Hernia (2018) 22:561–575
https://doi.org/10.1007/s10029-017-1724-6

REVIEW

Comparison of hernia registries: the CORE project

I. Kyle-Leinhase[1] · F. Köckerling[2] · L. N. Jørgensen[3] · A. Montgomery[4] · J. F. Gillion[5] · J. A. P. Rodriguez[6] · W. Hope[7] · F. Muysoms[1]

Received: 4 October 2017 / Accepted: 27 December 2017 / Published online: 6 January 2018

Abstract

Introduction The aim of the international CORE project was to explore the databases of the existing hernia registries and compare them in content and outcome variables.

Methods The CORE project was initiated with representatives from all established hernia registries (Danish Hernia Database, Swedish Hernia Registry, Herniamed, EuraHS, Club Hernie, EVEREG, AHSQC) in March 2015 in Berlin. The following categories were used to compare the registries: initiation and funding, data collection and use for certification of hernia centers, patient data and data protection, operative data, registration of complications and follow-up data.

Results The Danish Hernia Database is the only one to qualify as a genuine national registry where participation is compulsory for entry of all procedures by all surgeons performing a hernia operation. All other registries have to be considered as voluntary and completeness of data depends upon the participating hospitals and surgeons. Only the Danish Hernia Database and the Swedish Hernia Registry are publicly funded. All other registries are reliant on financial support from the medical technology industry. As an incentive for voluntary participation in a hernia registry, hospitals or surgeons are issued a certificate confirming that they are taking part in a quality assurance study for hernia surgery. Due to data protection and privacy regulations, most registries are obliged or have chosen to enter their patient data anonymously or coded. The Danish Hernia Database and Swedish Hernia Registry utilize a national personal patient code. In the Herniamed Registry, patient data are saved in a coded and anonymous format after obtaining the patient's informed consent.

Conclusion Despite the differences in the way data are collected for each of the listed hernia registries, the data are indispensable in clinical research.

keywords Hernia registry · Hernia database · Clinical trial platform

Introduction

Randomized clinical trials (RCTs) and meta-analyses are considered the gold standard of evidence-based medicine nowadays [1]. The strength of RCTs rests on their excellent internal validity, which is based largely on the power of

I. Kyle-Leinhase and F. Köckerling contributed equally to this publication.

✉ F. Köckerling
ferdinand.koeckerling@vivantes.de

1 EuraHS and Department of Surgery, Maria Middelares Hospital, Buitenring Sint-Denijs 30, 9000 Ghent, Belgium

2 HERNIAMED and Department of Surgery and Center for Minimally Invasive Surgery, Academic Teaching Hospital of Charité Medical School, Vivantes Hospital Spandau, Neue Bergstrasse 6, 13585 Berlin, Germany

3 DANISH HERNIA DATABASE and Digestive Disease Center, Bispebjerg Hospital, University of Copenhagen, Copenhagen, Denmark

4 SWEDISH HERNIA REGISTRY and Department of Clinical Sciences, Skåne University Hospital Malmö, Lund University, Malmö, Sweden

5 CLUB HERNIE and Unité de Chirurgie Viscérale et Digestive, Hôpital Privé d'Antony, Antony, France

6 EVEREG and Hospital Universitario del Mar, Barcelona, Spain

7 AHSQC and New Hanover Regional Medical Center, Wilmington, USA

randomization to ensure that the only difference between two treatment arms is their exposure to the treatment of interest [2]. But the applicability of RCTs to the care of patients in routine practice is limited. In particular, patients, providers, and concurrent care in the general population are different from those in RCTs, and the generalizability or external validity of RCTs may be limited. Although observational research does not reach the same level of internal validity as RCTs, well-designed observational studies can offer high external validity and provide a unique opportunity to evaluate treatments and their outcomes in routine practice [2]. Many important clinical questions have not, cannot, and will not be addressed in the context of an RCT. In these situations, clinicians rely on information provided by observational research [2]. In a comparison of observational studies and RCTs, the estimates of the treatment effects from observational studies and RCTs were similar in most cases [3]. Registries are ongoing prospective observational data-collection repositories [4]. A registry is defined as a systematic collection of a clearly defined set of health and demographic data for patients with specific health characteristics, held in a central database for predefined purposes [5]. Medical registries can serve different purposes, for instance as a tool to monitor and improve the quality of care or as a resource for research [5]. To be useful, data in a medical registry must be of good quality [5]. To optimize the quality of medical registry data, the participating centers should follow certain procedures designed to minimize inaccurate and incomplete data [5]. The intended use of registry data determines the necessary properties of the data [5].

In 1992, surgeons from eight Swedish hospitals initiated a registry for inguinal and femoral hernia repair [6]. The aim of the registry was to report on the operative techniques used and to analyze outcome measures in order to stimulate quality improvement [6]. A number of national and international registries have since been added [6–12].

The aim of this manuscript is to explore the databases of these hernia registries and compare them in content and outcome variables.

