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REVIEW

Update with level 1 studies of the European Hernia Society guidelines on the treatment of inguinal hernia in adult patients

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Abstract
Purpose In 2009, the European Hernia Society published the EHS Guidelines for the Treatment of Inguinal Hernia in Adult Patients. The Guidelines contain recommendations for the treatment of inguinal hernia from diagnosis till aftercare. The guidelines expired January 1, 2012. To keep them updated, a revision of the guidelines was planned including new level 1 evidence.
Methods The original Oxford Centre for Evidence-Based Medicine ranking was used. All relevant level 1A and level 1B literature from May 2008 to June 2010 was searched (Medline and Cochrane) by the Working Group members. All chapters were attributed to the two responsible authors in the initial guidelines document. One new chapter on fixation techniques was added. The quality was assessed by the Working Group members during a 2-day meeting and the data were analysed, especially with respect to any change in the level and/or text of any of the conclusions or recommendations of the initial guidelines. In the end, all relevant references published until January 1, 2013 were included. The final text was approved by all Working Group members.
Results For the following topics, the conclusions and/or recommendations have been changed: indications for treatment, treatment of inguinal hernia, day surgery, antibiotic prophylaxis, training, postoperative pain control and chronic pain. The addendum contains all current level 1 conclusions, Grade A recommendations and new Grade B recommendations based on new level 1 evidence (with the changes in bold).
Conclusions Despite the fact that the Working Group responsible for it tried to represent most kinds of surgeons treating inguinal hernias, such general guidelines inevitably must be fitted to the daily practice of every individual

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surgeon treating his/her patients. There is no doubt that the future of guideline implementation will strongly depend on the development of easy to use decision support algorithms tailored to the individual patient and on evaluating the effect of guideline implementation on surgical outcome. At the 35th International Congress of the EHS in Gdansk, Poland (May 12–15, 2013), it was decided that the EHS, IEHS and EAES will collaborate from now on with the final goal to publish new joint guidelines, most likely in 2015.

Keywords Inguinal hernia · Treatment · Guidelines

Introduction

Guidelines for surgical diseases are helpful tools for surgeons to stay updated with published evidence and adapt their practice to the current standards. Although the implementation of guidelines is a delicate matter, it is important that they incorporate the most recent data. The European Hernia Society (EHS) Guidelines on the treatment of inguinal hernia in adult patients were published in 2009 [1] and include all relevant literature until April 2007 (and for level 1 studies until May 2008). The guidelines expired January 1, 2012. Therefore, it was planned to perform an update of the guidelines, only including randomized controlled trials (RCT) or meta-analyses of RCTs.

Methodology

The original Oxford Centre for Evidence-Based Medicine (CEBM) ranking was used. All relevant level 1A and level 1B literature from May 2008 to June 2010 was searched (Medline and Cochrane) by the Working Group members. All chapters were attributed to the two responsible authors in the initial guidelines document. One new chapter on fixation techniques was added, because of the bulk of data available on this subject in recent years. These data were discussed by the Working Group members during a two-day meeting in Leuven, Belgium in June 2010. The quality was assessed and the data were analysed especially with respect to any change in the level and/or the text of any of the conclusions or recommendations of the initial guidelines. Only papers potentially affecting these statements are incorporated in the final text. A compilation of these data was made by the first author and updated until January 1, 2013 (including online publishing). This text was sent to all Working Group members for critical reading and commenting. All remarks were carefully checked by the first and last author and the final text was approved by all Working Group members. The addendum contains all current level 1 conclusions, Grade A recommendations and new Grade B recommendations based on new level 1 evidence (with the changes in bold).

A new ranking was proposed by the Oxford CEBM in 2011 [2]. This does not make a distinction anymore between level 1A and level 1B. It also explicitly refrains from making definitive recommendations. We decided to keep the distinction between level 1A and 1B and the grading of recommendations to be consistent with the previous guidelines.

The guidelines are the property of the EHS and they were financed through a grant by Ethicon. The sponsor had no direct or indirect influence on the methodology or the content of the guidelines.

Indications for treatment

In the guidelines, watchful waiting is considered to be an acceptable option for men with minimally symptomatic or asymptomatic hernias. A follow-up study of one of the RCTs showed that, after a median follow-up of 7.5 years (range 6.2–8.2), 46 of the 80 men randomised towards observation had conversion to operation. The estimated conversion rate for this group, with a mean age of 72 years at time of inclusion, was 16 % at 1 year, 54 % at 5 years and 72 % at 7.5 years. The main reason for conversion was pain. Two patients presented with an acute hernia (2.5 %) [3]. Due to the results of this study, these authors recommend now surgical repair for medically fit patients with a painless inguinal hernia. Therefore, although safe, we believe that watchful waiting should be considered in older patients or patients with major

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comorbidity. We propose to change the conclusions and recommendations as follows:

Conclusions

Level 1B	Watchful waiting is safe and an acceptable option for men with minimally symptomatic or asymptomatic inguinal hernias. It is very likely (>70 % chance) that, in time, the symptoms will increase leading to surgical intervention.
Grade B	It is recommended in minimally symptomatic or asymptomatic inguinal hernia in men to consider a watchful waiting strategy, especially when older or in the presence of major comorbidity.

