PART 3

Quality * Research * Global Management

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Chapter 22 Training and the Learning Curve

J. Bingener, R. Simmermacher, D. Lomanto and W. Reinpold

General Introduction

Depending on circumstances, training to perform IH repair has different competency goals. In rural or low resource settings, training may be focused on the basic ability to perform any inguinal repair for patients with significant symptoms without causing mortality or serious morbidity (see also chapter 28)[1].

This chapter's goal is to review evidence and provide guidance for two questions:

What are the learning curves of the different techniques?
What are the best methods for teaching groin hernia repair?

The advent of laparoscopic techniques directed attention to the technical learning curve of surgical procedures. Learning curricula initially focused on the number of repetitions needed to achieve outcomes similar to experts. It soon became clear that skills proficiency or competence, rather than number of repetitions, correlated to improved patient outcomes[2]. Technical competence is the ability to achieve a mastery level outcome in three consecutive attempts at a technical skill, where mastery level is calculated as the mean scores of several surgical experts

(surgeons with excellent patient outcomes) in the same skill[3]. The learning curve is defined as the time and effort necessary to achieve proficiency.

Assessing proficiency by objective standardized tools is possible but resource intense,[4,5] thus the number of procedures performed, years spent in training years, operative time and complication rates continue to be proxies for proficiency and metrics for learning curve progress.

Universally, options for training are diverse and evolving. Most surgical training programs include a time for supervised performance of IH repairs. HerniaSurge considers "supervision" as the presence of a trained expert in the operating room; however, the term is not well defined in the literature. Training components are both cognitive and technical: groin area anatomy, procedural steps, intraoperative decision making and manual dexterity. These components should be safely acquired before independent practice occurs.

This chapter will not address the learning curve for pioneering a new technique or technology. Recommendations to safely guide these developments can be found in the IDEAL framework for surgical innovation[6]. As a general rule, patient outcomes should be the same or better than for existing techniques once the novel approach is fully developed.

KQ22.a What is the learning curve for open inguinal hernia repair, anterior approach?

KQ22.b What is the learning curve for open inguinal hernia repair, posterior approach?

KQ22.c What is the learning curve for laparoscopic inguinal hernia repair, TEP?

KQ22.d What is the learning curve for laparoscopic inguinal hernia repair, TAPP?

KQ22.e What are the best methods to teach open hernia repair?

KQ22.f What are the best methods to teach laparoscopic inguinal hernia repair?

Statements and Recommendations

Statement	Open anterior mesh repair by unsupervised trainees with less than 60 cases or about 3 years' experience is on average associated with higher recurrence rate, longer operative times consistent with limited technical competency.	☒☐☐☐

Statement	Complication rates do not differ between consultants and supervised trainees regardless of training year. However, involvement of trainees may slightly prolong operative times.	☒☒☒☐

Statement	Adequate evidence does not exist to assess the learning curve for the open posterior approach.	☒☐☐☐	
Statement	Although learning curves may vary, on average the learning curve for TAPP repair may be similar to the learning curve for TEP repair.	☒☒☐☐	
Statement	A goal-directed curriculum including review of anatomy, procedure steps, intraoperative decision making and technical skills training shortens the learning curve for laparoscopic hernia repair and improves patient outcomes.	☒☒☒☐	
Recommendation	A goal-directed curriculum including review of anatomy, procedure steps, intraoperative decision making and proficiency based, simulation enhanced technical skills training should be available to trainees whenever possible.	☒☒☒☐	Strong
Recommendation	Supervision of trainees should be provided until they have reached safe proficiency levels. This averages around 60 procedures for open and around 100 procedures for laparo-endoscopic hernia repair for novices, depending on individual aptitude and the training environment.	☒☒☒☐	Strong

Evidence in Literature

Learning Curve - Tissue Repair

Primary tissue repair of groin hernias is generally considered easy and feasible and little is published about learning curves to independently perform a primary tissue repair in groin hernia patients. Therefore, no statement can be made regarding the learning curve for tissue repair. The mesh placement component of the open anterior approach is easier to learn for physicians already proficient in the anterior tissue repair[7,8] than for novices without any experience in hernia repair. The following statements derive from published literature regarding surgical trainees in the mesh repair era.

Learning Curve Open Repair

A registry study of 4,406 patients[9] demonstrated more recurrences if operating residents were unsupervised (unsupervised junior resident RR 21 (95% CI 7.3 – 58.9), p<0.001). Recurrence rates and operative times were also higher for junior residents (<4yrs of postgraduate training) in a large randomized trial[10] where residents were supervised. A 2012 study[11] found an average 16 minute longer operative time for residents versus consultants on procedures for 28,000 patients captured in the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP), confirming earlier reports by others[12]. In a recent study, 69 trainees were followed for 7 years with case log review and standardized technical competency assessments in UK NHS training programs. On average, the trainees achieved proficiency for independent IH repair after they'd performed 64 repairs (range 12-73) which usually was reached in their fourth year of training[13].

Learning Curve Laparo-endoscopic Repair TEP Approach

Irrespective of the definition, there seems to be consensus that laparo-endoscopic IH repair has a distinct learning curve. Evaluating learning curves in health technology is challenging[14].

Below is shown the reported complication rates (figure 1), operative times (figure 2) and recurrence rates (figure 3) from studies retrieved in our literature search. The learning curve for laparo-endoscopic TEP shows some variation; however it appears that, on average, more than 100 repairs are required to achieve outcomes comparable with open anterior mesh repair. Some surgeons and training programs may reach proficiency earlier, others later. Around 100 repairs represents about a 40% higher case number to achieve proficiency in TEP compared to open IH mesh repair. More experience may be required to achieve expert center outcomes. There is limited evidence that the learning curve may flatten after about 400 procedures[15].

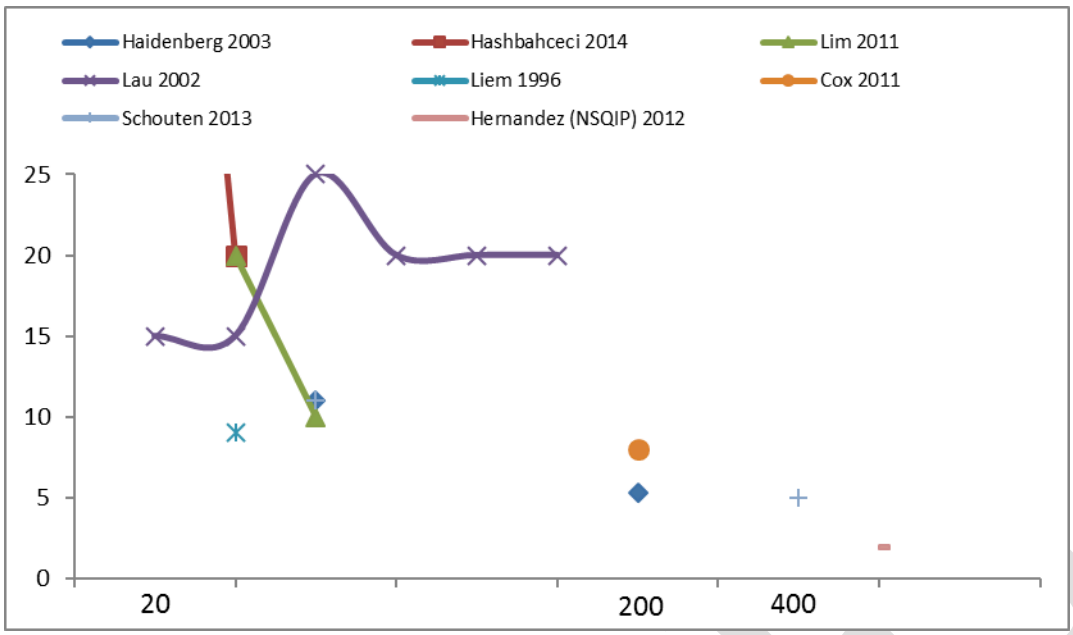

Figure 1: Published complications rates (% in y-axis) correlated with case numbers. In comparison, complication rates for open IH repair captured for > 4000 patients in the NSQIP data base is reported as 3%[15–22].

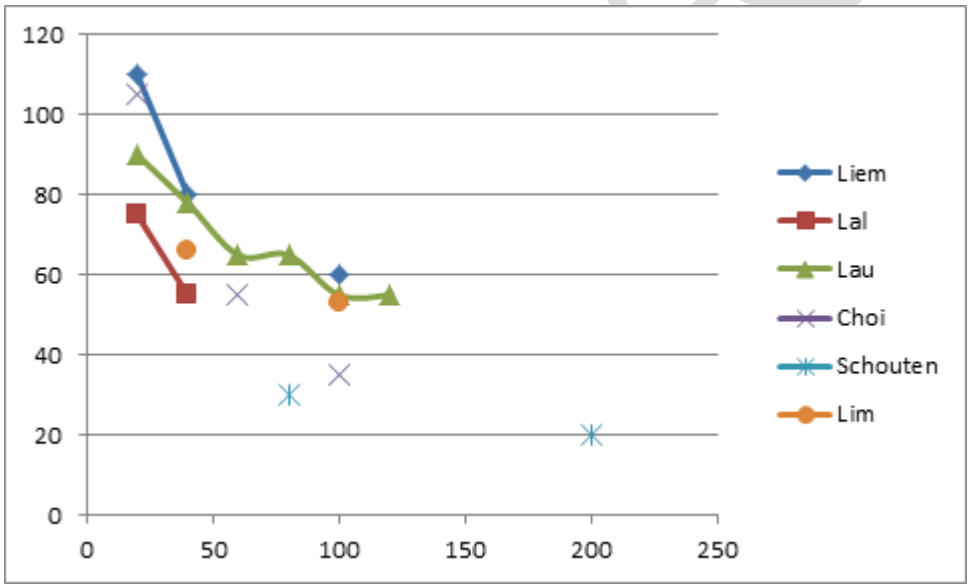

Figure 2: Reported operative time (Minutes in y-axis) in 6 studies[15,17,19,21,23,24] correlated with case number. Note the mean time reported for general surgeons (not trainees) in NSQIP comprising > 4,000 cases is 45 minutes/case[20].

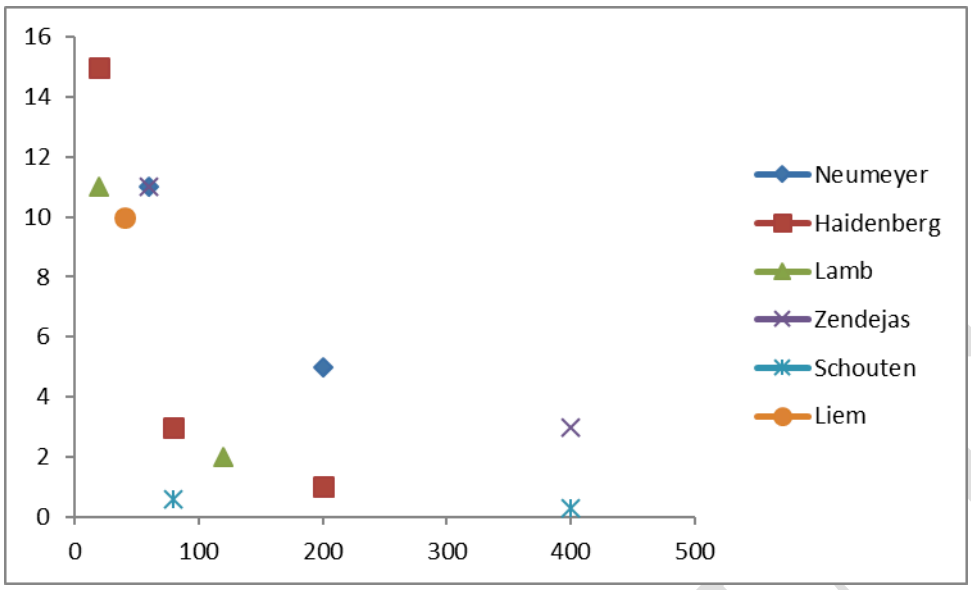

Figure 3: Reported recurrence rates (% in y-axis) in 6 published studies correlated with case numbers. Note most studies reported using 10-15 cm polypropylene mesh for repair[15,16,19,25–27].

