ASERNIP-S

Australian Safety and Efficacy Register of New Interventional Procedures - Surgical

Rapid Review

Herniorrhaphy for Inguinal and Femoral Hernia: Review of Clinical Evidence and Guidelines

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Australian Safety & Efficacy Register of New Interventional Procedures – Surgical

The Royal Australasian College of Surgeons

This report has been produced for the Victorian Government Department of Health

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Please note that this brief report, while broad in some aspects of systematic review methodology, should not be considered a comprehensive systematic review. Rather, this is a rapid review in which the methodology has been limited in one or more of the following areas to shorten the timeline for its completion: search strategy, inclusion criteria, assessment of study quality and data analysis. This report also contains non-systematic elements, such as qualitative information gathered from local surgeons. However, it is considered that these amendments would not significantly alter the overall findings of the rapid review when compared to a full systematic review.

The methodology used for the rapid review is described in detail, including the limits for this particular topic. These limits were applied following the requirements of the specific review topic, in consultation with the requester.

For a more comprehensive understanding of this topic, a broader analysis of the literature may be required. As such, all readers of this document should be aware of the limitations of this review.

This brief was prepared by Ms Lynda McGahan and Dr Ann Scott from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

Declaration of competing interest:

The authors of this publication claim no competing interests.

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Scope of the Report

The objective of this rapid systematic review is to facilitate the appropriate use of herniorrhaphy in adults with asymptomatic or minimally symptomatic inguinal or femoral hernia by providing a synthesis of the evidence on the following research questions.

1. Are there specific clinical or pathological features of inguinal and femoral hernias that indicate a threshold below which surgery is of low clinical value?
2. Is there evidence of effective alternative therapies to surgery for inguinal and femoral hernias?
3. Does the evidence show that watchful waiting of asymptomatic or minimally symptomatic inguinal and femoral hernias is an appropriate approach?
4. Is there evidence of successful strategies trialled in other jurisdictions to increase the appropriateness of surgical inguinal and femoral hernia repair or improve care (e.g. shared decision making strategies in the United Kingdom and Canada)?

Executive Summary

Context and policy issues

Herniorrhaphy, surgical repair of a hernia, is one of the most common procedures performed by general surgeons–over 40,000 hernia operations are performed annually in Australia. Hernias develop when a weakness in the abdominal wall allows the intestines and adipose tissue to protrude. Approximately 75 per cent of abdominal hernias are inguinal and 15 per cent are femoral. Symptoms include a bulge in the groin or abdomen that increases with coughing or straining, pain, numbness and irritation. While most hernias can be manipulated back into the abdomen, the intestines can become obstructed or strangulated when a hernia becomes irreducible.

Herniorrhaphy is typically performed to prevent bowel obstruction or strangulation because it is less risky than emergency surgery for a strangulated inguinal hernia (IH). However, a third of patients presenting with IH have few symptoms, and some patients develop chronic groin pain or recurrence following surgery. Recent evidence suggests that watchful waiting (WW) of asymptomatic or minimally symptomatic IH is a safe and acceptable alternative to surgical repair. No significant difference in pain has been noted between patients undergoing WW and those receiving surgical repair, and the annual rate of obstruction or strangulation is less than 1 per cent. However, the rate of cross over from WW to surgical repair increases over time, suggesting that WW may not be appropriate for all cases of minimally symptomatic IH. In Australia, 95 per cent of all IH cases managed annually are without obstruction.

The objective of this rapid systematic review (SR) is to facilitate the appropriate use of herniorrhaphy in adults with asymptomatic or minimally symptomatic IH or femoral hernia (FH) by providing a synthesis of the evidence on the following research questions.

1. Are there specific clinical or pathological features of inguinal and femoral hernias that indicate a threshold below which surgery is of low clinical value?
2. Is there evidence of effective alternative therapies to surgery for IH and FH?
3. Does the evidence show that watchful waiting of asymptomatic or minimally symptomatic IH and FH is an appropriate approach?
4. Is there evidence of successful strategies trialled in other jurisdictions to increase the appropriateness of surgical inguinal and femoral hernia repair or improve care (e.g. shared decision making strategies in the United Kingdom and Canada)?

Methods

A systematic search of MEDLINE, EMBASE, *The Cochrane Library*, the NHS Centre for Reviews and Dissemination databases and the websites of various international health technology assessment agencies and clinical practice guideline (CPG) clearinghouses was conducted to identify relevant SRs, health technology assessments, clinical guidelines and

comparative studies published in English from January 2005 (January 2009 for guidelines) to July 2014. A focused internet search was also conducted to identify grey literature. Study selection, data extraction and quality appraisal were undertaken by one reviewer. Two general surgeons from Melbourne, Victoria were surveyed to identify alternative non-surgical interventions, to characterise current surgical practice and surgical outcomes for patients with asymptomatic or minimally symptomatic IH or FH and to describe triage strategies or decision tools for determining whether surgical intervention is appropriate in patients asymptomatic or minimally symptomatic IH or FH.

Key results

Evidence regarding the clinical or pathological features of groin hernias that indicate a threshold below which surgical repair is of low clinical value, and information regarding the effectiveness of WW for asymptomatic groin hernias, was derived from two CPGs, three SRs, and a long-term follow-up (LTFU) study of a randomised controlled trial (RCT) that was included in the SRs. While level I evidence was the main information source used to answer the research questions, data from other sources, such as large prospective registries, may have conferred greater external validity on the conclusions. Although the patient demographics differed considerably between the two primary RCTs (Fitzgibbons et al. 2006; O'Dwyer et al. 2006) reported in the CPGs and SRs, most of the evidence was on asymptomatic IH in men. The LTFU study of an RCT included in the SRs was not necessarily representative of the original source population and suffered strong self-selection bias owing to the recruitment of volunteers. While the CPG recommendations took into consideration health benefits, risks and costs and were explicitly linked to the evidence that supported them, it was unclear whether or how study quality was considered in formulating the conclusions in the SRs.

Threshold of pathology for herniorrhaphy

Men with an asymptomatic or minimally symptomatic IH that is not painful and does not interfere with daily activities may be managed conservatively; however, in many cases pain will increase with time and surgical repair will become necessary. Cross over from WW to surgery was associated with increasing age and hernia size, low ASA physical status, being married and the presence of pain, chronic constipation or prostatism. The life expectancy for elderly men with an IH was the same regardless of whether they were treated with WW or surgical repair. Thus, operating on patients with asymptomatic or mildly symptomatic IH who are elderly or have significant comorbidity may not be justified. Patients with FH or symptomatic IH should be offered surgical repair. Large, minimally symptomatic IHs should also be considered for surgical repair based on their tendency to progress to larger scrotal hernias.

Effectiveness of alternative therapies for groin hernias

WW was identified as the only effective alternative to surgical repair for asymptomatic or mildly symptomatic groin hernias. External devices such as hernia trusses, trunks or belts

may be used to reduce hernias in non-surgical candidates; however, they are not recommended routinely due to discomfort, ineffectiveness and the risk of incarceration.

Watchful waiting of asymptomatic or minimally symptomatic hernias

WW is a safe and acceptable alternative to surgical repair for men with asymptomatic or minimally symptomatic IH. However, in many cases pain will increase over time and surgical repair will become necessary. The annual rate of irreducibility associated with WW was 0.4 per cent. The cumulative probability of complications increases with time and was higher in women than in men. Based on these findings, younger patients (under 50 years of age) with an asymptomatic groin hernia (especially IH) of more than 3 months duration and with limited comorbidity may be managed effectively with WW. It was recommended that WW for asymptomatic IH be considered for older patients and for those with significant comorbidity.

Strategies to increase the appropriateness of herniorrhaphy and improve care

No strategies for reducing the number of hernia repairs or improving care were identified from systematically searching the literature and contacting clinical experts. Clinical experts were not aware of any decision tools for use by general practitioners or patients when considering WW or surgery for asymptomatic groin hernia.

Conclusions and policy implications

The evidence suggested that herniorrhaphy should not be recommended routinely for the management of all cases of asymptomatic or minimally symptomatic groin hernia. There was consensus in the evidence that men with an asymptomatic or minimally symptomatic IH that is not painful and does not interfere with daily activities may be managed effectively with WW. However, in many cases pain will increase with time and surgical repair will become necessary. Patients with FH or symptomatic IH should be offered surgical repair. FHs incarcerate and strangulate with significantly greater frequency than IHs.

For patients with asymptomatic IH, there was no significant difference in pain experienced by those who opted for WW and those undergoing surgery, and the annual rate of obstruction or strangulation was less than 1 per cent. Operating on asymptomatic or mildly symptomatic patients, particularly those with comorbidities, may not be justified. The rate of cross over from WW to surgery was positively correlated with increasing age and hernia size, low ASA physical status, being married and the presence of pain, chronic constipation or prostatism. The incidence of chronic groin pain following herniorrhaphy ranged from 10 to 54 per cent, depending on technique, and the rate of recurrence ranged from 0 to 62 per cent.

WW was identified as the only effective alternative to surgical repair for asymptomatic or mildly symptomatic groin hernias. External devices such as trusses, trunks or belts may

be used to reduce hernias in non-surgical candidates, but they are not recommended routinely due to discomfort, ineffectiveness and the risk of incarceration. No effective decision-making strategies for determining the appropriateness of surgical repair were identified by systematically searching the literature and contacting experts.

Decision makers need to consider that while these results are in favour of reducing the number of hernia repairs in men with asymptomatic or minimally symptomatic IH, there is a 70 per cent chance that pain will increase over time and that patients will eventually need surgical repair. However, the data for this report was mainly derived from Level I evidence, so the study results may not be generalisable to all patients with asymptomatic or minimally symptomatic hernia. Data from large prospective registries, such as the one proposed as an audit and peer review tool by the European Hernia Society, may provide evidence with greater external validity. While WW is an alternative to surgical repair for men with asymptomatic or minimally symptomatic IH, clinicians need to weigh this option against potential complications and tailor a management plan to individual patient needs. Promotion of appropriate patient selection for herniorrhaphy will benefit from close collaboration between surgical and primary care clinicians to ensure adequate follow-up of asymptomatic patients who have undertaken WW.

Important note:

The information contained in this report is a synthesis of the best available evidence located at the time the searches were completed.

Abbreviations

AGREE	Appraisal of Guidelines for Research and Evaluation
AMSTAR	Assessment of Multiple Systematic Reviews
ASA	American Society of Anesthesiologists
BHS	British Hernia Society
CEBM	Centre for Evidence-Based Medicine
CI	confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CPG	clinical practice guideline
DARE	Database of Abstracts of Reviews of Effects
EHS	European Hernia Society
FH	femoral hernia
FU	follow-up
GDG	guideline development group
GP	general practitioner
GPP	good practice point
HEED	Health Economic Evaluations Database
HTA	health technology assessment
IH	inguinal hernia
INCA	INguinal hernia: Conservative or operative Approach
LTFU	long-term follow-up
MA	meta-analysis
NHSEED	National Health Service Economic Evaluation Database
NICE	National Institute for Health and Care Excellence
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	randomised controlled trial
SD	standard deviation
SIGN	Scottish Intercollegiate Guideline Network
SR	systematic review
TAPP	transabdominal preperitoneal

TEP	total extraperitoneal
TRIP	Turning Research Into Practice
WW	watchful waiting

1. Context and Policy Issues

Herniorrhaphy, surgical repair of a hernia, is one of the most common procedures performed by general surgeons. Worldwide over 20 million hernias are repaired annually; approximately 40,000 repairs are conducted in Australia. Hernias develop when a weakness in the abdominal wall allows adipose tissue or organs to protrude (The Society for Surgery of the Alimentary Tract 2013). Approximately 75 per cent of abdominal hernias are inguinal, 15 per cent are femoral and the remainder are umbilical or incisional hernias. An indirect inguinal hernia (IH) occurs when the intestines push through a weakness in the inguinal ring and descend along the spermatic cord in men, or the round ligament in women. Direct IH develops in men when the intestines enter a congenital weakness in the back wall of the inguinal canal. Femoral hernia (FH), which is common in women, occurs when the abdominal contents push through the ring of the femoral canal (The Society for Surgery of the Alimentary Tract 2013). The annual incidence of groin hernia increases with age from approximately 0.7 per 1,000 people between the ages of 45 and 64 years to 1.5 per 1,000 people over the age of 75 years (van den Heuvel et al. 2011).

The symptoms of hernia include a bulge in the groin or abdomen that increases with coughing or straining, pain or pressure at the hernia site and numbness or irritation due to pressure on surrounding nerves. Diagnosis is based on clinical palpation of the inguinal area and the femoral triangle. Hernias are classified based on location (indirect versus direct) and size (<1.5 cm, 1.5 to 3 cm and >3 cm) (Kulacoglu 2011). A reducible hernia can return into the abdomen either spontaneously or as a result of manipulation. A hernia becomes irreducible or incarcerated when the intestines or abdominal tissues fill the hernia sack and cannot be pushed back into place. The cumulative probability of irreducibility for IH is estimated at 30 per cent after 10 years (Hair et al. 2001). Several complications arise with irreducible hernias: the bowel can become obstructed when the intestines become intertwined with the hernia or become strangulated when the intestines are trapped in the muscular ring, blocking blood flow. Symptoms of abdominal pain and vomiting may indicate a life-threatening, strangulated intestine that requires immediate surgery. The cumulative probability of strangulation for IH is estimated at 4.5 per cent after 24 months, while that for FH is 45 per cent after 21 months (Gallegos et al. 1991).

Herniorrhaphy is typically performed to prevent bowel obstruction or strangulation and to reduce symptoms such as pain. The clinical threshold for proposing surgery in patients with groin hernias is low because surgical repair is considered safe and effective and is associated with a low rate of morbidity (van den Heuvel et al. 2011). Emergency surgery for a strangulated IH is associated with a higher mortality rate than elective surgery (>5% versus <0.5%, respectively) (European Hernia Society 2013). A variety of surgical approaches have been developed. While the open Shouldice technique offers a lower recurrence rate than other types of tissue reconstruction, muscle reinforcement using

mesh is superior to suture repairs (Antoniou et al. 2014; Kulacoglu 2011). The Lichtenstein open tension-free technique, in which a flat mesh is placed on the abdominal wall defect, offers a low recurrence rate and minimal morbidity, and is recommended by the European Hernia Society (EHS), the American College of Surgeons, the National Institute for Health and Care Excellence and the National Agency for Accreditation and Evaluation in Health (Kulacoglu 2011). Endoscopic and laparoscopic repairs are associated with less postoperative pain, fewer wound infections and an earlier return to work than open surgery (Kulacoglu 2011). Laparoscopic transabdominal preperitoneal (TAPP) repair and total extraperitoneal (TEP) repair are effective for groin hernias; however, they are associated with steep learning curves and increased perioperative morbidity (Antoniou et al. 2014). Individual patient factors and hernia characteristics must be taken into account when considering the various surgical techniques.

In Australia, IH was the seventh principal diagnosis between 2010 and 2011 and accounted for 42,375 elective surgery admissions: 24,593 (58%) to private hospitals and 17,782 (42%) to public hospitals (AIHW 2011). Patients admitted through wait listing underwent inguinal herniorrhaphy within 57 days at the 50th percentile and within 259 days at the 90th percentile. Of the IH cases managed between 2010 and 2011, approximately 95 per cent were without obstruction or gangrene and 80 per cent were unilateral hernias, of which 23 per cent were repaired laparoscopically (AIHW 2011).

Claims for laparoscopic IH and FH repair in private hospitals increased from 6,356 to 13,401 between 2003 and 2012; 95 per cent of claims were for men aged between 45 and 75 years (Medicare Australia 2013). In Victoria, 416 laparoscopic IH and FH repairs were performed per million people between 2011 and 2012; the rate in other states and territories ranged from 330 (Australian Capital Territory) to 782 (Tasmania) repairs per million people. Claims for repairing obstructed, incarcerated or strangulated hernias increased from 1,618 to 2,110 between 2004 and 2012, and 75 per cent of these claims were for men aged between 45 and 84 years. In Victoria, 109 repairs per million people were conducted for complications due to hernia between 2011 and 2012, while the rate in other states and territories ranged from 48 (Northern Territory) to 108 repairs per million people (Tasmania) (Medicare Australia 2013).

While most abdominal hernias can be repaired surgically, between 6 and 54 per cent of patients experience post-herniorrhaphy groin pain, surgical site infection, recurrence or injuries to nerves, blood vessels and nearby organs (O'Rourke and O'Rourke 2012). External devices such as hernia trusses, trunks or belts may be used to reduce hernias in an effort to avoid the risks associated with surgical repair. However, trusses are not recommended routinely owing to discomfort, ineffectiveness and the potential for incarceration and testicular atrophy (European Hernia Society 2013; Sanders et al. 2013; The Society for Surgery of the Alimentary Tract 2013).