Non-surgical diagnostics

We did not find any level 1 evidence for this item. However, we realised that the study by Höjer et al. [4] was inadequately cited. In this study concerning the use of CT scan, oral administration of contrast or use of Valsalva manoeuvre to increase the diagnostic value was not consistently done. In the 12 patients evaluated, sensitivity was 90 % (and not 83 % as stated before) but specificity was 0 % for one and 100 % for the other radiologists (and not 67–83 % as stated before).

Treatment of inguinal hernia

Open mesh vs. endoscopic mesh

In the guidelines, the open Lichtenstein and endoscopic inguinal hernia techniques are recommended as best evidence-based options for repair of a primary unilateral hernia providing the surgeon is sufficiently experienced in the specific procedure. To evaluate the long-term outcome of both of these procedures with respect to hernia recurrence and severe chronic pain, we performed previously a meta-analysis of all RCTs with a follow-up of >48 months, although we acknowledge the problem of the large variation in the definition of chronic pain. In addition, it needs to be stated that our previous meta-analysis included the paper by Eklund et al. [5] which dealt only with recurrent hernias; this aspect was not clearly stipulated in the text before. This paper has, therefore, been removed from the updated meta-analysis.

Since our last analysis, two new studies, comparing Lichtenstein with TEP with long-term follow-up, have been published [6–8]. We repeated the meta-analysis (random model) including the new data. Due to the study of Eklund et al. [6], in which one single surgeon was responsible for 33 % of the TEP recurrences, the difference in recurrence is now significant ($P = 0.03$) in favour of the Lichtenstein technique. In that study, it was presumed that 25 operations would be sufficient to overcome the learning curve. This is clearly not the case and it stresses again the importance of an adequate surgical technique and the steepness of the learning curve for endoscopic (especially TEP) inguinal hernia repair. Therefore, as Eklund et al. [6] did in their original paper, we also performed the meta-analysis excluding the data from this surgeon in both groups. In that case, the difference in the long-term recurrence rate between Lichtenstein and endoscopic surgery is not significant ($P = 0.12$) (Fig. 1). The results for severe chronic pain remain unchanged after inclusion of the Eklund [7] data and do not differ ($P = 0.34$) between the groups (Fig. 2).

O'Reilly et al. [9] published in 2012 a meta-analysis of surgical morbidity and recurrence after endoscopic and open repair (mesh and non-mesh) of primary unilateral inguinal hernia. They came to the conclusion that TEP is associated with an almost fourfold increased risk of recurrence when compared to open (mesh- and non-mesh) repair (RR 3.72; 95 % CI 1.66–8.35; $P = 0.001$), with a follow-up period ranging between 0.5 and 61 months. However, a drawback of this study is the heterogeneity in the endoscopic experience in the different studies included:

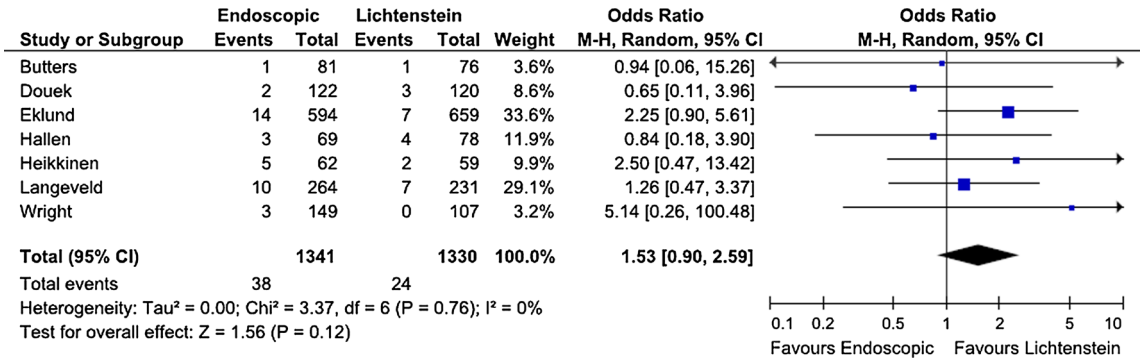

Fig. 1 Pooled data of seven studies on recurrence with follow-up >4 years after endoscopic vs. Lichtenstein inguinal hernia repair (excluding the data from one single surgeon in the study by Eklund et al. [6] (see text)

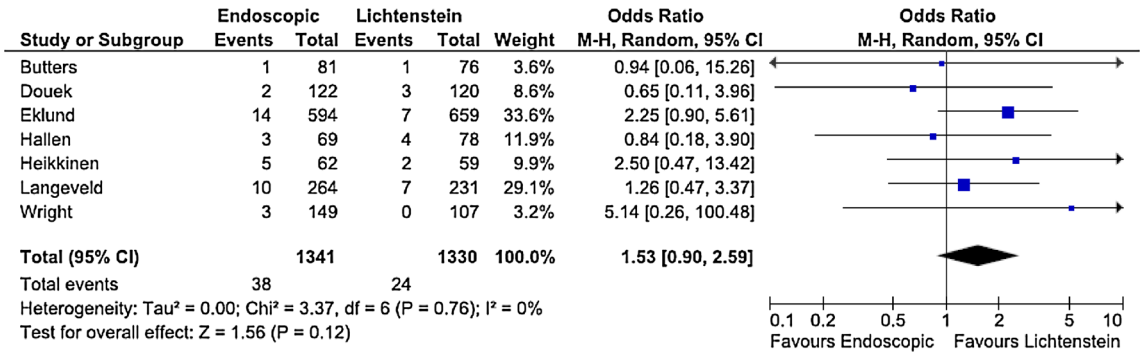

Fig. 2 Pooled data of seven studies on severe chronic pain with follow-up >4 years after endoscopic vs. Lichtenstein inguinal hernia repair

