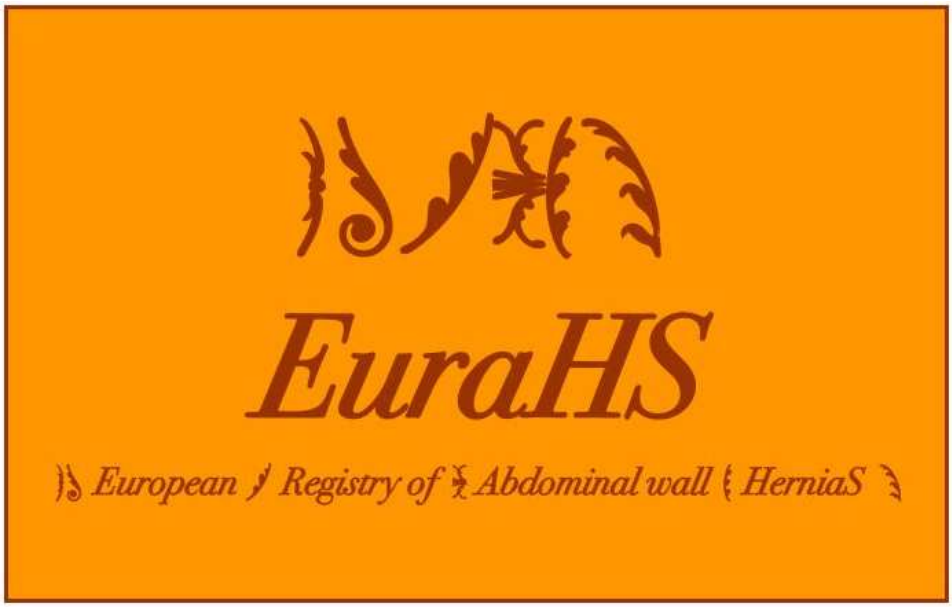

Annual Report EuraHS

2016

Table of contents

1. Words from the Project Manager of EuraHS

Dear member/partner of European Registry of Abdominal Wall Hernia (EuraHS)

As the Project Manager of EuraHS, I am honoured to present the fourth Annual Report of EuraHS. For the first time, I would like to take the initiative to thank all active users of EuraHS for their participation. Your continued active participation strengthened our registry in the last five years.

This report is intended to share some epidemiological description of data from the registry, give an overview of our achievements, as well as providing information about the new EuraHS group manager and insight into future developments planned for the EuraHS registry.

Since June 2012, the EuraHS database received patient enrolments from countries all over Europe and even outside Europe. Feedback from the users indicate EuraHS a valuable resource and a useful tool to collect prospective and retrospective patients data or even manage clinical trials on a multicentre and international levels.

Additionally, in 2016 our EuraHS QoL - Quality of Life score -more relevant to abdominal surgery patients - was validated and got published in Surgery. The validation has proven that this free-to-use tool in the database is valuable to hernia surgery. It is easy to answer for the patient and reproducible.

Today, the EuraHS platform is a highly developed scientific tool. The six routes of EuraHS and the unique Group Manager makes this database very valuable to scientific interested surgeons, as well as to surgeons who only wish to monitor their data. The aim of the EuraHS registry is to improve care for abdominal hernia patients. With new and continued study collaborations, support from industry and inclusion of patient data, this aim can be achieved to the benefit of hernia surgery.

Finally, I have to announce my resignation from EuraHS as of August 2017. Therefore, I would like to personally thank all EuraHS users, the EuraHS working group, our supporting companies and our IT team in Würzburg, Germany, for our excellent cooperation in the last five years. It was always a pleasure to work with you. And I would like to thank everybody for their trust and their support to make my tasks so enjoyable.

All feedback on details presented in this report is welcome.

Sincerely, Iris Kyle-Leinhase

Project Manager of EuraHS

2. Developments in EuraHS in 2016

2.1. Data transfer from EuraHS I to EuraHS II

Since the beginning of 2016, a new server is operative with the full version of EuraHS II. The transfer of data from EuraHS I into EuraHS II was completed by April 2016. Before the transfer was completed, the two databases (EuraHS I and EuraHS II) ran separately, making it difficult to perform a common data extraction and calculation.

The fully functional version of EuraHS II, which includes all routes of the EuraHS, allowed the transfer of all cases from EuraHS I. All members of EuraHS were informed of this and a back up of the EuraHS II was kept at the EuraHS data monitoring office. The transfer of data proceeded without major problems and the EuraHS II database is now accessible with all cases of the EuraHS I database (ventral, primary and parastomal route as well).

