading of references is given in Table 2)


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## 2. Results of E.A.E.S. Consensus Development Conference on Laparoscopic Appendectomy

Chairman: E. Eypasch, 2nd Department of Surgery, University of Cologne, Germany; C.K. Kum, Department of Surgery, National University Hospital, Singapore.

Panelists: O.J. McAnenna, Surgical Unit, University College Hospital, Galway, Ireland; M. McMahon, Leeds Institute for Minimally Invasive Therapy, The General Infirmary, Leeds, Great Britain; S. Attwood, Meath Hospital, Dublin, Ireland; E. Schippers, Department of Surgery, Clinic RWTH, Aachen, Germany; J. Jakimowicz, Department of Surgery, Catharina Hospital, Eindhoven, The Netherlands; W. van Erp, Department of Surgery, Diaconessenhuis, Eindhoven, The Netherlands. P. Testas, Service de Chirurgie Générale, Centre Hôspitalier Bicêtre, Le Kremlin-Bicêtre Cedex, France; J.A. Lujan Mompean, Department of General Surgery, University Hospital "Virgen de la Arrixaca," El Palmar, Murcia, Spain; J.S. Valla, Hôpital pour Enfants, Nice, France.

*Literature list with rating*

All literature submitted by the panelists as supportive evidence for their evaluation was compiled and rated (Table 2). The consensus statements were based on these published results.

*Question 1. What stage of technological development is laparoscopic appendectomy (LA) at (in Sept. 1994)?*

The definitions for the stages in technological development follow the recommendations of the Committee for Evaluating Medical Technologies in Clinical Use. The panel's evaluation as to the attainment of each technological stage by laparoscopic appendectomy, together with the strength of evidence in the literature, is presented in Table 3.

LA is presently at the efficacy stage of development because most of the data on feasibility and safety originate from centers with a special interest in endoscopic surgery. More data on its use in general and district hospitals are needed to ascertain its effectiveness. Detailed analysis on its cost-effectiveness and cost benefits is also lacking. Although a very promising procedure, it is not yet the gold standard for acute appendicitis.

*Question 2: Is LA safe and feasible?*

1. There is no evidence in published literature that LA is any less safe than open appendectomy (OA).
2. Operation time, depending on the experience of the surgeon, is similar or longer than the open procedure.
3. Postoperative complications—e.g., bleeding, intraabdominal abscess, reoperation—are not more frequent than OA in the published literature. However, the morbidity associated with widespread application is not yet known.
4. LA is not contraindicated for perforated appendicitis. However, more data for this subgroup of patients is needed.
5. LA may be attempted for an appendiceal abscess by an experienced surgeon if the abscess is to be treated early. Conversion to open surgery should be undertaken when difficulties are encountered. Alternatively, delayed elective LA can be performed after resolution of the abscess with antibiotic therapy.
6. LA can be used in children. It should be performed only by surgeons with ample experience in adult LA. Smaller instruments should be available to improve safety and ergonomy.
7. The safety of LA during pregnancy is not established.
8. The indication for elective LA is the same as for open elective appendectomy.

*Question 3: Is it beneficial to the patients?*

1. Laparascopy improves the diagnostic accuracy of acute right iliac fossa pain, especially in children and young women.
2. LA reduces wound infection rate.
3. There is less postoperative pain in adults. There are no data in children.
4. Hospital stay is similar or less than OA.
5. LA allows earlier return to normal activities.
6. The laparoscopic approach may lead to less postoperative adhesions.
7. Cosmesis may be better than OA.
8. All in all, LA has advantages over OA. However, the potential for serious injuries must be appreciated and avoided in order to make the postoperative advantages worthwhile.

*Question 4. What are the special technical aspects to be considered during LA?*

The statements here are meant to be guidelines. The surgeon at the operating table has to be the ultimate judge as to what is safe to do.

1. Convert to open surgery if the appendix cannot be found.
2. At diagnostic laparoscopy, there is no obligation to remove the appendix.
3. Bipolar coagulation is a perferred mode of coagulating the artery. Monopolar diathermy may be safe if the appropriate precautions are taken. Use of clips alone or in combination with coagulation is the alternative. Suture ligation of the artery is usually unnecessary. Lasers and staples are not cost-effective.
4. When the base of the appendix is healthy and uninflamed, one properly applied preformed ligature is probably enough. If in doubt, use two loops.