in 6/10 TEP studies, this was not mentioned and in the other four, it ranged between 10 and 30 cases. Moreover, 41.6 % of the TEP recurrence data were retrieved from the above-mentioned Eklund [6] trial. They also demonstrated a significant reduction in chronic pain and numbness in the endoscopic groups compared to open surgery.

Based on these new findings and after very careful consideration by all Working Group members, we propose not to change the recommendations but stress again the long learning curve for endoscopic repair, especially TEP (level 2C).

Mesh devices

At the time of the previous guidelines, only scarce data were available on the comparison of the Lichtenstein technique with mesh devices (Prolene™ Hernia System (PHS) or Plug and Patch). Short-term results were comparable (level 2B). Now, more data are available from meta-analyses and RCTs. Most studies have a follow-up of 1 year or more, although only two studies report a follow-up of >4 years (Testini et al. [10]: Plug and Patch; Sanjay et al. [11]: PHS). The results for the comparison Plug and Patch/Lichtenstein show a shorter operation time for the Plug and Patch (5–10 min), but are otherwise comparable on the short and long term [12, 13].

For the comparison PHS and Lichtenstein, also two meta-analyses of RCTs [12, 14] were published, together with one long-term (5 years) follow-up study [15]. Here also, no differences are reported with respect to recurrence rate or chronic pain. The data on operative time and (perioperative) complications are contradictory in both meta-analyses, although no differences were seen for postoperative wound hematoma or infection in both analyses.

Thus, Plug and Patch and PHS are acceptable forms of treatment for a primary inguinal hernia but have no benefit vs. the Lichtenstein technique, except a somewhat shorter operation time for the Plug and Patch technique. However, also the additional cost of the device needs to be taken into account, together with the small chance for mesh migration/erosion with the use of plugs, and the fact that in the PHS technique both an onlay and sublay mesh are placed, which might make the approach during a later operation for a recurrence more hazardous. Based on these data, the Working Group decided to change the conclusions and recommendations for the use of mesh devices; because of the limited number of long-term follow-up papers, the Working Group downgrades the recommendation to Grade B.

Conclusions

Level 1A	PHS and Plug and Patch (mesh plug) result in comparable outcome (recurrence and chronic pain) as the Lichtenstein technique (1–4 year follow-up).
Grade B	PHS and Plug and Patch (mesh plug) can be considered as an alternative treatment for Lichtenstein inguinal hernia repair.

Recurrent hernias after conventional open repair

The guidelines report level 1B evidence that endoscopic repair results in less postoperative pain and faster reconvalescence than the Lichtenstein technique in repair of recurrent inguinal hernia. A meta-analysis of four RCTs comparing endoscopic and open repairs for recurrent hernia after previous anterior repair confirms less postoperative pain and faster reconvalescence with the endoscopic repair, but at the expense of a longer operation time. However, one of these studies used in the open group a preperitoneal mesh according to the Stoppa technique [16]. Therefore, we performed for the endpoints recurrence and chronic pain (≥3 years) a new meta-analysis (random model) only including the 3 studies comparing Lichtenstein vs. endoscopic repair and including another RCT published recently [17]. This analysis shows that there is also an advantage for the endoscopic approach with respect to chronic pain (Fig. 3). There is no difference with respect to hernia recurrence.

Therefore, we suggest to adapt the conclusion of the guidelines as follows:

Conclusions

Level 1A	For recurrent hernias after conventional open repair, endoscopic inguinal hernia techniques result in less postoperative pain, faster reconvalescence and less chronic pain than the Lichtenstein technique.
Grade A	For the repair of recurrent hernias after conventional open repair, endoscopic inguinal hernia techniques are recommended.

Material reduced (or lightweight, large pore) meshes

In open groin hernia surgery, several meta-analyses of randomised trials have now shown that lightweight (flat) meshes do not have an advantage in the short-term, but are associated with less chronic (≥6 months) pain and foreign body feeling [18, 19], although the incidence of severe chronic groin pain is not decreased [20]. Importantly, this does not increase the recurrence rate at one year (range 6–60 months), although caution is still needed in large (direct) hernias with a potential increased risk for mesh migration into the defect, especially when some specific points for mesh fixation are not taken into account [21–23].

Longer follow-up data (3–5 years) are now available and these do not show any difference in recurrence rate but also not in incidence of chronic pain [24–26]. Thus, although for the prevention of chronic pain and foreign body sensation in the first year(s) after surgery, weight reduced large pore (>1,000 μm) prostheses should be preferred in Lichtenstein repair, the long-term advantages with respect to chronic pain are less clear.

