



Review

Defining the characteristics of certified hernia centers in Italy: The Italian society of hernia and abdominal wall surgery workgroup consensus on systematic reviews of the best available evidences



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ABSTRACT

Background: The terms “Hernia Center” (HC) and Hernia Surgeon” (HS) have gained more and more popularity in recent years. Nevertheless, there is lack of protocols and methods for certification of their activities and results. The Italian Society of Hernia and Abdominal Wall Surgery proposes a method for different levels of certification.

Methods: The national board created a commission, with the task to define principles and structure of an accreditation program. The discussion of each topic was preceded by a Systematic Review, according to PRISMA Guidelines and Methodology. In case of lack or inadequate data from literature, the parameter was fixed through a Commission discussion.

Results: The Commission defined a certification process including: “FLC - First level Certification”: restricted to single surgeon, it is given under request and proof of a formal completion of the learning curve process for the basic procedures and an adequate year volume of operations. “Second level certification”: Referral Center for Abdominal Wall Surgery. It is a public or private structure run by at least two already certified and confirmed FLC surgeons. “Third level certification”: High Specialization Center for Abdominal Wall Surgery. It is a public or private structure, already confirmed as Referral Centers, run by at least three surgeons (two certified and confirmed with FLC and one research fellow in abdominal wall surgery). Both levels of certification have to meet the Surgical Requirements and facilities criteria fixed by the Commission.

Conclusion: The creation of different types of Hernia Centers is directed to create two different entities offering the same surgical quality with separate mission: the Referral Center being more dedicated to clinical and surgical activity and High Specialization Centers being more directed to scientific tasks.

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1. Introduction

The terms “Hernia Center” (HC), and “Hernia Surgeon” (HS) have gained more and more popularity during the last decades, since the first announcement of two surgical centers dedicated to (groin) hernia treatment: the Shouldice Clinic [1] and Lichtenstein Hernia Institute [2]. To date, there are many facilities (independent structures or linked to general surgery units) called HC and reporting even consistent experiences mainly on websites [3–6]. One of the commonest type of Hernia center is characterized by an outpatient setting dealing mainly with inguinal hernia repair under local anaesthesia. Nevertheless, there is lack of clear protocols and methods for certification of their activities and results. In recent years, certification of surgical activity has become of primary importance and nowadays several independent certification programs are present for different kinds of surgery [7,8], working to certify experience and results of both surgeons and facilities. This is of primary importance especially for hernia surgery, clearly the most common kind of surgery performed in both specialized and general surgery units worldwide, since the progress in surgical techniques (both endoscopic and conventional) and in devices (meshes, reinforcements and biomaterials), leads to a more complex choice on the management of every single patient. Differentiated use of various techniques and approaches has been adopted as the so called “tailored approach” [9,10], implying an extensive knowledge of pathology, setting, techniques and devices. Accordingly, hernia surgery is becoming day by day more complex and demanding, increasing the need for this certification. Apart from independent programs of certification, Surgical Societies should propose a system for accreditation of their members. At present only the German Hernia Society (joined to the German Society for Visceral Surgery) [10] has proposed a detailed program for hernia centers certification, basing its process on few and precise parameters (number of procedures, recurrence, reoperation rates, infection, scientific activity) that seem to rely mainly on “expert opinion”.

The Italian Society of Hernia and Abdominal Wall Surgery (ISHAWS) – National Chapter of European Hernia Society (EHS) proposes a new method for different levels of certification for both hernia surgeons and hernia centers; the parameters to receive and maintain certification are derived from a multiple systematic review of the literature following the concept of best available evidences and the PRISMA guidelines [11].

2. Development process

After an introductory paper edited in September 2016 [12], on February 24th, 2017, during the annual meeting of the Italian School of Abdominal Wall Surgery held in Rome, the national board of ISHAWS created a commission of six surgeons, members of the society, with the task to define the principles and structure of an accreditation program for Hernia Centers across Italy:

The group had 9 meetings in which the program was developed. In each meeting a topic was discussed and approved before moving on to the next. The principles that were followed were:

1. Safety of the patient
2. Definition of the parameters from ad hoc systematic reviews in order to minimize bias
3. Conflict resolutions with discussion and majority decision

Thereafter during the Annual Congress of the Italian Society of Surgery (SIC), held in Naples on 16th October 2017, the results were finally approved.

The study protocol was registered in the Research Registry database (www.researchregistry.com) prior to the start of the systematic review. All aspects of the PRISMA statement (Preferred Items for Reporting of Systematic Reviews and Meta-analyses), were followed.

3. Certification process and research methodology

Hernia Centers must offer the patient high standards of care regardless of their level in the certification system. Thus the ISHAWS Commission has decided to develop a common methodology to define the threshold that guarantees high quality of cure. The process of certification for surgeons and centers has been developed considering the following parameters:

- 1 Learning curve
- 2 Volume of procedures
- 3 Surgical Outcomes (morbidity, mortality, Surgical Site Infections, Recurrence and Chronic Pain)

Regarding points 1 and 2, systematic reviews on PubMed and Scopus database have been conducted to define the minimum number required to master every single procedure on the belief that, in particular for open repairs, these number were not clearly identified. In case of lack of or inadequate data from literature review, the parameter was fixed through a Commission discussion. Titles and abstracts of all studies were analyzed to identify duplicates, not pertinent or not relevant studies. Additional researches have been made based on references of the previously selected studies. Papers deriving from non-randomized studies were evaluated according to the *MINORS* Score.

Regarding point 3, considering that literature on abdominal wall surgery is one of the broadest fields in general surgery, and this peculiarity has prompted multitudes of high-level studies and protocols [13], we decided to adopt the methodology of the Umbrella Review [14] with the aim to define the best outcome measures related to safety and effectiveness of procedures. Every single outcome was submitted to separate electronic and manual search through cross-referencing with its own MESH terms in combination with Boolean operators. The search was restricted to systematic reviews and meta-analyses, English language literature, on human and adult patients. Only papers in which the outcome was clearly indicated in the full text were selected for final analysis. Papers were screened manually by checking title and abstract for duplicate and non-pertinent papers, full texts of systematic reviews, and meta analyses to assess quality and extract data. Selected papers were graded according to AMSTAR score [15] and critically appraised. Whenever possible a paper was finally selected if the quality was judged sufficient. Data were gathered with a preformatted sheet and entered in a Windows Excel file. The outcomes were extracted directly or alternatively by pooling and expressed in the form of frequencies and percentages.

Strings and PRISMA flowcharts of each search are reported on [Appendix 1](#).

3.1. Learning curve

The commission identified the subsequent procedures:

- Anterior inguinal hernia repair (Lichtenstein, Plug and Patch, TIPP)
- Posterior inguinal hernia repair (Open Pre-peritoneal, TAPP, TEP)
- Open incisional/ventral hernia repair (abdominal wall reconstruction regardless of type of procedure, clinical scenario and open technique adopted AWR)
- Minimally invasive AWR (whenever an AWR was performed with laparo-endoscopic approach)

3.1.1. Inguinal hernia repair

The literature search identified 189 papers, with no duplicates; among them only 24 were considered relevant for the aim of this review, but four of them were excluded since lack of information. Two more papers were included after cross-referencing. Among 22 studies included in the review, 21 were on endoscopic approach (TAPP or TEP) [16–36] and one on open repair [37] ([Table 1](#)).