Materials and methods

The CORE (Comparison of Hernia Registries in Europe) project was initiated with representatives from all established European hernia registries in March 2015 in Berlin. Initially perceived as a European project, the scope was broadened to also include the Americas Hernia Society Collaboration (AHSQC) Registry. Each registry representative was contacted to present and verify information regarding the registry (Table 1).

The following information was obtained: Country(ies) of use, start date of registry, procedures included, compulsory or voluntary data entry, overseeing body, funding, user cost, access route, language, number of active users, whether data are validated and by what method, data analysis provided, and how the data are published. The following categories were used to compare the registries: initiation and funding, data collection and use for certification of hernia centers, patient data and data protection, operative data, registration of complications and follow-up data.

Results

The timeline for launch of registries included in the CORE project is shown in Fig. 1. Prospective hernia surgery registration was pioneered by Erik Nilsson in 1992 with the *Swedish Groin Hernia Registry* (SGHR) [6]. In 1998 the *Danish Groin Hernia Database* (DGHD) was established and was subsequently extended to ventral hernias (Danish Hernia Database) in 2007 [7]. The German *Herniamed* Registry included both inguinal and ventral hernias and was launched in 2009 [9]. In France the *Club Hernie* (CH) started their ventral hernia registry in 2011 across 30 specialized hernia surgeons [10]. Two registries were launched in 2012: *EuraHS* [8], and the Spanish *Registro Español de Eventraciones* (EVEREG) [11]. The Americas Hernia Society Collaboration (AHSQC) Registry followed in 2013 [12].

Table 1 Representatives of the participating registries

Representatives	Registries	Countries	Abbreviasions
William Hope	Americas Hernia Society Quality Collaboration Registry	United States	AHSQC
Jean Francois Gillion	Club Hernie	France	CH
Lars Nannestad Jørgensen	Danish Hernia Database	Denmark	DHDB
Iris Kyle-Leinhase Filip Muysoms	EuraHS	Belgium	EuraHS
José Antonio Pereira Rodriguez	Registro Espaniol de Eventraciones	Spain	EVEREG
Ferdinand Köckerling	Herniamed	Germany, Austria, Switzerland	Herniamed
Agneta Montgomery	Swedish Hernia Registry	Sweden	SHR

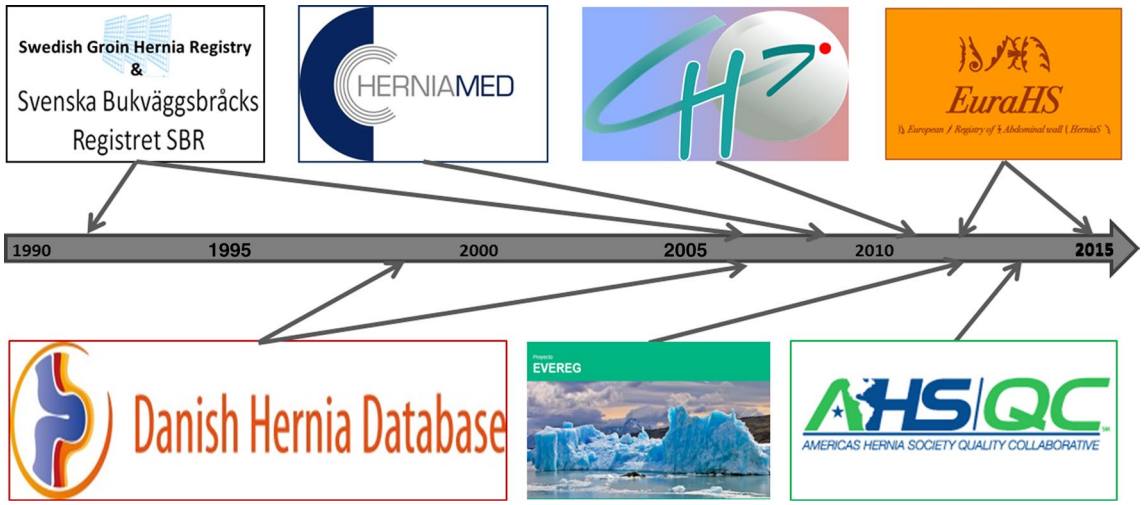

Fig. 1 Timeline of hernia registries

Compulsory or voluntary participation

The Danish Hernia Database is the only one to qualify as a genuine national registry where participation is compulsory for entry of all procedures by all surgeons performing a hernia operation. All other registries have to be considered as voluntary and completeness of data depends upon the participating hospitals and surgeons (Table 2).

National vs international registries

Most hernia registries only record data on hernia operations conducted in their own country. The Herniamed Registry is used in the German-speaking countries Switzerland, Austria and Germany. EuraHS with a multilingual interface is intended for use at international level (Table 2).