**Table 1.** Evaluation of feasibility and efficacy parameters for laparoscopic appendectomy by the panelists before the final discussion

| Stages of Technology assessment | Definitely better | Probably better | Similar | Probably worse | Definitely worse | % of consensus[a] | Strength of evidence 0–III[b] |
|---|---|---|---|---|---|---|---|
| **Feasibility:** | | | | | | | |
| Safety | | 1 | 8 | 2 | | 73% | II |
| Operation time | | | 3 | 7 | 1 | 73% | III |
| Postop complications | 1 | 6 | 4 | | | 64% | II |
| Mortality | | | 9 | 1[c] | | 82% | I |
| **Efficacy:** | | | | | | | |
| Diagnostic accuracy | 7 | 4 | | | | 100% | II |
| Wound infection | 8 | 3 | | | | 100% | III |
| Postoperative pain | 4 | 6 | 1 | | | 91% | II |
| Hospital stay | 2 | 6 | 3 | | | 73% | II |
| Return to normal activities | 5 | 5 | 1 | | | 91% | III |
| Postoperative adhesions | 1 | 7 | 2[c] | | | 73% | I |
| **Cosmesis** | 4 | 4 | 2[c] | | | 73% | 0 |
| **Overall Assessment** | 3 | 6 | 1 | 1 | | 73% | II |

[a] Percentage of consensus was calculated by dividing the number of panelists who voted better (probably and definitely), similar, or worse (probably and definitely) by the total number of panelists [11]
[b] Refer to Table 2 for definitions of grading system
[c] One panelist wrote "unknown" or left it blank. He is presumed to have voted with this minority group when percentage of agreement was calculated

Metal clips alone are not recommended; staples are too expensive and not required in most cases.
5. The appendix should be transected at about 5 mm from the last preformed ligature. It is unnecessary to bury the stump.
6. To avoid wound infection, the appendix should be removed through the port or if too big, within a pouch.
7. Peritoneal toilet is recommended in cases of intraabdominal contamination.
8. The antibiotic policy should be the same as for open appendectomy.

*Question 5. What are the training recommendations for LA?*

1. LA should be part of the resident's curriculum.
2. At least 20 cases of LA are needed for accredition in general surgery.

**Table 2.** Ratings of published literature on laparoscopic appendectomy

| Study type | Strength of evidence | Ref. |
|---|---|---|
| Clinical randomized controlled studies with power and relevant clinical endpoints | III | 2,6,10, 12, 23, 33 |
| Cohort studies with controls<br>Prospective, parallel controls<br>Prospective, historical controls<br>Case-control studies | II | 3, 4, 8, 13, 18, 19, 25, 27, 29, 32, 34, 36, 38 |
| Cohort studies with literature controls<br>Analysis of databases<br>Reports of expert committees | I | 1, 5, 7, 9, 14, 16, 20–22, 24, 26, 30, 37 |
| Case series without controls<br>Anecdotal reports<br>Belief | 0 | 15, 17, 28, 31, 35, 39 |

**Table 3.** Evaluation of stage of technology attained and strength of evidence

| Stages in technology assessment[a] | Level attained/ strength of evidence[b] |
|---|---|
| 1. Feasibility<br>Technical performance, applicability, safety, complications, morbidity, mortality | III |
| 2. Efficacy<br>Benefit for the patient demonstrated in centres of excellence | III |
| 3. Effectiveness<br>Benefit for the patient under normal clinical conditions, i.e., good results reproducible with widespread application | I |
| 4. Costs<br>Benefit in terms of cost-effectiveness | Unknown |
| 5. Gold standard | No |

[a] Mosteller F (1985) *Assessing Medical Technologies,* National Academy Press, Washington, D.C.
[b] Level attained, and if so, the strength of evidence in the literature as agreed upon by the panelists. Please refer to Table 2 for the definitions of the different grades


## *Summary*

Laparoscopic appendectomy is an efficacious new technology. Its safety and feasibility have been shown in the published literature, mainly from centers with a special interest in endoscopic surgery. However, a few cases of serious complications have been reported. Surgeons should be aware of the potential dangers.

Benefits for the patients, especially in terms of more accurate diagnosis, reduction of wound infection, and earlier return to work, have also been shown in controlled trials, albeit with small numbers of patients. Its effectiveness, compared to open appendectomy, when applied generally to all grades of hospitals, remains to be seen. The cost-effectiveness of LA is not known. Although promising, it is not yet the gold standard for acute appendicitis.


