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A European venous registry: pitfalls and opportunities

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Abstract

Introduction: Evidence based medicine is not the ideal way to assess and evaluate treatment success, failure and outcomes. Modern technology makes it possible to register a multitude of information. Advances in the venous field are fast and require a more efficient way to allow selection based on outcomes and quality. Registries are theoretically contain the data needed to investigate venous treatments and instruments.

Materials and methods: A literature review was performed and twenty-five articles were selected for review.

Results: Current registries fail to perform as needed and do not deliver the needed information. Separate frameworks and applications are available, but up until now no centralized and combined effort has been made to create a true all encompassing European venous registry.

Conclusions: A European venous registry containing standardized variables regarding all aspects of venous disease is needed to truly investigate and improve our care. An intuitive and integrated EHR application can facilitate the gathering of data needed to create such a registry. A number of rules apply though.

Keywords

Venous registry, EHR, EMR, data quality, data collection, RCT

Introduction

In modern medicine guidelines, treatment choices and almost all other major decisions are supposedly based on randomized controlled trials (RCT's). The general opinion among doctors and medical researchers for the last few decades is that RCT's are the only way to decide which therapy or diagnostic tool is best suited for a specific type of patient or disease, but this is not completely true.[1] Inclusion and exclusion criteria will always bias the group away from the real world population. Extrapolating results for a larger group or population might seem mathematically correct, but clinical practice more than often shows this to be not completely true.[1–3] For instance a significantly improved treatment in a randomized trial is performed in patients that do not fit the in and exclusion criteria, are performed by other physicians in other hospitals under different circumstances. The outcome of such a extrapolation is never analyzed, which means that in real life we do not know for if the expected outcome of the randomized controlled trials are realized. This lack of information influences costs and quality of care and is of importance to health insurance companies, hospitals and physicians. But also patients have the right to know and they are becoming more and more outspoken, demanding detailed statistics on their physician and their treatment in order to make sure they receive the "best" treatment.[3] RCT's cannot provide this information because they are fragmented, only look at a selection of treatments for specific diseases, under specific circumstances and are hard to interpret for patients.

In the field of venous disease much has changed the last few years. We've seen the rise of various thermal and non-thermal endovenous ablation techniques for treating superficial venous incompetence. Recently developed techniques like dedicated venous stenting, catheter directed thrombolysis and new treatments of i.e. the May-Thurner syndrome are showing the first positive results. Most of these results are coming from complicated multicenter RCT's, which are expensive and yield relatively low numbers of patients. For instance, the incidence of deep venous thrombosis is one in 10.000 patients, yet multicenter RCT's with $n = 200$ or less are still commonplace.

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Thus, many aspects of venous disease are still unknown:

- ''Natural'' development and progression
- The true QoL effects of various treatments in daily practice
- ''Best'' treatments

Registries are a potential better way to gather medical research data. A prospective registry should be able to capture outcomes and collect information on the complete population and thus gives an insight in the real-life effects and applications of medical techniques, treatments and advances. This can be used to improve the quality of care, reduce costs, improve the patient safety and allow quicker introduction and evaluation of new treatments and techniques.[5,6]

Registry (medical)

''Systematic collection of a clearly defined set of health and demographic data for patients with specific health characteristics, held in a central database.''

Registries are an upcoming and promising source for medical information, which is also reflected in various legislations in different countries, where maintaining clinical registries has become mandatory before treatments are reimbursed by the health care insurance companies, i.e. in Denmark (Danish National Patient Registry), Australia (National Joint Replacement Registry), UK (National clinical audit & registries) and the Netherlands (Dutch Institute for Clinical Auditing).

The current registries suffer from a number of drawbacks though, which limit their use and prevent them from gaining more popularity. In this paper we try to assess why registries fail to deliver what is promised and how they can be improved.

Methods

We performed a literature search in order to gain a better understanding of the factors that lead to successfully creating an efficient and effective registry, while maintaining validity and preventing bias.

NCBI's Pubmed was used with the following search terms:

#1: (registry[ti] OR registries[ti])
#2: (clinical[ti] OR medical[ti] OR patient*[ti])
#3: (validity[tiab] OR accuracy[tiab] OR quality control[tiab] OR data collection[tiab])

Two-hundred and twelve articles were identified by the combined search, of which 25 were selected for review. This selection was made on the article content, only descriptive and review articles on data quality/validity/collection in regard to medical registries were used, detailed analyses and results of specific registries and trials were excluded.