Table 2 Initiation and funding of registries

	Country	Routes	Release	Initiation	Compulsory or voluntary	Funding
Swedish Hernia Registry	Sweden	Inguinal Ventral	1992 2007	Non-profit team of surgeons	Voluntary	National Board of Health and Welfare
Danish Hernia Database	Denmark	Inguinal Ventral	1998 2007	Danish surgeons, non-profit	Compulsory	Public funding
Herniamed	Germany, Austria and Switzerland	Inguinal, primary ventral, incisional, parastomal, hiatal	2009	Non-profit organization, German Hernia Society (DHG)	Voluntary	PFM medical, Storz, FEG, BARD, Ethicon, Braun, MenkeMed, Dahlhausen, Medtronic
Club Hernie	France	Inguinal, primary ventral, incisional, parastomal	2011	Non-profit surgeon incentive	Voluntary	Bard, Cousin, Medtronic, Peters
EuraHS	Europe	Primary ventral incisional, parastomal, Hiatal, inguinal, open abdomen, abdominal wall closure, prophyl. meshes	2012 2015	Non-profit organization, European Hernia Society (EHS)	Voluntary	Medtronic, FEG, BARD, Ethicon
Evereg	Spain	Incisional	2012	Surgeons' incentive/B Braun	Voluntary	B. Braun
AHSQC	United States of America	Inguinal, primary ventral, parastomal	2013	Non-profit organization, Americas Hernia Society (AHS)	Voluntary	Bard, Allergan, Intuitive, Medtronic, W. L. Gore

Table 3 Data collection and certification

	Routes	Language	Data entry	Active users	Registered cases	Percentage of all hernias in the country	Complete data necessary for inclusion in analyses	Certification for the surgeon/institution
Swedish Hernia Registry	Inguinal	Swedish	Surgeon and follow-up by educated register secretary/nurse	90 centers	Inguinal: > 240,000	> 95%	Yes	No certification is provided
	Primary ventral, incisional, parastomal			> 10 centers	Primary ventral: > 2800 Incisional and parastomal: > 1800	15%	Yes	
Danish Hernia Database	Inguinal (including femoral)	Danish	Surgeon	> 300	Inguinal: > 200,000	90%	Yes	No certification is provided
	Ventral: incisional, umbilical, epigastric, port-site, parastomal, other (Spigeli, lumbar, etc.)				Ventral: > 45,000 (umbilical: > 22,500 Incisional: > 11,500 Epigastric: > 6500 Port: > 1500 Parastomal: > 1100)	80%	Yes	
Herniamed	Incisional, parastomal, hiatal, inguinal, umbilical, epigastric	English, German	Surgeon	> 500 in Germany, Austria, Switzerland	Inguinal: > 290,000 Umbilical: > 70,000 Incisional: > 50,000 Epigastric: > 16,000 Hiatal: > 9000 Parastomal: > 2000	15–20%	Yes	User certificates defined by certain outcome criteria
Club Hernie	Primary ventral, incisional, inguinal, parastomal, giant incisional	French	Surgeon and independent clinical research assistants	50	Inguinal: > 17,700 Ventral: > 7000	2–3%	Yes	Continuing medical education credits
EuraHS	Primary ventral, incisional, parastomal	English, German, French, Italian, Spanish, Polish	Surgeon	> 100 all over Europe	Incisional > 4175 Inguinal > 800 Hiatal: > 300	No data available for Europe	No	Certificate for registration from EuraHS
	Hiatal, inguinal, open abdomen, abdominal wall closure, prophyl. meshes	English, German, Dutch			Open abdomen > 400	No data available for Europe	No	

Table 3 (continued)

	Routes	Language	Data entry	Active users	Registered cases	Percentage of all hernias in the country	Complete data necessary for inclusion in analyses	Certification for the surgeon/institution
Evereg	Only incisional hernias, no primary hernias	Spanish	Surgeon	113 hospitals in Spain only	> 7300	No data available for Spain	Yes	No certification is provided
AHSQC	Primary, incisional, parastomal, inguinal	English	Surgeon, clinical teams, patient	> 200	> 20,000	No data available for USA	Yes	American Board of Surgery Maintenance of Certification Part IV; Centers for Medicare and Medicaid Services Qualified Clinical Data Registry

Funding

Only the Danish Hernia Database and the Swedish Hernia Registry are publicly funded. All other registries are reliant on financial support from the medical technology industry (Table 2).

Case numbers

The case numbers in the various registries will of course greatly differ in accordance with how long a hernia registry has been in existence, the number of participating hospitals and surgeons as well as with the size of the respective country (Table 3).

Certification of participation

As an incentive for voluntary participation in a hernia registry, hospitals or surgeons are issued a certificate (EuraHS, AHSQC, Herniamed) confirming that they are taking part in a quality assurance study for hernia surgery. Since participation in the Herniamed Registry constitutes a basic prerequisite for obtaining certification as a hernia center from the German Hernia Society (DHG), the DHG has defined certain outcome criteria (Table 3).

Data protection

Due to data protection and privacy regulations, most registries are obliged or have chosen to enter their patient data anonymously or coded. Registries often use only the patient's age or year of birth and mostly only a unique case identification number. The DHDB and SHR use a national personal patient code. In the Herniamed Registry, patient data are saved in a coded and anonymous format after obtaining the patient's informed consent. The latter can be deleted at any time upon the patient's request. All data classified as sensitive may be read and edited only by the treating institution for follow-up of the patients (Table 4).