There is no sufficient evidence for such recommendation in endoscopic groin hernia repair, as recently shown in a meta-analysis of eight RCTs (6 TEP, 2 TAPP) with a mean follow-up of 2–60 months [27], both with respect to short- or long-term outcome. Only one study by Bittner et al. [28] concerning small hernias (≤3 cm), not included in the meta-analysis, showed some minor benefits with an "extra-light" mesh (less analgesics, less impairment in physical activities).

Currently, insufficient data are available on the potential advantage of lightweight mesh devices. Therefore, the conclusions and recommendations below only refer to lightweight flat mesh.

The conclusion and recommendations change as follows: because of the unchanged incidence of severe chronic pain and the limited number of long-term follow-up papers, the Working Group downgrades the recommendation to Grade B.

Conclusions

Level 1B	Material reduced meshes have some advantages with respect to chronic pain and foreign body sensation in the first year(s) after open surgery. There is, however, no difference in the incidence of severe chronic pain. This advantage has not been shown in endoscopic repair.
Grade B	The use of lightweight/material reduced/large-pore (>1,000 μm) meshes in open inguinal hernia repair is advised (with caution for large (direct) hernias).

Fixation techniques (new chapter)

Penetrating fixating or traumatic devices like sutures, staples and tacks cause local trauma that may result in nerve injury and chronic pain and should, therefore, be used with caution. We include, therefore, a new chapter on fixation techniques in inguinal hernia repair studies with respect to acute and chronic pain and recurrence.

Open surgery

The first randomised study using cyanoacrylate glue as atraumatic mesh fixation in Lichtenstein repair (polypropylene mesh) showed less pain at day 1 but not after 1 week [29]. A prospective randomised multicentre trial

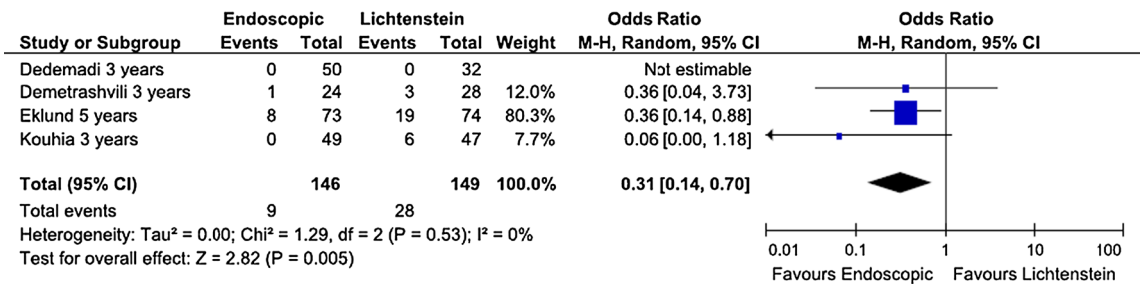

Fig. 3 Pooled data of four studies on chronic pain with follow up 3–5 years after endoscopic vs. Lichtenstein recurrent hernia repair after previous open repair

reports a significant reduction in postoperative pain at 1 and 6 months and a 45 % reduction in incidence of a composite endpoint regarding chronic disabling complications (pain/numbness/groin discomfort) at 1 year after Lichtenstein repair with fibrin glue (heavyweight) mesh fixation compared to standard suture fixation [30].

Two other RCTs comparing, respectively, cyanoacrylate glue fixation (under local anaesthesia) [31] and fibrin glue (under spinal anaesthesia) [32] with standard fixation of a large pore mesh during Lichtenstein repair showed less acute pain at 24 h and lower incidence of hematoma formation and less pain and numbness at 1 week and 1 month.

The first study on the use of the self-gripping Parietene Progrip© mesh (large pore polypropylene with resorbable polylactic acid micro grips) showed also less pain on the first postoperative day vs. the use of another large pore polypropylene mesh without gripping capacity [33]. Three other randomised studies comparing atraumatic (cyanoacrylate glue, self-fixating mesh) vs. suture fixation in Lichtenstein hernioplasty with a large pore mesh showed no difference in acute or chronic pain [34–36]. Atraumatic mesh fixation (glue, self-fixating mesh) is more expensive than standard fixation, although the operation time was shorter in the majority of the studies. All studies with at least 1-year follow-up showed no differences in recurrence rates.

Endoscopic surgery

Especially in endoscopic surgery, the type, number and location of traumatic fixation devices all play an important role and this makes it difficult to compare the different studies. Three different meta-analyses in TEP (follow-up time >1 year in 5/7 studies) did not show any difference between fixation or no fixation with respect to recurrence or acute or chronic pain [37–39]. The last meta-analysis also included the only available RCT in TAPP [40]. It should be noted that these studies were performed with standard polypropylene mesh and non-resorbable fixation devices. In addition, no specific distinction has been made for the type and size of the hernia. Indeed, most surgeons advocate mesh fixation in larger direct hernias to avoid early mesh dislocation and hernia recurrence.