Learning Curve Laparo-endoscopic Repair, TAPP Approach

Similar to TEP repair, TAPP repair appears to have a distinct learning curve compared to open anterior mesh repair. Five studies have addressed the topic,[28–32] two of them[28,29] from the same center. The development and learning of the TAPP repairs appears to be included in study[28]. After 300 repairs by the pioneers, complications and recurrences decreased significantly and these successes were passed on to subsequent trainees under well-defined and rigorous training conditions[28,29]. Notably, the program's trainees experienced an operative time learning curve similar to the pioneers and were still considered trainees after they had performed > 200 individual procedures. Another study[31] also reported on all results including the initial learning curve and stated that recurrence rates improved after 200 cases, as the mesh size was changed to a larger mesh. A different study[32] reported that there were significant improvements in conversions and admissions after 50 cases. Complication rates were halved, but were still 16% and did not reach statistically significantly differences from the initial rates (32%). We can thus extrapolate that the learning curve to get to outcomes comparable with open IH repair may have been longer.

Teaching Open Hernia Repair

The literature search for teaching open hernia repair revealed two procedure-specific papers. One[33] found that any simulation (high tech, low tech) improved performance over standard training with interactive simulation training showed the most improvement. Components of training are the understanding of anatomy, understanding of procedure steps and acquisition of technical skills, however, teaching anatomy on simulators does not necessarily lead to proficiency[34]. Video assessment[35] reliably reveals the proficiency level for open IH repair. One study[5] noted that the mental workload for experts in open IH repair is lower than for novices, supporting the need for cognitive learning prior to technical performance.

Teaching Laparoscopic Hernia Repair

A survey of more than 800 North American general surgeons and surgery residents found 59% felt they lacked the requisite training for laparoscopic hernia repair and 26% were interested in learning the technique. They were most likely to seek education in a course followed by expert proctoring[36]. The learning curve for the laparoscopic techniques may be significant enough to prevent some surgeons from offering the technique to their patients. This underscores the need for effective training methods to ensure that patients will benefit[36,37].

The Cochrane Collaboration published a systematic review on laparoscopic surgical box model training for surgical trainees with limited prior laparoscopic experience. The review included a variety of procedures, including laparoscopic hernia repair[38]. It found that laparoscopic box training improved patient outcome (e.g. length of stay), operative time and performance.

The review included a 2011 trial which demonstrated that by achieving a proficiency level in the simulation environment, residents performed better in the operating room than peers undergoing standard training and that their patients had fewer overnight admissions. The mastery training included cognitive learning (anatomy review & procedure steps learning) and technical skills training[3]. The trainees required on average 69 minutes (range 13-193 minutes) and 16 attempts (range 7-27) to be able to perform the hernia repair in the low tech model[39] in mastery time (2 min). When this was translated to the operating room, the operative time was statistically significantly improved by 6 minutes for operations with residents who underwent training compared to operations with those who did not. The NSQIP data suggest that surgeons unaccompanied by residents perform laparoscopic hernia repair on average 20 minutes faster. In this RCT, undergoing purposeful proficiency training shortened the in-OR learning curve. Others have proposed similar simulators, checklists and curricula[4,40–46] with the same goal. In laparoscopic training in general, high tech or low tech environments may be less important than the fact that knowledge and skills are translated and measured. While some believe that intensive mentor presence and teaching of pitfalls is pivotal,[40] other research disputes this[47,48]. Residents do seem to be less frustrated with the low tech simulation[49]. There is not enough data to prescribe the exact training modality in which the knowledge should be transferred. The available studies suggest that cognitive and technical components are essential for meaningful outcomes.

Discussion, Consensus and Grading Clarification

The listed literature describes the current review of evidence-based knowledge to the best of our abilities. Several large registry-based studies and at least one large RCT have recently provided updated information on the learning curves for open and laparoscopic hernia repair. While none of our sources represent perfect data, many have similar results which led us to provide strong statements and recommendations for anterior mesh repair and laparoscopic TEP repairs.

We did not find enough published evidence on open tissue repair or an open posterior approach to reach firm statements or recommendations. It is known that in the Shouldice Hospital surgeons are supervissed in 300 repairs, supporting our assumptions on learning curves to achieve expert performance.

In our review we postulated several benchmarks to delineate the progress of training to expert proficiency:

- Reaching minimum safety standards
- Reaching physician-reported outcomes similar to traditionally available procedures
- Reaching an institutional performance level at which the above are met and patient-reported outcomes exceed those of traditionally available procedures

Many surgeons have graciously described their experience with learning new procedures, especially the laparo-endoscopic TEP approach. In evaluating these reports in the literature, several considerations apply:

- Given the overall small number of expected complications for hernia repair, large numbers of procedures are needed to identify a statistically significant change in an outcome (e.g. complication, recurrence rate). When a statistically significant increase in complication increase occurs in small patient cohorts (e.g. n=20), that may signal a large effect size in complication rates.
- The development and learning of the techniques by early independent pioneers in the 1990s should be regarded separately from current structured surgical training programs.

Anecdotally, some surgeons find TAPP easier to learn than TEP. It is unknown why this perception exists. The data we reviewed on operative times and patient outcomes however do NOT strongly indicate that this is indeed correct. It may be that entry into the preperitoneal space from the more familiar intra-abdominal environment decreases the disorientation in the preperitoneal space that is not uncommon in new trainees. Or it may be that TAPP is indeed easier to learn.

Our statements and recommendations on how to teach laparoscopic skills was based on a systematic review of available studies that included a RCT on how to teach laparoscopic hernia repair. The mastery training used in the RCT did not close the gap to experts; it reduced it by a clinically relevant decrease in complications.

Other lower quality studies revealed largely similar results. There is however more available evidence on the learning curve than on the teaching methods. As more literature becomes available, the guidance on teaching methods may evolve as well.

In preparing these statements we've accessed new, good quality and relevant research. Thus, our statements and recommendations may update prior guidelines (e.g. EHS[50], EAES[51]). In addition, as stated above we set external benchmarks for the learning curve. For example, the fact that a complication rate decreased by 50% after 50 cases was important, however if the patient outcomes were still lagged other options (e.g. open mesh repair as described in a large database) we did not describe the learning curve as complete.

We ackknowledge that the statements and recommendation may represent challenges for training programs. Twenty-five years after the introduction of laparoscopic IH repair, surgeons and surgical trainees have however voiced concerns about being incompletely prepared[36,37]. Prior underestimation of the learning curve may have contributed to this unease and prevented patients from experiencing the benefits of a minimally invasive approach.

Chapter 23 Specialized Centers and Hernia Specialists

G. van Ramshorst, H.J. Bonjer, D. Cuccurullo, R. Bittner and H.M. Tran

Introduction

Terms like “specialization” or “specialized centers” are often undefined or poorly defined and rarely based on scientific standards of excellence. The term “hernia center” and terms like it are frequently used as marketing tools[52]. Studies on IH repair—with good results—are often published by surgeons specialized in hernia surgery.

In our opinion, the definition of a hernia specialist requires objective parameters of expertise, annual case load, outcomes and contributions to education and science. It is recommended that surgeons complete their learning curves in multiple techniques, thus facilitating a patient-specific approach to each individual dependent upon comorbidities and surgical history. Most experienced hernia surgeons support the use of this patient-tailored approach (see chapter 8)[53].

Recently, surgical procedures of various types have been qualified as “highly complex, low volume” and “low complex, high volume.” IH repair can reasonably be considered a high volume procedure in the right setting. It has been shown that regular operating theater teams can shorten room turnover times, preparation times and procedure times and thereby increase daily patient volumes[54]. The medical literature supports the notion that specialized centers with their high patient volumes achieve better results in laparoscopic and complex IH surgeries. The category “complex IH surgery” includes: multiple recurrences, chronic pain, and mesh infection[28,55,56].

As in other types of surgery, the incidence of surgical complications is in large measure inversely related to a hernia surgeon’s annual caseload. This is particularly true for laparoscopic hernia repair. The learning curve for open IH repair is shorter (see chapter 22 on Learning Curve).

In order to improve IH repair outcomes, a continuous quality control and improvement cycle is recommended. Patient follow-up should be organized to detect and register long- and short-term complications. Active involvement in training, education and science and a broad and deep clinical experience are essential for improving hernia surgery care. Regionalization of hernia care at specialized centers is vital as well.

The ability to discern a true hernia center of excellence from one with average experience and outcomes may lie in certification of hernia surgery centers. A seminal article from 2014 described the process and goals of hernia center certification in Germany[52]. The article details that two certification processes exist in Germany. The non-profit organization Surgical Review Corporation uses the designation, Certified Center of Excellence in Hernia Surgery (COEHS) while the German Hernia Society (GHS) and the German Society of General and Visceral Surgery use the term Certified Hernia Center[52].

Three certification levels exist.

Level 1	GHS seal of quality assurance in hernia surgery
Level 2	competence center for hernia surgery

Level 3 reference center for hernia surgery

All hernia surgeons in the healthcare system must be GHS and EHS members and subscribe to Hernia (http://www.springer.com/medicine/surgery/journal/10029)[52].

Level 1 certification requires at least an annual hernia repair volume of 30 cases per surgeon registered in the Herniamed registry and follow-up. At least 90% of all hernia patients must be entered into the Herniamed registry with information on comorbidities to allow for case mix variations. Quality outcome measures exist for infections, revisions, complications and follow-up rates.

Level 2 certification has higher annual volume stipulations and additional requirements for morbidity conferences, pain management and documentation (see Table 1).

Level 3 certification has still higher and more specific annual volume requirements and a variety of science- and education-based requirements. Level 3 (or reference) centers must be able to perform all laparoscopic and open techniques for hernia repair and must have formalized cooperative agreements with plastic surgeons (see Table 1).

Table 1: Overview of requirements for hernia centers in Germany

Level	Level 1 certified hernia center	Level 2 competence center	Level 3 reference center
No of hernia patients treated yearly	Min. 30	Min. 200 (min. 30 incisional hernia)	Min. 250 (min 50 incisional hernia, 5 complex hernias, 5 hiatal hernias)
Science	Membership German and European Hernia Society, subscription Hernia*	Yearly attendance at at least one hernia meeting	At least two presentations at a hernia congress or one publication
Education	-	-	Education seminars, guest visits

*Obligatory for all levels

KQ23.a Does a center's volume affect IH surgery outcomes?