Table 1

Details of the articles with number of enrolled patients, type of study and results regarding the learning curve.

First Author	Year	Study type	Patients enrolled	Number of procedure for Learning curve	Surgical Technique	MINORS Score
Liem [12]	1996	RCT	120	Not reported	TEP	–
Voitk [13]	1998	Retrospective non comparative	120 (122 hernias)	50	TEP	10
Lau [14]	2002	Retrospective comparative	120	80	TEP	12
De Turrís [15]	2002	Metanalysis	–	30–50	TAPP/TEP	–
Lal [16]	2003	Retrospective comparative	61	10	TEP	6
Haidenberg [17]	2003	Retrospective non comparative	264 (386 hernias)	40	TEP	8
Miserez [18]	2009	Training program in TEP	Not reported	30	TEP	–
Simons [19]	2009	EHS Guidelines	Not reported	50–100	TEP	–
Bitner [20]	2011	IEHS Guidelines	Not reported	30–100	TAPP/TEP	–
Choi [21]	2012	Retrospective non comparative	700	60	TEP	10
Putnis [22]	2012	Description of technique for learning curve	Not	Not Reported	TEP	–
Lim [23]	2012	Retrospective comparative	90 (95 hernias)	30–40	TEP	14
Schouten [24]	2013	Retrospective non comparative	3432 (3867 Hernias)	50-100; another decline of intra and post-operative outcomes after 400 procedures	TEP	10
Schouten [32]	2013	Retrospective non comparative	3432 (3867 hernias)	Not reported	TEP	10
Bokeler [25]	2013	Retrospective comparative	1221	Not reported	TAPP	17
Park [26]	2014	Retrospective comparative	112	60	TEP	12
Hasbahceci [27]	2014	Retrospective comparative	39 (42 hernias)	20	TEP	12
Mathur [28]	2016	Retrospective non comparative	149	18	TEP	9
Bansal [29]	2016	Prospective comparative	201	13–15	TAPP/TEP	13
Suguita [30]	2016	Retrospective comparative	239	65	TEP	12
Bracale [31]	2017	Retrospective comparative	83	Not reported	TAPP	18
Brown [33]	2017	Retrospective non comparative	30	60	Open	8

EHS and International EndoHernia Society (IEHS) guidelines [24] reported a minimum number of procedures needed to achieve the learning curve ranging between 50 and 100 (TAPP) or 30 and 100 (TEP), respectively. The parameter is consistent with the minimum number of procedures needed to stabilize the operative time estimated in 60 cases [34]. Conversely, there is only one paper describing a possible learning curve for open repair [37], concluding that 64 procedures represent the median caseload needed to a surgical trainee to be competent to perform the procedure unsupervised.

The Commission fixed at 60 cases as minimum number of procedures carried out under a tutoring program needed to complete the learning curve for minimally invasive hernia repair.

The Commission fixed at 60 cases the minimum number of procedures carried out under a tutoring program needed to complete the learning curve for open inguinal hernia.

3.1.2. AWR

The literature search identified 21 papers, with no duplicates. Among the 21 records only 5 were considered relevant for the aim of this review. Two of them were excluded due to lack of information.

The 3 studies [38–40] included in the review (Table 2) concern laparoscopic treatment. No data on open repair could be found. About laparoscopic approach, only 1 paper [40] clearly defined a minimum number of procedures to complete the learning curve, stating that the operative time was stabilized after 12 cases.

The Commission fixed at 20 cases as minimum number of procedures needed to complete the learning curve for laparoscopic AWR.

The Commission, in total absence of literature information for Open AWR, fixed at 20 cases the minimum number of procedures needed to achieve sufficient competency.

Table 2

Details of the articles with number of enrolled patients, type of study and results regarding the learning curve.

First Author	Year	Study type	Patients enrolled	Number of procedure for Learning curve	Surgical Technique	MINORS Score
Salameh [34]	2002	Retrospective comparative	29	Not reported	Laparoscopic	19
Bencini [35]	2004	Retrospective comparative	64	Not reported	Laparoscopic	15
Al-Harazi [36]	2014	Retrospective non comparative	181	12	Laparoscopic	10

Table 3
Groin (inguinal) hernia repair, volume.

Author	Year	Study Type	Patients enrolled	Procedures/year/surgeon	Surgical Technique	MINORS Score
Nordin [37]	2008	National Register	86409	Low volume surgeons (< 10 procedures/year) have a higher relative risk of reoperation	Open mesh repair	15
Andresen [42]	2016	National Register	14532	> 50 procedures/center per year to achieve lower reoperation rates	Laparoscopy	15
Aquina [39]	2015	Retrospective (National Database)	151322	> 25 procedures/year/surgeon, > 140 procedures/year/center to achieve lower reoperation rates	Open repair	19
Köckerling [40]	2016	Prospective online registry (Herniamed)	16290	> 25 procedures/year/surgeon to achieve lower recurrence rates	TEP/TAPP	20
Aquina [41]	2017	Retrospective (National Database)	124416	40-64 (medium volume) and > 65 (high volume) procedures/year/surgeon associated to lower reoperation rates	Both lap and open repair	18

3.2.2. AWR

The literature search identified 71 articles, with no duplicates. Only 10 records were considered relevant for the purpose of this review after abstract reading, but 4 were excluded since lack of information (specification on the number of procedures for surgeon/center per year and its impact on hernia recurrence). Both studies [45,47] included in the review, conducted by the same authors, are retrospective evaluations of records taken from hospital database, one of which include both laparoscopic and open repair, and the other one dealing with open repair only. Table 4 shows the details of the articles. Both studies conclude that a minimum of 20–25 procedures/year/surgeon are related to lower reoperation rates and lower perioperative costs, while facility characteristics (such as hospital volume) are not clearly related to the risk of reoperation [45,47].

The Commission fixed at 25 the minimum required volume/year/surgeon of open AWR.

The Commission fixed at 25 the minimum required volume/year/surgeon of laparoscopic AWR.

3.3. Surgical outcomes

In the outcome section for inguinal hernias were searched:

- Morbidity within thirty days from the procedure,
- mortality within thirty days from the procedure,
- recurrence regardless if clinically or confirmed by imaging,
- surgical site infections within thirty days from surgery, according to CDC definition
- chronic pain, defined as neuropathic pain lasting more than three months postoperatively

For AWR:

- morbidity within thirty days from the procedure,
- mortality within thirty days from the procedure,
- recurrence, regardless if clinically or confirmed by imaging,
- surgical site infection, within thirty days from surgery, according to CDC definition.

Table 4
Ventral (incisional) hernia repair, volume.