Atraumatic mesh fixation using fibrin sealant has also been evaluated in endoscopic hernia repair. Although, based on the data above, the ideal control group with respect to postoperative acute/chronic pain and recurrence would be a group without any fixation, this study has not been done so far. In one randomised TEP study with bilateral hernias, an endoscopic Hernia Stapler (Cooper ligament, medial edge, upper lateral corner) was compared with 2 ml fibrin sealant (1 ml on Cooper ligament and 1 ml over the inferior edge/upper medial corner) per side. There was no difference in postoperative pain, although analgesic consumption was lower in the glue group. With a median follow-up of 1.2 years (84 % FU), there was no significant difference in chronic pain (20 vs. 13.2 %; $P = 0.418$); no recurrences were seen in any group [41]. A comparable study was done in TAPP [42]. The mesh, cut with a slit for the spermatic cord structures, was fixed with the same endoscopic Hernia Stapler (three clips at the Cooper ligament and pubic tubercle, lateral to the internal ring and both slits fixed) or with 1 ml of fibrin sealant anterior and posterior to the mesh). An obvious short-term benefit was seen in the fibrin sealant group at 1 month (pain, quality of life,…); after 1 year, one recurrence was seen in this group (1 %). Although the VAS scores were lower in the fibrin sealant group after 1, 3 and 6 months, this was not the case after 1 year. In another TAPP study, Olmi et al. [43] also showed a short-term benefit (up to 1 month, but especially the first week) for fibrin glue fixation vs. tack fixation (two tacks medially, three laterally to the epigastric vessels and two on the Cooper ligament). Boldo et al. [44] compared autologous fibrin sealant and Protack in single patients with bilateral hernias undergoing TAPP; in this study with a follow-up of only 6 months, there was only a benefit of less pain in the glue group at 1 week. It should be noted that in this study the glue fixation took 30 min longer (60 vs. 32.5) because the authors closed the peritoneum also with glue; recurrence rate after 6 months was unacceptably high (13.6 % in the glue group vs. 9.9 % in the tack group) which was attributed to the learning curve effect. Another TAPP study with an experienced surgeon using a large pore mesh compared staples (endoscopic Hernia Stapler) and 2 ml of fibrin sealant. There was no short- or long-term benefit for glue fixation in this study. In each group, one recurrence was seen after 1 year (1.8 and 1.9 %) [45]. Also the study by Brügger et al. [46] using a large pore mesh showed no benefit on the short-term (6 weeks) or more.

In conclusion, the analysis of the type of fixation (none vs. atraumatic vs. resorbable or non-resorbable fixation devices) is seriously flawed by different factors such as the dependent variable under study (acute vs. chronic pain, recurrence, operative time, cost…) and the way this is evaluated, and the many independent variables (the type of repair, the type of hernia, the type of mesh and the type, number and location of the fixation devices). The conclusions and recommendations for the fixation

techniques in open and endoscopic hernia repair are, therefore, as follows:

Conclusions	
Level 1A	Traumatic mesh fixation (non-resorbable devices) in TEP (with heavyweight mesh) is unnecessary in most cases.
Level 1B	There is possibly a short-term benefit (postoperative pain) of atraumatic mesh fixation in the Lichtenstein procedure and in endoscopic procedures (TAPP). It offers no benefit with respect to chronic pain.
Grade B	When using heavyweight meshes, traumatic mesh fixation in TEP endoscopic repair should be avoided (with exception for some cases like large direct hernias). Atraumatic mesh fixation in the Lichtenstein technique and in TAPP endoscopic repair can be used without increasing the recurrence rate at 1 year.

Day surgery

A recent RCT comparing ambulatory care vs. inpatient care in patients of 65 years and older (excluding ASA IV and unstable ASA III) undergoing open inguinal hernia repair (Lichtenstein or PHS) under local anaesthesia (in ≥95 % of cases) showed no significant differences between both groups in the first 2 weeks postoperatively (high patient satisfaction, no readmissions) [47]. Because of this study, we propose to upgrade the conclusion from Level 3 to Level 1B.

Conclusions	
Level 1B	Selected older and ASA III patients are also eligible for day surgery (open repair, local anaesthesia).
Grade B	An operation in day surgery should be considered for every patient.

Antibiotic prophylaxis

For the mesh-based open repair, there are currently 12 RCTs and 7 meta-analyses/reviews with conflicting results. This is mainly due to the methods of performing the analysis and the interpretation/extraction of data.

The overall meta-analysis results of the 12 RCTs have to be corrected for a large clinical diversity (inclusion criteria variations regarding diabetes and recurrent hernia) and methodological diversity (surgical variations: timing of shaving, drain use, average surgical time, seroma aspiration) using the random model. Also the percentage of wound infection in the placebo group has a large variation between 0 and 15 %; to correct for this broad baseline percentage of wound infections we propose to enlarge the confidence interval from 95 to 99 % for the overall analysis. The same methods were followed as described in one of the earlier published meta-analyses [48]. The results of the analysis of data from all 12 RCTs demonstrate an incidence of wound infection of 82/1,862 (4.4 %) patients in the placebo group and 48/1,831 (2.6 %) after antibiotic prophylaxis. Although several authors describe this as a relevant reduction in percentage, it is not a significant one (OR 0.62; 99 % CI 0.38–1.02 (Fig. 4). Therefore, there is no significant benefit of antibiotic prophylaxis in inguinal hernia repair. There can also be some comment regarding the included two studies from 2010 (Fig. 4) since they are of a possibly lower quality because of their methods of randomisation but including or excluding them in the analysis does not influence the overall conclusions.