Results

Current registries

Various venous registries have been created over the last decade, with variable success.

Separate dedicated registries are known to have a poor compliance, for instance the American Venous Registry (AVR), which gathers data from 41 physicians in 37 hospitals in 27 states, registered 4014 venous ablation procedures between 2007 and 2011.[7] While this might sound impressive, a medium sized single dedicated venous clinic alone can perform up to 2500 procedures per year and in 2008 the amount of endovenous ablations in the United States was 16/10.000 persons. For the whole US population this means roughly 507.000 endovenous ablation procedures are performed each year. Thus the AVR only registers **0.2%** of all performed venous ablation procedures.

These poor results are not applicable to the AVR alone and can be attributed to a number of factors:

- It's complicated to add data to a registry.
- Data has to be entered twice; into the electronic medical record (EMR) and into the registry.
- Required registry parameters do no correspond with clinically used parameters.

Current medical registries rely on two methods for acquiring data:

- Manual data collection; mainly with case record forms (CRF)
- Automatic data collection; usually extracted from the electronic medical record (EHR/EMR)

Both methods are known to be susceptible for data errors, estimates are that for automatically collected data 2.0% is inaccurate and 6.0% is incomplete. For manually collected data the error margins are 4.6% inaccurate and 5.0% incomplete data.[8]

The role of the Electronic Health Record

Theoretically the ideal place to perform data collection for use in a registry would be the Electronic Health Record (EHR), also referred to as the Electronic Medical Record (EMR). The definition of an EHR is very similar to that of a registry: ''EHR (electronic

health record): A systematic collection of electronic health information about individual patients or populations.''

EHR's are gaining popularity as more and more hospitals switch to electronic systems, to replace the old and often cumbersome paper administration. Switching to a digital system has various theoretical advantages, ranging from efficiency gains to improved analysis of the healthcare processes.

Clearly there is a need and purpose for working EHR's, which is also reflected in various guidelines in different countries, such as the requirements of meaningful use mandated by the Centers for Medicare and Medicaid (CMS) in the United States, which offers financial support for institutions that prove to make meaningful use of the EHR system. Nationwide and specialty transcending EHR's have the possibility to transform multiple dimensions of modern healthcare.

But even though the benefits of digital record keeping are clear, a 2008 survey revealed the following number: 4484 physicians (62% response rate), 83% of all physicians, 80% of primary care physicians, and 86% of non-primary care physicians had no EHRs.[9] Also in the UK, the National Health Service reported in 2005: ''60,000,000 patients with a centralized electronic health record by 2010.'' - program cancelled in 2011: ''the National Programme for IT has not and cannot deliver to its original intent.''

More than 27 billion dollar has been made available to assist US healthcare institutes in reaching the government mandated EMR development stages before 2015.[10] This money will be paid out to institutes that can prove their adoption of all seven stages of EMR implementation as dictated by the American Recovery and Reinvestment Act (ARRA), a part of HITECH act. In 2009 only 11.9% of the US hospital made any use of an EMR system.[10]

While the number of EHR implementations might be increasing though, user acceptance and satisfaction are not.[11] Most EHR implementations suffer from poor design, are lacking user-friendliness and do not lead to improved efficiency at all. In theory EHR systems might be the solution for creating a true registry but a number of problems have to be solved first:

- Incompatibility between different vendors and systems, even between installations of the same product.
- Lacking standards of communication between EHR's.
- Structural data gathering is not facilitated, exporting and analyzing data stored in the EHR is cumbersome and usually not suited for research.