Statement

Statement	In order for centers and surgeons to be certified as either a hernia center or a hernia specialist, minimal requirements on numbers of operations, follow-up and quality control should be met.	☒☐☐☐

A significant correlation between surgical volumes and better outcomes was demonstrated in a systematic review of 16 studies[57]. However, this is not the case for all surgical interventions. The relationship between caseload and mortality held for pancreatic resections but not for colorectal surgery[58]. It may be that as intervention complexity increases—requiring an interdisciplinary approach and advanced complication management—caseload becomes more important. However, an interdisciplinary approach or special complication management is rare in IH repair.

What constitute high- and low-volume centers for IH repair is unclear, making outcome comparisons difficult. Two large case series reported excellent results in TAPP[28] or TEP[56] recurrence results, but small case series have reached similar endpoints[59–62]. One paper concluded that technique standardization and learning curve completion (of 50-100 cases) are the key parameters for performance quality[63].

Another study showed that in a high-volume center (defined as > 1,000 IH repairs/year) well-supervised trainees had longer operation times but similar complications rates and recurrences when compared with experienced surgeons[63].

Although the evidence is weak, it seems that learning IH repair well in a short time period requires a certain caseload. This experience may be easiest to obtain at a high-volume center.

KQ23.b Do surgical volumes affect the outcomes of IH surgeries?

Statements

Statement	A surgeon's caseload appears to more important for IH surgery outcomes than a center's caseload.	☒☒☐☐

Statement	A surgeon's case volume is inversely related to that surgeon's recurrence rate.	☒☒☒☐

A Swedish Hernia Registry study found that surgeons who performed one to five hernia repairs annually (any technique) had longer operation times and significantly higher reoperation rates

than surgeons who did more repairs[64,65]. An NHS study found comparable results [reference needed]. Surgeons' annual laparoscopic hernia repair caseload was inversely related to reoperation rates following laparoscopic repair of primary IH[66]. This was not the case for open repair. This study contained no information on surgeons' laparoscopic experience. The summed evidence suggests that higher case load correlates positively with fewer recurrences following primary laparoscopic IH repair.

A large RCT compared laparoscopic with open IH repair and found a 10.1% recurrence rate following laparoscopy[67]. In the study, 69 surgeons performed 989 repairs. Prior to the study's commencement, only twenty of the surgeons self-reported an experience of more than 250 repairs. For this highly-experienced group, the recurrence rate for laparoscopic repair of primary hernia dropped down to 5.1% and was comparable to recurrence rate after open repair at 4.1%. The study authors concluded that an experience of 250 IH repairs was necessary to achieve a significant difference in recurrence rates. They defined a new category, "highly experienced surgeons" as those who had performed more than 250 IH repairs.

A survey found that routine surgical practice varied with hernia surgery volume. Surgeons who performed more than 50 repairs annually were more likely to visualize and preserve inguinal nerves[68], a measure recommended for prevention of chronic pain. It is reasonable to assume that high volume surgeons are more focused on chronic pain prevention. Notably though, this study did not document chronic pain incidence in relation to surgical volume.

A review article noted that recurrence rates after Shouldice repair by hernia specialists (term not defined in the article) were lower when compared with repairs by non-specialists. Wound infection rates were comparable between the groups[69].

Few studies have compared high volume surgeons' outcomes with low volume surgeons' outcomes. Some studies have compared open IH repairs by residents with repairs by full-trained surgeons. In one study, residents took more time to dissect and mobilize the sac and had significantly higher postoperative complication rates. Recurrence rates however were similar. More chronic pain occurred in the specialist-repair group[70].

KQ23.c Does facility specialization affect IH surgery outcomes?

Emerging evidence suggests that high center volume is related to positive outcomes for a wide variety of surgical procedures and that reducing the number of centers undertaking complex surgical procedures is associated with better outcomes.

Complex IH repairs include those with re-recurrences, chronic pain or mesh infections. However, there are no studies comparing specialist with non-specialist center repairs of these cases.

Some have suggested that good outcomes in complex cases result from the aggregate effect of surgical expertise, high volumes, choice of more effective treatment modalities and other factors unrelated to surgical expertise. There may also be benefits of working with a highly skilled team that performs complex tasks repeatedly, has good knowledge of different techniques for abdominal wall repair and possesses extensive experience in the entire field of hernia surgery[71].

There may be a need for hernia centers that offer "a complete hernia service" using a "tailored approach"[52].

The National Outcomes Program established in 2009, evaluates healthcare outcomes in Italian hospitals and assesses the UK's National Health System (NHS). In addition to outcomes, the 2013 Program edition included a set of volume indicators for conditions with evidence of a volume-outcome association. However, due to a paucity of evidence, it is not possible to draw firm conclusions about hernia treatment from this data set[72].

Another trial was also unable to establish a clear relationship between high-volume hernia centers and improved outcome[73].

However, another group reported marked differences in outcomes in relationship to individual surgeon's volume at three hospital types. So-called "occasional operators" dominated at university hospitals and had a significantly higher relative risk of recurrence compared with medium and small hospitals[64]. This finding supports the concept of regionalization to specialized settings with high case volumes and greater experience.

The impact of creating a surgical specialty referral center has been studied as well, specifically the financial and institutional volume impact[74]. This study examined all hernia repairs in the period 2004 to 2011 comparing hernia repair type, volume and center financial performance. The ventral hernia repair (VHR) patient subset was further analysed for previous repairs, comorbidities, referral patterns and concomitant plastic surgery involvement.

Prior to hernia center establishment, hernia procedures averaged 156 annually (years 1999-2003). Over the next 8-year period, a total of 4,927 hernia repairs were performed with an average of 616 hernia procedures per year. Annual billing increased yearly from 7% to 85% and averaged 37% per year. Comparing 2004 with 2011, procedural volume increased 234%, and billing increased 713%. During that period, there was a 2.5-fold increase in open VHRs, and plastic surgeon involvement increased almost 8-fold, ($p=0.004$). In 2005, 51 VHR patients had a previous repair, 27.0% with mesh, versus 114 previous VHR in 2011, 58.3% with mesh ($p<0.0001$). For VHR, in-state referrals from 2004 to 2011 increased 340% while out-of-state referrals increased 580%. In 2011, 21% of all patients had more than 4 comorbidities, significantly increased from 2004 ($p=0.02$). It was concluded that the establishment of a tertiary, regional referral hernia repair center led to a substantial increase in surgical volume, complexity, referral geography, and financial benefit to the institution.

In the some European countries and the United States world, increase in surgical volume is often dependent on volume agreements with health insurance companies.

KQ23.d Does surgical specialization affect IH surgery outcomes?

Statement

Statement	Hernia specialists are surgeons with mastery/expert level hernia surgery skills who actively train, educate and perform research in their field.	☒☐☐☐

It is difficult to separate surgeon caseload from specialization since they are highly correlated. The literature on surgeon caseload is described above. A publication from one expert group opines "… there is a need for hernia centers in which hernia surgery is practiced by specially accredited hernia surgeons who as far as possible master all hernia surgical techniques and play an active role in training and continuing education as well as in the field of science." This statement goes a long way toward defining a hernia specialist.

Specialized hernia centers outperform general surgical centers in laparoscopic and complex IH surgeries[28,55,56]. Therefore, complex IH surgery should be performed by a hernia specialist.

In primary IH Lichtenstein repair, general surgeons' and supervised-residents' results were comparable with experts' results[75,76]. Similar findings were found for repairs with bilayer patches and plugs[77,78].

Hernia surgery specialization can significantly impact the type of hernia surgery performed in a region. Prior to year 2000, less than 1% of inguinal repairs were performed laparoscopically in the Australian Capital Territory, population 400,000. Following the adoption and popularization of TEP repair in the state by a specialized hernia surgeon, laparoscopic repairs increased annually to 39% in 2004. The value of hernia specialists in developing and promulgating new techniques and offering continuing education to fellow surgeons and surgeons-in-training cannot be underestimated.

Chapter 24 Costs

G. van Ramshorst, R. Bittner, H. Eker and W. Hope

Introduction

Factors influencing costs in inguinal hernia repair.

Cost calculations for IH repair are complex and difficult to perform[79]. Overall costs, including pretreatment, treatment and post-treatment medical care, societal and employer costs are rarely completely reported in studies. Moreover, it should be considered that costs are not equal to charges[80]. Charges are not necessarily related to costs, and are usually constructed using different formulas. Charges can vary greatly among hospitals and countries. Reimbursement of costs by insurance companies or patients varies widely between countries and hospitals, often depending

on negotiations related to volume agreements[81]. All of the aforementioned stages in the treatment process are associated with variable costs.

IH repair cost calculations are complex and difficult to perform[79]. Total costs, including pretreatment, treatment and posttreatment medical care, societal and employer costs are rarely reported completely.

Costs are not the same as charges[80]. Charges are not necessarily related to costs and are tabulated using different formulas. They also vary markedly amongst healthcare facilities and countries. Reimbursements of charges by insurance companies, other payers, and patients also vary widely.

Data demonstrate clearly that hernia surgery cost calculations are determined by a large number of variables including:

1. Patient-specific characteristics
2. Hernia pathology
3. Anesthetic type
4. Annual hernia case load
5. Procedure type
6. Surgeons' skills
7. Fixation type (including no fixation)
8. Complication frequency
9. Operative setting
10. Number of postoperative visits
11. Sick leave duration
12. Recurrence rate
13. Salaries of personnel
14. Equipment depreciation
15. Share of costs from relevant support services

As expected, published data on costs of an IH operation show huge variation, ranging from about 126 USD to more than 4,116 USD[82,83]. Even within one institution, there are huge variations in costs generated by individual providers[83].

Surgeons can only influence some of the factors above. Operating time, surgical intervention quality, and instrument and material choices are the surgeon's responsibility[84–88]. An individual surgeon's experience and skill may significantly impact cost when factors such as operating time, complication rates and recurrences are considered[84,87,89].

Studies report wide variations in quality of life and quality-adjusted life years (QALY) following IH repair. It is known for example, that patients receiving workmen's compensation take longer to return to work than those not receiving these compensations[81,90]. Patient-related factors such as age, comorbidity, work type, employment history, local culture, and physicians' expectations influence recovery time but their contribution to costs are difficult to evaluate[91,92]. Additional costs such as medication expenses, home care compensations and transportation-related expenditures add to the tally and are similarly difficult to capture fully. Rarely considered are patient loss of income, disability insurance costs, and costs associated with the patient's inability to care for others. Other relevant employer-related outlays include: insurance costs, productivity losses and worker replacement costs[81].

Complicating comparisons between studies on costs is the fact that currency conversions over time are problematic and in some studies only percentages of cost differences were estimated. In other studies percentages of effectiveness differences were used to calculate incremental cost per recurrence avoided and incremental cost per added day of work or usual activity[82].

Laparoscopic repair costs can change over time as new equipment is purchased, costs are spread over a higher volume of procedures, or the equipment is used for other procedures[93].

KQ24.a Is open or endoscopic inguinal hernia repair more cost effective?

Statements

Statement	Direct institutional costs are lower for open mesh repair than for laparoscopic mesh repair.	☒☒☒☒
Statement	Indirect societal costs are lower for laparoscopic mesh versus open mesh repair.	☒☒☒☒
Statement	Laparoscopic inguinal hernia repair is overall more cost effective than open inguinal hernia repair.	☒☒☒☐

KQ24.b What are the costs and cost differences between open and laparoscopic inguinal hernia repair?