A new possibility is currently available since six studies have a very high baseline infection percentage in

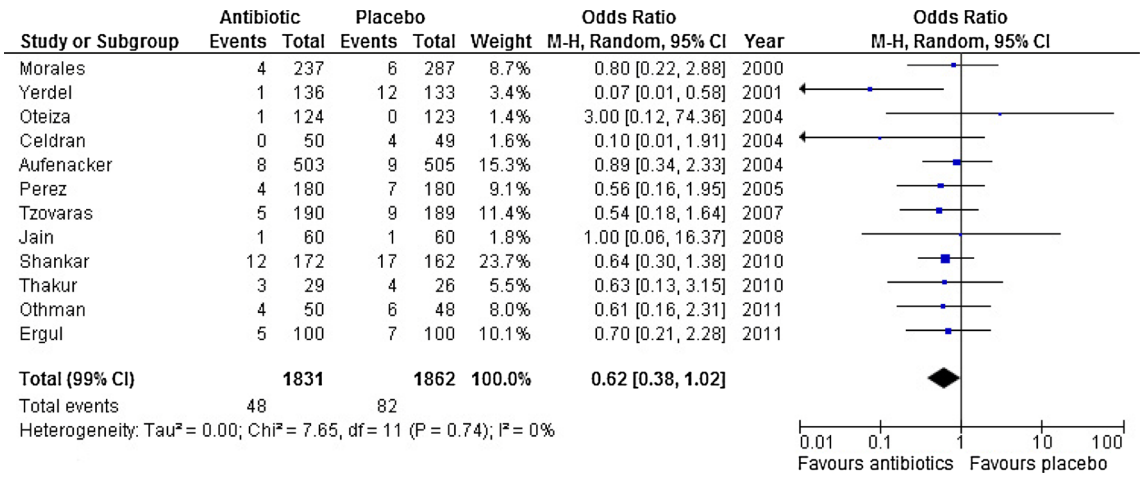

Fig. 4 Pooled data of 12 studies on the use of antibiotic prophylaxis in the prevention of wound infection after open mesh inguinal repair

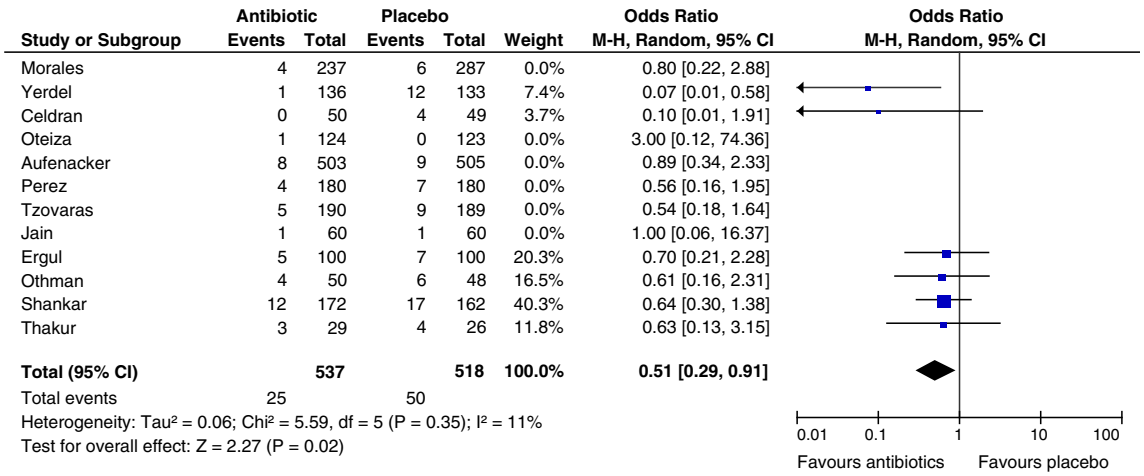

Fig. 5 Pooled data of six studies on the use of antibiotic prophylaxis in the prevention of wound infection in centres with a high baseline incidence (≥7 %) of wound infection after mesh inguinal repair

the placebo group (7.0–15.4 %); therefore, another analysis can be made to estimate the usefulness of antibiotic prophylaxis in the presence of a high incidence of wound infection. In this analysis (i.e. the presence of a high baseline incidence of wound infection), there is a significant benefit of the use of antibiotic prophylaxis (OR 0.51; 95 % CI 0.29–0.91), NNT 22 (Fig. 5).

In the presence of a low incidence of wound infections (0–4.8 %, the other six studies), there is no evidence of benefit from antibiotic prophylaxis (OR 0.74; 95 % CI 0.43–1.27).

The results of the analysis of data from nine available studies for prevention of deep infection demonstrate an infection in 8/1,360 patients (0.59 %) of the placebo and 5/1,375 patients (0.36 %) in the prophylaxis group with no significant benefit (OR 0.63; 95 % CI 0.20–1.98).

Based on these data, we propose to adapt the following conclusions and recommendations, whereas the other conclusions and recommendations remain unchanged.

Conclusions

Level 1A	In open mesh repair in low risk patients and a low incidence of wound infection, antibiotic prophylaxis does not significantly reduce the number of wound infections. In the presence of a high incidence of wound infection (>5 %) there is a significant benefit of antibiotic prophylaxis; NNT 22.
Grade A	In clinical settings with low rates of wound infection there is no indication for the routine use of antibiotic prophylaxis in elective open groin hernia repair in low risk patients. In institutions with high rates of wound infection (>5 %) the use of antibiotic prophylaxis is necessary.