Five factors

Five factors seem to be required in order to create a true, nationwide and all-compassing venous registry:

1. Integration in the daily workflow of physicians

In order to increase acceptance among physicians and enable efficiency and time savings it's important to match the daily workflow as closely as possible.[12] This would greatly increase compliance of the resulting registry and at the same time prevent errors in extracting or copying[8,13] the registry data. Time and costs are known to be major barriers for institutions when participating in clinical research.[14]

2. EHR and registry as one system

The perfect venous registry should be the result of an intuitive and smart EHR interface, without double entry, gathering research data in the background. Thus the EHR and registry are one system, instead of the now commonplace setup where the registry is created separately from the EHR by extracting or copying data.[15,16] Associated advantages are:

- Auto enrollment on specified diagnosis to ensure completeness of the dataset
- Real time data collection, which improves quality

3. Data quality and completeness

To ensure a high quality data, validity and completeness clear data definitions and guidelines for entering data are needed. Training for the physicians who enter data in the EHR/Registry system is advised.[8]

Other factors that contribute to improvement of these aspects:

- Completeness of data because of mandatory entry fields[17]
- Predefined data fields for easy entering, to reduce type errors and fulfill the registry definitions[17]

4. Data standardization

Data collection needs to be standardized for two reasons; 1. in order to assure and control quality, accuracy and completeness of the incorporated data.[2] and 2. to be able to compare outcomes between different providers.[18]

The importance of standardization is reported more than once and remains a challenge. In order to reach true standardization a framework needs to be constructed. This framework should contain the variables that are important for venous disease, such as specific

clinical scores, QoL measurements, which are then to be used by every physician participating in the data acquisition.[8] This assures that all entry data is equal at local, national and in the future even at an international level. Currently no such universal framework is present in venous disease. One step towards a standardized dataset can be made by appointing an official body, which can then regulate the guidelines of uniform rules to be used in a future data set.

5. Collaborative data gathering

Collaborative data gathering by similar institutions and specialties will greatly improve the compliance and amount of data ending up in the registry. This would also make it possible to compare different treatment options at different locations. Eventually the gathering data from the registry can be used to create prognostic models which aide in validating and optimizing individual treatments.[3] This is also interesting from the perspective of healthcare insurance providers, who are interested in quality and efficiency of care differences between different institutions. The five factors named are all related and influence each other. An optimized and intuitive EHR needs to be integrated in the daily workflow of the physician and should facilitate the daily practice.

This can be achieved by using standardized protocols and a guided process in order to conduct consultations and patient-contacts. The registry system should get its data from this integrated EHR and this way no additional work is required to include a new patient or to add follow-up data. A large database with research data will be the result, without any extra administration and with 100% registration. To ensure extracted data from this database to be suitable for scientific research and to conduct reliable treatment outcome studies all data should be comparable and valid. This can be achieved by using a universal framework for entering data. Steps are made to establish such a framework in venous disease, led by various governing bodies in the venous field. When such a framework becomes available the combined EHR/registry tool will lead to error reduction in data entry and eventually generate high quality research data. The need to set up a registry in a collaborative form comes from the urge of the development of prognostic models in order to validate and allow optimization of individual treatments and to be able to compare different treatment centers on efficacy of care.

Discussion

Current (venous) registries generally have poor compliance, a possible high number of erroneous and/or incomplete entries and in our opinion fail to perform as intended. On the other hand, RCT's are expensive when costs are compared.[19]

Various steps are being taken to create a better registry, but a lack of collaboration between various organizations active in the EHR/registry field leads to fragmentation and low compliance. Only when unity between different countries, specialties and institutes can be achieved will it be possible to start building a true European venous registry.

Intelligent and intuitive software applications can greatly reduce the amount of money and time needed to construct a framework and academic network to facilitate the creation of a European venous registry. Help from legislators and subsidies from healthcare insurance providers will speed up this process.

Conclusion

The perfect future venous registry should encompass the following features:

1. Integration in the daily workflow of physicians

When properly integrated this will lead to 100% registration, automatically, in the background. Doing so will greatly increase adoption among users and improve compliance.

2. EHR and registry as one system

All data collected with the EHR should end up in the registry, making it usable for scientific research.

3. Data quality and completeness

The registry should contain data from all available and relevant data repositories, therefore it is important for the EHR tool to correctly funnel and route the collected data stream.

4. Data standardization

This provides data exchange between different systems and institutions, allowing comparisons, large number multi center trials and easy referrals.

5. Collaborative data gathering

Easy collaboration makes it possible to gather large datasets and cover all aspects of venous disease. This way large academic hospitals, small private clinics and other institutions can work together and compare outcomes and treatment results. Collaboration will also facilitate the creation of an expert system, assisting physicians in their treatment decisions.

Conflict of interest

All the authors have no conflict of interest and nothing to disclose.

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