First Author	Year	Study Type	Patients enrolled	Procedures/year/surgeon	Surgical Technique	MINORS Score
Aquina [43]	2015	Retrospective (Hospital Database)	8047	24-35 (high volume) and > 36 (very high volume) procedures/year/surgeon to achieve lower reoperation rates and costs	Open repair	20
Aquina [41]	2017	Retrospective (Hospital Database)	78267	20-29 (medium volume) and > 30 (high volume) procedures/year/surgeon associated to lower reoperation rates	Both lap and open repair, including component separation techniques	18

3.3.1. Inguinal hernia – mortality

Only one paper [48] addressing the mortality rate of inguinal hernia was selected. The AMSTAR score for the paper is 3 reflecting a low methodological quality. The authors analyzed results coming from 14 retrospective case series. The estimated value is 0,5% among 85585 patients operated or submitted to watchful waiting trials.

Hernia Center Threshold Value fixed after consensus meeting: MORTALITY below 0.5% within 30 days postoperatively.

3.3.2. Inguinal hernia – morbidity

The primary search found 1000 papers. After complete analysis 3 of these met the inclusion criteria while 11 more papers were added by cross-referencing. Mean AMSTAR score of the eligible papers was 7.2. It was not possible to distinguish the grade of the adverse event according to classifications such as Clavien-Dindo [49] or the Comprehensive Complication Index [50].

Table 5 shows the characteristics of selected studies [51–56]. The meta-analysis with highest AMSTAR score [51] on mesh fixation in laparoscopic inguinal hernia defined a 6.2% vs 11.8% values for operated patients. Among papers scoring 8 on AMSTAR values have high variability ranging from 5.6% to 20.5% [59,61].

Hernia Center Threshold Value fixed after consensus meeting: OVERALL MORBIDITY below 10% within 30 days postoperatively.

3.3.3. Inguinal hernia – surgical site infection

Primary search found 844 references. After analysis 7 papers met the inclusion criteria and 11 were added by cross-referencing. Mean AMSTAR score of these papers was 6.9, with 8 papers scoring 8. Surgical Site infection values were extracted from the 8 best papers [54,56–62]. The majority of papers were meta analyses of randomized trials. Table 6 shows the characteristics of selected studies. The reported value for SSI ranged from 0% to 6.0% [60,66,67].

Hernia Center Threshold Value fixed after consensus meeting: SURGICAL SITE INFECTION below 3% within 30 days postoperatively.

3.3.4. Inguinal hernia - chronic postoperative pain

The primary search found 1466 references, of which 38 met the inclusion criteria and 2 added by cross-referencing. Mean AMSTAR score of these papers was 6.9, Values were extracted from the highest

Table 5

Details of the articles with number of analyzed patients, type of study and results regarding Surgical Site Infection after inguinal hernia repair. CS = case series; CC = case control study.

AUTHORS	YEAR	Study Type	MAJOR TOPIC	TECHNIQUE	AMSTAR	ANALYZED STUDIES	N° OF PATIENTS	SSI
Erdas [62]	2016	MET	ANTIBIOTIC PROPHYLAXIS	OPEN	8	16 RCT	5519	preoperative antibiotics 3,2% controls 4,8%
Li [63]	2012	MET	TECHNIQUE COMPARISON	OPEN	8	10 RCT E 2 CC	2860	preperitoneal 3,1% Lichtenstein 1,9%
Li [64]	2012	MET	MESH MATERIAL	OPEN and LAP	8	16 RCT and 5 CC	5389	lightweight mesh 1,0% heavyweight mesh 1,6%
Li [65]	2015	MET	FIXATION	LAP	8	8 RCT	1228	glue 0% mechanical 0%
Mazaki [66]	2013	MET	ANTIBIOTIC PROPHYLAXIS	OPEN	8	12 RCT	1902	preoperative antibiotics 3,0% controls 6.0%
Sanabria [67]	2007	MET	ANTIBIOTIC PROPHYLAXIS	OPEN	8	6 RCT	2507	preoperative antibiotics 1,38% controls 2,89%
Willaert [59]	2012	SYST	TECHNIQUE COMPARISON	OPEN	8	3 RCT	569	preperitoneal 0% Lichtenstein 0%
Zhu [61]	2014	MET	TECHNIQUE COMPARISON	OPEN vs LAP	8	10 RCT E 2 CC	1157	TEP 1,2% open preperitoneal 2,5%

scoring 14 studies [51–56,58–60,63–67]. Table 7 shows the characteristics of selected studies. Time elapsed from the operation to the evaluation of pain was at least 3 months according to the International Association for the Study of Pain (IASP) definition [68]. The incidence of chronic postoperative pain was from 1.6% to 22.1% [62,69] at 12 months.

Hernia Center Threshold Value fixed after consensus meeting: Chronic Postoperative Pain below 15% at three months follow-up.

3.3.5. Inguinal hernia - recurrence

The primary search identified 787 references, 18 of which fulfilling inclusion criteria, and 22 further papers were added by cross-referencing. Mean AMSTAR score of these papers was 6.9. Values were extracted from the 13 highest scoring studies

Table 6

Details of the articles with number of analyzed patients, type of study and results regarding Chronic Postoperative pain after inguinal hernia repair. CS = case series; CC = case control study.

authors	year	study type	major topic	technique	AMSTAR	analyzed studies	n° of patients	f-up pain (months)	pain incidence
Antoniou [56]	2016	MET	FIXATION	LAP	10	9 RCT	1454	NA	glue 6,2% mechanical 11,8%
Zhao [60]	2009	MET	TECHNIQUE COMPARISON	OPEN	8	10 RCT	2708	> 3	Lichtenstein 3,8–4,1% Mesh plug repair 4,7–6,0% Prolene Hernia System 1,1–4,1%
Li [64]	2012	MET	MESH MATERIAL	OPEN and LAP	8	16 RCT 5 CC	5389	6	lightweightmesh 10,4% heavyweightmesh 14,0%
Sajid [68]	2012	MET	MESH MATERIAL	OPEN	8	9 RCT	2310	12	lightweightmesh 12,9% heavyweightmesh 22,1%
Li [63]	2012	MET	TECHNIQUE COMPARISON	OPEN	8	10 RCT 2 CC	2860	> 6	Open preperitoneal 7,1% Lichtenstein 12,3%
Willaert [59]	2012	SYST	TECHNIQUE COMPARISON	OPEN	8	3 RCT	569	NA	Open preperitoneal 10,9% Lichtenstein 20,0%
de Goede [69]	2013	MET	FIXATION	LICHTENSTEIN	8	7 RCT	1185	3	glue 5,7% sutures 12,4%
Ladwa [58]	2013	MET	FIXATION	OPEN	8	7 RCT	1259	NA	glue 9,2% suture 13,1%
Koning [57]	2013	MET	TECHNIQUE COMPARISON	OPEN vs LAP	8	13 RCT	5404	3	TEP 12,4% Lichtenstein 16,8%
Liu [70]	2014	MET	FIXATION	OPEN	8	4 RCT 5 CC	1623	> 3	glue 2,4% suture 6,9%
Zhu [61]	2014	MET	TECHNIQUE COMPARISON	OPEN vs LAP	8	10 RCT 2 CC	1157	> 3	TEP 1,6% Open preperitoneal 2,5%
Li [65]	2015	MET	FIXATION	LAP	8	8 RCT	1228	> 3	glue 4,3% mechanical 8,3%
Fang [71]	2015	MET	MESH MATERIAL	OPEN	8	5 RCT	382	NA	biologic 9,5% synthetic 15,2%
Öberg [72]	2017	MET	MESH MATERIAL	OPEN and LAP	8	5 RCT 7CS	1200	18	Absorbable mesh 2,1% Synthetic mesh 7,6%

[51–56,58–60,63–65,67,69]. Table 8 shows the characteristics of selected studies. Twelve of these papers (92.3%) were meta-analyses and eight considered only randomized control trials. The reported recurrence rate was from 0.6% to 5.0% [58,71]. The commission decided to fix the follow-up time at 12 months, without restrictions on the technique used to diagnose the event.