Training

The long-term follow-up study of an RCT comparing Lichtenstein and TEP clearly shows the effect of experience on the recurrence rate in the TEP group [49]. Two RCTs are now available to support the fact that a preclinical simulation-based training program with residents improved not only clinical performance [50] but also patient outcomes [51] in TEP during the learning curve.

Conclusions

Level 1B	A preclinical resident training program improves the results of TEP.
Grade A	Preclinical training programs for TEP must be implemented.

Postoperative pain control

A systematic review of RCTs up to March 2009 [52] emphasises the use of a pre- or intraoperative field block (ilioinguinal, iliohypogastric, genitofemoral nerve) with or without local wound infiltration for all patients undergoing open inguinal hernia surgery. It is unclear if the use of ultrasonography adds substantially vs. blind administration of these blocks. Also the additional benefit of a continuous wound infusion with a local aesthetic or a TAP (transverses abdominis plane) block vs. a field block alone is unclear. The same authors describe a standardised approach to postoperative pain consisting of paracetamol and conventional NSAID or Cox-2-selective inhibitors, followed by opioid administration if needed.

Based on this systematic review, the authors adapt the conclusions and recommendations:

Conclusions

Level 1A	The use of a field block (ilioinguinal, iliohypogastric, genitofemoral nerve) in all patients undergoing open inguinal hernia repair provides significant postoperative pain relief.
Grade A	Field blocks are recommended in all patients undergoing open inguinal hernia repair

Causes and risk factors of chronic pain

There is now evidence from two RCTs that chronic pain diminishes over time. In a 10-year follow-up study of a randomised trial including 300 patients and comparing mesh vs. non-mesh repair for a primary inguinal hernia, a total of 153 could be followed up. Although the incidence of pain 6 months postoperatively was between 10 and 15 %, none of the patients in the non-mesh or mesh group suffered from persistent pain and discomfort interfering with daily activity [53]. Another RCT comparing endoscopic TEP vs. Lichtenstein repair in 1,370 patients showed a decrease from resp. 11 and 21.7 % of chronic pain at 1 year to resp. 9.4 and 18.8 % of chronic pain at 5 years, with the result between both groups still being significant. This trend was the same when looking only at mild or only at moderate/severe pain [7]. A prospective study in 464 patients undergoing endoscopic or open hernia repair revealed factors such as preoperative Activity Assessment Scale (AAS) score [54], open surgery and 30-day postoperative pain intensity as being risk factors for chronic pain [55]. The randomised study by Singh et al. [56] showed that preoperative pain, younger age, open surgery and 7-day postoperative pain were independent risk factors for chronic pain.

Conclusions

Level 1B	The risk of chronic pain after hernia surgery decreases with age. Preoperative pain and early postoperative pain are independent risk factors for chronic pain.
	Postoperative chronic pain diminishes over time.

Prevention of chronic pain

According to the guidelines, prophylactic resection of the ilioinguinal nerve in open surgery does not reduce the risk of postoperative chronic groin pain (level 2A). Johner et al. [57] demonstrated in a meta-analysis of all RCTs on preservation vs. routine division of the ilioinguinal nerve during open mesh repair (random model) that the pooled mean difference in the degree of pain at 6 months postoperatively on a 10-point scale was −0.33 (95 % CI −0.71 to 0.05), not favouring neurectomy to decrease the chance of developing chronic pain. A more recent meta-analysis of all RCTs (including two additional studies until February 2012) on preservation vs. routine division of the ilioinguinal nerve during open mesh repair for the prevention of chronic pain also showed no difference at 6 and at 12 months, both for incidence of postoperative pain and postoperative pain score [58].

When we combined all studies in this area with the longest follow-up interval in a new meta-analysis, there is no significant benefit of cutting the ilioinguinal nerve to prevent chronic postoperative pain (OR 0.54; 95 % CI 0.25–1.15) (Fig. 6). It remains speculative whether this approach would be beneficial in a subset of patients with preoperative risk factors for chronic pain.

This allows us to upgrade the previous conclusion:

Conclusions

Level 1A	Prophylactic resection of the ilioinguinal nerve does not reduce the risk of chronic pain after open hernia surgery
Grade A	Routine prophylactic resection of the ilioinguinal nerve during open inguinal hernia surgery to decrease the risk for chronic pain is not recommended.

Costs

A retrospective total cost-minimisation analysis of a RCT comparing TEP (using disposable instruments) and Lichtenstein (of whom only 5.5 % were done under local anaesthesia) during 5 years of follow-up showed a slightly higher total cost for the TEP group, both for the index operation and for possible postoperative complications [59]. However, the authors anticipated a break-even when reusable instruments would have been used. Based on these data, we propose not to change the conclusions and recommendations. We stress again that conclusions with respect to cost issues should be interpreted with care since local expertise, the used instrumentation (e.g. disposable vs reusable instruments, type of anaesthesia) and local health care/insurance issues (e.g. day surgery vs overnight stay, public vs private hospital setting) play a role to determine direct costs. Sociocultural differences with respect to work resumption increase the difficulty in interpretation when evaluating total (i.e. direct and indirect) costs. Ideally, the total cost for Lichtenstein repair in day surgery under local anaesthesia should be compared with endoscopic repair under general anaesthesia, also in day surgery, in the working population, both for unilateral and for bilateral hernias.