Recently two randomised controlled trials (RCTs), one conducted in the United Kingdom (O'Dwyer et al. 2006) and the other in North America (Fitzgibbons et al. 2006), reported that watchful waiting (WW) of minimally symptomatic IH was a safe and acceptable alternative to routine surgical repair. Neither of the studies found any difference in pain scores or quality of life measures between WW and surgical repair at the 2-year follow-up, and the annual rate of obstruction or strangulation was less than 1 per cent in the WW group. However, 23 per cent of patients in Fitzgibbons et al. (2006) and 26 per cent of patients in O'Dwyer et al. (2006) crossed over from WW to surgery within two years of follow-up. The crossover rate increased with subsequent follow-up, suggesting that WW may not be appropriate for all patients with minimally symptomatic hernia. In Australia, claims for repairing obstructed or strangulated hernias have risen over the last decade (AIHW 2011).

The objective of this rapid systematic review (SR) is to facilitate the appropriate use of herniorrhaphy in adults with asymptomatic or minimally symptomatic IH or FH by providing a synthesis of the evidence on the following research questions.

Research questions

1. Are there specific clinical or pathological features of IH and FH that indicate a threshold below which surgery is of low clinical value?
2. Is there evidence of effective alternative therapies to surgery for IH and FH?
3. Does the evidence show that watchful waiting of asymptomatic or minimally symptomatic IH and FH is an appropriate approach?
4. Is there evidence of successful strategies trialled in other jurisdictions to increase the appropriateness of surgical inguinal and femoral hernia repair or improve care (e.g. shared decision making strategies in the United Kingdom and Canada)?

2. Methodology

Literature review

Literature search strategy

A limited systematic search of MEDLINE, EMBASE, *The Cochrane Library*, the NHS Centre for Reviews and Dissemination databases and the websites of international health technology assessment (HTA) agencies and clinical practice guideline (CPG) clearinghouses was conducted to identify relevant research published in English from January 2005 (January 2009 for guidelines) to July 2014. A focused internet search was also conducted to identify grey literature. Filters were applied to limit the retrieval to SRs, HTAs, meta-analyses, guidelines, RCTs and non-randomised comparative studies. Details of the search strategies are provided in Appendix A.

Study selection criteria and methods

One reviewer screened all citations and selected studies. On initial screening, titles and abstracts were reviewed for relevance. Full-text publications were retrieved and assessed for inclusion based on the criteria in Table 1. Only studies conducted in Australia, Canada, Japan, New Zealand, the United States and European countries (except for those with transitional economies) were included for review. These countries, which have developed economies as defined by the United Nations, are likely to have populations whose health status, cultural norms, access to health care and disease burden are comparable to those in Australia (United Nations 2009).

Table 1: Study selection criteria

Population	Adults with minimally symptomatic or asymptomatic inguinal or femoral hernia
Intervention	Herniorrhaphy
Comparator	Non-surgical interventions (including watchful waiting)
Outcomes	Pain, function, disability, morbidity, recurrence For asymptomatic patients: need for surgery (emergency or non-emergency) and time to first surgery; complications, length of hospital stay, recurrence
Study design	HTA, SR, MA, RCT, non-randomised comparative study Evidence-based CPGs that provide criteria for or recommendations on herniorrhaphy for inguinal or femoral hernia

CPG: clinical practice guideline; HTA: health technology assessment; MA: meta-analysis; RCT: randomised controlled trial; SR: systematic review

Exclusion criteria

Studies were excluded if they: did not meet the selection criteria; were included in a selected SR; were duplicate or preliminary results; had incomplete or inappropriate methods; or were an ineligible study design. RCTs and non-randomised comparative studies published prior to the literature search end date reported in the most recent, eligible SR were also excluded.

Data extraction and analysis

One reviewer extracted data on patient characteristics, long-term clinical benefits and harms and guideline recommendations on WW and herniorrhaphy for asymptomatic IH and FH.

Critical appraisal of included studies

One reviewer evaluated the methodological quality of the included studies. SRs were evaluated using the 11-item Assessment of Multiple Systematic Reviews (AMSTAR) checklist (Shea et al. 2007), while the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument was used to appraise CPGs (Brouwers et al. 2010) The domains assessed by AMSTAR include design, study selection and data extraction, literature searching, study characteristics, quality assessment, methods used to combine findings, publication bias and conflict of interest. The domains assessed by AGREE II include scope and purpose, stakeholder involvement, rigour of development, clarity and presentation, applicability and editorial independence. RCTs and non-randomised comparative studies were evaluated using an instrument by Downs and Black (1998) that was modified to include the source of funding. Primary study evidence was assessed with regard to method of randomisation, concealment of randomisation, degree of blinding, use of intention-to-treat analysis and description of dropouts and withdrawals. Instead of calculating numeric scores, the strengths and weaknesses were described narratively for each study. The evidence presented in the selected studies was classified, where possible, using the levels of evidence defined by the National Health and Medical Research Council (Merlin et al. 2009) (Appendix B).

Data analysis

Study design, quantity of evidence, heterogeneity of interventions and populations and timelines prevented formal MA. Study characteristics, quality assessment and results were summarised narratively in relation to the research questions.

Expert opinion

Two general surgeons from Melbourne, Victoria were identified through personal referrals. The following set of six questions, developed in consultation with the Victorian Government Department of Health, was emailed to each surgeon.

1. What are the non-surgical interventions available in Victoria to patients with asymptomatic or minimally symptomatic IH or FH?
2. What are the failure rates for IH and FH repair?
3. What are the main considerations for general practitioners (GPs) and patients when considering WW rather than surgery for an asymptomatic or minimally symptomatic IH or FH?
4. For asymptomatic patients who opt for WW or non-surgical intervention:

   a. How many patients go on to have surgery and over what time period?
   b. How many patients require emergency surgery for bowel strangulation?
   c. Does WW carry a greater risk of complications and longer hospital stay in patients who eventually go on to have surgery, compared with patients who have surgery at hernia onset?

5. Are you aware of any local or international decision tools for GPs and patients to use when considering WW rather than surgery for IH or FH? Are these tools available in Victoria?
6. Do you know of any triage strategies trialled in other jurisdictions that have been effective in reducing the number of hernia repairs performed in asymptomatic or minimally symptomatic patients (e.g. strategies involving shared decision making between patients and doctors)?

Responses were de-identified, grouped into themes and reported narratively.

3. Studies Included in the Review

Literature search results

The literature search yielded 965 citations. Upon screening titles and abstracts, 24 potentially relevant articles were retrieved for full-text review. Reviewing references of studies and searching of grey literature identified one additional potentially relevant report. Of the 25 potentially relevant reports, two were included in a SR, four did not meet the study selection criteria, three were outdated guidelines and ten were an ineligible study design or were unable to be retrieved. Six studies were included in this review (Fitzgibbons et al. 2013; INCA Trialists Collaboration 2011; Miserez et al. 2014; Mizrahi and Parker 2012; Sanders et al. 2013; van den Heuvel et al. 2011). The study selection process is outlined in Appendix A (Figure A.1) and the excluded studies are listed in Appendix C.

Description of studies

Evidence regarding the specific clinical or pathological features of IH and FH that indicate a threshold below which surgery is of low clinical value was derived from two CPGs (Miserez et al. 2014; Sanders et al. 2013), three SRs (INCA Trialists Collaboration 2011; Mizrahi and Parker 2012; van den Heuvel et al. 2011) and one long-term follow-up (LTFU) study of an RCT (Fitzgibbons et al. 2013) that was included in the SRs. These sources also provided information on the appropriateness of WW for the management of asymptomatic or minimally symptomatic IH or FH. There were no relevant non-randomised comparative studies identified, nor was any relevant literature identified regarding effective alternative therapies to surgery or successful strategies trialled in other jurisdictions to reduce the number of hernia repairs or to improve care. The recommendation and evidence grading categories used in the CPGs are summarised in Appendix D (Table D.1); the characteristics of the included SRs and the LTFU study of an RCT are summarised in Appendix D (Table D.4).

Clinical practice guidelines

The EHS guideline (Miserez et al. 2014) provided an update of recommendations published by the EHS in 2009 (Simons et al. 2009) regarding WW for adult men with asymptomatic or minimally symptomatic IH (Appendix D, Table D.1). The updated recommendations were based on new high-level evidence from RCTs or meta-analyses of RCTs published between May 2008 and June 2010.

The British Hernia Society (BHS) provided evidence-based recommendations on the management of groin hernias in adults (Sanders et al. 2013). The guideline development group (GDG) formulated the recommendations based on a SR of the literature. Evidence related to clinical effectiveness was reviewed using established guides and classified using a hierarchical system that reflected the susceptibility to bias of particular study designs. In assessing the evidence, studies received a quality rating coded as "++",

"+" or "-". For treatment issues, the highest possible level of evidence was a well-conducted SR or meta-analyses of RCTs, or an individual RCT. Studies of poor quality were rated as "-" and were not used as a basis for the recommendations. Recommendations were derived using evidence, and consensus on decisions was achieved at formal meetings of the GDG. Recommendations were graded according to the level of evidence upon which they were based. For treatment, evidence from a SR, MA or RCT resulted in a Grade A recommendation; good quality cohort or case-control studies resulted in Grade B recommendations (Sanders et al. 2013).

Systematic reviews

The three SRs (level I evidence), containing between 5 and 30 studies involving 880 to over 10,000 patients, compared WW with surgical repair for asymptomatic or minimally symptomatic groin hernias (INCA Trialists Collaboration 2011; Mizrahi and Parker 2012; van den Heuvel et al. 2011) (Appendix D, Table D.4). Mizrahi et al. (2012) evaluated WW versus surgical repair in men with asymptomatic IH with respect to complications, cross over to surgery and pain. This SR included two RCTs (level II evidence), conducted in the United Kingdom (O'Dwyer et al. 2006) and North America (Fitzgibbons et al. 2006), which were reported in five articles (Chung et al. 2011; Fitzgibbons et al. 2006; O'Dwyer et al. 2006; Sarosi et al. 2011; Thompson et al. 2008) and involved 880 men with asymptomatic IH who were followed up from 1 to 7.5 years. The RCT by O'Dwyer et al. (2006) evaluated complications, cross over to surgery and pain after 1 year in 160 patients aged 55 years or older. The RCT by Fitzgibbons et al. (2006) evaluated complications, cross over to surgery and pain at 2 years in 720 men. Patient demographics were considerably different between the RCTs. British men assigned to WW were older (mean age 70 years) and asymptomatic for an average of 3.2 years, whereas the North American patients were younger (mean age 58 years) and 15 per cent had an IH for less than six weeks (Mizrahi and Parker 2012).

The INguinal hernia: Conservative or operative Approach (INCA) Trialists Collaboration compared WW with surgical repair in elderly men with asymptomatic or mildly symptomatic IH using a SR and a Markov model analysis (INCA Trialists Collaboration 2011). The SR included 26 studies (3 of level II evidence and 23 of level III-2 evidence; two were included in Mizrahi et al. (2012)) that reported on risk of incarceration or strangulation, mortality associated with elective and emergency hernia repair, risk of recurrence and rate of cross over from WW to surgical repair. RCTs comparing mortality associated with open and laparoscopic hernia repair, and those reporting pain before and after surgical repair or WW, were also included. Hospital admission data on the number of patients undergoing surgery who had IH with or without obstruction or gangrene were obtained from the National Medical Registry. Lengths of follow-up for the studies were not reported. Observed probabilities of incarceration or strangulation were converted into annual rates, assuming a constant rate of irreducibility and risk of recurrence. The life expectancy of a 50-year-old patient with an IH managed by WW or surgical repair was calculated using a Markov decision model over a 1-year cycle (INCA Trialists Collaboration 2011).

Van den Heuvel et al. (2011) evaluated WW and surgical repair in patients with asymptomatic groin hernia with respect to complications, cross over to surgery, pain and mortality up to 3.2 years after treatment allocation. Thirty studies (level of evidence not reported; 16 were included in INCA Trialists Collaboration (2011)) involving over 10,000 patients met the inclusion criteria: 14 reported on the rates of chronic pain, recurrence and mortality after elective herniorrhaphy, 17 reported on the rate of emergency repair for incarcerated or strangulated groin hernia and two RCTs compared WW with surgical repair for asymptomatic IH (Fitzgibbons et al. 2006; O'Dwyer et al. 2006). The rates of patient withdrawal or dropout in the included studies were not reported.

Long-term follow-up of a randomised controlled trial

Fitzgibbons et al. (2013) evaluated the long-term rate of cross over from WW to surgical repair in a subset of men who had completed 3.2 years of WW for asymptomatic IH in the RCT conducted by Fitzgibbons et al. (2006) (Appendix D, Table D.4). Upon completion of the RCT, 254 (69%) of 366 patients from the WW arm consented to undergo LTFU of seven years. These patients were sent a mail questionnaire annually to collect information about cross over to surgery and complications. Information on the reason for cross over, surgical details, postoperative pain and recurrence were captured for patients who crossed over from WW to surgery. Patients who continued with WW reported on hernia size, use of trusses, pain and satisfaction. While patients in the original RCT were recruited from both community and academic centres in five geographic locations in North America, enrolment in the LTFU excluded patients from one centre due to lack of approval from the institutional review board. At the end of the study, 167 (66%) patients had completed LTFU, nine had died, three had withdrawn consent and 75 had been lost to follow-up. The mean ages of the cross over and WW groups were 58 and 54 years, respectively (Fitzgibbons et al. 2013).

Appraisal of study quality

Summaries of the appraisal of the CPGs, SRs and the LTFU of an RCT are provided in Appendix D (Tables D.2 and D.5).

Clinical practice guidelines

The EHS guideline on the management of IH in adults (Miserez et al. 2014) provided an update of recommendations published by the EHS in 2009 (Simons et al. 2009) (Appendix D, Table D.2). Relevant literature published between May 2008 and June 2010 was identified by searching MEDLINE and *The Cochrane Library*. Two authors involved in preparing the original recommendations selected studies, assessed study quality and analysed any relevant data that may have affected the recommendations from the original guideline. Only studies with the potential to affect the conclusions or recommendations from the original guideline were incorporated. A compilation of the data was made by the first author and searches were updated until January 2013. The final recommendations were approved by a GDG whose members were derived from various

European countries and had expertise in a wide range of surgical hernia repair techniques. Several authors declared conflicts of interest directly related to the work, and the guideline was financed through a grant from Ethicon, Inc. (Somerville, NJ, USA). Only evidence from RCTs and meta-analyses of RCTs was considered; however, data from sources such as large prospective registries may have provided greater external validity than that from RCTs. Despite efforts to include all types of hernia surgeons on the GDG, implementation of the guidance must be fitted to the daily practice of individual surgeons and their patients. Regional and national differences in healthcare resources (e.g. availability of mesh and laparoscopic techniques) and reimbursement issues need to be taken into account. The development of decision support algorithms would facilitate implementation of the recommendations (Miserez et al. 2014). The EHS, the International Endo Hernia Society and the European Association for Endoscopic Surgery will publish new joint guidance in 2015.

The objective of the BHS guideline was to present the best evidence on groin hernia management and to provide clinicians with the information needed to deliver a high quality, cost-effective evidence-based hernia service across the United Kingdom (Sanders et al. 2013). A GDG comprising practitioners of both open and laparoscopic hernia repair, who were chosen by the Royal College of Surgeons of England and the BHS, developed the guideline with the assistance of an information specialist and methodologists. Grey literature sources were not systematically searched, which may have resulted in publication bias and an overestimation of the treatment effect in favour of the intervention. The recommendations were formulated with consideration of the health benefits, risks and costs of the treatments and were explicitly linked to the evidence that supported them. A large surgical registry was recommended as an audit and peer review tool, with emphasis on patient-based outcomes and best evidence. Tools for baseline assessment and costing were provided to facilitate implementation of the guideline, systems improvement and audit. The guideline was funded by an education grant from the surgical foundation, but conflicts of interest were not reported (Sanders et al. 2013).

Systematic reviews

All three SRs conducted comprehensive literature searches based on pre-defined criteria (INCA Trialists Collaboration 2011; Mizrahi and Parker 2012; van den Heuvel et al. 2011) (Appendix D, Table D.5). While two SRs reported independent study selection by two reviewers (INCA Trialists Collaboration 2011; Mizrahi and Parker 2012), none provided a list of excluded studies or complete study characteristics. Only one SR depicted the process of study selection using a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram and reported reasons for excluding studies (Mizrahi and Parker 2012). While the SR by the INCA Trialists Collaboration (2011) conducted duplicate data extraction, assessed trials for quality and reported risk of bias, sources of support and conflicts of interest, the other two SRs did not provide these details (Mizrahi and Parker 2012; van den Heuvel et al. 2011). It was unclear whether study quality was considered in formulating conclusions in two of the SRs (Mizrahi and

Parker 2012; van den Heuvel et al. 2011), or how study quality was used in formulating conclusions in the third (INCA Trialists Collaboration 2011). Funding sources and conflicts of interest were not reported in any of the SRs.

