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Introduction

What is the outcome of an abdominal wall hernia repair and how can it be measured?

Outcome of abdominal wall hernia repair is mostly described by evaluating the recurrence rate related to specific operation techniques or devices. The recurrence rate of a hernia operation is an important factor, but there are certainly more outcome parameters to be considered for hernia repair outcome assessment. The interpretation of outcome after hernia surgery is complex and influenced by the large number of variables included.

As described by Muysoms [1, 2], the outcome of abdominal wall hernia repair should be assessed in three main domains: hernia recurrence, operative and postoperative complications as well as quality of life assessment and patient-reported outcome measurements (PROMs).

Moreover, as illustrated in the triple P-triangle of abdominal wall hernia repair (Fig. 10.1), the operative outcome will be influenced by many patient-related variables, characteristics of the prosthesis used and the details of the surgical procedure.

In this chapter we will focus on two aspects:

- (1) The outcome parameters which describe the results of a surgery. Which parameters do we need to assess to fully describe the results of an abdominal wall surgery? By means of operative and postoperative complications, patient-reported outcome measurements (PROMs) and the recurrence rate.
- (2) How should we evaluate and register these outcome parameters? Consequently, reporting the outcome of a hernia operation in case control studies, through large randomized controlled trials (RCTs) or well-established hernia databases and registries.

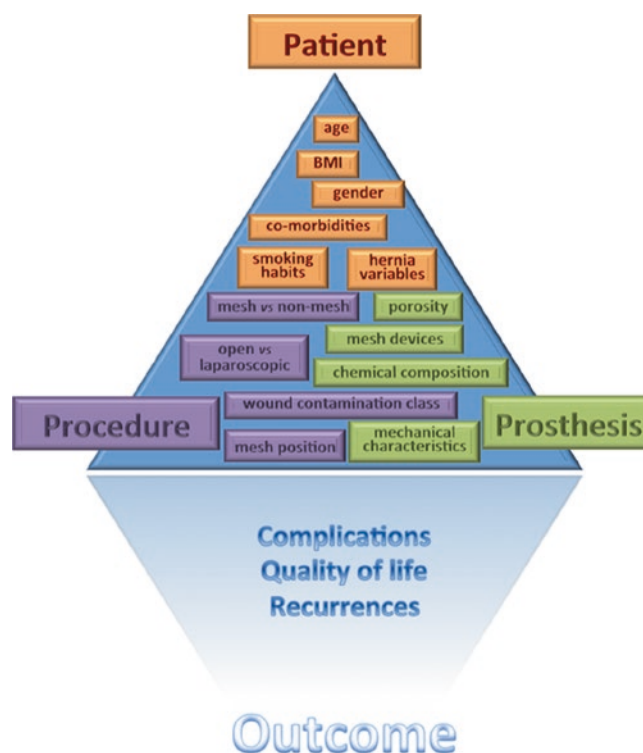


Fig. 10.1 Triple P-triangle of abdominal wall hernia repair

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Outcome

Complications

Each hernia operation is paired with a specific risk of either operative, postoperative or both complications, depending

on the severity of the intervention, the patient's condition and the used technique to repair the abdominal wall defect. Hernia-specific complications as pain, postoperative seroma or hematoma need to be defined either as a related consequence or as a complication. For example, postoperative pain is quite common and up to a specific grade accepted after surgery. When postoperative pain is much higher than it can be accepted after surgery, it needs to be considered a postoperative complication.

For that reason, complications being an important outcome parameter to evaluate hernia repair should be graded using clearly defined classifications of surgical complications [3] as the general surgical complications classification by Clavien-Dindo [3] or the seroma classification by Morales-Conde [4]. This is highly relevant to compare specific results to the results of other studies across the common literature.

General Surgical Complications: Clavien-Dindo Classification

Clavien et al. defined in 1992 the negative outcome after surgery in three groups [3]:

- Complication: “Any deviation from the normal postoperative course”
- Sequela: “An after-effect of surgery that is inherent to the procedure”
- Failure to cure: “If the original purpose of the surgery has not been achieved”

By using this classification (defined in Table 10.1), complications can be categorically described according to the severity of the complications. Recurrence is clearly “a failure of cure” and thus should be reported separately and can therefore not be considered a complication.