Statement and Recommendation

Statement	The higher institutional costs of laparoscopic inguinal hernia repair are mainly due to the use of expensive disposable equipment.	☒☒☒☐

Recommendation	From a cost-effectiveness perspective, day-case laparoscopic inguinal hernia repair with minimal use of disposables is recommended.	☒☒☒☐	Strong

Evidence in Literature

Open tissue IH repair under local anesthetic is the least costly technique when materials alone are considered. However, due to longer return-to-work times and higher recurrence rates it may be less cost-effective when compared to mesh repair[94–96].

Institutional costs were higher for laparoscopic repair (TAPP, TEP) when compared with open mesh techniques[62,84,85,97–123]. In experienced centers with minimal disposables use, the cost of laparoscopic repair may be equivalent to, or lower than, the cost of open surgery.

However, some study data used to arrive at this conclusion may be flawed. Operating times in excess of 60 minutes[92,94,98,99,102,103,109,110,115,116,122–124], high recurrence rates for laparoscopic repair (10%)[67,94,125] and high conversion rates (6-10%)[84,117,120] may indicate lack of experience. Studies not mentioning instrument and material types are unsuitable for cost calculations.

Most papers state that higher laparoscopic surgery costs mainly reflect the use of expensive disposables and longer operating times[82,85,92,103,107–112,120,126–128]. Multiple costs analyses demonstrate that if disposable trocars, graspers, preperitoneal balloons and stapling devices ("tackers") are included[129], direct costs are significantly higher for laparoscopic over open hernia repair. This was mainly true in the early laparoscopic hernia surgery era[84,91,98,99,102,110,119,121,126,130].

Now, institutional costs for laparoscopic hernia repair may be comparable to, or lower than, open hernia repair costs[81,92,93,119,131]. Some studies show that in large-volume laparoscopic surgery centers with minimal use of disposable instruments and no use of preperitoneal balloons and tackers for mesh fixation, the direct costs of laparoscopic repairs are comparable to open repairs [more references needed since you mention "some studies"[92]. One recent study found lower TEP/TAPP costs when compared to open mesh repair. Data for this study were collected in 15 German hospitals and were used to analyze costs. The authors concluded that laparoscopic approaches are not necessarily associated with higher resource utilization when compared to open mesh repairs[87]. A recent large English study had a similar finding[83]. This study concluded that the mean cost of laparoscopic versus open hernia repair is comparable but laparoscopic repairs appear to offer higher costs per QALY versus open repairs[83].

In contradiction to the results seen in studies of direct/hospital costs, nearly all RCTs, systematic reviews and meta-analyses demonstrate that indirect/societal costs for laparoscopic IH repair are lower than open mesh repair. This finding is accounted for by more rapid recovery with less pain[62,92,93,102,118,124,127,132], shorter sick-leave time[85,86,98,103,104,108,110,111,115,122,126–128,132–134], better physio metric test results[81,97], and decreased complications and recurrence rates as experience has grown[81,84,92,96,103,108,110,116,118,121,128,132–134].

If both direct and indirect costs are tabulated, laparoscopic hernia repair appears to be more cost-effective than open hernia repair[83,104,107,121,128,133,135–138].

KQ24.c Which surgeon-specific factors result in improved cost effectiveness?

Cost effectiveness may be enhanced by an increase in individual case load (more rapid depreciation of equipment costs, more experience)[139], shortening of the learning curve (resulting in decreased operating times), proper supervision of residents and junior consultants , surgical technique improvements (resulting in lower complication and recurrence rates), technique standardization, systematic training including simulation-based training[46,85,89,99,102,134,140] and use of non-disposable trocars and other instruments[85,92,93,109,138,141,142]. (see chapter 22 material on learning curves)

It has also been shown that, due to mesh technology improvements and a better understanding of the extent of inguinal floor dissection needed in hernias with defects of less than three centimeters, expensive fixation devices are unnecessary[143,144].

Chapter 25 Groin Hernia Registries

P. Nordin, A. Montgomery, L.N. Jorgensen, U. Klinge and T. Bisgaard

Introduction

Well-designed RCTs advance the scientific basis of our knowledge and promote evidence-based medicine because of their powerful internal validity[145,146]. However, some aspects of medical care cannot be easily addressed by RCTs. Studies from well-validated registries can provide important information as well. Registry studies of large populations have the unique strength of reflecting clinical reality (e.g. outcomes in routine clinical practice) and thus provide the surgical community a high level of external validity.

KQ25.a When compared with RCTs, do well-validated IH quality registries, and the studies done on their databases, offer additional valuable evidence-based information to hernia surgeons?

Statements and recommendation

Statement	Hernia registries, with high coverage, allow monitoring of clinical practice and provide high external validity whereas RCTs define effects of a specific intervention with minimal bias and high internal validity.	☒☒☐☐

Statement	Rare events can be detected early in hernia registries highlighting potential problems soon after new techniques and products are introduced into clinical practice.	☒☒☐☐	
Statement	Registry-based studies are important complements to RCTs, in guideline development.	☒☒☐☐	
Recommendation	Countries or regions should develop and implement registries for groin hernia patients.	☒☒☐☐	weak

Evidence in Literature

Hernia registries provide long-term monitoring of surgical quality in unselected patients and facilitate surgical care improvements at individual facilities[147,148]. Registries can serve as the basis for observational studies, may detect and lead to the analysis of rare events, may provide data needed for RCTs, and facilitate questionnaire studies. Also, patients may be recruited from registers for clinical trials that address specific questions outside a registry's scope.

Registry data reflects *effectiveness* in routine care and possesses high external validity, provided their coverage is broadly inclusive of a national population. In contrast, RCTs and other trials are investigational and often report on *efficacy* obtained in expert hands when interventions are optimally applied to carefully selected subjects[149]. (Table 1) RCTs are widely recognized as the criterion standard in the evaluation of pharmacological interventions, but problems may arise if surgical techniques are compared[146].

The optimal design for comparing surgical methods is a randomized study involving surgeons of equal skill levels who demonstrate equal levels of objectivity with the methods being compared. However, even in study settings, patient-related and surgeon-related factors which cannot be controlled influence outcomes. Technical skill variation will always exist and was demonstrated in an RCT measuring surgical skill[150]. In this study, low surgical performance scores were highly correlated with five-year hernia recurrence rates. The question naturally arises then, how to consider this issue when analyzing studies? Similarly, should RCTs be the only means we use to evaluate surgical methods?

Hernia surgery is usually considered within the purview of general surgery and is often performed by non-specialized surgeons or trainees[151]. Factors like patient age, gender, comorbidities, hernia-specific conditions and surgeons' preferences and experience might influence surgical indications and the choice of operative technique[152–154].

For the reasons cited above, RCTs and registries should be considered alongside one another when evaluating various aspects of hernia repair[155].

Ideally, a registry should follow patients from initial inclusion event to death. Provided consent is obtained to use personal identification numbers, patients can be tracked within a healthcare system and all subsequent encounters (e.g. reoperation) recorded[147,148,156]. It is also possible to link registries of various types to detect and analyze risk factors contributing to unfavorable outcomes.

Coverage and data validity are crucial for registry studies. If a registry enrolls nearly all hernia patient encounters, the risk of skewed patient selection is minimized. Additionally, care must be taken when entering registry data since incorrect or missing data limits a registry's soundness. These factors influence the external validity or generalizability of conclusions reached in studies involving registry data and patients. In a perfect world, registry data and the conclusions about those data would exactly match the world outside the registry. This ideal can likely never be realized, but regional and national registries do include enormous data sets. Studies can be performed about time trends for repair methods, materials used, anesthetic type, patient gender and others topics. In contrast to studies performed at a single institution, registry studies can shed light on rarer events and conditions like: IHs in females, femoral hernias, serious complications and mortality[157,158]. It has been demonstrated the results abstracted from Danish and Swedish databases have changed clinical practice nationwide[159–161].

Use of the checklists from the CONSORT statements, the STROBE curriculum and the RECORD statement are highly recommended to improve reporting quality for RCTs and observational studies[146,162,163].

The 2012 EHS consensus meeting also spawned recommendations for reporting outcome results in abdominal wall repair across different study types[164].

Table 1. Pros and cons with registry studies and RCTs

Figure 1. The potential coverage of patients operated on for an IH reported in a national or regional register compared to a randomized control trial.

Discussion

There are several examples of RCTs with a major role in advancing the scientific basis of our knowledge and promote evidence-based groin hernia surgery[84,165,166]. Hernia registers with high population based coverage, correct data and a great number of unselected patients have the unique possibility to study clinical reality and reflect outcomes in more routine clinical practice. Registry-based studies are therefore important complements to RCTs. Presently, there are several examples of evidence-based national registry studies which are generalizable to the realm of groin hernia surgery[64,148,157–161].

Chapter 26 Outcomes and Quality Assessment

D. Sanders, H. Eker and J. Bingener

Introduction

Surgical outcome reporting is important to understanding the postoperative course of patients undergoing different types of groin hernia repair. It also serves to clarify how outcomes are affected by preoperative, surgical and postoperative variables (e.g. comorbidities, mesh type, mesh fixation method, and others).

KQ26.a What are the currently used methods for measuring surgeon-specific outcomes following groin hernia repair?

KQ26.b What are the currently used methods for measuring patient-based outcomes following groin hernia repair?

Statement and recommendation:

Statement	There should be an internationally agreed upon set of parameters—with definitions—for groin hernia surgery.	☒☐☐☐	Strong
Recommendation	The development of hernia registries that include patient follow-up data and account for local healthcare structures is recommended for research and audit purposes.	☒☐☐☐	Strong *upgrade

Evidence and Discussion

A worldwide agenda now exists to ensure high standards in surgical practice by public dissemination of the outcomes of operations[167,168]. Quality outcome indicators can be either surgeon-specific/clinical (e.g. length of stay, recurrence, others) or patient-related (e.g. quality of life, patient satisfaction, others). Both are important in assessing quality and are interrelated. Devising a meaningful, intelligible and fair system for collecting data on quality is extremely complicated. Difficulties include:

What is measured?

Which outcomes?
Should risk adjustment be performed?
How should risk adjustment be done (if it is done)?

Will outcome measurement lead to conservatism in surgical practice?

How are measurements made and are they accurate?

Are data collected accurately and reliably?

Timing

When does a valid outcome manifest after an operation?
What follow-up time is required?
How is outcome information collected when routine follow-up is not done?

Practicality

Will outcome data collection significantly add to surgeons' workloads?
Will outcome data collection significantly add to other healthcare workers' workloads?
Will costs be increased?
Who will pay for these cost increases (if they occur)?

How will the data be used and accessed?

Data available to the lay public must be both understandable and detailed enough to provide valid decision-making tools
Will there be legal implications of outcome data collection and dissemination?
Will there be regulatory or governmental implications?

Seven clinical-outcomes assessment tools specific to hernia surgery are in use internationally[169–176], as is one patient-outcomes assessment tool[177]. Eight hernia registries exist (Swedish Hernia Registry, Danish Hernia Registry, HerniaMed, Club Hernie, EuraHS, Dutch Hernia Registry, Evereg and AHSQC).