Patient variables

In addition to the patient's age and gender, most registries also record details of previous operations, risk factors and comorbidities (Tables 4, 5). Only a few registries record the patient's occupation or information on sporting or exercise activities.

Table 4 Patient data

	Routes	Indentification	Contact details	Date of birth	BMI	Occupation	Smoker	Sport/exercise	Risk factors	Comorbidities
Swedish Hernia Registry	Inguinal	Anonymous, gender	No	Yes	Yes	No	Yes	No	Immunosuppression, collagen-related disease, increase risk for bleeding	Diabetes, pulmonary disease
	Primary ventral, incisional, parastomal								Immunosuppression, collagen-related disease, bleeding disease, steroids	
Danish Hernia Database	Inguinal	National identity code (CPR)	Yes	Yes	No	No	No	No	No	No
	Port-site, primary ventral, incisional, parastomal				Yes		Yes			Yes for incisional and parastomal hernia
Herniamed	Incisional, parastomal, hiatal, inguinal, umbilical, epigastric	No, only treating institution	No	No	Yes	No	Yes	No	Aneurysm, immunosuppression, thrombocyte aggregation inhibitors, coumarin derivate, coagulopathy, smoking	COPD, asthma, diabetes
Club Hernie	Primary ventral, incisional, inguinal, parastomal, giant incisional	Anonymous, gender	No	Age only	Yes	Yes	Yes	Yes	Aneurysm, immunosuppression, thrombocyte aggregation inhibitors, anticoagulant, personal history of hernia surgery, radiotherapy, chronic medical disease	ASA grading, diabetes, Hepatic disease, COPD, dysuria, constipation
EuraHS	Primary ventral, incisional, parastomal, hiatal, inguinal, open abdomen, abd. wall closure, prophyl. meshes	Anonymous, gender	No	Year only	Yes	Yes	Yes	Yes	Aneurysm, collagen-related disease, immunosuppression, thrombocyte aggregation inhibitors, personal history of hernia surgery	cardiac disease, COPD, diabetes, arterial hypertension, pulmonary disease, hepatic disease, renal disease, malignant disease
Evereg	Incisional	Anonymous, gender	No	Yes	Yes	No	Yes	No	Anticoag, antiplatelet, immunosupressants, smoking, personal history of hernia surgery	COPD, diabetes, cardiac disease, arterial hypertension, hepatic disease, renal disease, malignant disease

Table 4 (continued)

	Routes	Indentification	Contact details	Date of birth	BMI	Occupation	Smoker	Sport/exercise	Risk factors	Comorbidities
AHSQC	Primary ventral, incisional, parastomal, inguinal	Yes	Yes	Yes	Yes	No	Yes	Yes	Anticoagulant use, antiplatelet use, immunosuppressant use, nicotine use and route, history of hernia operation/open abdomen/myofascial release/surgical site infection, MRSA, currently active infection	Liver failure, ascites, HTN, diabetes, dialysis, COPD, dyspnea, inflammatory bowel disease, aneurysm

COPD Chronic obstructive pulmonary disease, *MRSA* Multiresistant *Staphylococcus aureus*

Operative data

Most registries record details of the operation such as urgency of the operation, hernia classification, hernia localization, operating time, operative technique, anesthesia type, mesh type, fixation technique, defect closure, drain utilization and antibiotic prophylaxis (Table 5).

Intra- and postoperative complications

Intra- and postoperative surgical and general complications are recorded and vary among registries (Table 6).

Follow-up data

Further variations are observed in the follow-up parameters and protocols as well as the follow-up achievements of the registries (Tables 7, 8). This can be explained by a huge variation in the structure of healthcare systems in different European countries. The quality and frequency of routine clinical follow-up varies due to clinical and financial limitations. Patients who experience postsurgical complications often do not present to the initial operating surgeons or institution.

Outcome measurement tools

All registries deliver feedback to their participating hospitals, surgeons and research groups via annual reports and Excel exported files (Table 9). Since registries have no proven system for checking the validy of entered data, they can suffer from selection and input bias. This is always a limitation of all data analyses from registries.

Discussion

Within the scope of the CORE project, representatives from seven hernia registers gathered to compare different aspects of their hernia registers. The CORE project examined aspects such as financing, data collection, certification, patient data, operative data, complications and follow-up of the patients. As registries were developed during various time periods where hernia surgery techniques and focus on outcomes have differed over time, differences between registries can be found. Financial resources have also had an impact on the quality of registries as have the ideas of individual surgeons.