Long-term follow-up of a randomised controlled trial

The objectives, patient characteristics, interventions, outcomes and findings were clearly described in the LTFU study by Fitzgibbons et al. (2013) (Appendix D, Table D.5). No statistically significant differences in baseline characteristics were found in participants with complete follow-up, compared with those who dropped out over time. The internal validity of the study was limited because the study population did not represent the entire population or centres that were included in the original RCT by Fitzgibbons et al. (2006). Five North American centres participated in the original RCT, but one was excluded from the LTFU study due to lack of approval from the international review board. In addition, the patient population consisted of only 254 (69%) of the 366 men in the original RCT (Fitzgibbons et al. 2006) who consented to LTFU after completing WW; of these 254 men, 167 (66%) completed LTFU. There was also a strong self-selection bias as participation in the LTFU study was voluntary. The authors reported that most participants came to the clinic because they were concerned about their hernia, which may account for the high rate of cross over to surgery among the elderly patients. Consequently, the authors stated that the study results may not be applicable to all patients with asymptomatic or minimally symptomatic IH. While participants were recruited over the same time period, the surgical interventions varied over time: the crossover patients in the original RCT underwent Lichtenstein open tension-free repair, whereas participants in the LTFU study received open repair with mesh (69%), open hernia repair (15%) and laparoscopic repair (8%)–data for the remaining 8 per cent of patients were not reported. The source of funding and conflicts of interest were not reported (Fitzgibbons et al. 2013).

4. Literature Review Results

Threshold of pathology for herniorrhaphy

Evidence from two CPGs (Miserez et al. 2014; Sanders et al. 2013), three SRs (INCA Trialists Collaboration 2011; Mizrahi and Parker 2012; van den Heuvel et al. 2011) and a LTFU study of an RCT (Fitzgibbons et al. 2013) that was included in the SRs provided information about specific clinical or pathological features of groin hernias that may indicate a threshold below which surgical repair is of low clinical value (Table 2).

Clinical practice guidelines

The BHS guideline recommended that patients with asymptomatic or minimally symptomatic primary or recurrent IH who have significant morbidity (American Society of Anesthesiologists [ASA] physical status 3 or 4), have received adequate information and do not want to undergo surgical repair can be managed conservatively in primary care (Sanders et al. 2013) (Appendix D, Table D.3). All other patients should be referred to secondary care. Surgical repair should be offered to patients with symptomatic IH and is recommended for patients with FH. A laparoscopic approach may be beneficial for patients at risk of chronic pain, including women, younger patients and those with small groin hernias. Open approaches, under local anaesthetic, may be beneficial for older patients and patients with comorbidities. While there was no evidence to suggest that TEP repair is superior to a TAPP approach, or vice versa, TAPP repair may be beneficial when there is uncertainty about the cause of groin pain as it can be used to assess intra-abdominal structures (Sanders et al. 2013).

The EHS and BHS guidelines both specified that while patients with an asymptomatic hernia can be managed conservatively, future surgery was likely, based on evidence from two SRs, two RCTs, one follow-up of an RCT and two clinical studies (Chung et al. 2011; Fitzgibbons et al. 2006; Gallegos et al. 1991; Hair et al. 2001; INCA Trialists Collaboration 2011; Mizrahi and Parker 2012; Sarosi et al. 2011) (Table 2).

Systematic reviews

Three SRs provided evidence regarding a clinical threshold of pathology below which surgery for asymptomatic groin hernia is of low clinical value (INCA Trialists Collaboration 2011; Mizrahi and Parker 2012; van den Heuvel et al. 2011) (Table 2) (Appendix D, Table D.6). Mizrahi et al. (2012) (level I evidence) systematically reviewed the results of two RCTs (Fitzgibbons et al. 2006; O'Dwyer et al. 2006) involving 880 men with asymptomatic IH who were randomly assigned to either WW or surgical repair. Both studies reported no significant differences in pain or discomfort between patients who had surgery and those who underwent WW at the 4-year follow-up (Mizrahi and Parker 2012). A significant proportion of patients crossed over to surgery (range 23% to 72%) depending on the duration of follow-up. Fitzgibbons et al. (2006) found that, in addition to increase in hernia size and pain, factors contributing to cross over included

being married and having a low ASA physical status, chronic constipation or prostatism. In surgical repair patients, the rate of operative complications ranged from 0 to 22 per cent–the rate of hernia recurrence was 2 per cent (Mizrahi and Parker 2012). The SR authors concluded that while both WW and surgical repair were safe, most patients developed symptoms over time with WW. Therefore, clinicians should weigh the benefits of management options against potential complications and tailor care plans to individual patient needs (Mizrahi and Parker 2012).

Table 2: Summary of evidence on threshold of pathology for herniorrhaphy

Intervention	Evidence Statements/Recommendations
Herniorrhaphy of low clinical value	• Patients with asymptomatic or minimally symptomatic primary or recurrent IH who have significant morbidity (ASA physical status 3 or 4), have received adequate information and do not want to undergo surgical repair. [1 CPG] • WW is recommended for minimally symptomatic or asymptomatic IH in older patients or those with major comorbidities. [1 CPG] • Elderly men with asymptomatic or mildly symptomatic IH. [1 SR] • No significant difference in pain or discomfort at 4-years' follow-up between men with asymptomatic IH who had surgery and men who underwent WW. [2 SR] • Patients reporting no pain preoperatively at rest reported significant pain scores one year after IH repair in a cohort study. [1 SR] • Patients who had an increase in hernia size, pain, low ASA physical status, chronic constipation or prostatism were more likely to require surgery. [1 SR]
Herniorrhaphy of benefit	• Surgical repair should be offered to patients with symptomatic IH. [1 CPG] • Surgical repair is recommended for patients with FH. [1 CPG] • Patients with an increased risk of incarceration or increased risk of morbidity and mortality after emergency repair should be excluded from conservative management. [1 SR] • While asymptomatic IH can be managed conservatively, it is likely that surgery will be required in the future. [2 CPGs, 2 SR] • The rate of cross over from WW to surgical repair for asymptomatic IH ranged from 23% to 72% over time due to increase in pain and hernia size [1 SR]; yearly rate of 12% [1 SR]; the rate of cross over was higher and time to cross over was shorter for elderly men (>65 years of age) [1 LTFU study of an RCT]. • Laparoscopic techniques may be used to repair groin hernias in women, patients at risk of chronic pain, younger patients and patients with small groin hernias. [1 CPG] • TAPP repair may be beneficial when the cause of groin pain is uncertain. [1 CPG]

ASA: American Society of Anesthesiologists; CPG: clinical practice guideline; FH: femoral hernia; IH: inguinal hernia; LTFU: long-term follow-up; RCT: randomised controlled trial; SR: systematic review; TAPP: transabdominal preperitoneal; WW: watchful waiting

In addition to reviewing the RCTs by O'Dwyer et al. (2006) and Fitzgibbons et al. (2006), the SR by the INCA Trialists Collaboration (level I evidence) (INCA Trialists Collaboration 2011) reviewed a cohort study (level III-2 evidence) by Page et al. (2002) that reported on the preoperative and postoperative pain associated with IH repair. After following up 63 per cent of 323 patients one year after assessing their preoperative pain scores, the authors noted that patients who did not have any pain at rest prior to surgery had significant pain scores one year after surgery (P=0.001) (Page et al. 2002). The INCA Trialists Collaboration (2011) calculated the yearly rate of cross over from WW to

surgical repair as 12 per cent, based on results from the RCTs by O'Dwyer et al. (2006) and Fitzgibbons et al. (2006). The mean mortality rate associated with elective IH repair was 0.2 per cent (range 0% to 1.8%) based on a review of 15 clinical studies (4 of level II evidence and 11 of level III-2 evidence). While the average life expectancy of a 50-year-old man without hernia was 26.95 years, Monte Carlo simulation showed that the mean life expectancy of a patient with IH undergoing surgical repair was 26.89 years (95% confidence interval [CI] 26.88 to 26.89). The authors concluded that the life expectancy for elderly men with IH was similar, regardless of whether they underwent WW or surgical repair. The SR concluded that doubts about operating on asymptomatic or mildly symptomatic elderly patients were justified (INCA Trialists Collaboration 2011).

Van den Heuvel et al. (2011) (level I evidence) systematically reviewed surgical repair versus WW for asymptomatic groin hernia with respect to complications and pain. Common short-term complications associated with surgical repair included pain, haematoma, seroma and wound infection; long-term complications included chronic groin pain and hernia recurrence. The incidence of chronic groin pain 2 years after herniorrhaphy varied by technique: 54 per cent for suture repair; 13 to 37 per cent for Lichtenstein open tension-free repair; and10 to 30 per cent for laparoscopic repair. The rate of hernia recurrence also varied by technique: 62 per cent for suture; 0 to 10 per cent for Lichtenstein open tension-free repair; and 2 to 4 per cent for laparoscopic tension-free mesh repair. Van den Heuvel et al. (2011) concluded that WW for asymptomatic groin hernia was a safe and cost-effective modality in patients younger than 50 years of age with an IH who had an ASA physical status of 1 or 2 and hernia symptoms for longer than three months. Patients with an increased risk of incarceration, morbidity or death following emergency repair should be excluded from conservative management (van den Heuvel et al. 2011).

Long-term follow-up of a randomised controlled trial

Fitzgibbons et al. (2013) evaluated the long-term rate of cross over from WW to surgical repair in 254 (69%) of the 366 patients with asymptomatic IH who underwent WW in the RCT by Fitzgibbons et al. (2006) (Appendix D, Table D.6). Men older than 65 years of age had a higher cross over rate than younger men (79% versus 62%); 54 per cent of patients cited pain as the reason for undergoing unilateral open hernia repair using mesh. The median time to cross over was shorter in men older than 65 years (3.7 years, 95% CI 2.4 to 6.9), compared with men younger than 65 years (8.3 years, 95% CI 6.6 to 10.0).

Effectiveness of alternative therapies

No relevant literature was identified regarding effective alternative therapies to surgery for IH or FH. External devices such as hernia trusses, trunks and belts may be used to reduce hernias in non-surgical candidates; however, trusses were not recommended routinely due to discomfort, ineffectiveness and the potential for incarceration and testicular atrophy (Miserez et al. 2014; Sanders et al. 2013). Other than WW, no other

non-surgical interventions for asymptomatic or minimally symptomatic groin hernias were identified by contacting clinical experts.

Effectiveness of watchful waiting

Evidence from two CPGs (Miserez et al. 2014; Sanders et al. 2013), three SRs (INCA Trialists Collaboration 2011; Mizrahi and Parker 2012; van den Heuvel et al. 2011) and one LTFU study of an RCT (Fitzgibbons et al. 2013) included in the SRs provided information about the effectiveness of WW for the management of asymptomatic IH or FH (Table 3).

Clinical practice guidelines

The EHS 2009 guideline (Simons et al. 2009), which was recently updated to include new evidence (Miserez et al. 2014), stated that WW was an acceptable option for men with minimally symptomatic or asymptomatic IH (Simons et al. 2009) (Appendix D, Table D.3). A follow-up study of the RCT by O'Dwyer et al. (2006) showed that, after a median of 7.5 years (range 6.2 to 8.2), 46 of the 80 men randomly assigned to WW had crossed over to surgical repair (Chung et al. 2011). The estimated conversion rate for the group, which had a mean age of 72 years at inclusion, was 16 per cent at one year, 54 per cent at five years, and 72 per cent at 7.5 years. The main reason for crossing over to surgery was pain—two patients (2.5%) had an acute hernia. Chung et al. (2011) concluded that most patients with a painless IH developed symptoms over time and suggested that surgical repair be recommended for medically fit patients with a painless IH. Based on these results, the GDG changed the guideline recommendation to state that while WW was a safe and acceptable option for men with minimally symptomatic or asymptomatic IH, it was likely (>70% chance) that symptoms will increase over time and that patients will eventually require surgical intervention (Miserez et al. 2014). It was recommended that WW for minimally symptomatic or asymptomatic IH be considered in older patients or those with major comorbidities (Miserez et al. 2014) Similarly, the BHS guideline specified that while patients with an asymptomatic hernia can be managed conservatively, it was likely that surgical repair will eventually be required (Sanders et al. 2013).

Systematic reviews

Three SRs provided evidence regarding the effectiveness of WW for asymptomatic groin hernia (INCA Trialists Collaboration 2011; Mizrahi and Parker 2012; van den Heuvel et al. 2011) (Appendix D, Table D.6). Mizrahi et al. (2012) (level I evidence) systematically reviewed the results of two RCTs (Fitzgibbons et al. 2006; O'Dwyer et al. 2006) involving 880 men with asymptomatic IH who were randomly assigned to WW or surgical repair. Both studies reported no significant differences in pain or discomfort in either patient group following the intervention. Both studies reported a significant rate of cross over (range 23% to 72%) depending on the duration of follow-up. The SR authors concluded that while both WW and surgical repair were safe, most patients developed symptoms

over time and required surgery. In WW patients, the rates of IH strangulation were 0.3 and 0.6 per cent at the 2-year and 4-year follow-up, respectively. Mizrahi and Parker (2012) stated that clinical management should be patient-specific and take into consideration the risk of complications.

A SR by the INCA Trialists Collaboration (2011) (level I evidence) also reviewed the RCTs by O'Dwyer et al. (2006) and Fitzgibbons et al. (2006). Pain-related activity limitation was similar for WW and surgical repair patients (5% versus 2% at 2-year follow-up, respectively) (Fitzgibbons et al. 2006). No significant difference in pain scores was noted between the patient groups at rest or during movement at 1-year follow-up (O'Dwyer et al. 2006). The INCA Trialists Collaboration (2011) reported that 23 per cent of patients who underwent WW in Fitzgibbons et al. (2006) crossed over to surgical repair within two years; 19 per cent crossed over to surgical repair within one year in O'Dwyer et al. (2006). In combining the results of these studies, the INCA Trialists Collaboration (2011) reported that 13 per cent (range 8% to 20%) of patients with asymptomatic and minimally symptomatic IH assigned to WW will cross over to surgical repair. On reviewing four retrospective cohort studies (evidence level III-2), in addition to the RCTs by O'Dwyer et al. (2006) and Fitzgibbons et al. (2006), the INCA Trialists Collaboration (2011) calculated that the annual rate of irreducibility associated with WW was 0.4 per cent (range 0.2% to 2.7%; event type differed between studies, e.g. irreducibility requiring operation, strangulation or incarceration, incarceration and strangulation, and strangulation). While the average life expectancy of a 50-year-old man without hernia was 26.95 years, Monte Carlo simulation showed that the mean life expectancy of a man with IH who underwent WW was 26.88 years (95% CI 26.87 to 26.88). The authors concluded that life expectancy and pain level for elderly men with IH were the same, regardless of whether they opted for WW or surgical repair (INCA Trialists Collaboration 2011).

Van den Heuvel et al. (2011) (level I evidence) compared WW with surgical repair for asymptomatic groin hernia with respect to complications, pain, mortality and rate of cross over to surgery. Approximately 7 per cent of all hernia repairs were emergency repairs for incarcerated or strangulated groin hernia, based on a review of 17 clinical studies (levels of evidence not reported). A Columbian epidemiological study reported an annual overall risk of incarceration and strangulation of 3.6 per 1,000 men and 5.4 per 1,000 women with groin hernia (Neutra et al. 1981). FHs incarcerate and strangulate more frequently than IHs, and patients with FH are eight times more likely to undergo an emergency repair than elective surgery (22% versus 3%, respectively). The risk of complications increased as the patient ages, with peak incidence occurring between 61 and 80 years of age. In addition, the cumulative probability of incarceration and strangulation increases over time. Three months following the onset of an IH, the cumulative probability of incarceration and strangulation was 2.8 per cent, increasing to 4.5 per cent after two years. For women, the cumulative probability was much higher: 22 per cent at 3 months and 45 per cent at 21 months (van den Heuvel et al. 2011).

Van den Heuvel et al. (2011) also assessed the RCTs by O'Dwyer et al. (2006) and Fitzgibbons et al. (2006), noting a complication rate of 1.8 per 1,000 patients per year in the WW group. The average rate of morbidity associated with elective groin herniorrhaphy was 8 per cent, based on a review of 14 clinical studies (level of evidence not reported). The average mortality rate following groin herniorrhaphy was 0.5 per cent.