Seroma: Morales-Conde Classification

Seroma can be considered an expected event after hernia surgery and up to specific grade accepted as short-term consequence after surgery or a procedure-related complication. To describe the consequences of seroma, Morales-Conde et al. proposed a classification of postoperative seroma [4] to distinguish clearly between postoperative incident and related complication (Table 10.2). This classification should be used describing postoperative seroma.

Surgical Site Infections (SSI)

Infection of the wound after hernia repair is a relevant complication that might induce significant morbidity and treatment costs and compromise the repair at longer term. The

Table 10.1 Classification and grading of surgical complications by Clavien and Dindo

Grade 0	No complications
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusion and TPN are included
Grade III	Requiring surgical, endoscopic and radiological interventions
Grade III a	Intervention not under general anaesthesia
Grade III b	Intervention under general anaesthesia
Grade IV	Life-threatening complication requiring IC/ICU management
Grade IV a	Single organ dysfunction
Grade IV b	Multi-organ dysfunction
Grade V	Death of the patient

Table 10.2 Classification of postoperative seroma after ventral hernia repair by Morales-Conde et al.

Seroma type	Definition	Clinical significance
0	No clinical seroma	No clinical seroma
I	Clinical seroma lasting <1 month	Incident
II	Clinical seroma lasting >1 month	
III	Symptomatic seroma that may need medical treatment: minor seroma-related complications	Complication
IV	Seroma that needs to be treated: major seroma-related complications	

– *Clinical seroma*: Those seromas detected during physical examination of patients which do not cause any problem or just a minimum discomfort that allows normal activity

– *Minor complication*: Important discomfort which does not allow normal activity to the patient, pain, superficial infection with cellulitis, aesthetical complaints of the patient due to seroma or seroma lasting more than 6 months

– *Major complication*: Infection, recurrence, mesh rejection or need to be punctured

Centers for Disease Control and Prevention (CDC) classifies surgical site infection (SSI) categorically for severity (Table 10.3). There is a correlation to the degree of wound contamination during surgery, stratified as described by the CDC classification of wound contamination: clean/clean-contaminated/contaminated/dirty (Table 10.4).

Table 10.3 CDC classification surgical site infection (SSI)

Superficial SSI	Date of event for infection occurs within 30 days after operative procedure (where day 1 = the procedure date) AND involves only skin and subcutaneous tissue of the incision AND patient has at least <i>one</i> of the following:
	a. Purulent drainage from the superficial incision
	b. Organisms identified from an aseptically obtained specimen from the superficial incision or subcutaneous tissue
	c. Superficial incision that is deliberately opened by a surgeon, attending physician or other designee and culture or non-culture-based testing is not performed and patient has at least one of the following signs or symptoms: pain or tenderness, localized swelling, erythema or heat
	d. Diagnosis of a superficial incisional SSI by the surgeon or attending physician or other designee
Deep SSI	The date of event for infection occurs within 30 or 90 days after the operative procedure (where day 1 = the procedure date) AND involves deep soft tissues of the incision (e.g. fascial and muscle layers) AND patient has at least <i>one</i> of the following:
	a. Purulent drainage from the deep incision
	b. A deep incision that spontaneously dehisces or is deliberately opened or aspirated by a surgeon, attending physician or other designee and organism is identified by a culture and patient has at least <i>one</i> of the following signs or symptoms: fever (>38 °C); localized pain or tenderness. A culture or non-culture-based test that has a negative finding does not meet this criterion
	c. An abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam or imaging test
Organ/Space SSI	Date of event for infection occurs within 30 or 90 days after operative procedure (where day 1 = the procedure date) AND infection involves any part of the body deeper than the fascial/muscle layers that is opened or manipulated during the operative procedure AND patient has at least <i>one</i> of the following:
	a. Purulent drainage from a drain that is placed into the organ/space (e.g. closed suction drainage system, open drain, T-tube drain, CT-guided drainage)
	b. Organisms are identified from an aseptically obtained fluid or tissue in the organ/space by a culture
	c. An abscess or other evidence of infection involving the organ/space that is detected on gross anatomical or histopathologic exam or imaging test evidence suggestive of infection