Hernia Center Threshold Value fixed after consensus meeting: RECURRENCE below 2% at 1 year follow-up with any diagnostic technique.

3.3.6. AWR – mortality

The primary search identified 468 references, 7 of which fulfilled inclusion criteria, and 3 papers added by cross-referencing. Overall 3 papers dealt with SAWR, 7 with CAWR, and none dealt with both. Mean

Table 7

Details of the articles with number of analyzed patients, type of study and results regarding AWR recurrence.

SAWR = Simple Abdominal Wall Repair; CAWR = Complex Abdominal Wall Repair; CS = case series; CC = case control study.

AUTHORS	YEAR	Study type	MAJOR TOPIC	TECHNIQUE	AMSTAR	STUDIES ANALYZED	PATIENTS	F-UP (months)	RECURRENCE COMPARISON (%)
Antoniou [56]	2016	MET	fixation	LAP	10	10 RCT	1455	13	glue 1,4% mechanical 1,0%
de Goede [69]	2013	MET	fixation	LICHTENSTEIN	8	7 RCT	1185	NA	glue 2,2% suture 2,0%
Koning [57]	2013	MET	technique comparison	OPEN vs LAP	8	13 RCT	5404	NA	TEP 5,0% Lichtenstein 2,7%
Ladwa [58]	2013	MET	fixation	OPEN	8	7 RCT	1259	NA	suture 1,6% glue 1,8%
Li [63]	2012	MET	technique comparison	OPEN	8	10 RCT 2 CC	2860	12–36	preperitoneal 0,8% Lichtenstein 1,9%
Li [64]	2012	MET	mesh material	OPEN and LAP	8	16 RCT 5 CC	5389	12	lightweight mesh 1,8% heavyweight mesh 0,8%
Li [65]	2015	MET	fixation	LAP	8	8 RCT	1228	> 6	glue 1,9% mechanical 1,0%
Liu [70]	2014	MET	fixation	OPEN	8	4 RCT 5 CC	1623	6–15	glue 0,6% suture 0,6%
Öberg [72]	2017	MET	mesh material	OPEN and LAP	8	5 RCT, 7 CS	1200	13	Absorbable mesh 2,0% Synthetic mesh 1,6%
Sajid [68]	2012	MET	mesh material	OPEN	8	9 RCT	2310	12	Lightweight mesh 2,7% Heavyweight mesh 1,4%
Willaert [59]	2012	SYST	technique comparison	OPEN	8	3 RCT	569	NA	preperitoneal 1,5% Lichtenstein 2,6%
Zhao [60]	2009	MET	technique comparison	OPEN	8	10 RCT	2708	NA	Lichtenstein 1,1% Mesh plug repair 1,6–2,5% PHS 0,3–0,4%
Zhu [61]	2014	MET	technique comparison	OPEN vs LAP	8	10 RCT 2 CC	1157	NOT STATED	TEP 2,2% Open preperitoneal 1,5%

Table 8

Details of the articles with number of analyzed patients, type of study and results regarding AWR mortality.

SAWR = Simple Abdominal Wall Repair; CAWR = Complex Abdominal Wall Repair; CS = case series; CC = case control study, PPP = Progressive preoperative pneumoperitoneum (Goni-Moreno protocol).

§ cumulativa data, not possible to differentiate among comparison arms.

AUTHOR	YEAR	AMSTAR	Study type	hernia type	ANALYZED STUDIES	n° of patients	MAJOR TOPIC	MORTALITY
Alam [78]	2016	2	SYST	CAWR	21 CS	313	TISSUE EXPANSION	PPP 0,7% Tissue expander 0% Botox 0%
Ferzoco [79]	2013	3	SYST	CAWR	11 CS	677	OPEN	0-5%
Eriksson [80]	2014	4	SYST	CAWR	14 MIXED	1198	OPEN	0% (0–5%)§
Wooten [81]	2017	4	SYST	CAWR	14 CS	103	TISSUE EXPANSION	4,8%
Feretis [82]	2015	4	SYST	CAWR	13 CS	220	OPEN VS LAP	3,10%§
Bellows [83]	2013	5	SYST	CAWR	60 CS	1212	OPEN	4,00%§
Hodgkinson [84]	2017	5	SYST	CAWR	16 CS	601	OPEN	2,50%
Carlson [75]	2008	4	SYST	SIMPLE	60 CS	6266	LAP	0,14%
Pham [76]	2009	5	SYST	SIMPLE	6RCT 8 CC	1066	OPEN VS LAP	open 0% lap 0%
Awaiz [77]	2015	8	MET	SIMPLE	6 RCT	751	OPEN VS LAP	open 0% lap 0%

AMSTAR score for SAWR papers was 5.7, and 3.9 for CAWR. The commission decided to analyze all papers for SAWR [70–72] and CAWR [73–79]. Table 9 shows the characteristics of selected studies. For SAWR cases the minimum reported value for mortality was 0% and the maximum 0.14% [76–78]. In CAWR cases [74,75] the reported mortality ranged from 0 to 5%.

Hernia Center Threshold Value fixed after consensus meeting: SAWR below 1%; CAWR below 5% within 30 days postoperatively.

3.3.7. AWR – morbidity

The primary search identified 2001 references, 14 of which fulfilled inclusion criteria, and 4 added by cross-referencing. Overall 11 papers dealt with SAWR, 6 with CAWR and 1 treated both. Mean AMSTAR score for SAWR was 6.7, 4.1 for CAWR, 3 for mixed. The commission decided to analyze for SAWR only papers with a score of 7 [72,80–83] or more and for CAWR 5 and more [78,79,84,85] (best available

quality). Values coming from mixed studies were not considered. Table 10 shows the characteristics of selected studies. The minimum reported value for morbidity was from 3.2% to 41.5% [72] for SAWR, and from 28.7% to 87.0% [78], for CAWR.

Hernia Center Threshold Value fixed after consensus meeting: SAWR below 30%; CAWR below 50% within 30 days postoperatively.

3.3.8. AWR – surgical site infections

The primary search identified 1164 references, 26 of which fulfilled inclusion criteria, and 7 added by cross-referencing. Overall 15 papers dealt with SAWR, 14 with CAWR and 4 treated both. Mean AMSTAR score for SAWR was 6.6, 4.5 for CAWR, 6.3 for mixed. The commission decided to analyze papers scoring 8 or more for SAWR [72,83,86–88], 5 or more for CAWR [78,79,85,89–91]. Values coming from mixed studies were not considered. Table 11 shows the characteristics of selected studies. The minimum and maximum reported values were respectively

Table 9

Details of the articles with number of analyzed patients, type of study and results regarding AWR morbidity.