Large registries have the theoretical advantage of being able to capture information on rare adverse outcomes and disseminate that information to the surgical community at large. RCTs, which are often performed at expert centers, may lack this feature. Registries also can inform regulatory agencies and the public about important outcome differences between healthcare facilities.

Accurate, complete and valid data entry is crucial. A voluntary registry or a system lacking validity checks is at high risk for selection bias and input bias. Registry establishment and maintenance is costly and a stable funding source must be assured prior to registry development.

What constitutes a good registry?

Reasonable construct validity for a registry requires a robust system of data collection, follow-up and validation, agreed upon at the national level, and practical for the structure of the healthcare system in which it is imbedded. To deter risk-averse patient selection, pre-defined risk adjustment models are suggested.

Healthcare systems' structures vary broadly worldwide resulting in problems designing international registries. In many countries, routine follow-up is not done due to clinical and financial constraints. Also, patients experiencing adverse events may not present to their original healthcare provider, making adverse event data collection more difficult.

Time burdens, financial constraints, resource limitations and other factors place tremendous pressures on healthcare systems and their personnel worldwide. Quality data entry into registry databases may increase workload since many of these data points are already in the medical record. A method of minimizing data entry duplication would be to ensure that registry data entry occurs during the recording of clinical data entry. This, of course, would require local and national coordination. International registries could incorporate this feature as well.

Patient Reported Outcomes

Patient Reporting of Outcome Measures (PROMs) is another method of measuring outcomes. The United Kingdom's National Health Service (NHS) has used PROMs since April, 2009 to assess the quality of all NHS-funded care from patients' perspectives[178]. PROMs measures patients' health status or health-related quality of life at a single point in time. Data are collected from short, self-completed questionnaires. For surgeries, health status information is gathered pre- and post-procedure. Two generic measures are used to assess patients' self-reported outcomes following groin hernia surgery.

- The EQ-5D Index, a general measure of patients' quality of life
- The EQ-VAS, which provides a simple snapshot of patients' self-reported health.

The EQ-5D Index gives a general overview of patients' self-reported quality of life on five dimensions: health, anxiety and depression, ability to self-care, ability to carry out usual activities, and experience of pain or discomfort. Patients' scores on these questions are combined to give an index ranging from -0.594 to 1.0 (best possible score).

A problem with this approach is that IH patients generally do not have major problems with anxiety, depression or ability to self-care, dimensions included in the Index. What they do have is a specific local problem, that this generic health questionnaire will not identify or measure. At least two studies have shown clearly that generic instruments have poor discriminatory powers for distinguishing between satisfied and dissatisfied hernia repair patients[83,179]. For unclear

reasons, the NHS has failed to adopt a condition-specific IH questionnaire. Outcome-specific disease measures for hernia surgery such as the Carolinas comfort score exist and have been validated[83].

Groin hernia repair outcome reporting is inconsistent and poorly defined, limiting meta-analyses, which themselves do not control for the differing definitions of assessed outcomes. A recent study published in the journal *Hernia* assessed type, frequency and definition of clinician-observed and assessed outcomes and PROMs for instrument validity and frequency of domain reporting[180]. Forty RCTs (10,810 patients) and seven meta-analyses (17,280 patients) were included in the review[180]. No single PROM was reported by any study. There were 58 different clinician-observed outcomes, with recurrence (n=47, 100 %), wound infection (n=33, 70.2%), hematoma (n=31, 77.5 %) and seroma formation (n=22, 46.8 %) being most frequently reported. All studies measured patients' views, although only 12 (30.0 %) used validated instruments. The SF36 was the most commonly used multidimensional valid PROM (n=7), and a visual analogue scale assessing pain (n=32) was the most frequently used one-dimensional scale. Non-validated questionnaires assessed 25 other aspects of patients' health. Two meta-analyses defined recurrence, and three defined chronic pain; although neither ensured that included RCTs adhered to the definitions.

These results suggest that a standardized core outcome set is needed for hernia surgery to improve outcome reporting and evidence synthesis.

Chapter 27 Dissemination and Implementation

M. Pawlak, A. Wijsmuller and H. Eker

Introduction

One of the goals of the HerniaSurge Group is the worldwide dissemination and implementation of our groin hernia management guidelines. They contain the most current evidence-based information and also show where scientific research is needed. They are important for guiding clinical practice and for the education of surgeons and for standardizing surgical training. However, without an ambitious implementation plan designed to reach targeted groups, the impact on hernia management could be disappointing [181,182]. Never before have any of the hernia surgery societies or inguinal guidelines focused on performing the difficult task of global recognition and awareness[183–186].

HerniaSurge will create a guideline implementation trajectory and a transparent dissemination plan.

Key Questions

KQ27.a What are the target groups for the guidelines?

KQ27.b What are the most important messages of the guidelines, both general and specific, for the targeted groups?

KQ27.c Which channels can be used for guidelines distribution?

KQ27.d How can the guidelines be supported by Internet tools, platforms, Apps and social media?

KQ27.e What is the evaluation strategy for the implementation process?

Recommendation

Recommendation	HerniaSurge recommends that all countries or regions develop a guidelines dissemination and implementation strategy. HerniaSurge offers support for this process.	☒☐☐☐	Strong

Target Groups
The groups needing information about guidelines content include:

- Surgeons and physicians treating groin hernia patients
- Healthcare providers performing services for the treatment of hernias
- Groin hernia patients and their family members

Message
HerniaSurge was established as a joint effort of the EHS, EAES, IEHS, AHS, AHPS, AMEHS and Australasian Hernia Society to develop guidelines for surgeons and healthcare providers who treat groin hernia patients. The guidelines include information on inguinal and femoral hernias in men and women and were developed according to the AGREE II instrument [187]. A set of key recommendations of the guidelines will be identified on a global level by a vote during the international hernia congresses. The focus of the dissemination process will be placed on these key recommendations while providing access to the whole guideline. The barriers to implementing recommendations were sought and described independently in relevant chapters.

Implementation and dissemination methods

- Branding – HerniaSurge. The aim is for the guidelines to be well-recognized, effective and disseminated worldwide.
- Translation of the key statements and recommendations of the guidelines into languages that are most spoken: Mandarin, Spanish, French, Portuguese, Arabic, Russian, Japanese and German.
- Website: www.HerniaSurge.com - a platform that consolidates the main aspects of the guidelines, gives insight into their development methodology, provides a database of the multimedia supplements and also includes resources for patients and medical professionals[188].
    1. Patient Resources
        - Short videos explaining the pathology of IH and the most common surgical procedures

        - A brief explanation of the purpose for which the guidelines were created
        - Highlights of the most important issues that are of particular interest to IH patients (e.g. the prevention and treatment of chronic pain)
    2. Resources for medical professionals
        - Full guidelines
        - Short explanations of main objectives, methods and key recommendations in several languages
        - Database with literature
- Social media: Facebook and LinkedIn pages including several selected topics (much more concise than the HerniaSurge website)
    1. Resources for patients: 3 to 4 videos as mentioned above with simple explanations on the aim of the guidelines and the key recommendations that are of particular interest to patients, translated into different languages
    2. Resources for medical professionals: short explanations on main objectives, methods and key recommendations in several languages
    3. Direct links to www.HerniaSurge.com
- Publication of the key recommendations with reference to the full guidelines (on the HerniaSurge website) through every Hernia or National General Surgery Society after an inventory of these societies worldwide.
- Presentation of the key recommendations worldwide at hernia congresses (EHS/AHS/EAES/Annual congresses of Hernia Societies)
- Mass media: several mass channels (for example Euronews, BBC, CNBC) should be approached through media and communication departments to communicate the existence of the first worldwide surgical guidelines. Spokesmen will be chosen for this task.

The use of Modern Multimedia and Network tools.

The aim is not only to offer written guidelines but also to offer assistance in their implementation.

- Video – tutorial videos for procedures. Videos of the most common hernia operations for the instruction of new learners (Lichtenstein, TEP, TAPP)
- Podcasts – recorded discussions on the guidelines conducted by recognized hernia experts and authorities. There will be a few selected essential topics like algorithms for groin hernia treatment pointing out the advantages and disadvantages of proposed procedures as well as defining the indications. Most importantly, this information will be submitted in an understandable and accessible fashion so that they are clear even for novice surgeons. The information should focus on the complexity of the treatment selection accordingly to defined factors such as gender, age, etc. These factors will be determined by the HerniaSurge Group and presented in the Podcast.

- Teaching – PowerPoint presentations will be developed and available on the website. Surgeons worldwide will be able to use these for teaching/learning in their own institutions.
- App – HerniaSurge will create an application for PC, smartphones and other devices which will help to analyze and select the best treatment option for individual patients according to the guidelines. Further it will contain critical information on the topic, an

anatomical atlas of the groin region, answers on all frequently asked questions and a knowledge quiz to entertain and stimulate the curiosity of residents and experts.

Evaluation and Revision

The dissemination process will be monitored and audited by each of the national chapters. The level of implementation will be determined by a predefined set of criteria (guidelines awareness, target groups' attitudes, application of recommendations, and the effect on medical care).

During the dissemination, a study will be performed examining the quality and effectiveness of the process of implementation in two to three test countries that will be selected by the HerniaSurge Group. The most important key recommendations will be used for those test countries based on the up-to-date status of hernia surgery. The dissemination will be conducted and monitored by dedicated PhD students. An evaluation after 5 years will be performed and analyzed so that improvements can be made.

The proposed dissemination plan is ambitious, however looking through the prism of today's society that is oriented on fast collection and processing of information we need a clear, yet modern method for dissemination. It will be an innovative project that will determine the trend for the possibility and potential success of introducing future guidelines.

Global Groin Hernia Management

Chapter 28 Inguinal Hernia Surgery in Low Resource Settings

P .Nordin, D. Sanders, I. Konaté, R. Sani and M.P. Simons

Introduction

HerniaSurge (www.herniasurge.com) develops guidelines intended for use globally. This chapter contains guidelines on the performance of safe, cost-effective IH repair in low resource settings (LRSs).

There is a substantial burden of disease in countries where the majority of the world's groin hernia patients live. Although herniorrhaphy is one of the most commonly performed surgeries in LRSs[189–191], needs exceed capacity. This surgical "under-production" over time results in high hernia prevalence in populations. This in turn results in a high proportion of emergency surgery and significant morbidity and mortality[192–199]. This, despite the fact that groin hernia repair is highly cost effective[200–202].

Key Questions:

KQ28.a What is the epidemiology of inguinal hernia in LRSs?

KQ28.b Which types of inguinal hernia repairs are currently performed in LRSs?

KQ28.c What is the recommended operation for inguinal hernias in low resource environments?

KQ28.d What are the logistical challenges for safe groin hernia repair in low resource environments?

KQ28.e Should any special precautions be taken?

KQ28.f What is the most suitable mesh?

KQ28.g What is the best way to educate surgeons in a sustainable manner in LRSs?

KQ28.h How can the internet and other technologies be used to teach physicians in LRSs?