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(Grading of references is given in Table 2)


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## 3. Results of E.A.E.S. Consensus Development Conference on Laparoscopic Hernia Repair

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Panelists: J.-H. Alexandre, Department de Chirurgie, Hôpital Broussais, Paris, France, M. Büchler, University Hospital for Visceral and Transplantation Surgery, Bern, Switzerland, J.L. Dulucq, Department de Chirurgie, M.S.P. Bagatelle, Talence-Bordeaux, France, P. Go, Department of Surgery, University Hospital Maastricht, Maastricht, The Netherlands, J. Himpens Hôpital Universitaire St. Pierre, Department de Chirurgie, Bruxelles, Belgique, Ch. Klaiber, Department of Surgery, General Hospital, Aarberg, Switzerland, E. Laporte, Department of Surgery, Policlinica Teknon, Barcelona, Spain, B. Millat, Department de Chirurgie, Centre Hospitalier Universitaire, Montpellier, France, J. Mouiel, Department de Chirurgie Digestive, Hôpital Saint Roche, Nice, France, L. Nyhus, The University of Illinois at Chicago, College of Medecine, Department of Surgery, Chicago, U.S.A., V. Schumpelick, Department of Surgery, Clinic RWTH, Aachen, Germany

*Literature list with rating*

All literature submitted by the panelists as supportive evidence for their evaluation was compiled and rated (Table 2). The consensus statements were based on these published results.

*Question 1. Is there a need for the classification of groin hernias, and if so, which classification should be used?*

Several classifications for groin hernias have been proposed (Alexandre, Bendavid, Gilbert, Nyhus, Schumpelick). The majority of the panelists refer to Nyhus's classification (Table 3). It is suggested that this classification be applied in future trials. However, the accuracy and reproducibility of any classification in laparoscopic hernia repair still must be demonstrated.

In any case, the minimal requirements for future studies are classifications which accurately describe the defects:

- The type: direct, indirect, femoral or combined
- State of the internal ring (dilated or not)
- Presence and size of the posterior wall defect
- Size and contents of the sac
- Whether primary or recurrent

**Table 1.** Evaluation of feasibility and efficacy for laparoscopic herniorrhaphy by the panelists before the final discussion

| Stages of technology assessment | Definitely better | Probably better | Similar | Probably worse | Definitely worse | Strength of evidence[b] 0–III |
|---|---|---|---|---|---|---|
| **Feasibility:** | | | | | | |
| Safety of intraabdominal techniques | | | 6 | 5 | 1 | I |
| Safety of extraabdominal techniques (54%)[a] | 1 | 4 | 7 | 1 | | I |
| Operation time (77%) | | 2 | 1 | 8 | 2 | II |
| **Adverse events:** | | | | | | |
| Spermatic cord injury (54%) | 1 | 4 | 7 | 1 | | I |
| Testicular vessel injury (62%) | 1 | 7 | 4 | 1 | | I |
| Nerve injury (50%) | | 3 | 6 | 3 | | I |
| Ileus (intraabdominal methods) (70%) | | 1 | 2 | 4 | 3 | I |
| Bleeding (73%) | 1 | 7 | 2 | 1 | | I |
| Wound infection (70%) | 1 | 6 | 3 | | | I |
| Reoperation (50%) | 1 | 4 | 3 | 2 | | I |
| Disability (75%) | 1 | 8 | 2 | 1 | | I |
| Mortality (92%) | | | 11 | | 1 | I |
| **Efficacy:** | | | | | | |
| Postoperative pain (85%) | 4 | 7 | | 1 | 1 | II |
| Hospital stay (58%) | 3 | 4 | 4 | | 1 | II |
| Return to normal activities (75%) | 4 | 5 | 2 | | 1 | II |
| Cosmesis | 2 | 3 | 4 | | | I |

**Table 1.** Continued

| Stages of technology assessment | Definitely better | Probably better | Similar | Probably worse | Definitely worse | Strength of evidence[b] 0–III |
|---|---|---|---|---|---|---|
| Recurrence | 1 | 4 | 5 | | 1 | I |
| **Overall assessment (64%)** | | 7 | 2 | 2 | | II |

[a] Percentage of agreement calculated by dividing the number of panelists who voted better (probably and definitely), similar, or worse (probably and definitely) by the total number of panelists[9]
[b] Refer to Table 2 for definitions of grading system