After the data transfer, the EuraHS I server was shut down.

2.2. Description of the GROUP MANAGER

Initiated at the end of 2015 and fully operational at the beginning of 2016, the EuraHS Group Manager function gave EuraHS new options for data sharing and communication in hernia surgery. The Group Manager function is a unique tool supporting global research activities. It gives the EuraHS user the ability to share cases for prospective as well as retrospective studies.

Developed at the University of Würzburg, Germany, the Group Manager function enables the user to share data with colleagues for joint research projects e.g. clinical studies. This can be done within a single research group or at national and international levels.
Each group is run by an individual group manager (the user who created the group).

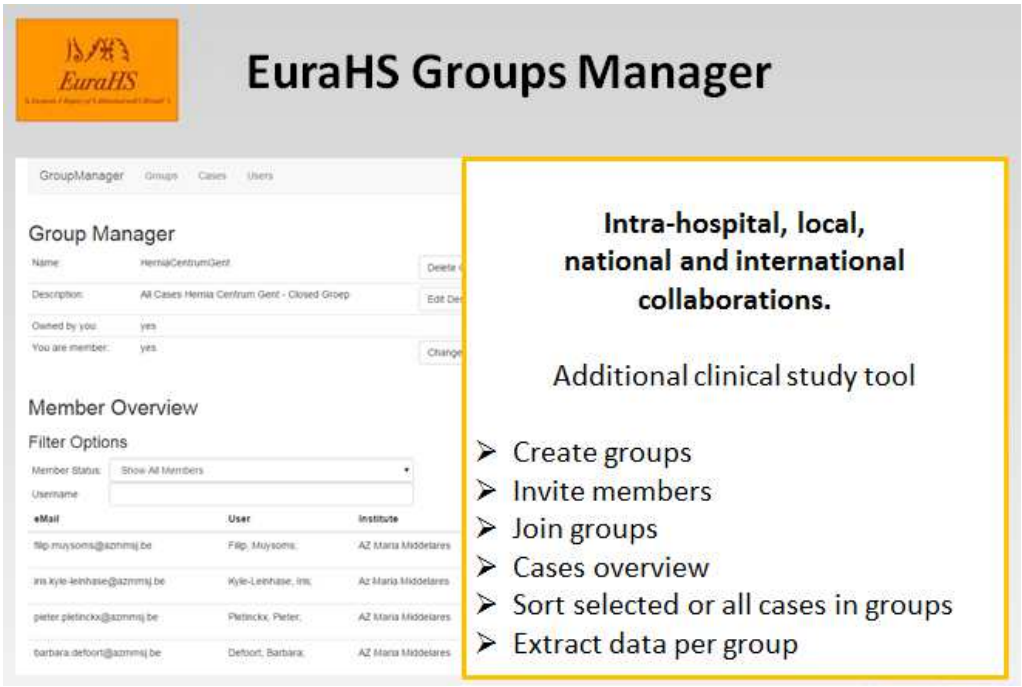

Figure 1: The new EuraHS Group Manager

This group manager can invite other users to join the group and can accepted joining requests on the behalf of the group. Furthermore, the group manager can extract the data from all group members for a combined analysis.

In all cases, each user retains ownership of his data. Cases cannot be seen by other members of the group and case data cannot be changed. This is the case owner's individual task.

In EuraHS, there are 3 options to become a member of a specific group:
The easiest way to join a group is via an invitation. An invitation can come from the manger of a specific group or from another group member, as already mentioned above. The second way is for the EuraHS user to request group membership of a group of his interest. Thirdly, all EuraHS users can also become members of a group by creating their own group.

The Group Filter Option gives an overview of all currently existing groups in EuraHS. This overview is in alphabetical order and gives information about each group; a short description as well as the owner of the group.

Moreover, the new EuraHS Group Manager helps to store and organize cases. As a frequent user of the EuraHS platform, the amount of cases in the different routes will grow quickly, which makes it difficult to organize existing cases in the different groups. As EuraHS is not using patient-identifying data, it is also difficult to identify a specific case by the pseudonym only.
The Case Overview displays all cases of one user by the six different routes. Additionally, in the case overview, the EuraHS User can link his cases to groups that he is a member of. With this functionality, retrospective study set-up is possible.