Table 10.4 CDC classification wound contamination class

Clean	An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital or uninfected urinary tracts are not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria
Clean-contaminated	Operative wounds in which the respiratory, alimentary, genital or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered
Contaminated	Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (e.g. open cardiac massage) or gross spillage from the gastrointestinal tract and incisions in which acute, nonpurulent inflammation is encountered including necrotic tissue without evidence of purulent drainage (e.g. dry gangrene) are included in this category
Dirty or infected	Includes old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation

Patient-Reported Outcome Measurements and Quality of Life Assessment

As mentioned above, the outcome of a hernia operation cannot solely be measured by the rate of complication or by the occurrence of a hernia recurrence only. Patient-reported outcome measurements (PROMs) that evaluate the quality of a hernia surgery are considered an important factor besides the recurrence rate as outcome measurement parameter [5]. Patients can have an asymptomatic recurrent hernia, yet still be very satisfied with the outcome.

Moreover, implantation of a permanent prosthesis to stabilize the abdominal wall can induce a foreign body feeling associated with the development of chronic pain or restriction of the patients' activities, all resulting in a tremendous impact on the patients' quality of life (QoL).

To address the patient for personal outcome reporting, elementary scores such as the VAS (visual analogue scale)

and the VRS (verbal rating scale) for pain can be applied. Additionally, more complex quality of life questionnaire have found their way into clinical routine after hernia surgery.

Visual Analogue Scale (VAS) for Pain

The VAS score is often routinely used in hospitals for measuring postoperative pain and for management of pain medication. The patient is asked to mark the amount of experienced pain on a calibrated line of 10 cm long [6]. The lower side of the line is mentioned to be “0 = no pain” and the upper side as “10 = the worst imaginable pain”. For immediate pain estimation especially in the early postoperative period, the VAS is a feasible tool, but it has to be considered less valuable to assess long-term chronic pain.

Verbal Rating Scale (VRS)

Using the VRS, the patient is only verbally asked to grade the level of experienced pain in four levels. For assessing of the development of chronic pain, the VRS seems a better tool than the VAS [6], but it cannot be implemented preoperatively.

This score, defined by Cunningham et al. [7], evaluates pain into four main categories:

- *No pain* = no discomfort experienced.
- *Mild pain* = occasional pain or discomfort that did not limit activity, with a return to pre-hernia lifestyle.
- *Moderate pain* = pain preventing return to normal preoperative activities.
- *Severe pain* = pain that incapacitated the patient at frequent intervals or interfered with activities of daily living.

Generic Quality of Life Scores Short-Form 36 (SF-36)

A questionnaire used to evaluate the quality of life after hernia surgery is the Short-Form 36 (SF-36). Although the SF-36 is frequently used in studies on abdominal wall surgery, it should be considered too generic to use for evaluation of QoL after abdominal wall repair [8].

For quality of life assessment after hernia repair, several more hernia-specific quality of life instruments have been developed and were validated in the last years:

Carolina Comfort Scale™ (CCS), Inguinal Pain Questionnaire (IPQ), Ventral Hernia Pain Questionnaire (VHPQ), Hernia-related Quality of Life (HerQles) and the EuraHS-Quality of Life QoL score (EuraHS-QoL) of the EHS.

Carolina Comfort Scale™ (CCS™)

The CCS has been developed as a questionnaire to assess the QoL of patients that had a hernia repair using a prosthetic material [8, 9]. The use of the CCS needs approval of the Carolina Medical Centre and its use will be charged.

The CCS contains 23 questions with a 6-point scale from 0 to 5 to report sensation of the mesh, pain or movement limitation for eight different activities. Added to the numerical scale is a descriptive scale: 0 = no symptoms, 1 = mild but not bothersome symptoms, 2 = mild but bothersome symptoms, 3 = moderate and/or daily symptoms, 4 = severe symptoms and 5 = disabling symptoms. The total score ranges from 0 to 115.

The CCS was used successfully to demonstrate QoL improvement after hernia repair [10]. Unfortunately, many questions of the CCS are related to the sensation of the implanted mesh and are therefore not applicable for preoperative QoL assessment.