Long-term follow-up of a randomised controlled trial

Fitzgibbons et al. (2013) evaluated the long-term rate of cross over from WW to surgical repair in a subset of men who underwent WW for asymptomatic IH in the RCT by Fitzgibbons et al. (2006) (Appendix D, Table D.6). Eighty-one (32%) of the WW patients underwent surgical repair, at a median follow-up of 3.2 years (range 2 to 4.5), before the original study ended. Upon completion of the RCT, 254 (69%) of the 366 patients from the WW arm consented to LTFU of seven years, with a maximum follow-up of 11.5 years. Kaplan-Meier analyses estimated that 50 per cent of WW patients converted to surgery by 7.3 years (95% CI 5.3 to 8.4) and 68 per cent had undergone surgery 10 years post-randomisation. Three patients from the WW group required emergency surgery for complications. The incidence of hernia accident was 0.2 per 100 person-years for the entire cohort; 0.6 per 100 person-years for patients younger than 65 years and 0.1 per 100 person-years for patients older than 65 years. The authors concluded that while WW was a safe strategy over the long-term, patients, especially those who are elderly, should be informed that they will likely need surgical repair eventually. The authors noted that the results had limited external validity and should not be extrapolated to all patients with asymptomatic or minimally symptomatic groin hernia (Fitzgibbons et al. 2013).

Table 3: Summary of evidence on WW for asymptomatic IH and FH

Intervention	Evidence Statements/Recommendations
WW for IH	• WW is safe and cost-effective in patients with an IH who are younger than 50 years of age, have an ASA physical status of 1 or 2 and have had symptoms for >3 months. [1 SR] • WW is a safe, acceptable option for men with minimally symptomatic or asymptomatic IH; it is likely that symptoms will increase over time, eventually leading to surgical intervention. [1 CPG, 3 SRs, 1 LTFU of an RCT] • No significant difference between WW and surgical repair with respect to pain or discomfort for patients with asymptomatic or minimally symptomatic IH. [3 SR] • Annual rate of irreducibility associated with WW was 0.4% (range 0.2% to 2.7%). [1 SR] • Rates of IH strangulation were 0.3% and 0.6% at the 2-year and 4-year follow-up. [1 SR] • Mean life expectancy of a patient with IH undergoing WW was 26.88 years, compared with an average life expectancy of 26.95 years without hernia (95% CI 26.87 to 26.88). [1 SR]
WW for FH	• Annual overall risk of incarceration and strangulation was 3.6 per 1,000 men and 5.4 per 1,000 women with groin hernia, based on an epidemiological study. [1 SR] • FHs incarcerate and strangulate far more frequently than IHs. [1 SR] • FHs are eight times more likely to require emergency rather than elective repair. [1 SR] • The risk of complications increases with age, peaking between 61 and 80 years of age. [1 SR] • Cumulative probability of incarceration and strangulation increases with time and is significantly higher in women than in men. [1 SR]

ASA: American Society of Anesthesiologists class; CPG: clinical practice guideline; FH: femoral hernia; IH: inguinal hernia; LTFU: long-term follow-up; RCT: randomised controlled trial; SR: systematic review; WW: watchful waiting

Strategies to increase the appropriateness of herniorrhaphy and improve care

No relevant literature was identified regarding successful strategies to increase the appropriateness of herniorrhaphy or improve care for patients with asymptomatic or minimally symptomatic IH or FH. Clinical experts were not aware of any triage strategies trialled in other jurisdictions that have been effective in reducing the number of hernia repairs in asymptomatic patients, nor were they aware of any decision tools for GPs or patients to use when considering WW.

5. Expert Opinion

Responses were received from two general surgeons, each from a major hospital in Melbourne, Victoria, who were asked to provide their expert opinion on the six questions below.

Question 1: What are the non-surgical interventions available in Victoria to patients with asymptomatic or minimally symptomatic IH or FH?

Both surgeons agreed that there are no interventions, other than surgery, that will cure a hernia. Some symptomatic relief can be obtained from oral analgesia. While some patients find abdominal wall binders helpful in relieving symptoms, they are generally not beneficial and may cause more harm than benefit in a minimally symptomatic patient. The only reasonable non-surgical option is regular observation.

Question 2: What are the failure rates for IH and FH repair?

IHs comprise at least 95 per cent of groin hernias and have a higher recurrence rate after surgery than FHs. The failure rate for IH repair, with resulting recurrence, is between 3 and 4 per cent. There is some evidence that laparoscopic hernia repair is associated with a higher recurrence rate than standard open repair. The failure rate for FH repair is not well documented.

The largest recent study on recurrence rates comes from Denmark (Burcharth 2014). Of 85,314 people who underwent IH repair, 3.8 per cent experienced a recurrence. This study also included a MA of 375,620 patients, which showed that the risk factors for hernia recurrence included being female, having direct IH repair as the first procedure and having an operation for recurrent hernia. Patient age, hernia size, the presence of bilateral hernia and smoking did not affect the recurrence rate.

Since the risk of bowel incarceration is negligible, most hernias are repaired to alleviate pain. The risk of chronic or severe pain after IH repair is 20 per cent and 5 per cent, respectively, suggesting that herniorrhaphy is not a very effective treatment.

Question 3: What are the main considerations for GPs and patients when considering WW rather than surgery for an asymptomatic or minimally symptomatic IH or FH?

Patient age and comorbidity are the most important factors to consider. Since the benefit of repair is minimal in asymptomatic patients, patients should generally be counselled against operative repair to avoid unnecessary operative risk.

WW is particularly applicable for patients who:

- Are unfit for surgery due to medical issues, age or use of anticoagulant therapy;
- Have a direct IH where there is a low risk of strangulation;

- Have a recurrent hernia after previous surgical repair (the risks of further surgery are greater than for a first procedure).

One surgeon commented that large, minimally symptomatic IHs are more likely to rapidly progress to larger scrotal hernias; in such cases even patients with minimal symptoms should be considered for hernia repair if they are fit for surgery. In the case of FHs, the risk of strangulation is much greater and there is no place for WW if the patient is able to undergo surgery.

Question 4: For asymptomatic patients who opt for WW or non-surgical intervention:

a. How many patients go on to have surgery and over what time period?

One surgeon quoted data from the United States where 25 per cent of patients will have surgery within two years and almost 70 per cent will require an operation within 10 years. The other surgeon also quoted data from a US study (Fitzgibbons et al. 2013) that followed up 254 men with minimally symptomatic IH. Over a 7-year period, 80 per cent of men older than 65 years and 60 per cent of men younger than 65 years required surgery. The main reason for altering from WW to surgery was pain. The study concluded that WW was a reasonable strategy, but that symptoms will generally progress to the point where surgery is required.

b. How many patients require emergency surgery for bowel strangulation?

One surgeon commented that very few patients will require emergency surgery for strangulation or incarceration (<1% over 10 years). The other surgeon concurred, stating that Fitzgibbons et al. (2013) reported a rate for emergency surgery of 1.2% and no deaths over a 7-year period.

c. Does WW carry a greater risk of complications and longer hospital stay in patients who eventually go on to have surgery, compared with patients who have surgery at hernia onset?

There is no evidence that this is the case. Studies have shown that the chance of strangulation is greater in the early phase of hernia development; long-standing hernias are less likely to strangulate. Conservative management may not be appropriate in patients who have an acute onset of hernia, even if it is relatively asymptomatic. Another consideration is that in elderly patients IH can be a presenting feature of underlying colon pathology, particularly carcinoma. Therefore, colonoscopy may be indicated in these patients if there is a sudden onset of IH, particularly when it is associated with a change in bowel habit.

Question 5: Are you aware of any local or international decision tools for GPs and patients to use when considering WW rather than surgery for IH or FH? Are these tools available in Victoria?

Neither surgeon was aware of any validated tools.

Question 6: Do you know of any triage strategies trialled in other jurisdictions that have been effective in reducing the number of hernia repairs performed in asymptomatic or minimally symptomatic patients (e.g. strategies involving shared decision making between patients and doctors)?

Neither surgeon was aware of any validated triage strategies.

6. Discussion

Findings

This rapid review summarised evidence regarding the clinical threshold of pathology below which herniorrhaphy is of low clinical value for patients with IH or FH, the effectiveness of alternative treatments to herniorrhaphy, the effectiveness of WW for asymptomatic or minimally symptomatic IH or FH and strategies trialled in other jurisdictions to increase the appropriateness of hernia repair and improve care.

Threshold of pathology for herniorrhaphy

Evidence regarding specific clinical or pathological features of groin hernias that indicate a threshold below which surgical repair is of low clinical value was derived from two CPGs (Miserez et al. 2014; Sanders et al. 2013), three SRs (INCA Trialists Collaboration 2011; Mizrahi and Parker 2012; van den Heuvel et al. 2011) and a LTFU study of an RCT (Fitzgibbons et al. 2013). While men with an asymptomatic or minimally symptomatic IH that is not painful and does not interfere with daily activities may be managed conservatively, pain will likely increase over time and many patients may eventually require surgery (INCA Trialists Collaboration 2011; Miserez et al. 2014; Mizrahi and Parker 2012; Sanders et al. 2013; van den Heuvel et al. 2011). Patients with asymptomatic or minimally symptomatic primary or recurrent IH who have significant morbidity (ASA physical status 3 or 4) and do not want to undergo surgical repair may be managed conservatively (Sanders et al. 2013). Operating on asymptomatic or mildly symptomatic elderly patients may not be justified (INCA Trialists Collaboration 2011). Younger patients (under 50 years of age) with an asymptomatic groin hernia, especially an IH, of more than 3 months' duration and with limited morbidity (ASA physical status 1 or 2) may also be managed effectively through WW (van den Heuvel et al. 2011).

The rate of cross over from WW to surgical repair increased over follow-up, ranging from 23 per cent at two years to 72 per cent at 7.5 years (Mizrahi and Parker 2012). These findings are in agreement with expert opinion from two surgeons in Victoria. Patients who were married or elderly, or had increasing hernia size, pain, low ASA physical status, chronic constipation or prostatism were more likely to require surgical repair (Fitzgibbons et al. 2013; Sarosi et al. 2011).

Patients with FH or symptomatic IH should be offered surgical repair (Sanders et al. 2013). Patients at risk of chronic pain, including women, younger patients and those with small hernias, may benefit from a laparoscopic approach. In cases of diagnostic uncertainty, the TAPP approach may be of benefit (Sanders et al. 2013). According to expert opinion, large, minimally symptomatic IHs should be considered for surgical repair because of their tendency to progress to larger scrotal hernias.

Among surgical patients, the rates of mortality and morbidity were 0.5 per cent and 8 per cent (van den Heuvel et al. 2011), respectively; the rate of operative complications ranged

from 0 to 22 per cent (Mizrahi and Parker 2012). Patients who do not have preoperative pain at rest may experience significant pain up to a year after surgical repair (Page et al. 2002). The incidence of chronic pain following herniorrhaphy ranged from 0 to 54 per cent, depending on the surgical technique, and the rate of recurrence ranged from 0 to 62 per cent (van den Heuvel et al. 2011).

Alternative therapies for groin hernias

External devices such as hernia trusses, trunks or belts may be used to reduce hernias in non-surgical candidates, but they are not recommended routinely owing to discomfort, ineffectiveness and the potential for incarceration and testicular atrophy (Miserez et al. 2014; Sanders et al. 2013). Apart from WW, no other non-surgical interventions were identified for managing asymptomatic or minimally symptomatic groin hernias. These findings were in agreement with the expert opinion provided by two Victorian surgeons.

Watchful waiting for asymptomatic or minimally symptomatic hernias

Evidence on the effectiveness of WW for asymptomatic IH or FH was provided by two CPGs (Miserez et al. 2014; Sanders et al. 2013), three SRs (INCA Trialists Collaboration 2011; Mizrahi and Parker 2012; van den Heuvel et al. 2011) and a LTFU study of an RCT (Fitzgibbons et al. 2013). WW was a safe and acceptable management option for men with asymptomatic or minimally symptomatic IH; however, pain is likely to increase with time, leading to surgical repair for many patients (INCA Trialists Collaboration 2011; Miserez et al. 2014; Mizrahi and Parker 2012; Sanders et al. 2013; van den Heuvel et al. 2011). The estimated rate of cross over from WW to surgery for men aged 72 years was 16 per cent at one year, 54 per cent at five years, and 72 per cent at 7.5 years (Chung et al. 2011). Based on these findings, it was recommended that WW for asymptomatic IH be considered in older patients and those with comorbidities (Chung et al. 2011; Miserez et al. 2014). There was no significant difference between WW and surgical repair with respect to life expectancy or pain in elderly men with IH (INCA Trialists Collaboration 2011).

The rate of cross over from WW to surgical repair in the long-term was also evaluated in a LTFU study of an RCT for a subset of men who underwent WW for asymptomatic IH (Fitzgibbons et al. 2006). The proportion of men aged 58 years who converted from WW to surgery was 32 per cent at two years, 50 per cent at 7.3 years and 68 per cent at 10 years (Fitzgibbons et al. 2013). Based on these findings, patients should be informed, particularly if they are elderly, that they are likely to require surgical repair eventually (Fitzgibbons et al. 2013).

The yearly rate of irreducibility associated with WW in patients with IH was 0.4 per cent (range 0.2% to 2.7%; event types differed between studies, e.g. irreducibility requiring operation, strangulation or incarceration, incarceration and strangulation, and strangulation) (INCA Trialists Collaboration 2011). The cumulative probability of incarceration increased with time, from 2.8 per cent three months after onset of IH to

4.5 per cent after 24 months in men and from 22 per cent at three months to 45 per cent at 21 months in women (van den Heuvel et al. 2011).

Approximately 7 per cent of all hernia operations were emergency repairs for incarcerated or strangulated groin hernias (van den Heuvel et al. 2011). FHs incarcerate and strangulate more frequently than IHs. Patients with FH were eight times more likely to undergo an emergency repair than elective surgery (22% versus 3%) (van den Heuvel et al. 2011).

Strategies to increase the appropriateness of herniorrhaphy and improve care

A limited, systematic search of the literature and contact with clinical experts did not identify any strategies for increasing the appropriateness of hernia repair or improving care. The clinical experts were not aware of any decision tools for use by GPs or patients when considering WW versus surgery for IH or FH.

Limitations of the evidence

Evidence on the clinical threshold of pathology below which herniorrhaphy is of low clinical value for patients with groin hernias and the effectiveness of WW for asymptomatic IH or FH was derived from two CPGs (Miserez et al. 2014; Sanders et al. 2013), three SRs (INCA Trialists Collaboration 2011; Mizrahi and Parker 2012; van den Heuvel et al. 2011) and a LTFU study of an RCT (Fitzgibbons et al. 2013). There was potential for publication bias and missing information in that none of the SRs or CPGs cited a formal systematic search for grey literature. While level I evidence provided most of the information used to answer the research questions, data from sources such as large prospective registries may have conferred greater external validity on the conclusions. Detailed study characteristics and quality of included studies were seldom fully reported in the SRs. While the patient demographics differed considerably between the two main RCTs (Fitzgibbons et al. 2006; O'Dwyer et al. 2006) reported in the CPGs and SRs, most evidence was based on men with asymptomatic IH.

The LTFU study of an RCT included in the SRs suffered strong self-selection bias as a result of voluntary participation and had low external validity. While the CPG recommendations took into consideration health benefits, risks and costs and were explicitly linked to the evidence that supported them, it was unclear whether or how study quality was considered in formulating the conclusions in the SRs.

This report was limited in that, even after systematically searching the literature and contacting clinical experts, no non-surgical interventions, other than WW, were identified for managing asymptomatic or minimally symptomatic groin hernias. Similarly, no information was found regarding decision tools for patient management or strategies for reducing the number of hernia repairs or improving care. However, this does not preclude the existence of such alternative interventions, decision tools or management strategies. No Australian CPGs were identified; the included CPGs were developed in

Europe, and there may be inherent differences between the populations and healthcare contexts of the two regions that limit the transferability of the recommendations. While current and inclusive of evidence up to July 2014, this rapid review may become outdated when the EHS, the International Endo Hernia Society and the European Association for Endoscopic Surgery publish new joint guidance in 2015. Future guideline implementation will depend on developing effective decision support algorithms for tailoring hernia management to individual patient needs and evaluating the effect of guideline implementation on patient outcomes (Miserez et al. 2014).