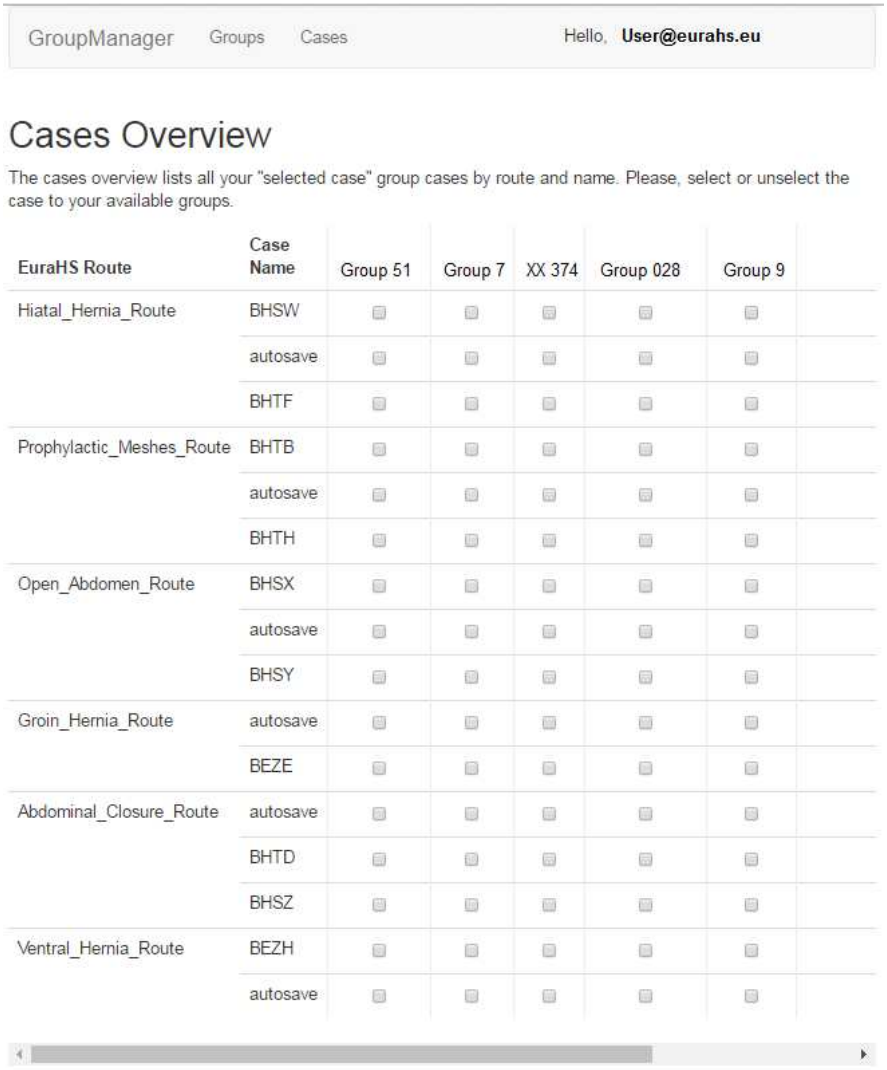

Figure 2: EuraHS Group Manager; cases overview

Please find here the link to the detailed Group Manger Guide in EuraHS
http://www.eurahs.eu/EuraHS-Group-Manager-Guide.php.

2.3. Validation of the EuraHS QoL Score

Additionally, in 2016 the EuraHS QoL - Quality of Life score was validated for groin hernias. Results of the Liquor trial were published in Surgery.

A prospective, multicenter, observational study on quality of life after laparoscopic inguinal hernia repair with ProGrip laparoscopic, self-fixating mesh according to the European Registry for Abdominal Wall Hernias Quality of Life Instrument.

Muysoms FE, Vanlander A, Ceulemans R, Kyle-Leinhase I, Michiels M, Jacobs I, Pletinckx P, Berrevoet F.

BACKGROUND:

There is an increasing interest in patient-reported outcome measurement to evaluate hernia operations. Several hernia-specific quality of life (QoL) scales have been proposed, but none are constructed for preoperative assessment.

METHODS:

The European Registry for Abdominal Wall Hernias (EuraHS) proposed the short, 9-question EuraHS-QoL instrument for assessment pre- and postoperatively. The EuraHS-QoL was evaluated in a prospective, multicenter validation study alongside the Visual Analogue Scale, Verbal Rating Scale, and Carolina Comfort Scale (https://clinicaltrials.gov; NCT01936584).