It would be desirable to directly compare and combine data from the various hernia registries; therefore, the present analysis suggests potential adjustments to the way data are collected to improve data comparability in the

Table 5 Operative data

	Routes	Pre-op data collection	Use of classifications (EHS)	Anatomical considerations	Operating time	Antibiotic use	Reducibility of the hernia	Defect closure	Registration of concomitant abdominal surgery
Swedish Hernia Registry	Inguinal	Yes	Size and localization	Yes	Yes	Yes	Yes	No	Yes, but no report of type
	Primary ventral, incisional, parastomal							Yes	Yes
Danish Hernia Database	Inguinal	No	No	Yes	No	No	No	Yes	Yes, but no report of type
	Port-site, primary ventral, incisional, parastomal					Yes, only for incisional and parastomal			
Herniamed	Incisional, parastomal, hiatal, inguinal, umbilical, epigastric	Yes	Yes	Yes	Yes	Yes	No	Yes	No
Club Hernie	Primary ventral, incisional, inguinal, parastomal, giant incisional	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
EuraHS	Primary ventral, incisional, parastomal, hiatal, inguinal, open abdomen, abd. wall closure, prophyl. meshes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Evereg	Incisional	Yes	No	Yes	Yes	No	No	Yes	Yes
AHSQC	Primary ventral, incisional, parastomal, inguinal	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes

future. The recommendations for reporting outcomes should be given particular attention [13].

Despite the differences in the way data are collected for each of the listed hernia registries, the data are indispensable in clinical research. As a consequence of the numerous innovations in hernia surgery (surgical procedures, meshes, fixation devices), hardly any other area of surgical study has such a high need for clinical trials and data collection, comparison and analysis. Registries play a vital role in this innovation process [14]. In addition, there is insufficient public funding available to perform RCTs [15, 16]. Furthermore, the costs for conducting RCTs have increased dramatically over the last decades [17]. Therefore, RCTs should be more feasible embedded within registries [18].

Table 6 Registration of complications

	Routes	Intraoperative wound contamination	Intraoperative complications	Postoperative complications	Mesh infection	Mesh removal	Post-surgical death	Intra-hospital pain
Swedish Hernia Registry	Inguinal	No	Bleeding and injuries to other organs, cardiac and pulmonary, technical problems	Hematoma, urinary retention, infection, severe pain, reoperation (bleeding, infection, severe pain, ileus, other). Complication is graded: Mild, severe, life-threatening	Superficial, deep and reoperation.	Yes	30-day mortality	No
	Primary ventral, incisional, parastomal	Yes	Bleeding and injuries to other organs, cardiac and pulmonary, technical problems, bladder injury, intestinal damage, severity of the injury and equipment failure	Bleeding, seroma/hematoma, SSI, mesh infection, intestinal injury, ileus, non-surgical complications, others	Superficial, deep and reoperation	No	30-day mortality	No
Danish Hernia Database	Inguinal	No	No	No (data obtained from the National Patient Registry)	No	No	30-day mortality	No
	Port-site, primary ventral, incisional, parastomal	Yes, only for incisional and parastomal						
Herniamed	Incisional, parastomal, hiatal, inguinal, umbilical, epigastric	Yes	Bleeding and injuries to other organs	Complications within 30 days, non-surgical and surgical complications (bleeding, wound healing disorder, deep infection, seroma, hematoma), complication-related reoperations	Yes (deep infection)	No	Yes	Yes

Table 6 (continued)

	Routes	Intraoperative wound contamination	Intraoperative complications	Postoperative complications	Mesh infection	Mesh removal	Post-surgical death	Intra-hospital pain
Club Hernie	Primary ventral, incisional, inguinal, parastomal, giant incisional	Yes	Bleeding, adhesions, technical problems and injuries to other organs	Complications within 30 days, Clavien-Dindo grading, non-surgical complications, SSO, Surgical others, length of stay, ICU requirement, unplanned return to OR, Re-admissions within 30 days	Yes	Yes	Yes	Yes
EuraHS	Primary ventral, incisional, parastomal, hiatal, inguinal, open abdomen, abd. wall closure, prophyl. meshes	Yes	Bleeding, adhesions, technical problems and injuries to other organs	Bleeding, intestinal injury, impaired wound healing, ileus, SSI, seroma, non-surgical complications; Clavien-Dindo grading	Superficial, deep and reoperation	Yes	Yes	Yes, but not for all routes
Evereg	Incisional	Yes	Yes	Yes	Yes	Yes	Yes	Yes
AHSQC	Primary, incisional, parastomal, inguinal	Yes	Bleeding, adhesions, technical problems and injuries to other organs	Yes	Yes	Yes	Yes	No