7. Conclusions and Implications for Policy

There was consensus in the evidence that men with asymptomatic or minimally symptomatic IH, which is not painful and does not interfere with daily activities, may be managed in primary care with WW. However, in many cases pain will increase over time and surgical repair will eventually become necessary. Patients with asymptomatic IH managed with WW showed no significant difference in pain compared with surgery recipients, and the rate of obstruction or strangulation with WW was less than 1 per cent annually. The life expectancy for elderly men with IH was the same, regardless of whether they opted for WW or surgical repair. Therefore, operating on patients with comorbidities and a minimally symptomatic IH may not be justified. An increased likelihood of cross over from WW to surgery was associated with increasing age and hernia size, low ASA physical status, being married and presence of pain, chronic constipation or prostatism. Patients with FH or symptomatic IH should be offered surgical repair. FHs are far more likely to incarcerate or strangulate than IHs. The incidence of chronic groin pain following herniorrhaphy ranged from 10 to 54 per cent, depending on technique, and the rate of recurrence ranged from 0 to 62 per cent.

WW was identified as the only alternative to surgical repair for asymptomatic or mildly symptomatic groin hernias. External devices such as trusses, trunks or belts may be used to reduce hernias in non-surgical candidates, but they were not recommended routinely due to discomfort, ineffectiveness and risk of incarceration. No effective strategies for reducing the number of hernia repairs were identified in the literature or by contacting clinical experts.

While these results are in favour of reducing herniorrhaphy in men with asymptomatic or minimally symptomatic IH, decision makers need to consider that it is very likely (>70% chance) that pain will increase over time, necessitating surgical repair. Level I evidence provided the basis for answering the research questions, but it was unclear to what extent the conclusions could be extrapolated to the general population of patients with asymptomatic or minimally symptomatic inguinal or femoral hernia. While WW is an alternative to surgical repair for men with asymptomatic or minimally symptomatic IH, clinicians should weigh this option against potential complications and tailor management to individual patient needs. Future implementation of strategies to encourage appropriate patient selection for herniorrhaphy or WW may depend on the development of decision support algorithms tailored to individual patients and the evaluation of surgical outcomes after guideline implementation.

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References

Australian Institute of Health and Welfare (AIHW) 2011, *Australian hospital statistics 2009-10*, AIHW, Canberra, viewed September 2014, <http://www.google.com.au/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CDIQFjAA&url=http%3A%2F%2Fwww.aihw.gov.au%2FWorkArea%2FDownloadAsset.aspx%3Fid%3D10737418865&ei=7C1eUaL7JaSPiAf9h4DYDA&usg=AFQjCNF675-tZOgC6sBUkvJnyQguKDDspw&sig2=80Ol1u5oPzIozTvwMbvDzw&bvm=bv.44770516,d.aGc>.

Allen, PI, Zager, M & Goldman, M 1987, 'Elective repair of groin hernias in the elderly', *British Journal of Surgery*, vol.74(11), pp. 987.

Álvarez, JA, Baldonedo, RF, Bear, IG, Solís, JAS, Álvarez, P & Jorge, JI 2004, 'Incarcerated groin hernias in adults: Presentation and outcome', *Hernia*, vol.8(2), pp. 121-6.

Andrews, NJ 1981, 'Presentation and outcome of strangulated external hernia in a district general hospital', *British Journal of Surgery*, vol.68(5), pp. 329-32.

Antoniou, SA, Pointner, R & Granderath, FA 2014, 'Current treatment concepts for groin hernia', *Langenbeck's Archives of Surgery*, vol.399(5), pp. 553-8.

Askew, G, Williams, GT & Brown, SC 1992, 'Delay in presentation and misdiagnosis of strangulated hernia: Prospective study', *Journal of the Royal College of Surgeons of Edinburgh*, vol.37(1), pp. 37-8.

Bay-Nielsen, M, Kehlet, H, Strand, L, Malmstrøm, J, Andersen, FH, Wara, P, Juul, P & Callesen, T 2001a, 'Quality assessment of 26 304 herniorrhaphies in Denmark: A prospective nationwide study', *Lancet*, vol.358(9288), pp. 1124-8.

Bay-Nielsen, M, Perkins, FM & Kehlet, H 2001b, 'Pain and functional impairment 1 year after inguinal herniorrhaphy: A nationwide questionnaire study', *Annals of Surgery*, vol.233(1), pp. 1-7.

Brasso, K, Nielsen, KL & Christiansen, J 1989, 'Long-term results of surgery for incarcerated groin hernia', *Acta Chirurgica Scandinavica*, vol.155(11-12), pp. 583-5.

Brouwers, M, Kho, ME, Browman, GP, Cluzeau, F, Feder, G, Fervers, B, Hanna, S & Makarski, J on behalf of the AGREE Next Steps Consortium 2010, 'AGREE II: Advancing guideline development, reporting and evaluation in healthcare', *CMAJ*, vol.182(18), pp. E839-42.

Burcharth, J 2014, 'The epidemiology and risk factors for recurrence after inguinal hernia surgery', *Danish Medical Journal*, vol.61(5), pp. B4846.

Chung, L, Norrie, J & O'Dwyer, PJ 2011, 'Long-term follow-up of patients with a painless inguinal hernia from a randomized clinical trial', *British Journal of Surgery*, vol.98(4), pp. 596-9.

Downs, SH & Black, N 1998, 'The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions', *Journal of Epidemiology and Community Health*, vol.52(6), pp. 377-84.

European Hernia Society (EHS) 2013, *Treatment of inguinal hernia in adult patients*, EHS, viewed Jan 20 2013, <http://www.herniaweb.org/fileadmin/downloads/library/EHS_Guidelines_orig.pdf>.

Fitzgibbons Jr, RJ, Giobbie-Hurder, A, Gibbs, JO, Dunlop, DD, Reda, DJ, McCarthy Jr, M, Neumayer, LA, Barkun, JST, Hoehn, JL, Murphy, JT, Sarosi Jr, GA, Syme, WC, Thompson, JS, Wang, J & Jonasson, O 2006, 'Watchful waiting vs repair of inguinal hernia in minimally symptomatic men: A randomized clinical trial', *Journal of the American Medical Association*, vol.295(3), pp. 285-92.

Fitzgibbons Jr, RJ, Ramanan, B, Arya, S, Turner, SA, Li, X, Gibbs, JO & Reda, DJ 2013, 'Long-term results of a randomized controlled trial of a nonoperative strategy (watchful waiting) for men with minimally symptomatic inguinal hernias', *Annals of Surgery*, vol.258(3), pp. 508-14.

Gallegos, NC, Dawson, J, Jarvis, M & Hobsley, M 1991, 'Risk of strangulation in groin hernias', *British Journal of Surgery*, vol.78(10), pp. 1171-3.

Haapaniemi, S, Sandblom, G & Nilsson, E 1999, 'Mortality after elective and emergency surgery for inguinal and femoral hernia', *Hernia*, vol.3(4), pp. 205-8.

Hair, A, Duffy, K, McLean, J, Taylor, S, Smith, H, Walker, A, Macintyre, IMC & O'Dwyer, PJ 2000, 'Groin hernia repair in Scotland', *British Journal of Surgery*, vol.87(12), pp. 1722-6.

Hair, A, Paterson, C, Wright, D, Baxter, JN & O'Dwyer, PJ 2001, 'What effect does the duration of an inguinal hernia have on patient symptoms?', *Journal of the American College of Surgeons*, vol.193(2), pp. 125-9.

INCA Trialists Collaboration 2011, 'Operation compared with watchful waiting in elderly male inguinal hernia patients: A review and data analysis', *Journal of the American College of Surgeons*, vol.212(2), pp. 251-9.e4.

Kauffman Jr, HM & O'Brien, DP 1970, 'Selective reduction of incarcerated inguinal hernia', *The American Journal of Surgery*, vol.119(6), pp. 660-73.

Kulacoglu, H 2011, 'Current options in inguinal hernia repair in adult patients', *Hippokratia*, vol.15(3), pp. 223-31.

Kulah, B, Kulacoglu, IH, Oruc, MT, Polat Duzgun, A, Moran, M, Ozmen, MM & Coskun, F 2001a, 'Presentation and outcome of incarcerated external hernias in adults', *American Journal of Surgery*, vol.181(2), pp. 101-4.

Kulah, B, Polat Duzgun, A, Moran, M, Kulacoglu, IH, Mahir Ozmen, M & Coskun, MSF 2001b, 'Emergency hernia repairs in elderly patients', *American Journal of Surgery*, vol.182(5), pp. 455-9.

Kurt, N, Oncel, M, Ozkan, Z & Bingul, S 2003, 'Risk and outcome of bowel resection in patients with incarcerated groin hernias: Retrospective study', *World Journal of Surgery*, vol.27(6), pp. 741-3.

Lewis, DC, Moran, CG & Vellacott, KD 1989, 'Inguinal hernia repair in the elderly', *Journal of the Royal College of Surgeons of Edinburgh*, vol.34(2), pp. 101-3.

Lichtenstein, IL 1987, 'Herniorrhaphy. A personal experience with 6,321 cases', *American Journal of Surgery*, vol.153(6), pp. 553-9.

Malek, S, Torella, F & Edwards, PR 2004, 'Emergency repair of groin herniae: Outcome and implications for elective surgery waiting times', *International Journal of Clinical Practice*, vol.58(2), pp. 207-9.

McEntee, G, Pender, D, Mulvin, D, McCullough, M, Naeeder, S, Farah, S, Badurdeen, MS, Ferraro, V, Cham, C, Gillham, N & Matthews, P 1987, 'Current spectrum of intestinal obstruction', *British Journal of Surgery*, vol.74(11), pp. 976-80.

Medicare Australia 2013, *Medicare item reports*, Medicare Australia, Canberra, viewed September 2014, <http://www.mbsonline.gov.au/>.

Merlin, T, Weston, A & Tooher, R 2009, 'Extending an evidence hierarchy to include topics other than treatment: revising the Australian 'levels of evidence', *BMC Medical Research Methodology*, vol.9(34), doi:10.1186/1471-2288-9-34.

Miserez, M, Peeters, E, Aufenacker, T, Bouillot, JL, Campanelli, G, Conze, J, Fortelny, R, Heikkinen, T, Jorgensen, LN, Kukleta, J, Morales-Conde, S, Nordin, P, Schumpelick, V, Smedberg, S, Smietanski, M, Weber, G & Simons, MP 2014, 'Update with level 1 studies of the European Hernia Society guidelines on the treatment of inguinal hernia in adult patients', *Hernia*, vol.18(2), pp. 151-63.

Mizrahi, H & Parker, MC 2012, 'Management of asymptomatic inguinal hernia: a systematic review of the evidence', *Archives of Surgery*, vol.147(3), pp. 277-81.

Nehme, AE 1983, 'Groin hernias in elderly patients. Management and prognosis', *American Journal of Surgery*, vol.146(2), pp. 257-60.

Neuhauser, D 1977, 'Elective inguinal herniorrhaphy versus truss in the elderly', In: Bunker, JP, Barnes, BA & Mosteller, F, *Costs, risks and benefits of surgery*, Oxford University Press, New York.

Neumayer, L, Giobbie-Hurder, A, Jonasson, O, Fitzgibbons Jr, R, Dunlop, D, Gibbs, J, Reda, D & Henderson, W 2004, 'Open mesh versus laparoscopic mesh repair of inguinal hernia', *New England Journal of Medicine*, vol.350(18), pp. 1819-27.

Neutra, R, Velez, A, Ferrada, R & Galan, R 1981, 'Risk of incarceration of inguinal hernia in Cali, Colombia', *Journal of Chronic Diseases*, vol.34(11), pp. 561-4.

Nilsson, E, Kald, A, Anderberg, B, Bragmark, M, Fordell, R, Haapaniemi, S, Heuman, R, Lindhagen, J, Stubberöd, A & Wickbom, J 1997, 'Hernia surgery in a defined population: A prospective three year audit', *European Journal of Surgery*, vol.163(11), pp. 823-9.

Nilsson, H, Stylianidis, G, Haapamäki, M, Nilsson, E & Nordin, P 2007, 'Mortality after groin hernia surgery', *Annals of Surgery*, vol.245(4), pp. 656-60.

O'Dwyer, PJ, Norrie, J, Alani, A, Walker, A, Duffy, F & Horgan, P 2006, 'Observation or operation for patients with an asymptomatic inguinal hernia: A randomized clinical trial', *Annals of Surgery*, vol.244(2), pp. 167-73.

O'Rourke, MG & O'Rourke, TR 2012, 'Inguinal hernia: aetiology, diagnosis, post-repair pain and compensation', *ANZ Journal of Surgery*, vol.82(4), pp. 201-6.

Ohana, G, Manevwitch, I, Weil, R, Melki, Y, Seror, D, Powsner, E & Dreznik, Z 2004, 'Inguinal hernia: Challenging the traditional indication for surgery in asymptomatic patients', *Hernia*, vol.8(2), pp. 117-20.

Oishi, SN, Page, CP & Schwesinger, WH 1991, 'Complicated presentations of groin hernias', *The American Journal of Surgery*, vol.162(6), pp. 568-71.

Page, B, Paterson, C, Young, D & O'Dwyer, PJ 2002, 'Pain from primary inguinal hernia and the effect of repair on pain', *British Journal of Surgery*, vol.89(10), pp. 1315-8.

Palumbo, LT & Mighell, SJ 1954, 'Primary inguinal hernioplasty in geriatrics', *Geriatrics*, vol.9(1), pp. 8-14.

Palumbo, LT & Sharpe, WS 1971, 'Primary inguinal hernioplasty in the adult', *Surgical Clinics of North America*, vol.51(6), pp. 1293-307.

Ponka, JL & Brush, BE 1974, 'Experiences with the repair of groin hernia in 200 patients aged 70 or older', *Journal of the American Geriatrics Society*, vol.22(1), pp. 18-24.

Primatesta, P & Goldacre, MJ 1996, 'Inguinal hernia repair: Incidence of elective and emergency surgery, readmission and mortality', *International Journal of Epidemiology*, vol.25(4), pp. 835-9.

Rai, S, Chandra, SS & Smile, SR 1998, 'A study of the risk of strangulation and obstruction in groin hernias', *Australian and New Zealand Journal of Surgery*, vol.68(9), pp. 650-4.

Ross, S, Scott, N, Grant, AS, O'Dwyer, P, Wright, D, McIntosh, E, Donaldson, C & MacIntyre, I 1999, 'Laparoscopic versus open repair of groin hernia: A randomised comparison', *Lancet*, vol.354(9174), pp. 185-90.

Sanders, DL, Kurzer, M and the members of the Groin Hernia Surgery Guidance Development Group 2013, *British Hernia Society groin hernia guidelines*, Association of Surgeons of Great Britain and Ireland, London, United Kingdom, viewed September 2014, <http://www.britishherniasociety.org/wp-content/uploads/2013/06/Groin-Hernia-Guidelines-BHS-2013.pdf>.

Sarosi, GA, Wei, Y, Gibbs, JO, Reda, DJ, McCarthy, M, Fitzgibbons, RJ & Barkun, JS 2011, 'A clinician's guide to patient selection for watchful waiting management of inguinal hernia', *Annals of Surgery*, vol.253(3), pp. 605-10.

Shea, BJ, Grimshaw, JM, Wells, GA, Boers, M, Anderson, N, Hamel, C, Porter, AC, Tugwell, P, Moher, D & Bouter, LM 2007, 'Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews', *BMC Medical Research Methodology*, vol.7(10), doi:10.1186/471-2288-7-10.

Simons, MP, Aufenacker, T, Bay-Nielsen, M, Bouillot, JL, Campanelli, G, Conze, J, de Lange, D, Fortelny, R, Heikkinen, T, Kingsnorth, A, Kukleta, J, Morales-Conde, S, Nordin, P, Schumpelick, V, Smedberg, S, Smietanski, M, Weber, G & Miserez, M 2009, 'European Hernia Society guidelines on the treatment of inguinal hernia in adult patients', *Hernia*, vol.13(4), pp. 343-403.

The Society for Surgery of the Alimentary Tract (SSAT) 2013, *SSAT Patient Care Guidelines - Surgical Repair of Groin Hernias* [website], viewed September 2014, <http://www.ssat.com/cgi-bin/hernia6.cgi>.

Thompson, JS, Gibbs, JO, Reda, DJ, McCarthy Jr, M, Wei, Y, Giobbie-Hurder, A & Fitzgibbons Jr, RJ 2008, 'Does delaying repair of an asymptomatic hernia have a penalty?', *American Journal of Surgery*, vol.195(1), pp. 89-93.

Tingwald, GR & Cooperman, M 1982, 'Inguinal and femoral hernia repair in geriatric patients', *Surgery, Gynecology &Obstetrics*, vol.154(5), pp. 704-6.

United Nations 2009, *List of country groupings and sub-groupings for the analytical studies of the United Nations World Economic Survey and other UN reports*, United Nations, New York, NY, viewed September 2014, <http://unpan1.un.org/intradoc/groups/public/documents/un/unpan008092.pdf>.

van den Heuvel, B, Dwars, BJ, Klassen, DR & Bonjer, HJ 2011, 'Is surgical repair of an asymptomatic groin hernia appropriate? A review', *Hernia*, vol.15(3), pp. 251-9.