Inguinal Pain Questionnaire (IPQ) and Ventral Hernia Pain Questionnaire (VHPQ)

Fränneby et al. validated the Inguinal Pain Questionnaire (IPQ), evaluating pain and difficulties in performing activities after groin hernia repair [11]. The same Swedish group from the Karolinska Institute published and validated in 2011 the Ventral Hernia Pain Questionnaire (VHPQ) to evaluate QoL after ventral hernia repair [12].

Both scores are free of charge by the used after request to the authors.

EuraHS-Quality of Life Score (EuraHS-QoL)

The EuraHS-QoL was developed by the EuraHS working group at the request of the European Hernia Society (EHS). The EuraHS-QoL score was recently validated for laparoscopic inguinal hernia repair, and a validation study for ventral hernia repair is ongoing [13].

The reason to implement the development of this QoL instrument is fourfold:

- Development of an instrument that can be used both pre- and postoperative
- Free of charge use for the surgeon and implementation in the online EuraHS register
- Development of considerably shorter questionnaire that should find a broader acceptance
- Creation of an instrument that can be used both in groin and ventral hernia patients

Questions were chosen as most relevant for QoL assessment before and after hernia repair [1]. The EuraHS-QoL

The image shows the EuraHS-QoL score English version questionnaire. It consists of several parts:

- Header:** Logos for EuraHS and the European Registry for Abdominal Wall Hernias (EuraHS), along with the text 'EuraHS QoL' and 'version: English'.
- Form Fields:** A box for 'name of study' and 'study number'.
- Instructions:** A paragraph explaining the EuraHS-QoL score and a list of 9 questions to be answered.
- Section 1: Pain at the site of the hernia** (Pre-operative): A table with 3 rows (Pain in rest, Pain during activities, Pain felt during the last week) and 11 columns (0-10 scale).
- Section 2: Restrictions of activities because of pain or discomfort at the site of the hernia** (Pre-operative): A table with 4 rows (Restriction from daily activities, Restriction outside the house, Restriction during sports, Restriction during heavy labour) and 11 columns (0-10 scale, with 'X' for 'do not perform this activity').
- Section 3: Cosmetic discomfort** (Pre-operative): A table with 3 rows (Shape of your abdomen, Site of the hernia) and 11 columns (0-10 scale).
- Section 1: Pain at the site of the hernia repair** (Post-operative): A table with 3 rows (Pain in rest, Pain during activities, Pain felt during the last week) and 11 columns (0-10 scale).
- Section 2: Restrictions of activities because of pain or discomfort at the site of the hernia repair** (Post-operative): A table with 4 rows (Restriction from daily activities, Restriction outside the house, Restriction during sports, Restriction during heavy labour) and 11 columns (0-10 scale, with 'X' for 'do not perform this activity').
- Section 3: Cosmetic discomfort** (Post-operative): A table with 3 rows (Shape of your abdomen, Site of the hernia and the scar) and 11 columns (0-10 scale).
- Personal data:** A box for 'name', 'date of birth', 'date of today', and 'date of operation'.

Fig. 10.2 EuraHS-QoL score English version. (Printed with permission from the EuraHS working group represented by Filip Muysoms MD)

score is a short hernia-specific questionnaire with nine questions that can be scored by the patient in an 11-point scale from 0 to 10. An example in the English language for preoperative assessment is shown in Fig. 10.2.

The EuraHS-QoL questions are divided in three main domains:

- Pain (range 0–30)
- Restriction of activities (range 0–40)
- Aesthetical discomfort (range 0–20)

The total score ranges from 0 to 90, with the lower scores being the most favourable outcome.

Recurrence Rate

The number of patients who develop a recurrent abdominal wall hernia is considered most important to evaluate the success of a hernia surgery. In fact, the recurrence rate is an important factor, but certainly not the only outcome parameter to judge the final outcome and success of a hernia repair surgery. Moreover, recurrence rate evaluation strongly depends and can even be limited by different aspects as:

- The lack of grading for severity
- The impact on the patient

- Distinction of recurrence versus patients satisfaction
- Lack of clear data registration to diminish the risk of bias in determining the recurrence rate

Furthermore, the number of incisional hernia recurrences increases over time [14–17], so it is strongly recommended (as reported in the EHS guidelines on the closure of abdominal wall [18]) to follow the patient for a period of at least 12–24 months. Moreover, the number of patients with follow-up and the reasons for eventual lost to follow-up should be clearly reported to diminish a bias in evaluation. Only a follow-up rate above 80% makes the recurrence rate a reliable parameter to describe the surgical outcome.