Table 7 Follow-up data part 1

	Routes	Time scale post-op follow-up	FU achievements
Swedish Hernia Registry	Inguinal	1 month, re-entry for a recurrence	> 90%
	Primary ventral, incisional, parastomal	1, 6 months	> 90%, respective 50%
Danish Hernia Database	Inguinal, port-site, primary ventral, incisional, parastomal	Until patient death or emigration from data linking with the Danish Patient Registry	100% for all included patients
HerniaMed	Incisional, parastomal, hiatal, inguinal, umbilical, epigastric	1, 5, 10 years	Per contract with surgeon > 85%
Club Hernie	Primary ventral, incisional, inguinal, parastomal, giant incisional	1 month by the surgeon clinically, 2 years and 5 years systematic control done by phone questionnaires by independent clinical research assistant blinded to the technique used. Additional if needed	> 85% at 2y FU for all correctly registered patients
EuraHS	Primary ventral, incisional, parastomal, hiatal, inguinal, open abdomen, abd. wall closure, prophyl. meshes	1 month, 1 year, 2 years; additional time points between and after the fixed follow-up moments are possible	> 50% for 1 year; big differences in users
Evereg	Incisional	1 month, 6 months, 1 year, 2 years. Additional if it's needed	> 35%
AHSQC	Primary ventral, incisional, parastomal, inguinal	1 month, 6 months, 1 year, 2 year, each year after operation	90% 30 day; targeted long-term follow-up (based on individual populations of interest)

It has been shown that the introduction of the Danish Hernia Database improved the quality of inguinal hernia surgery from a national perspective [19]. A review based on three European hernia registries demonstrated the range of insightful findings that can be gleaned from hernia registries [20]. Registries can also play an important role in monitoring new devices by the industry (post marketing surveillance) [21]. This is of paramount importance as registries are called upon to provide more data for this specific purpose, because in the context of the current regulation environment at least in the European Union countries, the need of post marketing surveillance of medical devices has increased. As the main aim of the new European Union Medical Device Regulation is better patient safety industry, insurance companies and governments should ultimately contribute to fund hernia registries.

Currently, over 170 analyses from various hernia registries (Danish Hernia Database—http://www.herniedatabasen.dk 84; Swedish Hernia Registry—http://www.svensktbrackregister.se 55; Herniamed—http://www.herniamed.de 22; EuraHS—http://www.eurahs.eu 5; AHSQC—http://www.ahsqc.org 5; Club Hernie—http://www.club-hernie.com 1; EVEREG—http://www.evereg.es 1) have been published. The number of published articles clearly indicates that RCTs and registry-based observational studies have become partners in the evolution of medical evidence in hernia surgery [20]. As there is a discrepancy between the actually published data from hernia registries and the number listed in PubMed the use of the registry name as key word for the publication should be obligatory.

Many important questions in the field of hernia surgery have only been studied in registry studies [20]. Thus, the registers in hernia surgery are of great importance for clinical research. One clear advantage of the registry concept is having the ability to detect and analyze low rate potentially clinically relevant or even catastrophic events. Due to the increasing complexity in hernia surgery, hernia centers are increasingly being established worldwide [22].

Public media are increasingly aware of the fact that surgery can only be improved if its results are known [23]; the registry data are increasingly used for quality control [24], for example, in the certification of hernia centers [25]. A hernia center should be required to participate in a registry and submit as complete as possible data on all hernia patients [25].

Limitation of all data analysis from registries is always selection and input bias. The American College of Surgeons National Surgical Quality Improvement Program (NSQIP) mandates that participating hospitals assigns a NSQIP trained clinical reviewer to collect data on a stratified sampling of patients. Ongoing education for the reviewers as well as auditing is designed to ensure data reliability. This can be a model for the future, but calls for adequate financial support. This model can also prevent misuse of a registry by participating hospitals for marketing purposes.

Table 8 Follow-up data part 2

	Routes	Post-operative complications	Post-operative pain	Seroma	Infection	Recurrence	Reoperation	Mortality	QoL measurements
Swedish Hernia Registry	Inguinal Primary ventral, incisional, parastomal	Registered by the coordinator	Yes Yes	Yes	Yes	At reoperation Yes and at reoperation	Yes	Yes	IPQ 2 No
Danish Hernia Database	Inguinal, port-site, primary ventral, incisional, parastomal	Only if requiring reoperation or readmission	No	Only if requiring reoper. or re-adm.	Only if requiring reoper. or re-adm.	Only if requiring reoper. or re-adm.	Yes	Yes, derived from national identity code	No
HerniaMed	Incisional, parastomal, hiatal inguinal, umbilical, epigastric	Secondary bleeding, intestinal lesion, wound healing disorder, ileus, deep infection	Pain (VAS scale)	Yes	Yes	Yes	Yes	Yes	No
Club Hernie	primary ventral, incisional, inguinal, parastomal, giant incisional	SSI, post-op bulging, mesh infection	Yes	Yes	SSI, post-op bulging, mesh infection	Yes	Yes	Yes	Club Hernie QoL Score
EuraHS	Primary ventral, incisional, parastomal, hiatal, inguinal, open abdomen, abd. wall closure, prophyl. meshes	SSI, post-op bulging, mesh infection	VAS, chronic pain: Cunningham classification	Yes	Yes	Yes	Yes	Yes	EuraHS QoL score, Giqli score
Evereg	Incisional	Yes	Chronic pain, VAS	Yes	Yes	Yes	Yes	Yes	No
AHSQC	Primary ventral, incisional, parastomal, inguinal	SSI, SSO, NSQIP complications	Yes	Yes	Yes	Yes	Yes	Yes	HerQLes, NIH PROMIS