Williams, JS & Hale, HW 1966, 'The advisability of inguinal herniorrhaphy in the elderly', *Surgery, Gynecology & Obstetrics*, vol.122(1), pp. 100-4.

Appendix A: Literature Search and Retrieval

The search was developed and carried out prior to the study selection process.

Databases searched and search terms

The databases and resources searched are shown in Table A.1. Searches were restricted to studies published in English from January 2005 (January 2009 for CPGs) to July 2014. A focused internet search for HTA reports and CPGs on inguinal and femoral hernia management was also conducted. In addition, the websites of relevant specialist societies were also searched (Table A.1).

Table A.1: Databases and resources searched

Database	Edition/Date Searched
Ovid MEDLINE (including In-Process & Other Non-Indexed Citations)	2005 to 2014, July 28, 2014 (RCTs and clinical trials) 2009 to 2014, July 28, 2014 (SRs and meta-analyses)
EMBASE	2005 to 2014, July 28, 2014 (RCTs and clinical trials) 2009 to 2014, July 28, 2014 (SRs and meta-analyses)
The Cochrane Library	Issue 7, July 2014 2005 to 2014, July 28, 2014
NHS Centre for Reviews and Dissemination databases	2005 to 2014, July 28, 2014
HTA agencies	
Agency for Healthcare Research and Quality (AHRQ) http://search.ahrq.gov/	July 30, 2014
BlueCross BlueShield Association http://www.bcbs.com/blueresources/tec/	July 30, 2014
Canadian Agency for Drugs and Technologies in Health (CADTH) http://www.cadth.ca/en/	July 30, 2014
Institute of Health Economics http://www.ihe.ca/	July 30, 2014
Medical Services Advisory Committee (MSAC) http://www.msac.gov.au/	July 30, 2014
National Institute for Health and Care Excellence http://www.nice.org.uk/	July 30, 2014
Clinical practice guidelines	
BMJ Best Practice http://bestpractice.bmj.com	July 23, 2014
Guidelines International Network (G-I-N) http://www.g-i-n.net/library/international-guidelines-library	July 23, 2014
National Guideline Clearinghouse http://www.guideline.gov/	July 23, 2014

Table A.1: Databases and resources searched (cont'd)

Database	Edition/Date Searched
National Health and Medical Research Council Guidelines https://www.nhmrc.gov.au/guidelines	July 23, 2014
National Institute for Health and Care Excellence guidance http://guidance.nice.org.uk/	July 23, 2014
New Zealand Guidelines Group http://www.health.govt.nz/about-ministry/ministry-health-websites/new-zealand-guidelines-group	July 23, 2014
NHS Evidence in Health and Social Care https://www.evidence.nhs.uk/	July 23, 2014
Scottish Intercollegiate Guidelines Network (SIGN) http://www.sign.ac.uk/search.html	July 23, 2014
World Health Organization http://www.who.int/publications/guidelines/en/	July 23, 2014
Targeted internet search	
American Hernia Society http://americanherniasociety.org	July 30, 2014
Asia Pacific Hernia Society http://www.aphernia.org/	July 30, 2014
British Hernia Society http://www.britishherniasociety.org/	July 30, 2014
European Hernia Society https://www.europeanherniasociety.eu	July 30, 2014
Society for Surgery and Alimentary Tract http://www.ssat.com/	July 30, 2014
VIC Health http://www.health.vic.gov.au/	July 30, 2014

RCT: randomised controlled trial; SR: systematic review

Search terms

For MEDLINE, searches on the key concepts of treatment for IH and FH are detailed in Table A.2. This search strategy was conducted using the Ovid SP platform and was restricted by language, year and study type. The search strategy was also translated and run in EMBASE, *The Cochrane library* and the Centre for Reviews and Dissemination databases; searches were restricted by language, year and, where appropriate, publication type. In addition, a NOT MEDLINE limiter was applied to the EMBASE searches.

Table A.2: Ovid MEDLINE search

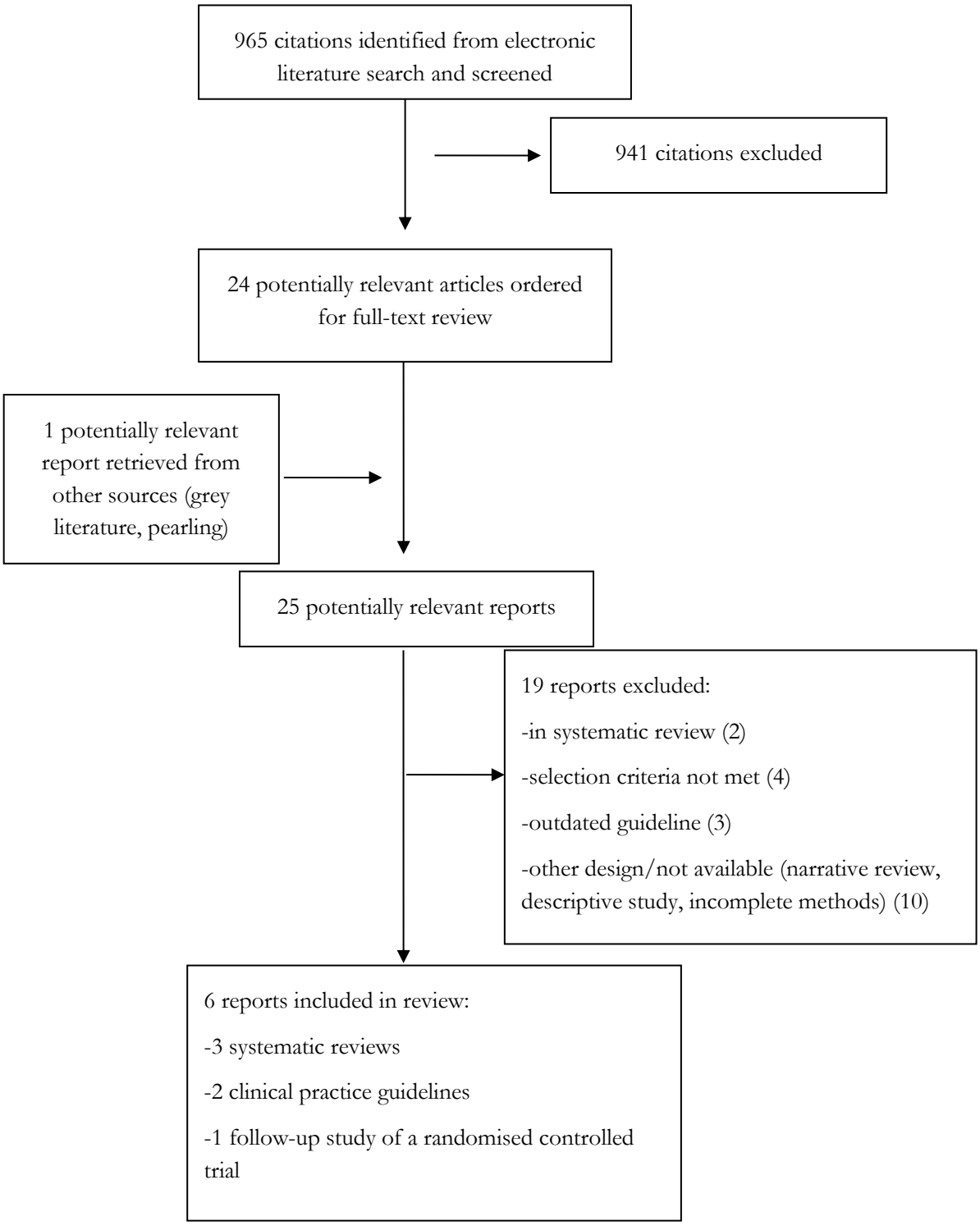
Search ID	Key Concept	Search
1	Inguinal hernia	Exp. Hernia, Inguinal/ OR ((Exp Hernia OR hernia*) AND inguinal)
2	Femoral Hernia	Exp. Hernia, Femoral/ OR ((Exp Hernia OR hernia*) AND femoral)
3	Inguinal or femoral hernia	1 OR 2
4	Treatments	Exp Therapeutics/ OR Exp Herniorrhaphy/ OR Exp Watchful Waiting/ OR surger* OR surgical OR repair OR herniorrhaphy OR hernioplasty OR therap* OR management OR treatment*
5	Treatments for inguinal or femoral hernias	3 AND 4
6	Limited to Systematic reviews	5 restricted to systematic reviews & meta-analysis, English language, year 2005 - 2014
7	Limited to clinical trials	5 restricted to RCT & clinical trials, English language, year 2005 - 2014
8	Limited to Guidelines	5 restricted to CPGs, English language, year 2009 - 2014
9	Combined results	6 OR 7 OR 8

CPG: clinical practice guideline; RCT: randomised controlled trial

Note: Ovid SP platform was used to search MEDLINE, EMBASE, *The Cochrane Library* and the Centre for Reviews and Dissemination databases; EMBASE searches were limited to non-MEDLINE journals.

Study selection

Figure A.1: Flow diagram of the study selection process



Appendix B: Evidence Hierarchy

Table B.1: National Health and Medical Research Council evidence hierarchy (Merlin et al. 2009)

Level	Intervention	Diagnostic accuracy	Prognosis	Aetiology	Screening Intervention
I	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive persons with a defined clinical presentation	A prospective cohort study	A prospective cohort study	A randomised controlled trial
III-1	A pseudo-randomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation	All or none	All or none	A pseudo-randomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: ▪ Non-randomised, experimental trial ▪ Cohort study ▪ Case-control study ▪ Interrupted time series with a control group	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: ▪ Non-randomised, experimental trial ▪ Cohort study ▪ Case-control study
III-3	A comparative study without concurrent controls: ▪ Historical control study ▪ Two or more single arm study ▪ Interrupted time series without a parallel control group	Diagnostic case-control study	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: ▪ Historical control study ▪ Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series	Case series

Appendix C: Excluded Studies

Included in systematic review

Chung, L, Norrie, J & O'Dwyer, PJ 2011, 'Long-term follow-up of patients with a painless inguinal hernia from a randomized clinical trial', *British Journal of Surgery*, vol.98(4), pp. 596-9.

Sarosi, GA, Wei, Y, Gibbs, JO, Reda, DJ, McCarthy, M, Fitzgibbons, RJ & Barkun, JS 2011, 'A clinician's guide to patient selection for watchful waiting management of inguinal hernia', *Annals of Surgery*, vol.253(3), pp. 605-10.

Selection criteria not met

Bittner, R, Arregui, ME, Bisgaard, T, Dudai, M, Ferzli, GS, Fitzgibbons, RJ, Fortelny, RH, Klinge, U, Kockerling, F, Kuhry, E, Kukleta, J, Lomanto, D, Misra, MC, Montgomery, A, Morales-Conde, S, Reinpold, W, Rosenberg, J, Sauerland, S, Schug-Paß, C, Singh, K, Timoney, M, Weyhe, D & Chowbey, P 2011, 'Guidelines for laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal Hernia [International Endohernia Society (IEHS)]', *Surgical Endoscopy*, vol.25(9), pp. 2773-843.

Magnusson, J, Videhult, P, Gustafsson, U, Nygren, J & Thorell, A 2014, 'Relationship between preoperative symptoms and improvement of quality of life in patients undergoing elective inguinal herniorrhaphy', *Surgery*, vol.155(1), pp. 106-13.

National Institute for Health and Care Excellence (NICE) 2010, *NICE implementation uptake report: Laparoscopic surgery for inguinal hernia repair*, NICE, London, United Kingdom, viewed September 2014, <http://www.nice.org.uk/proxy/?sourceUrl=http%3a%2f%2fwww.nice.org.uk%2fmedia%2fD7A%2f57%2fUptakeReportLapHerniaPublicationApril.pdf>.

Work Loss Data Institute 2013, *Hernia*, Work Loss Data Institute, Encinitas, CA, viewed September 2014, <http://www.guideline.gov/content.aspx?id=47582>.

Outdated guidelines

European Hernia Society (EHS) 2013, *Treatment of inguinal hernia in adult patients*, EHS, viewed September 2014, <http://www.herniaweb.org/fileadmin/downloads/library/EHS_Guidelines_orig.pdf >. (Superseded by Miserez et al. 2014.)

Rosenberg, J, Bisgaard, T, Kehlet, H, Wara, P, Asmussen, T, Juul, P, Strand, L, Andersen, FH & Bay-Nielsen, M 2011, 'Danish Hernia Database recommendations for the management of inguinal and femoral hernia in adults', *Danish Medical Bulletin*, vol.58(2), pp. C4243. (Based on outdated European Hernia Society (2009) guideline and consensus decisions from Danish Database meetings.)

Simons, MP, Aufenacker, T, Bay-Nielsen, M, Bouillot, JL, Campanelli, G, Conze, J, de Lange, D, Fortelny, R, Heikkinen, T, Kingsnorth, A, Kukleta, J, Morales-Conde, S, Nordin, P, Schumpelick, V, Smedberg, S, Smietanski, M, Weber, G & Miserez, M 2009, 'European Hernia Society guidelines on the treatment of inguinal hernia in adult patients', *Hernia*, vol.13(4), pp. 343-403.

Other design or not available

Antoniou, SA, Pointner, R & Granderath, FA 2014, 'Current treatment concepts for groin hernia', *Langenbeck's Archives of Surgery*, vol.399(5), pp. 553-8.

Bernhardt, GA, Kornprat, P, Cerwenka, H, El-Shabrawi, A & Mischinger, HJ 2009, 'Do we follow evidence-based medicine recommendations during inguinal hernia surgery? Results of a survey covering 2441 hernia repairs in 2007', *World Journal of Surgery*, vol.33(10), pp. 2050-5.

Jing, EY, Liu, YL, Yang, KH & Guo, TK 2010, 'Laparoscopic compared with open methods of groin hernia repair in adults: a systematic review of clinical controlled trials', *Chinese Journal of Evidence-Based Medicine*, vol.10(7), 875-81.

Gopal, SV & Warrier, A 2013, 'Recurrence after groin hernia repair-revisited', *International Journal of Surgery*, vol.11(5), pp. 1-49.

Kulacoglu, H 2011, 'Current options in inguinal hernia repair in adult patients', *Hippokratia*, vol.15(3), pp. 223-31.

Lertsithichai, P & Pornchai, S 2012, 'Factors influencing loss to follow-up after elective inguinal herniorrhaphy', *Journal of the Medical Association of Thailand*, vol.95(1), pp. 37-41.

Muysoms, F, Campanelli, G, Champault, GG, DeBeaux, AC, Dietz, UA, Jeekel, J, Klinge, U, Kockerling, F, Mandala, V, Montgomery, A, Morales Conde, S, Puppe, F, Simmermacher, RK, Smietanski, M & Miserez, M 2012, 'EuraHS: the development of an international online platform for registration and outcome measurement of ventral abdominal wall hernia repair', *Hernia*, vol.16(3), pp. 239-50.

O'Rourke, MG & O'Rourke, TR 2012, 'Inguinal hernia: aetiology, diagnosis, post-repair pain and compensation', *ANZ Journal of Surgery*, vol.82(4), pp. 201-6.

The Society for Surgery of the Alimentary Tract (SSAT) 2013, *SSAT Patient Care Guidelines - Surgical Repair of Groin Hernias* [website], viewed September 2014, <http://www.ssat.com/cgi-bin/hernia6.cgi>.

Treadwell, J, Tipton, K, Oyesanmi, O, Sun, F & Schoelles, K 2012, *Surgical options for inguinal hernia: comparative effectiveness review*, Comparative Effectiveness Review No. 70, Agency for Healthcare Research and Quality (AHRQ) Publication No. 12-EHC091-EF, AHRQ, Rockville, MD, viewed September 2014, <www.effectivehealthcare.ahrq.gov/reports/final.cfm>.