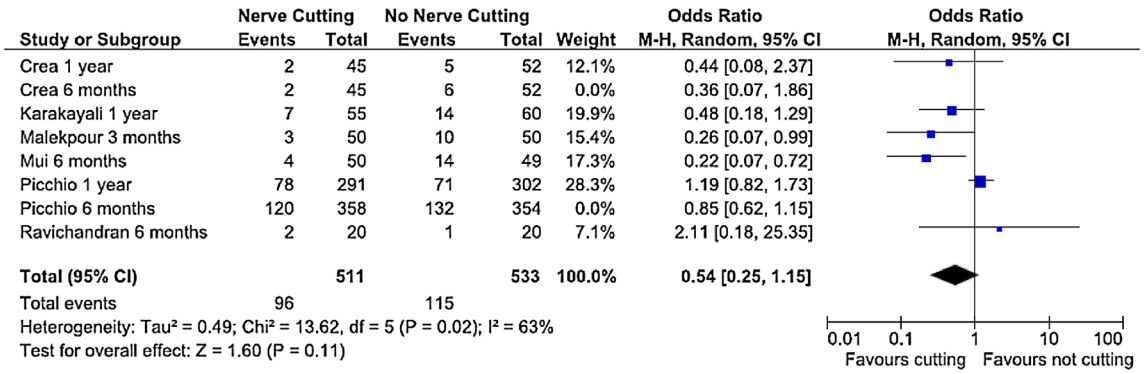

Fig. 6 Pooled data of six studies (with the longest follow-up interval) on the benefit of cutting the ilioinguinal nerve to prevent chronic postoperative pain

Discussion

This 2013 update of the European Hernia Society Guidelines on the treatment of inguinal hernia in adult patients provides the latest overview of the level 1 evidence in the published literature up to January 1, 2013, since the publication of the guidelines in 2009. One might argue about the fact that only level 1 evidence is incorporated and not the data from other important literature sources such as large prospective registries. A valid criticism is the fact that the external validity of RCTs, often performed in expert centres and, therefore, representing only the efficacy of the intervention, can be questioned and that the extrapolation of these data to the real world (i.e. effectiveness) should therefore be done with caution. On the other hand, we feel that updating the guidelines with level 1 evidence will at least keep the guidelines actualised to a large extent. Another argument might be that the update is already outdated at the time of publication, since published (meta-)analyses in 2013 were not taken into account. However, we tried to anticipate on this and we explored recently published meta-analyses to check if their conclusions would potentially alter the conclusions and recommendations of the current update. This did not seem to be the case.

Despite the fact that the Working Group responsible for it tried to represent most kinds of surgeons treating inguinal hernias, such general guidelines inevitably must be fitted to the daily practice of every individual surgeon treating his/her patients. Regional and national differences in health care resources (e.g. availability of mesh and laparoscopy) and reimbursement issues should also be taken in account, especially for issues where only lower level of evidence is available.

There is no doubt that the future of guideline implementation will strongly depend on three things; the first is the development of easy to use decision support algorithms tailored to the individual patient [60]. With the current technology available, these algorithms must be promoted via interactive websites and easy to use mobile applications. The apps of the Scottish Intercollegiate Guidelines Network are a good example (http://sign.ac.uk/guidelines/apps/index.html). Awareness raising activities should not only motivate professionals to use them but should also include patients and patient organisations as target group. The second aspect is to track adoption of guidelines and how they have an impact on outcome. This can only be evaluated when including patient and surgical data into large prospective registries. If improvement of outcome is confirmed, guidelines provide an ideal framework for audit and could be a tool for professional organisations to evaluate individual surgical practice and provide continuing medical education. Last but not least, as already alluded to above, the outcome data coming from national and supranational registries reflect the effectiveness of a certain intervention. In such a way, they can be used again to adapt the original guidelines on the condition that a rigorous data entry of consecutive patients with source data verification and a sound statistical analysis including multivariate models can be guaranteed.

Apart from the EHS, two other societies have recently also published guidelines or consensus statements on the treatment of inguinal hernia. In 2011, the International Endohernia Society (IEHS) published guidelines on endoscopic treatment for inguinal hernias, focusing on surgical technique and perioperative management of the endoscopic repair [61]. In 2013, the European Association for Endoscopic Surgery (EAES) published the results of a Consensus Development Conference on the endoscopic repair of groin hernias [62], combining the evidence with the opinions of experts and the surgical community. At the 35th International Congress of the EHS in Gdansk, Poland (May 12–15, 2013), a plenary session was devoted to the issue of guidelines. It was decided that both the EHS and IEHS would finish an update of their guidelines and that the three societies will collaborate from now on with the

final goal to publish new joint guidelines, most likely in 2015, on behalf of EHS, IEHS and EAES.

Conflict of interest The guidelines are the property of the EHS and they were financed through a grant by Ethicon. The sponsor had no direct or indirect influence on the methodology or the content of the guidelines.

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