RESULTS:

We included 101 patients undergoing unilateral laparoscopic inguinal hernia repair with ProGrip laparoscopic, self-fixating mesh. Clinical follow-up at 12 months was 87% complete. The EuraHS-QoL score shows good internal consistency (Cronbach's $\alpha \geq .90$), good test-retest reliability (Spearman correlation coefficient $r \geq 0.72$), and high correlation for pain with the Visual Analogue Scale, the Verbal Rating Scale, the Carolina Comfort Scale pain scale (r between 0.64 and 0.86), and for restriction of activity with the Carolina Comfort Scale movement scale (r between 0.65 and 0.79). Our results show significant improvement in quality of life at 3 weeks compared with preoperative and further significant improvement at 12 months ($P < .05$). No late complications or recurrences were recorded. An operation was performed in day surgery (>75%) or with a <24-hour admission (>95%) in the majority of the patients.

CONCLUSION:

The EuraHS-QoL instrument is a short and valid patient-reported outcome measurement following groin hernia repair. Laparoscopic inguinal hernia repair with ProGrip laparoscopic, self-fixating mesh results in a favorable outcome and significant improvement of quality of life compared with the preoperative assessment.

This proves that the EuraHS QoL is more relevant to abdominal surgery patients. The validation has shown that this free-to-use tool in the EuraHS database is valuable to hernia surgery. It is easy to answer for the patient and reproducible.

3. Conferences

In 2016, EuraHS was invited to two major hernia conferences. The interest of the hernia community in the work of registries and EuraHS clearly shows that the EuraHS registry is going the right way with its offering of a free hernia platform to a broad group of surgeons.

3.1. 13. Hernientage, Berlin, Germany

Figure 3: 13. Hernientage, Berlin, Germany

EuraHS was also invited to the 13. Berliner Hernientage in Berlin, Germany, where two oral presentations were made. Dr. Filip Muysoms presented the European perspective in register based hernia research to the audience.

The project Manager, Iris Kyle-Leinhase was invited to present the findings of the CORE project to the German hernia society: Welche Hernien-Register haben wir in Europa und welche Unterschiede bestehen? (Which Hernia registries do we have in Europe and what are the differences?)

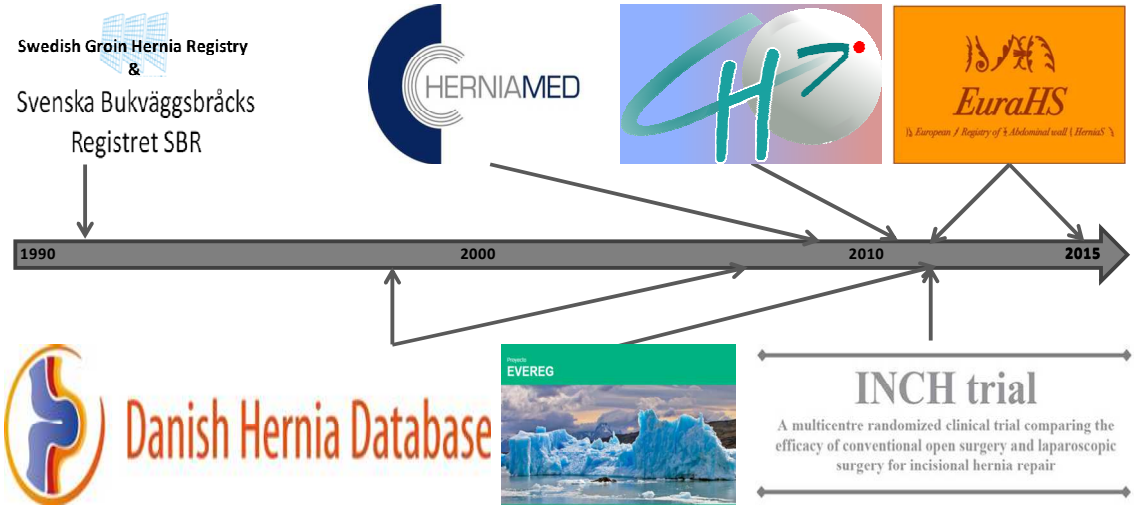

Figure 4: The Core project, overview of existing Hernia registries in Europe

3.2. 38th International Congress European Hernia Society, Rotterdam, the Netherlands

At the invitation of the congress presidents Prof. Lange and Prof. Simmermacher, Dr. Filip Muysoms presented the EuraHS database to the audience. In his presentation to the members of the EHS, Dr. Muysoms delivered an excellent overview of the construction and the function of EuraHS.