Appendix D: Summary of Evidence

Table D.1: Grading of recommendations and levels of evidence

Study, Country	Recommendation Grading	Evidence Categories/Grading
CPGs on the treatment of inguinal hernias		
Miserez et al. (2014) Europe	A. Supported by SR or at least two RCTs of good quality. Level of evidence 1A, 1B. B. Supported by good cohort studies or case-control studies. Level of evidence 2A, 2B. C. Supported by case series, cohort studies of low quality or "outcomes" research. Level of evidence 2C, 3. D. Expert opinion, consensus committee. Level of evidence 4. Ranking by Oxford CEBM no longer distinguishes between level 1A and 1B and refrains from providing definitive recommendations; however, the European Hernia Society maintained the distinction between level 1A and 1B and graded recommendations per previous guidance.	1A: SR of RCTs with consistent results from individual (homogeneous) studies 1B: RCTs of good quality 2A: SR of cohort or case-control studies with consistent results from individual (homogeneous) studies 2B: RCT of poorer quality or cohort or case-control studies 2C: Outcome studies, descriptive studies 3: Cohort or case-control studies of low quality 4: Expert opinion, generally accepted treatments
CPGs on the treatment of inguinal and femoral hernias		
Sanders et al. (2013) United Kingdom	A. At least one MA, SR or RCT rated as 1++ and is directly applicable to the target population, or a SR of RCTs; or body of evidence that consists of studies rated 1+, is directly applicable to the target population and demonstrates overall consistency of results, or evidence drawn from a NICE technology appraisal. B. A body of evidence that includes studies rated 2++, is directly applicable to target population and demonstrates overall consistency of results, or extrapolated evidence from studies rated 1++ or 1+. C. A body of evidence that includes studies rated 2+, is directly applicable to target population and demonstrates overall consistency of results, or extrapolated evidence from studies rated 2++. D. Evidence level 3 or 4, or extrapolated evidence from studies rated 2+, or formal consensus. D (GPP). A good practice point is a recommendation for best practice based on the experience of the GDG.	1++: High quality MA, SR of RCTs or RCT with very low risk of bias 1+: Well-conducted MA or SR of RCTs with low risk of bias 1-: MA, SR of RCTs or RCT with high risk of bias 2++: High quality SR of case-control or cohort studies, or high quality case-control or cohort studies with very low risk of confounding, bias or chance and a high probability that the relationship is causal 2+: Well-conducted case-control or cohort studies with low risk of confounding, bias or chance and a moderate probability that the relationship is causal 2-: Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal 3: Non-analytical studies (case reports, case series) 4: Expert opinion

CPG: clinical practice guideline; CEBM: Centre for Evidence-Based Medicine; GDG: guideline development group; GPP: good practice point; MA: meta-analysis; NICE: National Institute for Health and Care Excellence; RCT: randomised controlled trial; SR: systematic review

Table D.2: Summary of critical appraisal of clinical practice guidelines

Study, Country	Strengths	Limitations
CPGs on the treatment of inguinal hernias		
Miserez et al. (2014) Europe	The objective was to update the European Hernia Society 2009 guideline with level I evidence to improve clinical management and reduce practice variation. Research questions, target patient populations and users were specified. The GDG was drawn from as many European countries as possible to include members with as many surgical techniques as possible. Two authors, involved in preparing initial guidance, selected evidence and assessed study quality. Data were analysed with respect to any change in the level or text of the conclusions or recommendations of the initial guideline. Updated guideline recommendations were specific, lend consideration to health benefits and risks and were explicitly linked to supporting evidence. All working group members approved final recommendations. A procedure for updating the guideline was provided.	While relevant level 1A and 1B literature from May 2008 to June 2010 was searched using MEDLINE and *The Cochrane Library*, and updated until January 2013, initial guidance was based on searching MEDLINE, EMBASE and *The Cochrane Library*. Limiting the number of databases searched for the update may have limited the evidence available for review. Only level I evidence studies with potential to affect the conclusions or recommendations of the initial guideline were considered for study. Data from other sources, such as large prospective registries, could provide greater external validity than RCTs. The criteria for study selection and the method by which studies were assessed for quality was not reported. The method by which conclusions and recommendations were formulated was not well reported. Despite efforts to include all types of inguinal hernia surgeons on the GDG, guidelines must be tailored to the daily practice of each individual surgeon treating individual patients. Some chapters of the guideline were intended for general practitioners, which were not represented on the GDG. Key review criteria for monitoring or audit were not clearly reported. Future guideline implementation will depend on the developing a user friendly decision support algorithm tailored to individual patients and on evaluating the effect of guideline implementation on surgical outcomes. Ethicon, Inc. (Somerville, NJ, USA) financed the guideline through a grant, and several authors declared conflicts of interest directly related to the work.

Table D.2: Summary of critical appraisal of clinical practice guidelines (cont'd)

Study, Country	Strengths	Limitations
CPGs on the treatment of inguinal and femoral hernias		
Sanders et al. (2013) United Kingdom	A GDG comprising practitioners of both open and laparoscopic hernia repair, who were chosen by the Royal College of Surgeons of England and the British Hernia Society, developed the guideline. An information specialist provided assistance and Royal College of Surgeons of England staff provided methodological support. Objective, clinical questions and target population were specifically described. Evidence was identified by systematically searching MEDLINE, EMBASE, *The Cochrane Library*, DARE, CINAHL, HEED, NHSEED, SIGN and TRIP up to October 2012. Methods for developing the research questions, outcomes, study selection, grading of evidence and data synthesis were reported. Recommendations were derived using, and explicitly linked to, the evidence that supported them and based on informal consensus achieved at formal GDG meetings to finalise agreement and audit criteria. Health benefits, risks and costs were considered in formulating the recommendations. Guideline recommendations were current and updates will be commissioned every three years. Local infrastructure and resources may not be in place to deliver a complete service, including laparoscopic and open groin hernia repair, and this may be a barrier to implementing the guideline. A large surgical registry was recommended as an audit and peer review measurement tool, with emphasis on patient-based outcome data and best evidence. Tools for baseline assessment and costing were available to facilitate CPG implementation, systems improvement and audit.	Grey literature sources were not systematically searched, resulting in possible publication bias and overestimation of the treatment effect in favour of the intervention.

CINAHL: Cumulative Index to Nursing and Allied Health Literature; CPG: clinical practice guideline; DARE: Database of Abstracts of Reviews of Effects; GDG: guideline development group; HEED: Health Economic Evaluations Database; NHSEED: National Health Service Economic Evaluation Database; RCT: randomised controlled trial; SIGN: Scottish Intercollegiate Guideline Network; TRIP: Turning Research into Practice

Table D.3: CPG recommendations on the treatment of inguinal and femoral hernias

Guideline, Author, Year, Country	Recommendations
Recommendations on the treatment of inguinal hernias	
Miserez et al. (2014) Europe	WW is safe and an acceptable option for men with minimally symptomatic IH (that does not interfere with daily activities) or asymptomatic IH (without pain/discomfort). It is very likely (>70% chance) that, in time, the symptoms will increase leading to surgical intervention [Level 1B]. It is recommended in minimally symptomatic or asymptomatic IH in men to consider a WW strategy, especially when older or in the presence of major comorbidity [Grade B].
Recommendations on the treatment of inguinal and femoral hernias	
Sanders et al. (2013) United Kingdom	Patients with occult/asymptomatic/minimally symptomatic primary or recurrent IH AND who have significant comorbidity (ASA physical status 3 or 4) AND who do not want surgical repair (after receiving information) can be managed conservatively through primary care [Grade B]. All other patients should be referred to secondary care [Grade B]. Hernia trusses should not be routinely used [Grade D (GPP)]. Surgical repair should be offered to patients with a symptomatic IH. Patients with asymptomatic hernias can be managed conservatively, but there is a likelihood of requiring surgery in the future [Grade B] (2 SR, 2 RCTs with follow-up, 2 clinical studies) (Chung et al. 2011; Fitzgibbons et al. 2006; Gallegos et al. 1991; Hair et al. 2001; INCA Trialists Collaboration 2011; Mizrahi and Parker 2012; Sarosi et al. 2011). Surgical repair is recommended for patients with a femoral hernia [Grade B]. Groin hernias in women should be repaired laparoscopically [Grade B]. Laparoscopic approach may be beneficial for those at risk of chronic pain (younger patients, severe groin pain with only small hernia on presentation) [Grade D (GPP)]. Open approach under local anaesthetic may be beneficial in older patients or those with comorbidity [Grade D (GPP)]. In the management of unilateral primary IH, there is conflicting information on whether laparoscopic repair reduces the incidence of chronic pain and improves outcomes. Majority of meta-analyses concluded that the incidence and severity of pain (acute and chronic) were lower after laparoscopic repair, compared with open repair, but there were limitations in the studies used [Grade B]. Resource cost at time of surgery is higher for laparoscopic surgery (TEP and TAPP approaches), compared with open surgery [Grade D]. There is no evidence supporting TEP repair ahead of the TAPP technique, or vice versa [Grade C]. TAPP approach may be beneficial if there is diagnostic uncertainty in cases of groin/lower abdominal pain since it can be used to grossly assess intra-abdominal structures [Grade D (GPP)]. All adult IH should be repaired using flat mesh (or non-mesh Shouldice technique) [Grade A]. There is no clinical advantage of plugs, compared with flat mesh, for open IH repair [Grade A]. A cost-effective, lightweight (large pore) mesh should be used [Grade A]. There is insufficient evidence to make a recommendation on the use of mesh for femoral hernia [Grade D (GPP)].

ASA: American Society of Anesthesiologists Class; GPP: good practice point; IH: inguinal hernia; RCT: randomised controlled trial; SR: systematic reviews; TAPP: transabdominal preperitoneal; TEP: total extraperitoneal; WW: watchful waiting

Table D.4: Summary of systematic review and randomised controlled trial (LTFU study) characteristics

Study, Country	Study Design	Patient Characteristics	Intervention	Comparator	Outcomes Measured
Systematic reviews on the treatment of inguinal hernias					
Mizrahi et al. (2012) United Kingdom	SR of 2 RCTs (reported as 5 articles) (Chung et al. 2011; Fitzgibbons et al. 2006; O'Dwyer et al. 2006; Sarosi et al. 2011; Thompson et al. 2008) Participants: 880 patients Literature search: 1966 to 2011 Follow-up: 2 to 7.5 years	Men with asymptomatic IH O'Dwyer et al. (2006): 160 men, >55 years of age (mean age 70 years), visible bulge, reducibility required, 3 years post-diagnosis Fitzgibbons et al. (2006): 770 men, >18 years of age (mean age 58 years), any size hernia, reducibility not required, 6 weeks post-diagnosis	WW	Herniorrhaphy (Lichtenstein open tension-free repair)	Complications, rate of cross over to surgery, pain
INCA Trialists Collaboration (2011) The Netherlands	SR with Markov model data analysis (26 studies) (Allen et al. 1987; Álvarez et al. 2004; Askew et al. 1992; Bay-Nielsen et al. 2001a; Fitzgibbons et al. 2006; Gallegos et al. 1991; Hair et al. 2001; Kauffman Jr and O'Brien 1970; Kulah et al. 2001a; Kulah et al. 2001b; Kurt et al. 2003; Nehme 1983; Neuhauser 1977; Neumayer et al. 2004; Neutra et al. 1981; Nilsson et al. 2007; O'Dwyer et al. 2006; Ohana et al. 2004; Oishi et al. 1991; Page et al. 2002; Palumbo and Mighell 1954; Primatesta and Goldacre 1996; Rai et al. 1998; Ross et al. 1999; Tingwald and Cooperman 1982; Williams and Hale 1966) Participants: Not reported Literature search: 1990 to not reported Follow-up: Not reported Markov model: 1-year cycle to calculate life expectancy of a 50-year-old man with IH treated with WW or surgical repair Assumptions: limited to two surgical procedures, 30% of patients experiencing recurrence will undergo secondary repair, risk of complication after previous hernia repair same as risk in WW group	Elderly men with asymptomatic or mildly symptomatic IH Age: >50 years Hospital data from the National Medical Registry regarding admission and number of patients with IH with/without obstruction and/or gangrene who underwent surgery	WW	Herniorrhaphy	Complications, rate of cross over to surgery, pain, mortality

Table D.4: Summary of systematic review and randomised controlled trial (LTFU study) characteristics (cont'd)

Study, Country	Study Design	Patient Characteristics	Intervention	Comparator	Outcomes Measured
Systematic review on the treatment of inguinal and femoral hernias					
Van den Heuvel et al. (2011) The Netherlands	SR of 30 studies (Allen et al. 1987; Álvarez et al. 2004; Andrews 1981; Askew et al. 1992; Bay-Nielsen et al. 2001b; Brasso et al. 1989; Fitzgibbons et al. 2006; Gallegos et al. 1991; Haapaniemi et al. 1999; Hair et al. 2000; Kauffman Jr and O'Brien 1970; Kulah et al. 2001a; Kulah et al. 2001b; Kurt et al. 2003; Lewis et al. 1989; Lichtenstein 1987; Malek et al. 2004; McEntee et al. 1987; Nehme 1983; Nilsson et al. 1997; O'Dwyer et al. 2006; Ohana et al. 2004; Oishi et al. 1991; Palumbo and Mighell 1954; Palumbo and Sharpe 1971; Ponka and Brush 1974; Primatesta and Goldacre 1996; Rai et al. 1998; Tingwald and Cooperman 1982; Williams and Hale 1966) Participants: >10,000 Literature search: Not reported Follow-up: 1 to 3.2 years	Patients with asymptomatic groin hernia (IH or FH)	WW	Herniorrhaphy	Complications, rate of cross over to surgery, pain, mortality
LTFU of randomised controlled trial on the treatment of inguinal hernias					
Fitzgibbons et al. (2013) United States	LTFU of Fitzgibbons et al. (2006) RCT Participants: 366 patients were randomly assigned to WW in Fitzgibbons et al. (2006); 254 (69.4%) of these patients were enrolled in LTFU and 167 (66%) completed follow-up. Follow-up: 7 to 11.5 years	Men with asymptomatic or minimally symptomatic IH Mean age of cross over group: 58.24 years (SD 13.03) Mean age of WW group: 54.18 years (SD 14.38)	WW	Cross over to surgical repair	Rate of cross over to surgery, complications

FH: femoral hernia; IH: inguinal hernia; LTFU: long-term follow-up; RCT: randomised controlled trial; SD: standard deviation; SR: systematic review; WW: watchful waiting

Table D.5: Summary of critical appraisal of the included systematic reviews and randomised controlled trial (LTFU study)

Study, Country	Strengths	Limitations
Systematic reviews on the treatment of inguinal hernias		
Mizrahi et al. (2012) United Kingdom	Comprehensive literature search based on pre-defined criteria. Study selection by two independent reviewers according to well-defined criteria, reported as PRISMA flow chart. Reasons for exclusion of studies were reported.	A list of excluded studies was not reported. Methods of data extraction and quality assessment were not reported. Study characteristics were incomplete. Included studies contained patients of varying age and hernia duration, which may have prevented results from being pooled as a meta-analysis; authors reported this heterogeneity as a risk of bias. It was unclear whether study quality was taken into consideration in the conclusions. Funding source and conflicts of interest were not reported.
INCA Trialists Collaboration (2011) The Netherlands	Comprehensive literature search based on pre-defined criteria. Two reviewers independently extracted data and assessed evidence according to the Oxford Centre for Evidence-Based Medicine evidence hierarchy. All general hospitals, academic hospitals and a few categorical hospitals are associated with the National Medical Registry from which national patient data were derived for modelling. Markov model developed with input by the INguinal hernia: Conservative or operative Approach Trialists Collaboration. Second-order one-way and multi-way sensitivity analyses were conducted to determine input parameters that influenced life expectancy, along with best and worst case scenarios. Funding source was reported and authors reported no conflicts of interest.	A list of excluded studies was not reported. Method of study selection was not reported. Study characteristics were incomplete. In developing the Markov decision model, probabilities of incarceration or strangulation and risks of recurrence were converted into annual rates assuming a constant rate of irreducibility and risk of recurrence, respectively. Authors assumed the risk of incarceration or strangulation after previous hernia repair was the same as the risk in WW.
Systematic review on the treatment of inguinal and femoral hernias		
Van den Heuvel et al. (2011) The Netherlands	Comprehensive literature search based on pre-defined criteria. Handsearching and referral by experts identified additional articles.	Risk of publication and time lag bias as systematic review failed to report searching for grey literature. Potential for selection bias as a single reviewer selected and analysed studies. A list of excluded studies was not reported. Methods of data extraction and quality assessment were not reported. Study characteristics were incomplete. Study quality was not reported and it was unclear whether study quality was considered in formulating conclusions. Risk of bias, sources of support and conflicts of interest were not reported.