Also, clinical examination by a surgeon is considered efficient to determine the presence or absence of a hernia recurrence. Additionally the inclusion of medical imaging like ultrasound or CT scan evaluation will significantly increase the level of evidence for recurrence [19–21].

Registries

How Should We Evaluate and Register These Outcome Parameters?

Surgical outcome reporting is important in understanding the postoperative course for patients undergoing hernia repair and in learning how outcomes are affected. Registration of

performed hernia operations is necessary to evaluate this outcome as well as the personal performance of the surgeon. This includes the registration of the surgical technique, the prostheses and fixation materials used, the operative time, operative and postoperative complication as well as effective long-term patient follow-up.

As a fact, we can only learn about our own abilities when we register our performance and our daily medical practice and patient care in one way or the other. Only if surgeons can realistically judge their own ability and learn about their strengths, weaknesses and benchmarks, can performance in hernia surgery be increased in the future.

Hernia surgery is currently described by:

- Case reports, case-control studies
- Randomized controlled trials (RCTs)
- Hernia-specific congresses
- Reviews and meta-analyses
- Hernia classifications and guidelines

In addition, large hernia registries using standardized data entry for risks factors, comorbidities, outcome of surgical procedures and effective long-term follow-up have increased the knowledge of hernia surgery tremendously in the last few years.

Case-Control Studies

Case-control studies or cohort studies are primary types of observational studies to evaluate the effects and outcome of new methods or material in hernia surgery. To address investigative questions in hernia surgery, large randomized controlled trials are not always indicated or time-efficient to conduct (see Chap. 5).

In the field of surgery, hernia surgery is a unique subfield. No other surgical discipline encloses so many different techniques and sub-techniques. Moreover, the development and evaluation of surgical material as meshes and fixation devices is evolving rapidly. Well-designed observational studies are needed to evaluate the efficiency of hernia techniques and surgical materials. Observational studies are important to investigate the correlation between surgical interventions and their outcomes, such as recurrence rate or complications.

Randomized Controlled Trials (RCTs)

Large randomized controlled trials (RCTs) are the gold standard in clinical research. In the last decades, hernia surgery has profited enormously from the results being published resulting from these RCTs. However, RCT methodology, which was first developed for drug trials, can be difficult to conduct for surgical investigations and improvements. RCTs are mostly performed in hernia expert centres and lack the demonstration of real-time surgical reality. RCTs are

designed for specific defined questions in strict correlation with specific techniques, materials or patients outcome. Taking into consideration that these RCTs also have a strict defined set-up with more or less narrow inclusion and exclusion criteria, results produced from the RCTs do not always mirror daily clinical practice.

Hernia Registries

Large registries, as the Danish Hernia Database, collecting lots of data in a wide surgical community for various aspects in hernia surgery reflect a broad surgical community. In contrast to RCTs, data can be collected in a shorter time frame. Complications corresponding specific techniques of surgical materials that occur rarely can be detected earlier with huge patient numbers.

Nevertheless the outcome of the patients undergoing a specific procedure can be registered in both systems: RCTs and registries. Moreover, clearly defined and standardized registries are favourable to register the outcomes of RCT. Using a common hernia registry for data recording of RCT helps to unique data gathering and reporting. This gives an advantage when large RCTs are compared in meta-analyses. On the other hand, large patient registries can function as a source for innovative concepts for RCT.

In conclusion, RCTs and hernia registries can benefit from each other, more than standing in conflict (Fig. 10.3).

Development of Registries in Europe

At this moment, several hernia-specific registries coexist in Europe and in the United States as shown in Fig. 10.4.

The Swedish Groin Hernia Registry pioneered in 1992, followed by the Danish Groin Hernia Database in 1998. The first registry to include the inguinal and the ventral hernia route was the German Herniated Registry released in 2009.