VAS visual analog scale, *SSI* surgical site infection, *SSO* surgical site occurance, *NSQIP* National Surgical Quality Improvement Program, *QoL* quality of life, *HerQLes* hernia-related quality-of-life survey, *Gigli score* gastrointestinal quality of life index, *NIH PROMIS* National Institute of Health patient-reported outcome measurement information system

Table 9 Provision of data and validation

	Routes	Data analysis provided	Validation
Swedish Hernia Registry	Inguinal	Annual report on website and report to each center; individual surgeons get their results via the center; publication of data on the website, reports on national and international congresses	Random external validation; selected units are monitored each year by a specially educated team
	Primary ventral, incisional, parastomal	Individual surgeons get their results via the center; publication of data on national and international congresses	Not at the moment, planned
Danish Hernia Registry	Inguinal, port-site, primary ventral, incisional, parastomal	National education programs; feedback to surgeon; reports for research projects; publications in international papers; publication of data on international congresses	High validity has been demonstrated between patients´ files and entered data in the registry. Moreover, data are validated on an annual basis against certain quality standards, defined for groin and ventral hernia repair
HerniaMed	Incisional, parastomal, hiatal, inguinal, umbilical, epigastric	Study reporting per route and per section (demographic, status, surgery, mesh, complications, pain) possible. Excel export in real time for surgeons and groups; publication of data	Validation of the data via the German Hernia Society; 1st year: participant has to sign that he/she entered 90% of all hernia operations; after 3 years random audit
Club Hernie	Primary ventral, incisional, inguinal parastomal, giant incisional	Excel export in real time for surgeons and groups; real time comparisons with the group; publication of data on national and international congresses	Asking the patient, the clinical research assistant makes a retro-control of the surgeon's input. In case of any difference, a control of the medical chart is done
EuraHS	Primary ventral, incisional, parastomal, hiatal, inguinal, open abdomen, abd. wall closure, prophyl. meshes	Excel export in real time per route or per case, case summary function, publication of data on international congresses. Annual report on website	Data validation is done by the constributing surgeons, as they are the owner of their data.
Evereg	Incisional	Excel export in real time for surgeons and groups; data report only for members of board; comparison with the group only available for the Executive Committee; publication of data on international congresses	Annual monitoring by an Executive Committee
AHSQC	Primary ventral, incisional, parastomal, inguinal	Real-time risk adjusted reports provided, comparing individual surgeon or hospital performance compared to collaborative; yearly individual surgeon reports; collaborative-wide analyses	Systematic data assurance including completion and accuracy

In summary, while the seven existing hernia registries worldwide may differ in structure, together they contribute to raising the quality of hernia surgery. Assurance of data quality is critical to registries. This aspect should be taken into account in the evaluation of registry data. It would be desirable to harmonize outcome variables. The registries are of great importance for clinical research and are complimentary to RCTs for quality assurance, monitoring innovations, and potential certification of hernia expert centers. Combining all registry data in a common database would be desirable to allow additional knowledge to be gained.

Authors' contribution All authors were responsible for their registry and provided all relevant information's about their registry in the manuscript. All authors carefully checked the manuscript and gave advices for corrections. All authors gave their final approval for the current version of the manuscript.

Compliance with ethical standards

Conflict of interest LNJ, AM and JAPR declare no conflict of interest. IKL declares conflict of interest directly related to the submitted work. JFG, WH and FM declare conflict of interest not directly related to the submitted work. FK declares conflict of interest directly and not directly related to the submitted work.

Ethical approval This study did not need approval from an ethic committee.

Human and animal rights This study does not contain any studies with participants or animals performed by any of the authors.

Informed consent Informed consent was not required for this study.