Statements and Recommendations

Statement	Due to a substantial lack of access to surgery, inguinal hernia prevalence in LRSs is unacceptably high.	☒☒☒☐	
Statement	In LRSs there is a lack of basic surgical training, expertise in inguinal hernia repair techniques, and resources to safely perform mesh repair. Mainly (modified) Bassini techniques are used.	☒☐☐☐	
Recommendation	LRSs should focus teaching the performance of high volume inguinal hernia repair by a standardized technique (Lichtenstein) under local anesthesia preferably using a low-cost mesh (e.g. mosquito mesh).	☒☒☐☐	Weak
Recommendation	The use of low-cost mesh (with known chemical and physical characteristics, which are comparable to commercial prosthetics) is suggested.	☒☒☐☐	Weak
Recommendation	When using a non-licensed low-cost mesh, outcome audits at a local level are suggested.	☒☐☐☐	Weak
Recommendation	It is suggested that at least one dose of an appropriate prophylactic antibiotic be administered prior to inguinal hernia repair in LRSs. Whether to administer antibiotics for 24 hours or more is unknown.	☒☐☐☐	Weak

Recommendation	An overarching plan to improve access to safe inguinal hernia surgery in LRSs is needed. It is suggested that this plan contain simple guidelines and a sustainability strategy which should allow implementation and maintainability, independent of international aid.	☒☐☐☐	Weak

Evidence in Literature

KQ28.a What is the epidemiology of inguinal hernia in LRSs?

IH epidemiology literature is limited, from both the developed world and particularly from LRSs. IH incidence—measure of probability of IH occurrence in a population within a specified time—is difficult to firmly establish although it seems unlikely that incidence varies much between countries. In contradistinction, IH prevalence—population proportion with IH at a given time—appears to be significantly higher in countries with poor healthcare access[199,203–207]. The assumption is that most cases go untreated in resource-poor settings. The discrepancy in incidence versus repair rate results in high prevalence. This in turn has a huge economic impact on countries least able to shoulder that burden[202].

A 1996 United Kingdom (UK) study found a lifetime risk of IH repair of 27% for men and 3% for women, an immense IH disease burden[189]. Data from sub-Saharan Africa paints a very different clinical picture. A 1978 study of rural Ghanaian men estimated that 7.7% had an IH[208]. However, a 1969 study showed that the prevalence of IH was as high as 30% on Pemba Island in East Africa[209].

A prospective cohort study compared IHs in Ghana and the UK and revealed that two-thirds of Ghanaian hernias extended into the scrotum. This was the case in only 7% of UK IHs[210]. The majority of these were longstanding right-sided indirect hernias. Ghanaian subjects had an average age of 34 years versus 62 years in the UK cohort.

Inguinal hernias, occurring in the young, have a major impact on fragile economies. In the Ghanaian study, 64% of subjects experienced daily activity limitations and16.3% of these individuals were unable to work.

A truly startling percentage of IH repairs are done on an emergent basis in sub-Saharan Africa – 65% in Ghana, 76% in Uganda, 33% in Sierra Leone and 25% in Nigeria[205,211–214]. In contrast, 6 % of IH repairs are performed as emergency in the EU[215]. A 2007 Nigerian study reported that 20% of emergent IH repair patients died[216].

In 2012, data from the National Health and Nutrition Examination Survey prospective cohort study of IHs were used to estimate IH disease burden in Ghana[204]. Per this approach, the IH prevalence in the Ghanaian general population is 3.15% (range 2.79-3.5%). The number of symptomatic hernias was estimated at 530,082 (range 469,501 to 588,980). The annual incidence of symptomatic hernias was 210 per 100,000 individuals (range 186/100,000 to 233/100,000). It was concluded that at the estimated Ghanaian IH repair rate of 30 per 100,000, a backlog of one million hernias needing repair develops each decade. The cost of repairing all symptomatic hernias in Ghana was estimated to be 53 million USD. Hernia elimination over a 10-year period would cost 106 million USD. Nearly five million disability-adjust life years (DALYs) would be

saved by the repair of prevalent cases of symptomatic hernia in Ghana. These findings are supported by another study which estimated the unmet burden of IHs in sub-Saharan Africa[217]. This study reported that the average district hospital performs 30 hernia repairs per 100,000 individuals per year (95% CI: 18-41), leaving an unmet need of 175 per 100,000 annually.

The same model was used to estimate Tanzanian IH prevalence[203]. The prevalence of IH in Tanzanian adults was 5.36% while an estimated 12% of men had hernias. This equates to 683,904 Tanzanian adults with symptomatic IH. The annual incidence of IH in Tanzanian adults was 163 per 100,000 people. At Tanzania's current hernia-repair rate, a nearly one million hernia-in-need-of-repair backlog will develop over ten years. Repair of the prevalent symptomatic hernias in Tanzania would save 4.4 million DALYs.

A 2012 study using data from the 2010 Global Burden of Disease (GBD) database quantified the burden of digestive diseases avertable by surgical care at first-level hospitals in low- and middle-income countries (LMICs)[207]. The study calculated the potential decrease in digestive disease burden if quality surgical services were universally available and accessible at first-level hospitals. It concluded that 74% of the burden of inguinal/femoral hernias in East Europe and Central Asia was avertable.

These disparities in surgical coverage highlight issues possibly amenable to rapid improvement. In East Europe and Central Asia, for example, the excess hernia burden can likely be addressed with few additional resources. Other regions may require a comprehensive reordering of priorities and resources to address their IH burden.

KQ28.b Which types of inguinal hernia repairs are currently performed in LRSs?

Groin hernia repair techniques have evolved over time[218]. During the last 25 years, techniques with synthetic mesh have become the norm and are now the preferred technique in high-resource settings. They have demonstrated superiority over conventional non-mesh procedures, particularly because of their lower recurrence incidence[219–221]. Additional practice changes in high-resource environments are laparoscopy and day-case surgery[222,223].

In LRSs, where out-of-pocket expenditures are significant and families often cope by borrowing money or selling assets to pay for surgery, mesh is often either unavailable or unaffordable. Most IHs in these settings are still repaired with the Bassini method (and many modifications) because of the high cost of mesh and the lack of training in mesh repair[205,224–226].

Occasional exceptions have been reported. A study from Nigeria found that mesh repair was well accepted with few complications at one-year follow-up[227]. Similarly, in rural Ghana and Uganda, mesh repair has been successfully used without significant complications[228,229]. In India, mesh repair seems to be more common (or perhaps more commonly written about) than in other LRSs[230]. Laparoscopy has been introduced in India as well[231]. Nevertheless, mesh cost remains prohibitive in most LRSs.

KQ28.c What is the recommended operation for an inguinal hernia in low resource settings?

Most people with IHs live in LRSs. Many operative innovations such as laparo-endoscopic and mesh repair methods cannot be widely used in LRSs due to cost. Solutions that provide cheaper alternatives and do not compromise the safety and effectiveness of mesh repair are needed. One alternative to expensive synthetic mesh is sterilized low-cost mosquito mesh. It too is a similar synthetic product originally intended for another purpose but is in use for hernia surgery in several locations[230,232–234]. Several studies of mosquito mesh have shown promising results in terms of tissue reaction, outcomes, and cost effectiveness[228,229,235,236].

One animal study concluded that mosquito mesh might serve as a cheap substitute to other forms of mesh when the latter is unaffordable or unavailable[237]. Two randomized trials have compared mosquito mesh with commercial mesh. One involved 40 patients from Burkina Faso and found no differences in outcomes at 30-day follow-up[238]. One recent trial with 302 patients from eastern Uganda had a follow-up of 12-35 months. All patients included were operated on with the anterior mesh technique according to Lichtenstein, under local anesthesia, and the vast majority as day cases. Recurrence rate and postoperative complications did not differ significantly between low-cost mesh and those undergoing hernia repair with commercial mesh[229]. Hernia repair with mosquito mesh has also been found to be highly cost effective in both Ghana and Ecuador[202,239].

KQ28.d What are the logistical challenges for safe groin hernia repair in low resource settings?

The challenge for hernia surgery in LRSs is to integrate the organizational structure of surgical care into the larger healthcare system[206]. The healthcare systems in LRSs have variations in the range of services offered between hospitals in the same country[240]. Studies have shown that properly functioning small hospitals and health centers in rural areas can deliver effective basic low cost surgical services[192,241]. However, many of them suffer from a lack of trained staff, equipment and integration of services delivery[242]. A well-functioning hospital offering a narrow range of vital surgical services can be part of an integrated model of healthcare delivery. Integration aims to improve the service in relation to efficiency and quality, thereby maximizing use of resources and opportunities[243]. The benefit of integration has been demonstrated in several settings[244].

Health practitioners should have appropriate surgical and anesthetic equipment and supplies. It is important for hospitals to be able to administer appropriate anesthesia, whether local (LA), spinal, general (GA) or with tracheal intubation[241].

A meta-analysis demonstrated a striking disparity between anesthesia-related mortality in LRSs when compared with high income countries[245]. Factors contributing to this disparity included: few qualified anesthetists, lack of appropriate training, limited supplies for safe patient monitoring, and limited supplies for the safe administration of anesthesia[246].

Adequate surgical training of practitioners and the use of LA permit the vast majority of IH repairs to be done in LRSs. Studies have shown that IH repairs with LA allow return to normal activity a day earlier than GA, important in LRSs[247]. Local anesthesia costs significantly less than spinal anesthesia and GA, another advantage in LRSs[240].

Given these limitations and the inherently higher risk of GA, it is recommended that groin hernia repairs in LRSs be performed under LA.

Several strategies can be used to overcome the logistical challenge of cost. Surgical instrument packs and other materials can be bought at a discount from non-profit organizations. Healthcare facilities and manufacturers can donate these materials close to their expiration dates[248]. If medical personnel and equipment are in short supply, short-term surgical missions by charitable organization can help reinforce the existing infrastructure. Sanitary mobile surgical platforms can be used in environments lacking modern sterile facilities[249]. While short-term surgical missions have been promoted as a method of alleviating disease burden, the best way for charitable organizations to support surgical care in LRSs is through partnerships with local hernia societies and health practitioners[249,250]. Teaching and training local teams should be performed next to alleviate the waiting list. A partnership of this type is occurring presently in Ghana with Operation Hernia http://www.operationhernia.org.uk/ [240]. The effectiveness should particularly be evaluated in respect to the retention of surgical skills of the newly trained staff, to improvements in outcomes, and to the retention, in-country, of local healthcare providers[249,250].

A sustainable model to improve hernia surgery in LRS requires a national commitment to providing access to surgical services, especially in rural areas, and to adequately training practitioners. Safe, effective, accessible and cost-effective surgical services must be available to meet needs in LRSs[251].

KQ28.e Should any special precautions be taken?

Only a few studies exist on interventions like antibiotics or nutritional supplementation pre- or post-surgery in LRSs[202,213,252–254]. One additional study analyzed IH patients in Ghana, Nigeria and the Ivory Coast operated on between 2005 and 2010. Mesh—either a standard brand polypropylene mesh or sterilized mosquito net—was used. Antibiotics were administered at the surgeon's discretion, with most patients receiving them[255].

Summary statements from the studies cited above include:

- Antibiotics are recommended, particularly when mesh is implanted
- For incarcerated hernias without bowel necrosis, a mesh repair with antibiotic coverage might be recommended
- Antibiotics are recommended in all strangulated hernia repairs with or without bowel necrosis
- Antibiotic administration was not standardized across the studies
- No recommendations about nutritional supplementation were made

Clearly, multi-centered RCTs in LRSs are needed to guide decision making about antibiotic use and nutritional supplementation.

KQ27.f Which mesh is most suitable for IH repair in LRSs?