SAWR = Simple Abdominal Wall Repair; CAWR = Complex Abdominal Wall Repair; CST = Component Separation Technique; CS = case series; CC = case control study.

AUTHORS	YEAR	AMSTAR	MET/ SYST	MAJOR TOPIC	technique	hernia type	ANALYZED STUDIES	N° of patients	MORBIDITY
Hodgkinson [84]	2017	5	SYST	TECHNIQUE COMPARISON	OPEN	CAWR	16 CS	601	25%
Bellows [83]	2013	5	SYST	MATERIAL COMPARISON	OPEN	CAWR	60 CS	1212	87% (OVERALL)
Deerenberg [90]	2015	5	SYST	TECHNIQUE COMPARISON	OPEN	CAWR	55 CS	3945	CST 50%
Slater [89]	2013	8	MET	MATERIAL COMPARISON	OPEN	CAWR	25 CS	1152	APONEUROPLASTY 55%
Tandon [85]	2016	7	MET	TECHNIQUE COMPARISON	LAP	SAWR	9 CC, 7CS	2963	ALLODERM 46,5%
Nguyen [86]	2014	7	MET	TECHNIQUE COMPARISON	OPEN	SAWR	2 RCT,1 REV, 6 CC	1672	PERMACOL 28,7%
Awaiz [77]	2015	8	MET	TECHNIQUE COMPARISON	OPEN vs LAP	SAWR	6 RCT	751	SURGISIS 45,7%
Salvilla [87]	2012	8	MET	TECHNIQUE COMPARISON	OPEN vs LAP	SAWR	15 OBSERVATIONAL STUDIES	2452	CLOSURE 3,2%
Sauerland [88]	2011	8	SYST	TECHNIQUE COMPARISON	OPEN vs LAP	SAWR	10 RCTs	880	NONCLOSURE 22,3%
									SUTURE REPAIR 3,8%-6,6%
									MESH REPAIR 7,3%-7,7%
									VLS 38,8%
									OPEN 41,5%
									9%-38%
									LAP 6,4%
									OPEN 7,6%

Table 10

Details of the articles with number of analyzed patients, type of study and results regarding AWR Surgical Site Infections.

SAWR = Simple Abdominal Wall Repair; CAWR = Complex Abdominal Wall Repair; CST = Component Separation Technique; CS = case series; CC = case control study.

AUTHORS	YEAR	AMSTAR	MET/ SYST	MAJOR TOPIC	technique	hernia type	ANALYZED STUDIES	N° of patients	SURGICAL SITE INFECTIONS
Bellows [83]	2013	5	SYST	MATERIAL COMPARISON	OPEN	CAWR	60 CS	1212	OVERALL 52,80%
Deerenberg [90]	2015	5	SYST	TECHNIQUE COMPARISON	OPEN	CAWR	55 CS	3945	NON MESH 13–41%
Hodgkinson [84]	2017	5	SYST	TECHNIQUE COMPARISON	OPEN	CAWR	16 CS	601	OPEN MESH 9–48%
Darehzereshki [96]	2014	6	MET	MATERIAL COMPARISON	OPEN	CAWR	8 CS	1229	LAP 8%
Holihan [95]	2016	7	MET	TECHNIQUE COMPARISON	OPEN	CAWR	13 MIXED	411	OVERALL 46%
Jensen [94]	2014	7	MET	TECHNIQUE COMPARISON	OPEN vs END	CAWR	5 CS	163	BIO 10,9%
Awaiz [77]	2015	8	MET	TECHNIQUE COMPARISON	OPEN vs LAP	SIMPLE	6 RCT	751	SYNTH 36,5%
Sauerland [88]	2011	8	SYST	TECHNIQUE COMPARISON	OPEN vs LAP	SIMPLE	10 RCTs	880	BRIDGE 37,4%
Timmermans [91]	2014	8	MET	TECHNIQUE COMPARISON	OPEN	SIMPLE	7 CS + 1 PROSPECTIVE + 2 RCTs	1948	CST + MESH 24,1%
Zhang [92]	2014	8	MET	TECHNIQUE COMPARISON	OPEN vs LAP	SIMPLE	11 MIXED	1003	ENDOSC CST 18%
Holihan [93]	2017	9	MET	TECHNIQUE COMPARISON	OPEN and LAP	SIMPLE	25 MIXED	na	OPEN CST 43%
									VLS 5,8%
									OPEN 8,4%
									LAP 3,1%
									OPEN 13,3%
									ONLAY 11,8%
									SUBLAY 3,1%
									LAP 2,8%
									OPEN 16,2%
									SUTURE 8.6%
									MESH 5.1%

3.1% [83] and 16.2% [87] for SAWR, 13% [85] and 52.8% [78] for CAWR.

Hernia Center Threshold Value fixed after consensus meeting: SAWR below 10%; CAWR below 30% within 30 days postoperatively.

3.3.9. AWR – recurrence

The primary search identified 1343 references, 41 of which fulfilled the inclusion criteria. Overall 25 papers dealt with SAWR, 15 with CAWR and 3 treated both. Mean AMSTAR score for SAWR was 6.32, 4.1 for CAWR, 6.3 for mixed. The commission decided to include in analysis papers with an AMSTAR score of 7 and more for SAWR [72,81,83,86,92,93], and of 4 and more for CAWR

[75,77–79,85,91,94–96]. Values coming from mixed studies were not considered. Table 12 shows the characteristics of selected studies. The minimum and maximum reported values were respectively 2.4% [97] and 22.3% [80] for SAWR and 5% [75] and 24.3% [79] for CAWR. Data concerning time point of follow-up were very sparse, and so the commission decided to introduce 1 year and 3 years postoperatively to register recurrence.

Hernia Center Threshold Value fixed after consensus meeting: Recurrence SAWR below 5% at 1-year follow-up, and 15% at 3 years follow-up; CAWR below 10% at 1-year follow-up, and 20% at 3 years follow-up; any diagnostic technique.

Table 11

Details of the articles with number of analyzed patients, type of study and results regarding AWR Recurrence.

SAWR = Simple Abdominal Wall Repair; CAWR = Complex Abdominal Wall Repair; CST = Component Separation Technique; CS = case series; CC = case control study.