Figure 5:.38th International Congress European Hernia Society, Rotterdam, the Netherlands

In another presentation (Registries and improvement cycles), Dr. Muysoms highlighted the advantages of using a hernia registry in general and the EuraHS database in particular. He further discussed the need for improvement within the hernia world to learn about the importance of our existing registries and highlighted the measurable effects of the outcome published from registries in the last decades. Nevertheless, he strongly recommended to further invest into the development of registries and moreover the need for communication and data pooling from the different existing databases in Europe. One of his key points was to remind the audience that there is a lot of work still to be done to stimulate a larger community of surgeons to use these databases.

The EuraHS project manager, Iris Kyle-Leinhase, presented the usefulness of registries to the hernia community. In her speech she pointed out that surgical outcome reporting is important in understanding the postoperative course for patients undergoing hernia repair and in learning how the outcomes are affected. There are too many variables in hernia surgery: the patient, the procedure and the prosthesis (publication by Muysoms et al.).

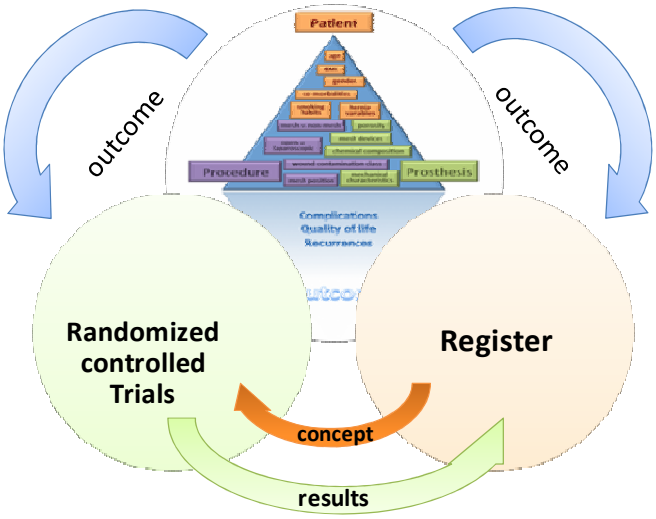

Figure 6:. The concept of registries and RTCs in hernia surgery

Big random controlled trials (RCTs), which are mostly performed in hernia expert centers to answer specific questions in correlation with techniques, materials or patients outcome, do not always display the state of art in real-time hernia surgery. By comparison, large registries collect lots of data in a wide surgical community for different aspects in hernia surgery.

The outcome of the patients undergoing a specific procedure can be registered in both systems. Even the outcomes of RCTs can be registered in defined and standardized registries. But moreover, registries can implement ideas for RCTs as complications which rarely occur can be detected earlier with larger patient numbers.

Most importantly, registries can function as an informational instrument for regulatory bodies and patients about existing hernia products on the market and the performance of hernia surgeons within different centers.

3.3. DHG Meeting, Wurzburg, Germany

At the 14. Jahrestagung Deutsche Herniengesellschaft e.V. 2016, the EuraHS project manager, Iris Kyle-Leinhase, presented the new EuraHS II to the German public. Especially the Groeps Manager, a unique tool under all registries, caught a lot of attention from the audience.
As off our delight, a very impressive speech was given by a representative from the German Military, about the use of the Open Abdomen Route in EuraHS and the first yearly results.

4. EURAHS STATISTIC FROM THE LAUNCH IN 2012 UNTIL June 2016

4.1. MEMBERS IN EURAHS

At of the end of 2016, 104 members registered in the new EuraHS version from countries all over Europe and 12 users were even countries from outside Europe.

4.2. TOTAL CASES EURAHS

Due to the recent start up of the new additional route of EuraHS and data pooling in 2016, the cases numbers are expectedly low. Therefore, the complete analysis of these data has not been performed as it would not result in statistically relevant numbers.

	Number of cases	% of all cases
Ventral Hernia Route	**3433**	74,248%
Groin Hernia Route	**640**	13,48%
Hiatal Hernia Route	**155**	3,35%
Open Abdomen Route	**396**	8,56 %
Total:	**4624**	

* This table represents only selected data extracted from the EuraHS registry..

5. Copyright

6. Impressum

Statistical analysis and preparation of bi-annual reports of the EuraHS 2016 were made by:

Iris Kyle-Leinhase, PhD. – Project Manager of EuraHS

Felix Herrmann. – Department of Artificial Intelligence and Applied Informatics, Wuerzburg University, Germany

Filip Muysoms, MD – President of EuraHS

Ulrich Dietz, MD – Secretary of EuraHS

7. Correspondence address

Iris Kyle-Leinhase, PhD
Project Manager EuraHS
AZ Maria Middelares – Department of Surgery
Buitenring Sint-Denijs 30; 9000 Ghent; Belgium
Email: iris.kyle-leinhase@eurahs.eu