In most resource-poor countries, sutured repair—with significantly inferior results compared with mesh—is common, since commercial mesh is either unavailable or unaffordable[189,256].

The hernia healthcare industry has developed over 200 mesh types with costs ranging from 40 to 6,000 USD per piece[257]. The most commonly used macro-porous polymers are polypropylene and polyester. Meshes differ marginally in their ultrastructure, filament type/construction, pore size, weight/density, tensile strength and elasticity[257]. Commercial hernia meshes are class II medical devices and are required to undergo the Food and Drug Administration (FDA) pre-market notification process in the United States or the Medicines and Healthcare products Regulatory Agency (MHRA) or other authority approval in the UK and Europe prior to market release[258]. Clearly these approved meshes are suitable for use in LRSs but are generally unaffordable there and therefore not used.

The use of mosquito net as an alternative to commercial prosthetics was pioneered in India by Dr Tongaonkar[230]. The first multicenter trial was performed there, using indigenous autoclaved and sterilized mosquito net mesh composed of polyethylene and polypropylene. The study reported a 6.9% incidence of complications, comparable to complications seen with Prolene mesh, with only one recurrence (0.27%) and no adverse mesh reactions at up to 5-year follow-up. More recently, a number of studies in developing countries have examined hernia repair with locally-available mosquito net of various types[233,237,238,259–263]. Mosquito nets vary in construction, but most commonly consist of cotton, polyethylene, nylon and polyester polymers[264].

Net pore size must be less than 1.2 mm to stop mosquitoes. However many nets use a pore size of 0.6 mm in order to stop other biting insects[264]. Several studies have demonstrated that mosquito net can be implanted with low complication rates, but not all mosquito nets are the same. In addition to pore size differences, some are constructed of unsuitable polymers, have coatings such as DEET, and have biomechanical properties that may produce intense inflammation, all of which may lead to mesh complications.

There are legitimate concerns about infection risk, foreign body reaction, the effectiveness of sterilization procedures in LRS hospitals, and the safe use of locally-sourced and prepared mosquito net for implantation.

A 2013 study compared the characteristics of mosquito net to other FDA- and MHRA-approved commercial meshes[236]. The tested mosquito net was a low-density polyethylene homo-polymer (LDPE), knitted from monofilament fibers, the mean pore diameter was 1.9 mm, with a 91.2% porosity, 53.7 g/m^2 mean mesh weight, and linear mass density of 152 denier, comparable to the "large pore" (class I) commercial meshes. The bursting force for polyethylene mosquito net was greater than that for UltraPro and Vypro (43.0 vs 35.5 and 27.2 N/cm, respectively). The mosquito net exhibited less anisotropy when compared with commercial meshes.

A randomized trial of nylon mosquito net versus commercial mesh in 40 IH patients from Burkina Faso found no difference in short-term 30-day follow-up outcomes[238].

A ten-year retrospective analysis was done of consecutive patients who underwent a total of 651 IH LDPE net repairs and were followed for 12-18 months. Thirty-two patients were lost to follow-up. Six superficial surgical site infections occurred (0.9%), as did one seroma (0.1%), and two hematomas (0.3%). Two patients reported chronic pain (0.3%). No recurrences or mesh

rejections were reported. The LDPE net was less than 0.03% the cost of commercial mesh[263].

A recently published RCT comparing LDPE mesh with commercial mesh including 302 male patients concluded that there was no significant difference in recurrence or complication rates[229]. The follow-up rate was 97.3% after two weeks and 95.6% after one year. Recurrence occurred in 1 patient (0.7%) assigned to LDPE mesh and in no patients assigned to commercial mesh (absolute risk difference, 0.7 percentage points; 95% confidence interval [CI], −1.2 to 2.6; p=1.0). Postoperative complications occurred in 44 patients (30.8%) assigned to the low-cost mesh and in 44 patients (29.7%) assigned to the commercial mesh (absolute risk difference, 1.0 percentage point; 95% CI, −9.5 to 11.6; p=1.0).

When mosquito net is used, tension-free IH repair is approximately one-third the cost of repair with a conventional alternative[233,235,239]. This finding is supported by a meta-analysis, which also found no increase in septic complications or recurrences[265].

Mosquito net steam sterilization at 121°C has been recommended but long-term follow-up data confirming sterility is lacking. Most of the currently used LDPE net is sterilized with ethylene oxide[228].

Cost-effectiveness analyses have estimated the overall cost associated with mesh repair to be 12.88 USD per DALY averted (assuming 120.02 USD/hernia repair and 9.3 DALYs averted/person)[202,239]. Based on this figure, hernia repair using low-cost mesh is a more cost-effective intervention than oral dehydration or at-home HIV/AIDS treatment with antiretroviral therapy[207].

Before universal acceptance of mosquito net for IH repair can be achieved however, careful audit and follow-up studies are required, which may be difficult to do in LRSs.

KQ28.g What is the best way to sustainably educate surgeons in LRSs?

Groin hernia surgery is the most common surgery performed in LRSs even though access to surgical services is very limited. A lack of skilled healthcare personnel exacerbates this access problem. In sub-Saharan Africa for example, most surgical and anesthesia services are provided by general physicians or non-physician clinicians rather than specialists[266,267]. Hernia is a neglected condition in LRSs. Strategies to provide education, training, and resources and reorder priorities are necessary to change this situation.

Many surgical skill educational programs exist but are not especially focused on hernia surgery. It is known that continuing education improves patient safety[267]. A conceptual hernia surgery education program could focus on three groups of LRS surgeons.

- Surgeons needing focused training and skill development
    - Hernia societies can create a hernia surgery certificate program whereby LRS surgeons receive a certificate of completion/competence after finishing a supervised course of study and demonstrate competent performance of a series of IH repair skills.
- Healthcare provider continuous education and skills training

    - Open to surgeons and all others involved in IH patient care activities
    - May involve periodic visits from referral hospital personnel, telemedicine, review of educational materials
    - On-site support and training in hernia surgery by surgeon specialists from referral hospitals to outlying facilities
- Operators/surgeons in outlying hospitals
    - Can be visited on a rotating or as-needed basis by hernia specialists in a series of "surgical camps"

Few studies have evaluated the impact of short international training trips on the practice of local physicians following training trip participation. One study conducted in Ghana and Liberia reported on a two-day surgical training course on tension-free mesh repair performed in a resource-limited setting. It also looked at the course's impact on local surgical practice. It concluded that a brief training course can significantly improve local practice. Operation Hernia is a UK-registered charity initiative involving the EHS and the Plymouth-Takoradi (Ghana) Hospital which trains, and teaches hernia surgery, in Africa. It sends volunteer teams to work alongside African surgeons, training them in local anesthetic administration and guiding/mentoring during hernia operations. Teams operate on a large volume of cases in a short time, often in two theatres simultaneously[8,206,268].

When deciding which surgical services to offer facility capabilities and infrastructure must be considered. A well-equipped facility is necessary to support a strong education program in LRSs[267]. Per the WHO Safe Surgery Initiate, operating theatres must be of adequate size, have appropriate lighting and have dependable electricity and water at a minimum[251].

KQ28.h How can the internet and other technologies be used to teach physicians in LRSs?

Continuing education/training and data collection should be the focus of using new technologies to improve hernia surgery in LRSs. Internet use has already been highlighted by the cooperation between LMICs and high income countries (HIC) in the Global Surgery Project[269] http://www.lancetglobalsurgery.org. Internet-based technologies are efficient ways of sharing surgical experience and may be a way to expand surgical education and strengthen local expertise in LRS[270,271]. One article describes that two surgeons from Paraguay and Brazil were trained by two international experts to perform a Lichtenstein IH repair using Google Glasses via an interactive online video stream[271]. Multi-media are now used to disseminate medical content through archived and live video allowing physicians to stay current in a variety of settings[272]. Most LRS physicians are connected to the World Wide Web. Advanced interactive technology allows experts to be virtually present, and assist through tele-mentoring, while other surgeons perform operations[271,272].

Internet-based data collection will facilitate the rapid development of hernia registries in LRSs as well as world hernia registries. The EHS now offers the global surgical community an online platform for registration and outcome measurements of abdominal wall hernia repairs (http://www.eurahs.eu/HOME.php)[170].

The challenge in the short-term is the optimization of medical technology and clinical practice in order to deliver the best medical care and the highest patient satisfaction at the lowest cost[273]. Research is needed on the impact of internet use and other technologies to achieve safe effective surgery globally.

Research, General Practitioners and Patients perspectives

Chapter 29

Questions for research (ALMOST READY)

Chapter 30

Summary for General Practitioners

N. van Veenendaal and M.P. Simons

Background

Definition

A groin hernia is defined as a protrusion of viscera or adipose tissue through the inguinal or femoral canal. This protrusion results in either an inguinal or femoral hernia.

In day-to-day practice a classification system for groin hernias is seldom used other than to describe hernia types in general terms such as: lateral/indirect, medial/direct, recurrent and femoral.

An occult hernia is an asymptomatic hernia not detectable by physical examination.

Epidemiology

The lifetime incidence of a groin hernia is 27% to 43% in men and 3 to 6% in women. Inguinal hernias (IHs) occur 9 to 12 times more commonly in men. Femoral hernias occur approximately 4 times more commonly in women.

Etiology/pathology

Numerous risk factors—mostly a combination of genetic and acquired features—exist for the development of primary IHs in adults. Risk factors associated with IH formation are inheritance, a previous contra-lateral hernia, male gender, elderly age, impaired collagen metabolism, low body mass index, obesity and a history of prostatectomy.

Symptoms

Groin hernias can be either asymptomatic or symptomatic. Approximately one-third of patients with IHs are asymptomatic. Roughly 70% of asymptomatic individuals with IHs will develop symptoms within five years, generally pain or discomfort.

Diagnostics

History, physical examination and diagnostic work-up

History and physical examination are usually all that are required to confirm the diagnosis of a clinically evident groin hernia. Approximately 95% of IHs can be diagnosed by physical examination. IHs produce swelling supero-medial to the pubic tubercle and femoral hernias cause infero-lateral swelling. However, in practice this subtle distinction is often difficult to discern.

Imaging may be required if there is vague groin swelling and diagnostic uncertainty, poor localization of swelling, intermittent swelling not present at time of physical examination and other groin complaints without swelling. Physical examination and ultrasound combined are suitable for diagnosing patients with vague groin swelling or possible occult groin hernias. When groin ultrasound is negative or non-diagnostic, a dynamic MRI, dynamic CT or even herniography can be considered. Dynamic in this context refers to Valsalva maneuver during testing in an attempt to force a possibly occult or small hernia into its abnormal channel and more clearly demonstrate its presence.

In female patients, the existence of a femoral hernia should be excluded in all cases of a hernia in the groin. No clinical or diagnostic test can reliably distinguish inguinal from femoral hernias women.

For the evaluation of patients suspected of having a recurrent groin hernia clinical examination and ultrasound are the most suitable. In case of diagnostic doubt after the ultrasound, MRI or CT can be considered.

Management of groin hernia

Treatment indications

Not all IHs require surgical treatment. There is a low risk of complications like incarceration or strangulation in asymptomatic or minimally symptomatic men with IHs. Therefore, in men, a watchful waiting management strategy is safe for minimally symptomatic or asymptomatic IHs. However, the crossover rate to surgery in men with minimally symptomatic or asymptomatic IHs is high due to the development of symptoms, mostly pain. Approximately 70% of men with these hernias will require surgery within five years.