AUTHORS	YEAR	AMSTAR	MET/ SYST	MAJOR TOPIC	technique	hernia type	ANALYZED STUDIES	N° of patients	F-UP (months)	RECURRENCE
Beale [101]	2012	4	SYST	MATERIAL COMPARISON	OPEN	CAWR	29 CS	1257	9–36	ALLODERM 31,4% PERMACOL 25% SURGISIS 40,2%
Chatterjee [100]	2014	4	SYST	COST ANALYSIS	OPEN	CAWR	6 CS	764	NA	CST + MESH 4,5% CST ALONE 8,9% 10% (0–33%)
Eriksson [80]	2014	4	SYST	TECHNIQUE COMPARISON	OPEN	CAWR	14 CC/CS	1198	36	
Feretis [82]	2015	4	SYST	TECHNIQUE COMPARISON	OPEN VS LAP	CAWR	CS	220	11,2	19,20%
Atema [99]	2016	5	MET	MATERIAL COMPARISON		CAWR	32 CS	6170	12	<i>potent. contaminated</i> SYNTHETIC 9% BIOLOGIC 21% <i>contaminated</i> SYNTHETIC 11% BIOLOGIC 38%
Bellows [83]	2013	5	SYST	MATERIAL COMPARISON	OPEN	CAWR	60 CS	1212	13,6	52,80%
Deerenberg [90]	2015	5	SYST	TECHNIQUE COMPARISON	OPEN	CAWR	55 CS	3945	12–120	NON MESH 13%–41% OPEN MESH 9–48% LAP 8%
Hodgkinson [84]	2017	5	SYST	TECHNIQUE COMPARISON	OPEN	CAWR	16 CS	601	26,7	46%
Darehzereshki [96]	2014	6	MET	MATERIAL COMPARISON	OPEN	CAWR	8 CS	1229	NA	BIOLOGIC 10,9% SYNTHETIC 36,5%
Castro [98]	2014	7	MET	TECHNIQUE COMPARISON	OPEN vs LAP	SIMPLE	6 RCT	566	NA	LAP 4,4% OPEN 23,5%
Nguyen [86]	2014	7	MET	TECHNIQUE COMPARISON	OPEN	SIMPLE	2 RCT, 1 REV, 6 CC	1672	6–146	SUTURE REPAIR 6,6% MESH REPAIR 7,3%
Sajid [97]	2013	7	MET	TYPE OF MESH FIXATION	LAP	SIMPLE	4 RCT	207	3–22	MECHANICAL 0% SUTURE 0%
Awaiz [77]	2015	8	MET	TECHNIQUE COMPARISON	OPEN vs LAP	SIMPLE	6 RCT	751	NA	VLS 5,8% OPEN 8,4%
Sauerland [88]	2011	8	SYST	TECHNIQUE COMPARISON	OPEN vs LAP	SIMPLE	10 RCT	880	12–136	LAP 3,1% OPEN 13,3%
Timmermans [91]	2014	8	MET	TECHNIQUE COMPARISON	OPEN	SIMPLE	7 CS + 1 CC + 2 RCTs	1948	NA	ONLAY 11,8% SUBLAY 3,1%
Zhang [92]	2014	8	MET	TECHNIQUE COMPARISON	OPEN VS LAP	SIMPLE	11 RCT, CC, CS	1003	2–135	LAP 2,8% OPEN 16,2%
Holihan [93]	2017	9	MET	TECHNIQUE COMPARISON	OPEN AND LAP	SIMPLE	25 RCT, CC, CS	na	NA	SUTURE 8.6% MESH 5.1%

4. Definition of certified surgeons and centers

The Commission defined a certification process including:

- First level Certification: ISHAWS FLC restricted to single surgeon
- Second level certification: ISHAWS Referral Center for Abdominal Wall Surgery
- Third level certification: ISHAWS High Specialization Center for Abdominal Wall Surgery

All certified hernia surgeons as well as the leading surgeons of a certified hernia center must be members of the Italian Society of Hernia and Abdominal Wall Surgery (Italian Chapter of the European Hernia Society) at the moment of application, and keep the state of regular members for all the period of the accreditation.

Fig. 1 summarizes pathway, organization and standards of care of the proposed system.

4.1. FIRST LEVEL CERTIFICATION (FLC) – single surgeon

The certified surgeon must own the skills to offer the patient procedures and solutions to face all the possible clinical scenarios and

complications. According to this principle, the certified member is a general surgeon covering the needs for concomitant procedures such as visceral, laparoscopic and basic vascular surgery. The First Level of Certification is given under request and proof, in form of a short surgical report, of a formal completion of the learning curve process for the basic procedures and an adequate volume of operations per year. The FLC is assigned in a provisory form after the application is received and checked. After 12 months the certification has to be confirmed: the surgeon must send a report with individual volumes and results fulfilling standards of treatment.

The applicant surgeon should have performed (to consider completed his/her learning curve), according to the previously mentioned systematic reviews and to the Commission statement, in order to receive and maintain the first level of certification:

- 120 inguinal hernia repairs (60 by open approach, 60 laparo/endoscopic, optional open pre-peritoneal)
- 40 AWR (20 open, 20 laparoscopic).

The applicant surgeon must also provide a volume of:

- 50 inguinal hernia repairs (25 open, 25 laparo/endoscopic);

Table 12
Summary of the requirements for each step of the proposed Italian Certification System.

LEARNING CURVE FOR APPLYING FOR FIRST LEVEL CERTIFICATION		
	Open approach	Laparo/endoscopic approach
Inguinal hernia repairs	60 cases	60 cases
AWR	20 cases	20 cases

SURGICAL VOLUME		
	Inguinal Hernia	AWR
First Level Certification (individual surgeon)	25 open cases 25 laparo/endoscopic cases	25 open 25 laparoscopic
Second Level Certification (two surgeons)	100 cases	40 simple AWR 10 complex AWR
Third Level Certification (two surgeons + 1 discent)	130 primary cases 20 complex cases	30 simple AWR 20 complex AWR

INGUINAL HERNIA REPAIR QUALITY PARAMETERS		
	Time from intervention	Maximum acceptable value
Mortality	30 days	0.5%
Morbidity	30 days	10%
Surgical Site Infections	30 days	3%
Recurrence	1 year	2%
Chronic Postoperative pain	3 months	15%

INCISIONAL/VENTRAL HERNIA REPAIR (AWR) QUALITY PARAMETERS			
	Time from intervention	SAWR	CAWR
Mortality	30 days	1%	5%
Morbidity	30 days	30%	50%
Surgical Site Infections	30 days	10%	30%
Recurrence	1 year 3 years	5% 15%	10% 20%

- 50 incisional hernia repairs (25 open and 25 laparoscopic) per year.

4.2. SECOND LEVEL CERTIFICATION: ISHAWs Referral Center for Abdominal Wall Surgery

4.2.1. Organizational requirements

The Referral Center is a public or private structure run by at least

two surgeons, both members of ISHAWs, both certified with FLC ISHAWs and already confirmed. Accordingly the second level is received one year after the request of FLC and is given in a provisional form. Volumes and outcomes of the center are evaluated at the time of application submission and after one year to obtain the definitive certification. The.

Commission defined that the following facilities should be present:

- weekly dedicated outpatient clinic
- possibility of admitting emergency patients
- surgeon on call 24/7 and anesthesiologist on call 24/7
- Intensive Care Unit on site or in network
- Laboratory testing on site, CT scan available on site or in network, transfusion center on site

4.2.2. Surgical requirements

The commission decided that:

The type of procedures offered in the Referral Center should be:

- Inguinal hernia repair by anterior and posterior approach (open or laparoscopic)
- AWR by open and laparoscopic approach

The year volume requirements for the center be the following:

- Inguinal hernia repair: 100 procedures
- AWR: 50 procedures (among them at least 10 cases of complex AWR according to Slater definition [100])

Surgical Outcomes for inguinal hernia:

- Mortality < 0.5%
- Morbidity < 10%
- Infection < 3%
- Chronic pain < 15%
- Recurrence < 2%

Surgical Outcomes for AWR.