References

1. Demange MK, Fregni F (2011) Limits to clinical trials in surgical areas. Clinics 66(1):159–161. https://doi.org/10.1590/s1807-59322011000100026
2. Booth CM, Tannock IF (2014) Randomised controlled trials and population-based observational research: partners in the evolution of medical evidence. BJC 110:551–555. https://doi.org/10.1038/bjc.2013.725
3. Benson K, Hartz AJ (2000) A comparison of observational studies and randomized, controlled trials. N Engl J Med 342(25):1878–1886. https://doi.org/10.1056/NEJM200006223422506
4. McNeil JJ, Evans SM, Johnson NP, Cameron PA (2010) Clinical-quality registries: their role in quality improvement. MJA 192(5):244–245
5. Arts DGT, de Keizer NF, Scheffer GJ (2002) Defining and improving data quality in medical registries: a literature review, case study, and generic framework. J Am Med Inform Assoc 9:600–611. https://doi.org/10.1197/jamia.M1087
6. Nilsson E, Haapaniemi S (2000) The Swedish hernia register: an 8 years experience. Hernia 4:286–289
7. Helgstrand F, Rosenberg J, Bay-Nielsen M, Friis-Andersen H, Wara P, Jorgensen LN, Kehlet H, Bisgaard T (2010) Establishment and initial experinces from the Danish Ventral Hernia Database. Hernia 14:131–135. https://doi.org/10.1007/s10029-009-0592-0
8. Muysoms F, Campanelli G, Champault GG, DeBeaux AC, Dietz UA, Jeekel J, Klinge U, Köckerling F, Mandala V, Montgomery A, Morales Conde S, Puppe F, Simmermacher RKJ, Smietanski M, Miserez M (2012) EuraHS: the development of an international online platform for registration and outcome measurement of ventral abdominal wall hernia repair. Hernia 16:239–250. https://doi.org/10.1007/s10029-012-0912-7
9. Stechemesser B, Jacob DA, Schug-Pass C, Köckerling F (2012) Herniamed: an internet-based registry for outcome research in hernia surgery. Hernia 16:269–276. https://doi.org/10.1007/s10029-012-0908-3
10. Gillion JF, Fromount G, Lepère M, Letoux N, Dabrowski A, Zaranis C, Barrat C, The Hernia-Club Members (2016) Laparoscopic ventral hernia repair using a novel intraperitoneal lightweight mesh coated with hyaluronic acid: 1-year follow-up from a case–control study using the Hernia-Club registry. Hernia 20:711–722. https://doi.org/10.1007/s10029-016-1501-y
11. Pereira JA, López-Cano M, Hernández-Granados P, Feliu X, on behalf of the EVEREG group (2016) Initial results of the National Registry of incisional hernia. CIR ESP 94(10):595–602. https://doi.org/10.1016/j.ciresp.2016.09.008
12. Poulose BK, Roll S, Murphy JW, Matthews BD, Todd Heniford B, Voeller G, Hope WW, Goldblatt ML, Adrales GL, Rosen MJ (2016) Design and implementation of the Americas Hernia Society Quality Collaborative (AHSQC): improving value in hernia care. Hernia 20:177–189. https://doi.org/10.1007/s10029-016-1477-7
13. Muysoms FE, Deerenberg EB, Peeters E, Agresta F, Berrevoet F, Campanelli G, Ceelen W, Champault GG, Corcione F, Cuccurullo D, DeBeaux AC, Dietz UA, Fitzgibbons RJ Jr, Gillion JF, Hilgers RD, Jeekel J, Kyle-Leinhase I, Köckerling F, Mandala V, Montgomery A, Morales Conde S, Simmermacher RKJ, Schumpelick V, Smietanski M, Walgenbach M, Miserez M (2013) Recommendations for reporting outcome results in abdominal wall hernia. Hernia 17:423–433. https://doi.org/10.1007/s10029-013-1108-5
14. Köckerling F (2014) The need for registries in the early scientific evaluation of surgical innovations. Front Surg. https://doi.org/10.3389/fsurg.2014.00012
15. Rangel SJ, Efron B, Moss RL (2002) Recent trends in national institutes of health funding of surgical research. Ann Surg 236(3):277–287. https://doi.org/10.1097/01.SLA.0000026721.64592.F4
16. Royal College of Surgeons of England (2013) Brifing of house of lords short debate on the impact of NHS innovation and research strategies. RCS Publications, London
17. Shore BJ, Nasreddine AY, Kocher MS (2012) Overcoming the funding challenge: the cost of randomized controlled trials in the next decade. J Bone Jt Surg Am 94(Supplement 1):101–106. https://doi.org/10.2106/jbjs.l.00193
18. James S, Rao SV, Granger CB (2015) Registry-based randomized clinical trials—a new clinical trial paradigm. Nat Rev Cardiol 12(5):312–316. https://doi.org/10.1038/nrcardio.2015.33
19. Kehlet H, Bay-Nielsen M, For the Danish Hernia Database Collaboration (2008) Nationwide quality improvement of groin hernia repair from the Danish Hernia Database of 87,840 patients from

1998 to 2005. Hernia 2008(12):1–7. https://doi.org/10.1007/s10029-007-0285-5
20. Köckerling F (2017) Data and outcome of inguinal hernia repair in hernia registers—a review of the literature. Innov Surg Sci. https://doi.org/10.1515/iss-2016-0206
21. Köckerling F, Simon T, Hukauf M et al (2017) The importance of registries in the postmarketing surveillance of surgical meshes. Ann Surg. https://doi.org/10.1097/sla.0000000000002326 **(Epub ahead of print)**
22. Kulacoglu H, Oztuna D (2015) Current status of hernia centres around the globe. Indian J Surg 77(Suppl 3):1023–1026. https://doi.org/10.1007/s12262-014-1115-5
23. Landro L (2015) How to make surgery safer. Wall Street Journal (Newspaper/Magazine Article)
24. Rosser D, Lilford R (2013) Using surgeons' outcome data for quality control. Health Service Journal, HSJ is part of Wilmington Healthcare Limited, Southfields, Essex
25. Köckerling F, Berger D, Jost JO (2014) What is a certified hernia center? The example of the German Hernia Society and German Society of general and visceral surgery. Front Surg 1:26