**Table 2.** Ratings of published literature on laparoscopic hernia repair

| Study type | Strength of evidence | Ref. |
|---|---|---|
| Clinical randomized controlled studies with power and relevant clinical endpoints | III | 42, 43, 54 |
| Cohort studies with controls<br>Prospective, parallel controls<br>Prospective, historical controls<br>Case-control studies | II | 7, 15, 36 |
| Cohort studies with literature controls<br>Analysis of databases<br>Reports of expert committees | I | 2, 3, 5, 6, 8–10, 13, 14, 16–21, 23–35, 38–41, 44–51, 55–61 |
| Case series without controls<br>Anecdotal reports<br>Belief | 0 | 1, 4, 11, 12, 22, 37, 52, 53 |

*Question 2. In what stage of technological development is endoscopic hernia repair (in Sept. 1994)?*

Endoscopic hernia repair is presently a *feasible* alternative for conventional hernia repair if performed by *experienced* endoscopic surgeons. It appears to be *efficacious* in the *short term*. It has *not yet* reached the *effectiveness* stage in *general practice*. Detailed analysis on *cost-effectiveness* and *cost benefits* are lacking. Although some aspects of endoscopic hernia repair are very promising (e.g., recurrence and bilateral hernia), it cannot be considered the standard treatment. (See table 4.)

*Question 3. Is endoscopic hernia repair safe?*

Endoscopic hernia repair may be *as safe* as the open procedure. However, up until now, safety aspects have not been sufficiently evaluated. Most panelists agreed that it has the same potential for serious complications as in open surgery—such as postoperative ileus, nerve injury, and injuries to large vessels.

Reporting all complications, fatal or not, is encouraged and necessary for further evaluation.

**Table 3.** Nyhus classification for groin hernia[a]

| Type of hernia | Anatomical defect |
|---|---|
| I | Indirect hernia-normal internal ring |
| II | Indirect hernia-dilated internal ring |
| III A | Direct hernia-posterior wall defect |
| III B | Large indirect hernia-posterior wall defect |
| III C | Femoral hernia |
| IV | Recurrent hernia |

[a] See reference 40

*Question 4. Is endoscopic hernia repair beneficial to the patient?*

The potential reduction in the incidence of hematoma and clinically relevant wound infections has yet to be proven.

Postoperative pain seems to be diminished.

Although it seems to allow earlier return to normal activities, postoperative disability and hospital stay are highly dependent on activity, motivation, and social status of the patient as well as the structure of the health-care system.

Objective measurement (e.g., standardized exercise tests) should be developed and used to evaluate return to normal activity.

**Table 4.** Stages of technology assessment in endoscopic hernia repair

| Stages in technology assessment[a] | Level attained strength of evidence[b] |
|---|---|
| 1. Feasibility | |
| Technical performance, Applicability, Safety, Complications, Morbidity, Mortality | I |
| 2. Efficacy | |
| Benefit for the patient demonstrated in centers of excellence | II |
| 3. Effectiveness | |
| Benefit for the patient under normal clinical conditions, i.e., good results reproducible with widespread application. | 0 |
| 4. Costs | |
| Benefit in terms of cost-effectiveness | 0 |
| 5. Gold standard | No |

[a] F. Mosteller (1985) Assessing medical technologies. National Academy Press Washington
[b] Level attained, and if so the strength of evidence in the literature as agreed upon the panelists. Please refer to Table 2 for the definitions of the different grades

As in other endoscopic procedures, there is a potential for better cosmetic results.

The long-term recurrence rate for endoscopic hernia repair is not known.

*Question 5. Who is a potential candidate for endoscopic hernia repair?*

Candidates:
- Type III A–C
- Recurrences (type IV), bilateral hernia
- Type II?

Contraindications:

Absolute:
- High-risk patients for general anesthesia or conventional surgery
- Uncorrected bleeding disorders
- Proven adverse reaction to foreign material
- Major intraabdominal disease (e.g., ascites)

Relative:
- Incarcerated or scrotal (sliding) hernia
- Young age (sac resection only)
- Prior major abdominal operations

*Question 6. What concepts should be used in the future evaluation of endoscopic hernia repair?*

There is a definite need for classification and randomized controlled (multicenter) trials with clear endpoints:

- Complication and recurrence rates (>5 years, with <5% lost to follow-up)
- Pain and physical activity resumption
- Size, type, and route of mesh placement

Endoscopic techniques should be compared to conventional hernia or open preperitoneal prosthetic mesh repair techniques vs laparoscopic transabdominal preperitoneal (TAPP) and/or extraperitoneal or totally preperitoneal repair (TPP).

*Question 7. Should endoscopic hernia repair be performed outside clinical trials?*

In 1994, we recommend that endoscopic hernia repair should only be performed after appropriate training and with some sort of quality control.

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(Grading of references is given in Table 2)


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