Table D.5: Summary of critical appraisal of the included systematic reviews and randomised controlled trial (LTFU study) (cont'd)

Study, Country	Strengths	Limitations
LTFU of randomised controlled trial on the treatment of inguinal hernias		
Fitzgibbons et al. (2013) United States	The objectives, patient characteristics, interventions, outcomes and main findings were clearly described. No differences were reported in baseline characteristics and total follow-up time in study participants with complete follow-up, compared with those who dropped out over time. While study participants and outcome assessors were aware of treatment allocation, compliance with interventions and outcome measures were reliable. Kaplan-Meier analysis was used to adjust for patients who died, withdrew or were lost to follow-up. The study assessed WW and cross over to surgery in adults of all ages with asymptomatic or minimally symptomatic IH in five different centres, including academic and community hospitals in North America.	Limited internal validity. Study population may not be representative of the entire source population or facilities. While five North American centres participated in the original RCT by Fitzgibbons et al. (2006), one was excluded from LTFU because internal review board approval could not be obtained. Poor external validity as the patient population consisted of 254 (69%) men (of 366 in the original RCT) who consented to LTFU after completing the WW arm in Fitzgibbons et al. (2006). Participation in LTFU was voluntary, so there was strong self-selection bias. Study authors reported that most study participants came to the clinic because of concern about their hernia, which is when they were invited to participate in the study. Therefore, the conclusions may not be applicable to all patients with asymptomatic or minimally symptomatic IH. Authors reported that the recruitment process may account for the high cross over rate in elderly patients. They suggested that it would be prudent to inform patients that the high cross over rate applies to patients attending a clinic for hernias and may not apply to all patients with asymptomatic or minimally symptomatic IH. While study participants were recruited during the same time period, the surgical interventions varied over time. Patients in the original RCT were randomly assigned to WW or Lichtenstein open tension-free repair, while WW participants who crossed over to surgical repair during LTFU most frequently underwent open repair with mesh (69%), but may have undergone open hernia repair (15%) or laparoscopic repair (8%). Funding source and conflicts of interest were not reported for LTFU.

IH: inguinal hernia; LTFU: long-term follow-up; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-analyses; RCT: randomised controlled trial; WW: watchful waiting

Table D.6: Summary of findings from systematic reviews and randomised controlled trial (LTFU study)

Study, Country	Main Study Findings	Authors' Conclusions
Systematic reviews on the treatment of inguinal hernias		
Mizrahi et al. (2012) United Kingdom	**WW versus herniorrhaphy for IH in men** SR of 2 RCTs involving 880 men reported in 5 studies (Chung et al. 2011; Fitzgibbons et al. 2006; O'Dwyer et al. 2006; Sarosi et al. 2011; Thompson et al. 2008) RCT by Fitzgibbons et al. (2006), sponsored by the American College of Surgeons, reported pain and complications in 720 men randomly assigned to WW (n=364) or surgical repair (n=356) at five centres in North America (FU 2 to 4.5 years): Thompson et al. (2008) reported outcomes (complication, recurrence and pain) in 353 patients from Fitzgibbons et al. (2006) who underwent surgical repair (n=288), compared with delayed surgical repair after 6 months of WW (n=65) (FU not reported) Sarosi et al. (2011) reported rate of cross over to surgical repair at 2-year FU in 336 WW patients from Fitzgibbons et al. (2006) RCT by O'Dwyer et al. (2006) reported pain and complications in 160 men randomly assigned to WW (n=80) or surgical repair (n=80) (FU 1 year): Chung et al. (2011) reported on the LTFU (7.5 years) of 80 WW patients from O'Dwyer et al. (2006) (80 WW, 80 surgical repair) (FU 5 years, range 6.2 to 8.2) *Pain scores*: SR of 2 RCTs, involving 880 men, compared WW with surgical repair; both studies reported no difference in pain or discomfort between the two groups (FU 4.5 to 5 years) *Rate of cross over to surgery*: SR of 2 RCTs involving 880 men compared WW with surgical repair; a significant rate of cross over from WW to surgical repair, ranging from 23% to 72%, was reported due to increase in hernia size and pain *Complications*: SR of 1 RCT involving 720 men compared WW with surgical repair; rates of IH strangulation were 0.27% and 0.55% at 2-year and 4-year FU in WW patients. Surgical complications ranged from 0% to 22.3%; hernia recurrence rate was 2.1%.	"The treatment of asymptomatic IH forces the clinician to choose between two treatment options, each of which is safe. However, most patients will develop symptoms (mainly pain) over time and will require operation. We believe that, as in any medical condition, the surgeon should weigh treatment options against possible complications and tailor management to the specific patient." (p. 280)

Table D.6: Summary of findings from systematic reviews and randomised controlled trial (LTFU study) (cont'd)

Study, Country	Main Study Findings	Authors' Conclusions
INCA Trialists Collaboration (2011) The Netherlands	**WW versus herniorrhaphy for IH in men** SR with Markov model data analysis (26 studies) (Allen et al. 1987; Álvarez et al. 2004; Askew et al. 1992; Bay-Nielsen et al. 2001a; Fitzgibbons et al. 2006; Gallegos et al. 1991; Hair et al. 2001; Kauffman Jr and O'Brien 1970; Kulah et al. 2001a; Kulah et al. 2001b; Kurt et al. 2003; Nehme 1983; Neuhauser 1977; Neumayer et al. 2004; Neutra et al. 1981; Nilsson et al. 2007; O'Dwyer et al. 2006; Ohana et al. 2004; Oishi et al. 1991; Page et al. 2002; Palumbo and Mighell 1954; Primatesta and Goldacre 1996; Rai et al. 1998; Ross et al. 1999; Tingwald and Cooperman 1982; Williams and Hale 1966) *Pain Scores:* SR of 2 RCTs (Fitzgibbons et al. 2006; O'Dwyer et al. 2006) and a cohort study (Page et al. 2002) reported preoperative and postoperative pain for IH repair; Fitzgibbons et al. (2006) reported that pain-limiting activities were similar for WW versus surgical repair (5.1% versus 2.2%; P=0.52) after 2 years. O'Dwyer et al. (2006) reported that pain scores at rest or movement after 1 year did not differ between patients who underwent WW, compared with surgical repair (at rest: 3.7 and 5.2 mm, P=0.34; on movement: 7.6 and 5.7 mm, P=0.39, respectively). Page et al. (2002) followed up 63% of 323 patients at 1 year for which preoperative pain scores at rest and on movement were reported; patients not reporting any pain preoperatively at rest had significant pain scores at 1 year (P=0.001). *Rate of cross over to surgery:* SR of 2 RCTs (Fitzgibbons et al. 2006; O'Dwyer et al. 2006) evaluated rate of cross over from WW to surgical repair; Fitzgibbons et al. (2006) reported 85 of 364 (23%) WW patients crossed over to surgical repair within 2 years of FU; 73 of these patients (86%) reported progression of pain or discomfort as the reason for cross over; yearly rate of cross over was 11.7%. O'Dwyer et al. (2006) reported that 15 of 77 (20%) patients crossed over to surgical repair within 1 year; risk of cross over was 19.5%. Combined results: 13% (range 8.0% to 19.5%) of mildly symptomatic and asymptomatic IH patients assigned to WW will cross over to surgical repair *Rate of complications:* SR of 4 retrospective cohort studies (Gallegos et al. 1991; Hair et al. 2001; Neuhauser 1977; Neutra et al. 1981) and 2 RCTs (Fitzgibbons et al. 2006; O'Dwyer et al. 2006) compared WW with surgical repair; observed probabilities of incarceration or strangulation were converted into an annual rate, assuming a constant rate of incarceration or strangulation; yearly rate of irreducibility associated with WW was 0.4% (range 0.2% to 2.7%; event type differed between studies) *Rate of mortality:* SR of 16 studies (Allen et al. 1987; Askew et al. 1992; Bay-Nielsen et al. 2001a; Fitzgibbons et al. 2006; Gallegos et al. 1991; Kurt et al. 2003; Nehme 1983; Neuhauser 1977; Neumayer et al. 2004; Nilsson et al. 2007; O'Dwyer et al. 2006; Ohana et al. 2004; Oishi et al. 1991; Primatesta and Goldacre 1996; Tingwald and Cooperman 1982; Williams and Hale 1966) evaluated mortality associated with elective hernia repair: mean mortality rate was 0.2% (range 0% to 1.8%)	"The available data suggest that life expectancy for elderly male IH patients associated with WW or surgical repair differs very little. Therefore, the general doubt about operating on mildly symptomatic and asymptomatic elderly hernia patients illustrated by two recent randomised trials investigating preoperative and postoperative pain for these types of management is justified. Sensitivity analyses showed mortalities associated with elective and emergency repair and rate of incarceration and/or strangulation in their reported ranges to be an influence on type of policy. In case of asymptomatic and mildly symptomatic patients, there seems to be no difference in pain relief between WW and surgical repair."(p. 257)

Table D.6: Summary of findings from systematic reviews and randomised controlled trial (LTFU study) (cont'd)

Study, Country	Main Study Findings	Authors' Conclusions
	Life expectancy based on Markov model: Life expectancy for a 50-year-old man without a hernia based on age- and sex-specific mortality from United States life tables of the general population was 26.95 years. Second-order Monte Carlo simulation showed that the mean life expectancy for a patient with IH who underwent WW was 26.88 years (95% CI 26.87 to 26.88), compared with 26.89 years (95% CI 26.88 to 26.89) for a patient who underwent surgical repair. Sensitivity analyses showed the optimal decision to be sensitive to the procedural mortality rates and annual incarceration and strangulation rates. In case of mortality associated with emergency repair being lower than its threshold value of 4.2%, the optimal choice was WW. In case of mortality associated with elective repair being >0.2%, or risk of incarceration and/or strangulation being lower than its threshold value of 0.5%, the optimal choice was WW.	
Systematic review on the treatment of inguinal and femoral hernias		
Van den Heuvel et al. (2011) The Netherlands	**WW versus herniorrhaphy for groin hernia** SR of 30 studies (Allen et al. 1987; Álvarez et al. 2004; Andrews 1981; Askew et al. 1992; Bay-Nielsen et al. 2001b; Brasso et al. 1989; Fitzgibbons et al. 2006; Gallegos et al. 1991; Haapaniemi et al. 1999; Hair et al. 2000; Kauffman Jr and O'Brien 1970; Kulah et al. 2001a; Kulah et al. 2001b; Kurt et al. 2003; Lewis et al. 1989; Lichtenstein 1987; Malek et al. 2004; McEntee et al. 1987; Nehme 1983; Nilsson et al. 1997; O'Dwyer et al. 2006; Ohana et al. 2004; Oishi et al. 1991; Palumbo and Mighell 1954; Palumbo and Sharpe 1971; Ponka and Brush 1974; Primatesta and Goldacre 1996; Rai et al. 1998; Tingwald and Cooperman 1982; Williams and Hale 1966) *Rate of complications of chronic pain, recurrence and mortality after elective groin herniorrhaphy:* SR of 14 studies reported on complications after groin hernia (Allen et al. 1987; Bay-Nielsen et al. 2001b; Haapaniemi et al. 1999; Lewis et al. 1989; Lichtenstein 1987; Nehme 1983; Nilsson et al. 1997; Ohana et al. 2004; Oishi et al. 1991; Palumbo and Mighell 1954; Ponka and Brush 1974; Primatesta and Goldacre 1996; Tingwald and Cooperman 1982; Williams and Hale 1966). Common short-term complications included pain, haematoma, seroma and wound infection; long-term complications included chronic groin pain and recurrence; average morbidity rate was 8%. The incidence of chronic groin pain after herniorrhaphy varied by technique: 54% for suture repair; 13% to 37% for Lichtenstein open tension-free repair; and10% to 30% for laparoscopic repair. Recurrence rates varied by technique: 62% for suture; 0% to 10% for Lichtenstein open tension-free repair; and 2% to 4% for laparoscopic tension-free mesh repair. Average mortality rate after groin herniorrhaphy was low (0.5%). *Rate of complications of groin hernias:* SR of 17 studies reported on the rate of emergency repairs for incarcerated or strangulated groin hernias; 7% of all hernia repairs were emergency repairs (Bay-Nielsen et al. 2001b; Gallegos et al. 1991; Haapaniemi et al. 1999; Hair et al. 2000; Kauffman Jr and O'Brien 1970; Kulah et al. 2001a; Lewis et al. 1989; Malek et al. 2004; Nehme 1983; Nilsson et al. 1997; Ohana et al. 2004; Oishi et al. 1991; Palumbo and Sharpe 1971; Ponka and Brush 1974; Primatesta and Goldacre 1996; Tingwald and Cooperman 1982; Williams and Hale 1966)	""WW for asymptomatic groin hernias is a safe and cost-effective modality in patients who are under 50 years old, have an ASA physical status of 1 or 2, an inguinal hernia, and a duration of signs of more than 3 months. Patients with an increased risk of incarceration or with an increased risk of higher morbidity and mortality after emergency repair should be excluded from conservative management."(pp. 251 and 258)

Table D.6: Summary of findings from systematic reviews and randomised controlled trial (LTFU study) (cont'd)

Study, Country	Main Study Findings	Authors' Conclusions
	A Columbian epidemiological study assessing incidence of incarceration and strangulation reported an overall risk of incarceration and strangulation of 3.6 per 1,000 men and 5.4 per 1,000 women with groin hernia per year (Neutra et al. 1981). FHs incarcerate and strangulate significantly more frequently than IHs; 8-fold increase in ratio of FH in emergency repair (22% emergency repair versus 2.7% elective repairs; risk increases with age). Peak incidence of incarceration and strangulation occurs between 61 and 80 years; cumulative probability of incarceration and strangulation: 4.5% at 24 months in men and 45% at 21 months in women. *Rate of complications of emergency groin herniorrhaphy:* Morbidity and mortality of emergency herniorrhaphy was higher than for elective repair: average morbidity 32% and average mortality 5.8%, compared with 8% and 0.5%, respectively for elective repair. Mortality rate after emergency repair increases when age is >49 years, patient has an ASA physical status >2, in presence of FH or when bowel resection is required. *Rate of recurrence after emergency groin herniorrhaphy:* Tension-free mesh repair in the management of emergency groin hernias was not associated with higher rates of complications or recurrence compared with its use in elective repairs *WW of asymptomatic groin hernias:* SR of 2 RCTs (Fitzgibbons et al. 2006; O'Dwyer et al. 2006) compared WW with surgical repair for the treatment of asymptomatic IH. Fitzgibbons et al. (2006) showed that both groups reported less pain at 2-year FU than at baseline; two cases (0.6%) of incarceration were observed in the WW group. O'Dwyer et al. (2006) showed no difference in pain between groups at 12-month FU; one case of acute hernia (1.3%). Incidence of incarceration in WW group was 1.8 and 6.25 per 1,000 patients per year. These rates did not correspond with the average emergency rate of 7%. This may be because a considerable number of patients with groin hernia do not consult a physician and do not undergo elective repair, resulting in a higher elective/emergency ratio.	
LTFU of randomised controlled trial on the treatment of inguinal hernias		
Fitzgibbons et al. (2013) United States	**WW versus herniorrhaphy for IH in men** *Rate of cross over to surgery:* LTFU of 254 men undergoing WW for IH showed that 81 (31.9%) of patients crossed over to surgical repair before the end of the original study (Fitzgibbons et al. 2006), with a median FU of 3.2 years (range 2 to 4.5). Estimated cumulative crossover rate using Kaplan-Meier analysis was 68% at 7 years, with a maximum FU of 11.5 years. Kaplan-Meier analyses estimated that 50% of patients cross over to surgery by 7.3 years (95% CI 5.3 to 8.4) after randomisation. The estimated crossover rate was 68% at 10 years after randomisation. Median time to cross over was shorter in men older than 65 years (3.7 years, 95% CI 2.4 to 6.9) than in younger men (8.3 years, 95% CI 6.6 to 10; P=0.001). Men older than 65 years had a considerably higher rate of cross over than younger men (79% versus 62%). The most common reason for cross over was pain (54%). The most frequent surgery performed was unilateral open hernia repair using mesh.	"WW remains a safe strategy even on long-term FU. However, patients who present to their physicians to have the hernia evaluated, especially if they are elderly, should be informed that they will almost certainly come to surgery eventually. These results should not be extrapolated to the broader population of all patients with asymptomatic or minimally symptomatic hernias." (pp 513)

Table D.6: Summary of findings from systematic reviews and randomised controlled trial (LTFU study) (cont'd)

Study, Country	Main Study Findings	Authors' Conclusions
	Rate of complications: A total of 3 patients from WW required emergency surgery, but there were no deaths. The incidence rate of hernia accident was 0.2 per 100 person-years for the whole cohort, 0.56 per 100 person-years for patients younger than 65 years and 0.11 per 100 person-years for patients older than 65 years. Two men (1.7%) in the WW group developed a contralateral hernia and were managed conservatively. Four men (2.8%) developed a recurrent hernia and one man had repair of the recurrent hernia. In patients managed conservatively, 96 men (95%) were satisfied, four men (4%) were neutral and one man (1%) was dissatisfied. Of the 141 patients who crossed over to surgery during the original study and registry follow-up, five men (3.55%) developed a contralateral hernia, but none of the patients had this hernia repaired. Among the crossover patients, 125 men (93%) were satisfied, seven men (5.2%) were neutral and three men (2.2%) were dissatisfied with surgery.	

ASA: American Society of Anesthesiologists; CI: confidence interval; FH: femoral hernia; FU: follow-up; IH: inguinal hernia; LTFU: long-term follow-up; RCT: randomised controlled trial; SR: systematic review; WW: watchful waiting