- Mortality < 1%
- Morbidity < 30%
- Infection < 10%
- Recurrence < 5% at 1 year follow-up, < 15% at 3 years follow-up

Surgical Outcomes for complex AWR.

- Mortality < 5%
- Morbidity < 50%

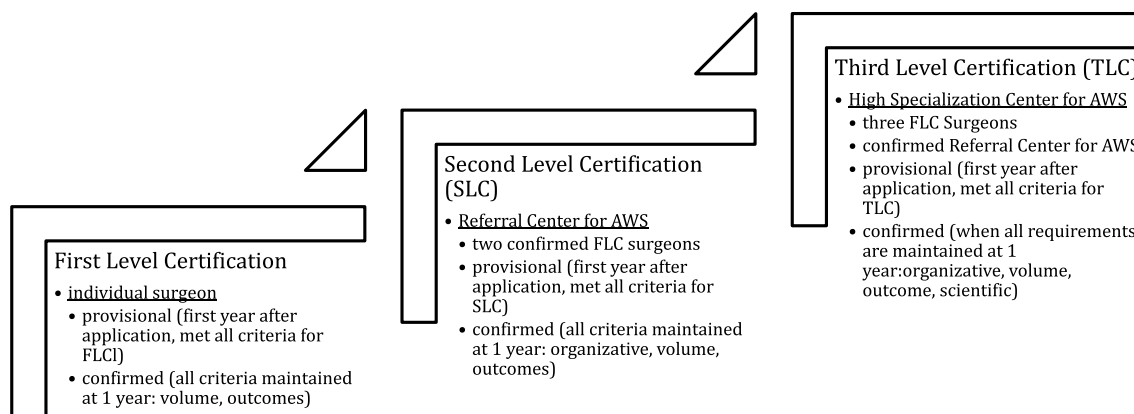


Fig. 1. Summary of pathway, organization and standards of care of the proposed system.

- Infection < 30%
- Recurrence < 10% at 1 year follow-up, < 20% at 3 years follow-up

The commission requires as mandatory multidisciplinary approach with:

- Plastic surgeon on site or in network
- Advanced wound management (negative pressure, etc)

Adequate follow-up and tools for outcome evaluation.

- Recurrence: Mandatory 1 year follow-up \geq 70% for inguinal hernia; 5 years follow-up \geq 70% for AWR
- Follow-up technique: In the case of inguinal hernia, to optimize strategy, according to Lopez Cano et al. [101] a selective follow-up on the basis of a dedicated phone questionnaire is considered sufficient. In the case of AWR the clinical visit is currently the choice. Every doubt can be confirmed by imaging.
- Evaluation of Patient reported outcome: pain. The Numeric Rating Scale is considered sufficient to assess pain during admission and follow-up visit.
- Evaluation of Patient reported outcome: Quality of Life. Several questionnaire are available for the task, the commission recommends EuraHSQoL [100] because is easy to be administered, is validated, effective, free to use, reliable [101].

4.2.3. Scientific requirements

The Referral center for abdominal wall surgery should serve as a training site for the Italian School providing cases and opportunity to learn for surgeons who want to specialize in abdominal wall surgery. Surgeons in the center do have to show certificate of attendance as participant or speaker to a minimum of three meetings or workshops on AWS every year and an EHS congress every two years. The center must participate to collaborative national studies organized by ISHAWS, providing cases when requested.

4.3. THIRD LEVEL CERTIFICATION: ISHAWS High Specialization Center for Abdominal Wall Surgery

4.3.1. Organization requirements

The High Specialization Center is a public or private structure run by at least three surgeons, members of ISHAWS, two of them certified with FLC ISHAWS and already confirmed, the third being a fellow, a PhD or resident with a formal research assignment. The third level of certification is given to confirmed Referral Centers already meeting the criteria of the superior certification. Accordingly, the third level can be achieved only at minimum one year after the second level is requested. Again the third level is given in a provisional form at the time of application submission and confirmed one year after (see values below). The entire process from first level application to third level lasts at minimum two years.

Facilities, surgical requirements, follow-up evaluations and surgical outcomes are the same as those required for Referral Centers, plus:

Year volume requirements for the center are the following:

- Inguinal hernia repair 150 procedures, among them 20 complex cases (defined as recurrent or scrotal hernias)
- AWR 50 procedures (among them at least 20 cases of complex AWR according to Slater definition [100]).

4.3.2. Scientific requirements

The High Specialization Center should serve as a training site for the Italian School providing cases and opportunity to learn to surgeons who want to specialize in abdominal wall surgery.

The center must organize a course or workshop yearly, and at least 2 of the four following initiatives.

- Publish one paper on abdominal wall surgery yearly on a journal with impact factor
- Organize collaborative trials
- Participation to EHS annual congress with abstracts or invited presentation
- Research on materials and new technologies

5. Discussion

Quality in surgery is a highly debated issue in current literature and the institution of a certification system along with creation of hernia centers is a step forward for abdominal wall surgery (AWS) for a two-fold reason: first it is a way to assure the presence on the territory of reliable referral centers and secondarily it endorses the concept of subspecialty in the field. Sub-specialization has been introduced by oncologic surgery and followed by endocrine and obesity surgery, AWS was the last to introduce centralization [3–6], but it is clear that advantages do exist. This concept as a matter of fact very well fits AWS: there's a high volume procedure (inguinal hernia repair) that requires repetition and appropriateness to maintain good outcome at low costs and, on the other hand, a low volume/high complexity clinical scenario represented by CAWR. This latter requires technical skills, clinical judgment and experience to be mastered correctly, moreover in light of the reported mortality [74,75,78] which places this type of surgery at highest position among hazardous subspecialties [102,103].

ISHAWS decided to create this certification system because is the national society devoted to the study of abdominal wall defects and the national chapter of the European Hernia Society. The proposed method will be implemented in Italy and the current paper is a proposal of a methodology to define quality and standards in an evidence based environment (level 1 evidence) reducing at minimum the reliance on expert opinion (level 5) as done by previous experiences [10]. The aim is to make freely available the results of this new approach to the scientific community and show its possible evolution.

The creation of different types of Hernia Centers is not on the purpose of offering different standards of care to the patients but is oriented to the creation of two different entities. They will offer the same surgical quality with separate mission as tested by the same thresholds for quality outcomes and organizational parameters: the Referral Center being more dedicated to clinical and surgical activity and High Specialization Centers being more directed to scientific tasks and referral for complex cases. The assumption of the commission is a greater prevalence of Referral Centers and very few High Specialization Centers promoting clinical studies and organizing the activity. The presence of a certified center should not interfere with the normal activity of generalist hospitals (ideally dealing with straightforward or emergent procedures) but should offer a hub for more challenging and unusual cases. The effect of the creation of a certified hernia center as already described in literature is not a rise in volume but rather an important change in the referral pattern of patients. For this reason along with relatively low volume threshold we fixed a higher level of complexity that ultimately would reflect the central role of these structure [104].