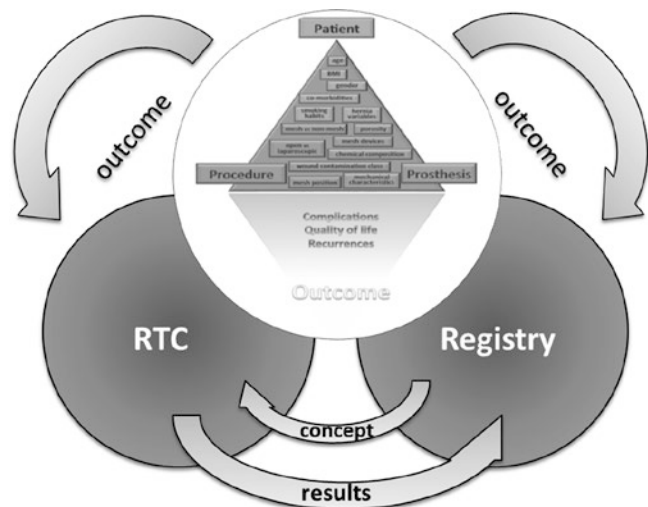


Fig. 10.3 Surgical outcome registration in randomized controlled trials (RCTs) and hernia registries

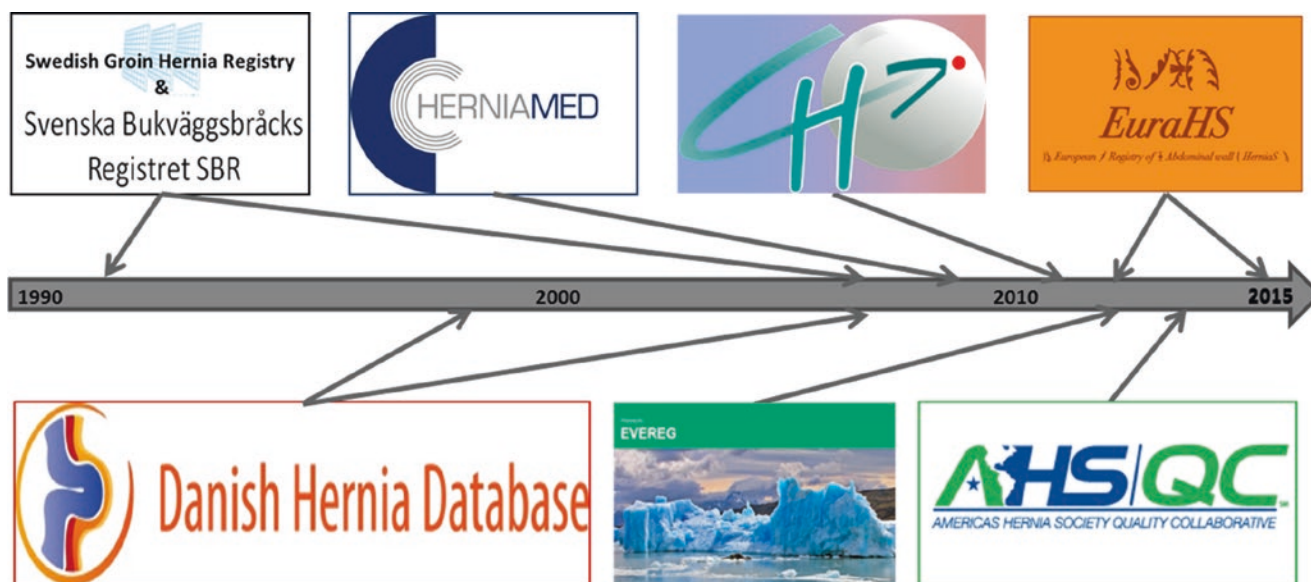


Fig. 10.4 Hernia registries since 1992

While the French Club Hernie, a database for inguinal and ventral hernia, was initiated in 2011 by a selected group of surgeons combining their investigational efforts. The year 2012 was a very productive year in terms of hernia registries with three hernia registries to be released: EuraHS, the Spanish Evereg database and the INCH trial.

EuraHS is the official database of the European Hernia Society (EHS) and is used all over Europe in multiple languages [1].

For the United States, the AHSQC, the hernia registry of the AHS, was launched in 2013.

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