Based on current literature it is not possible to determine if a watchful waiting management strategy is safe for symptomatic men with IHs. The risk of an IH becoming incarcerated is less than 3% per year. About 5% of men with groin hernias require emergent repair. In patients with symptomatic IHs surgical repair is recommended.

Femoral hernias carry a higher risk of incarceration and strangulation than IHs. Approximately 17% of women with groin hernias require emergent repair. Therefore, timely repair is recommended in women with groin hernias. In femoral hernia patients, even if symptoms are vague or absent, timely surgery is recommended.

At all times surgeons will tailor their treatment based on their expertise, patient- and hernia-related characteristics, local/national resources and logistics.

Surgical treatment

Worldwide, more than 20 million patients undergo groin hernia repair yearly. A generally accepted technique, suitable for all IHs, does not exist. There are many different techniques in routine use with varying advantages and disadvantages. Surgical repair of a groin hernia can be performed with or without mesh, using either an open approach or a laparo-endoscopic one. The surgeon will discuss the advantages and disadvantages of each technique with the patient. This is dependent upon the surgeon's expertise, local and regional resources and patient preferences.

Eighty-five percent of all IH repairs are performed using an open approach. In high resource settings, 15-55% are performed laparo-endoscopically. It is recommended that patients with symptomatic IHs be treated with a mesh-based repair technique. The Lichtenstein technique with the onlay placement of a flat mesh is the criterion standard in open hernia repair and most frequently used. Trans-abdominal preperitoneal (TAPP) and total extra-peritoneal (TEP) are laparo-endoscopic techniques in which a mesh is inserted in the preperitoneal plane. In TEP a totally preperitoneal approach is used with or without the help of a dissection balloon. In TAPP a laparoscopy is performed. TAPP and TEP have similar operative times, overall complication risks, postoperative acute and chronic pain incidence and recurrence rates. When a mesh is not available, the Shouldice technique is the first choice in non-mesh IH repair. The Shouldice technique has lower recurrence rates that other suture repairs.

A simple IH operation can be performed on a day surgery basis, unless the patient's comorbidities require clinical observation. Day surgery does require that adequate aftercare is organized. Day surgery of patients with complex IHs is suggested only in selected cases.

Women with groin hernias are advised to undergo laparoscopic repair with preperitoneal mesh placement.

Again, groin hernia management will be based on surgeon's expertise, patient- and hernia-related factors, available resources and logistics.

Complications

Surgical treatment of an IH is successful in the majority of cases. Complications of IH repair include: recurrences, chronic postoperative pain, wound infections, urinary and sexual dysfunction, hematoma, seroma, visceral and vascular injury (uncommon), late postoperative complications and mortality.

Risk factors for recurrent IHs are: incorrect surgical technique, female gender, direct IHs, a sliding hernia, collagen metabolism disorders and obesity. Recurrence necessitate reoperation in 5-15% of cases.

Ten to twelve percent of IH repair patients experience at least a bothersome level of moderate pain that impacts daily activities. Risk factors for chronic postoperative inguinal pain include: young age, female gender, high preoperative pain and, early high postoperative pain. Long-term disability due to chronic pain occurs in 10-12% of patients.

The incidence of urinary retention following IH repair varies from less than 1% to 20%. The most common predisposing factor is the use of general or regional anesthesia. The incidence of sexual dysfunction causing symptoms of a moderate to severe degree is around 5-6%. Impairment of testicular function and fertility occurs in less than 1%.

Hematoma incidence is reduced after endoscopic IH repair compared with open repair. Most hematomas resolve spontaneously over 2-4 weeks and can be managed expectantly. Those with large, symptomatic or infected hematomas should be urgently referred back to their surgeons.

The reported incidence of seroma formation after IH repair varies between 0.5 and 12%. Seroma formation risk factors are: coagulopathy, congestive liver diseases and cardiac insufficiency. There is no evidence that binders and other compression devices prevent hematoma and seroma formation. Most seroma resolve spontaneously over six to eight weeks. Since infections following seroma aspiration are regularly described, only symptomatic seromas need to be treated.

Serious complications, such as bowel, bladder and vascular injuries, rarely occur during hernia surgery. They are more common (although still rare) during endoscopic versus open repair.

Death in the 30 days following IH repair is very rare and mainly associated with emergent repair or related to medical comorbidities.

Postoperative instructions

Postoperative pain can be reduced by paracetamol, NSAIDs, or selective COX-2 inhibitors. The combination of paracetamol and an NSAID may be particularly effective.

A period of rest or a lifting restriction is not necessary after an IH operation. Patients can do what they feel capable of doing.

Chapter 31

Groin Hernias – A Patient's Perspective

N. van Veenendaal, M.P. Simons, M.D. Burg

Groin Hernia – Definition and Some General Comments

Groin hernias occur due to muscular weakness in the lower abdominal wall in the general area of the crease between one's leg and abdomen. This weakness results in abdominal contents (abdominal organs, fat or bowels/intestines) bulging through the weak area.

Men and women can develop groin hernias but they are far more common in men.

A bulging or swelling in the groin region is often the first sign of a groin hernia. Pain or vague discomfort can occur but is not always present. Pain and bulging may worsen with coughing, sneezing, lifting, straining or prolonged standing. Occasionally, groin pain without bulging or swelling may indicate that a groin hernia is present. Sometimes, a groin hernia may be found by your healthcare provider on a routine physical examination.

Certain individuals are at increased risk for the development of a groin hernia. The table below lists certain features that may make groin hernia development more likely.

- Male gender
- Those with family members who have groin hernias
- So-called "impaired collagen metabolism" (collagen is a protein in many body tissues like muscle)
- Those with a previous hernia
- The elderly
- Those who've undergone removal of the prostate gland
- The obese
- Those who are extremely thin (so-called "low body mass index")

Hernia "incarceration"
Some groin hernias are "incarcerated" or trapped in their abnormal locations. The hernia contents then can't return to their proper position in the body.

Hernia "strangulation"
Strangulated hernias are those that don't have proper blood supply. This means that whatever is in the hernia bulge may begin to die. Hernias that are suddenly far more painful than usual, red or larger than usual are likely to be strangulated. Vomiting or the inability to move one's bowels can also mean that a hernia is strangulated.

When to see a doctor
Immediately see a doctor if your groin hernia, that normally goes easily back into place, suddenly does not. Seek immediate medical attention if you have a groin hernia and develop any of the "strangulation" signs listed above. Immediate surgery may be required.

Groin Hernia Diagnosis
Your medical history (what you tell the doctor) and the physical examination are usually all that are required to diagnose a groin hernia. An ultrasound or other testing can be done if the diagnosis is not obvious.

Groin Hernia Treatment

Groin hernias do not disappear without treatment; in fact, they often get larger and more painful with time. If you suspect that you have a groin hernia, see your general physician or surgeon. Your surgeon can discuss treatment options.

If you're a man with a groin hernia that causes few or no symptoms then a "watch-and-wait" approach may be reasonable. This is because the risk of serious complications— incarceration or strangulation—is low, making watchful waiting a safe strategy. Realize however, that over time, many groin hernias without symptoms may start causing problems—mostly pain—and require surgery.

Women with groin hernias are often operated upon semi-urgently—even if they don't have symptoms—because their risk of hernia strangulation is higher than men.

Surgeons will tailor their treatment of your groin hernia based on a variety of factors including: their expertise, your medical history, the hernia itself, local (hospital and other) resources, and other considerations, including your wishes.

Groin Hernia Operations – Types and Details

Groin hernia surgeries are incredibly common. Worldwide, more than 20 million people have groin hernia repairs each year! It is important to realize that with groin hernia surgery, "one size does NOT fit all" and one repair technique, suitable for every situation, does NOT exist.

There are many different repair techniques in routine use with varying advantages and disadvantages. Your surgeon will discuss these and other issues with you and your family before proceeding.

Groin hernia repair can be done with or without mesh. Mesh, if it is used, serves to reinforce and strengthen the area of the hernia.

Also, either an "open" or a "laparo-endoscopic" or so called "key hole" approach can be used to fix a groin hernia. An "open" approach (which may also involve mesh) means that a surgical incision is made in the groin and the repair is done through this one incision. In a "laparo-endoscopic" approach, one or more small incisions are made and repair is done with the aid of tiny cameras and other small specialized surgical equipment. Many variations on these general themes are routinely used today.

Mesh is proven to be safe and is well tolerated by the human body.

Repair of your groin hernia may well be done in a day surgery (or "same day") surgery center. This means that you'll get to go home the day of your surgery once you're fully awake, recovered and ready.

Depending on your particular circumstances, groin hernia surgery can be done painlessly with local (area of the hernia only), regional (in a larger region of the body) or general (whole body) anesthesia. Again, your surgeon and the anesthsiologist will discuss these options with you.

Complications
No operation is risk free. Like every other operation, groin hernia surgery complications include: bleeding, infections, blood clot formation, pneumonia and others. Thankfully, these are all very rare.

Specific groin hernia complications are: hematoma, seroma, pain and recurrence.

Hematoma
A hematoma is a collection of blood in the body's tissues and can be recognized by a bluish discoloration and swelling in the area of the surgery, usually several days after surgery. The hematoma (blood) can spread to the base of the penis and scrotum in men, or into the labia majora (vaginal lips) in women. It usually goes away on its own after several days and should not concern you. A hematoma causing severe pain, marked swelling or black discoloration of the skin should prompt an urgent doctor visit.

Seroma
A seroma is a collection of blood plasma (not blood cells but the clear liquid in blood) that commonly collects after groin hernia surgery. Most go away without treatment in 6 to 8 weeks. Very large or infected seromas (both very uncommon) may require drainage. See your surgeon if you are concerned and he/she will advise you.

Pain
Pain—of some type—occurs after nearly all surgeries. Your surgeon will advise the proper treatment so that you are comfortable as you recover. The pain following groin hernia repair is usually mild and is commonly well treated with paracetamol and other non-narcotic pain relievers.

Some patients suffer from longer lasting or more moderate pain. Pain not controlled with recommended medications, or moderate, severe or long-lasting pain should prompt a visit to your surgeon. Severe chronic pain (thankfully very rare) can be debilitating and should prompt a visit to your surgeon who will advise other treatment options.

Recurrence
Groin hernias can recur in a small number of patients. See your surgeon if you start having the groin symptoms again that caused you to see a doctor originally. Treatments are available.

Groin Hernia Operation – Recovery
Expect some pain or groin discomfort after surgical repair of your hernia. Depending on the surgical technique used and other factors (like the complications described above) almost all patients should be completely comfortable within 1 to 2 weeks. Use your pain relievers as recommended as you recover. Support the surgical area during coughing, sneezing or straining in the first few days after your operation. Do routine activities that you feel capable of doing. A period of rest or a lifting restriction is not necessary after a groin hernia operation.

Most surgeons will use dissolvable stitches, which do not need to be removed. If non-dissolvable stitches were used, they will be removed after a week.

If you have urgent questions or problems please consult your general practitioner , your surgeon or a hospital.

Further Reading
The following website is endorsed by the HerniaSurge Guidelines Group: www.herniasurge.com

If information in this leaflet is missing or unclear, please inform the HerniaSurge Group via their website.

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