Being recurrence rate the most important quality indicator in hernia surgery is recurrence rate. Great debate has been raised in the past years concerning the way to correctly express this outcome and the important effect exerted by diagnostic techniques and type and rate of follow-up, as well as the attitude of the surgeon and patients towards reintervention [105]. When deciding the source to derive our parameters, we acknowledged that national registries would offer complete and reliable data, in particular those coming from countries like Denmark and Sweden, where patients can be tracked from hospital to hospital with a national personal code [45]. However, data from national registries have been considered misleading for their variability in approaches and results, since in most cases they come from generalist centers where hernia surgery is not a subspecialization or a specific

topic of interest or, as a matter of fact the surgeon has less experience. In light of this considerations ISHAWS decided to rely only on trials coming from international centers with dedicated activity in the field and consider them the target to identify quality in abdominal wall surgery. Even this approach have several source of bias, accordingly the final aim of this accreditation process will be, as already mentioned, to dynamically derive and confirm the parameters from hernia centers contributing to a compulsory central database as already implemented in other countries [10].

We acknowledge the limitations of this system.

First, a systematic review was conducted with the intention of minimizing arbitrary definitions of the “best value” to obtain certification, the drawback of this approach lies in the necessity to introduce a concept of “safety threshold” whenever the data are absent or need interpretation. Accordingly, when entering areas with high quality meta-analysis and low heterogeneity (i.e. inguinal hernia, simple incisional and ventral hernias), the commission observed numeric values converging towards the same thresholds, that was adopted as depicted from the umbrella review. On the other side, when there were less clear data, that is the case of learning curve, and complex abdominal wall, the commission choose convenient thresholds to cover the worst values reported in literature, on the principle that usually they are derived from larger series coming from specialized centers, thus representative of experienced and dedicated surgeons. Under this same principle it was decided the threshold of 15% at 3 months for postoperative pain. This was probability the more heterogeneously defined parameter in the literature of inguinal hernia because of time and modality of its evaluation. With this value we included possibly every type of painful sensation irrespective of its impact on daily activities and patient wellbeing. We devise to reduce the threshold as soon as we will have a common value representative of our hernia center experiences and derived from shared tools.

Second, the main issue created by the institution of limits and thresholds is the actual control of the results, currently, an offline database was developed with the aim of helping centers gathering their own data and follow-ups. To date the national databases available across Europe have shown a great efficiency on the scientific plane and in post-marketing surveillance becoming a formidable tool to analyze outcomes of techniques and materials in real life environments. We believe in their importance and the next step will be the creation of a voluntary database compatible with EurAHS relying on the data coming from certified surgeons more likely to comply to spontaneous data entry. In the mean time, to assure the correctness of results reporting, in this very early stage, the ISHAWS board has requested certification from the management of the hospital in which the center is embedded, before accepting the data. Moreover, sample analysis will be performed to further confirm reliability. For the purpose ISHAWS has created Regional Delegates responsible for the control of the Centers, they will make a site visit every two years on the purpose of certification renewal.

Third, while the approach to gathering values from systematic reviews and umbrella reviews represents a novelty in this field, several of the secondary attributes and facilities requested to build up a hernia center were derived from previous experience in different fields. For example the Italian society for Obesity surgery has similar criteria for certification of bariatric centers (https://www.sicob.org/area_04_medici/90_accreditamento.aspx) which were directly introduced in our system. Furthermore, the principle adopted when deciding the presence of a definite asset was the safety for the patient, in this light for example the presence of a transfusion centers is considered mandatory for the nature of certain procedures such as the treatment of massive defects.

The choice to restrict the number of procedures is meant for a simplification of the parametrical system of accreditation. We decided to focus our attention on the most frequently performed techniques, those representing the core aspect of abdominal wall surgery

accounting for the majority of the treated cases and with the more reliable data available. Two reasons are behind this assumption: first the idea of establishing rigid parameters for every single subset of patients (e.g. female, elderly, cirrhotic) or procedure would multiply the values and ultimately make difficult and maybe impossible to meet all the criteria in every single center. Secondly, there are procedures like lumbar or Spigelian hernia repair which, even if not rare, are not extensively studied (total lack of data on learning curve and volumes) and other techniques which actually share similar treatment strategies (umbilical hernia, femoral hernia) with the approaches chosen by the commission.

Several aspects of the accreditation system were defined clearly, on purpose it was still left uncoded the implementation of published international guidelines. Currently, on the topic of inguinal hernia treatment several societies have published their own guidelines and recently a collaborative international document has been published on the topic [106]. Parastomal hernia repair guidelines are also available and soon further recommendation will be produced on other subjects of AWS, mainly by EHS. We are convinced that the activity of a certified hernia center should follow guidelines, but recently in Italy the matter has changed its relevance. Starting from 2018, according to a new national law and in response to surgical community requests, the penal liability of the operating surgeon has been removed in case of adverse event if the medical procedure is done in accordance to guidelines. This law prescribes that accepted guidelines should be prepared by Italian scientific societies: thus currently ISHAWS is deeply involved in this process, translating and adapting international guidelines whenever they are already present. In all other cases, such as incisional and ventral hernia, ISHAWS is working on their definition through systematic revision. Italian Hernia Centers, accordingly, will be asked to conform to these guidelines whenever they will be ready and externally validated.

The systematic review of the literature performed for the present study has convinced us that several aspects of AWS are lacking of evidence and deserve further insights. Not surprisingly Inguinal Hernia has been submitted to high quality studies of validation of the techniques; in particular, laparo/endoscopic surgery has received a rigorous and meticulous process of assessment and comparison to open surgery, but the latter lacking, for example, of a clear definition of its learning curve. On the contrary, the unreliable and heterogeneous parameters retrieved for incisional and ventral hernia repair were expected. This field seems unexplored for what concerns the open techniques and totally lacking evidences for the optimal treatment of complex cases. Accordingly, the first aim of the certified Centers will be the organization of trials to help further clarification of the uncertain aspects of AWS along with the use of materials and the role of new technologies.

Currently seven centers have formally requested to be certified and started the process, after implementation of the certification system, there will be a period of 2 years of evaluation and possible modification of the parameters according to the actual results of the centers, we consider these seven centers as those that will definitely validate the present certification system and help define the true applicability of this new concept. The Commission will have new meetings after two years to refresh this stated standards of care.

Ethical approval

No ethical approval.

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Author contribution

CS, GC, DC, DPG, PN, UMB are members of the ISHAWS commission

that elaborated the research strategy and results.

DP, GM and OI adjuvated CS, UMB and GC to elaborate the reviews and participated in the writing process.

GC, PI and EG independently controlled the results accordingly to the PRISMA statement and checklist.

LF, PB, FC, AM, MC, FG and FC are members of ISHAWS Board that independently checked and revised the manuscript prior to submission.

Conflicts of interest

No conflicts of interest exist.

Research registration number

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Guarantor

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.ijss.2018.04.052>.

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