Auditing a Nationwide Vascular Registry – The 4-year Finnvasc Experience


Departments of Surgery: Helsinki1, Tampere2, Rovaniemi3, Joensuu4, Lahti5, Seinäjoki6, Jorvi7, Savonlinna8, Kotka9, Mikkeli10, Hämeenlinna11, Kuopio12, Vaasa13, Kemi14, Kokkola15, Jyväskyla16, Kajaani17, Lappeenranta18, Oulu19

20 The rest of the Finnvasc Study Group in charge of data collection are: J. Hannukainen (Pori); J. Pitkänen (Vantaa); A. Rajalin (Turku); J. Rämö (Helsinki); H. Sell (Lohja); R. Syrjälä (Äänekoski); J. Tapaninen (Maarianhamina)

Objective: To assess the validity of a national vascular registry.

Materials and methods: 17,465 vascular and endovascular procedures, immediate reoperations excluded, registered in the Finnvasc registry from 26 centres during the years 1991–1994.

Chief outcome measures: Comparison of the number of registered procedures with hospital records, comparison of initial registrations with a random sample of re-registration and comparison of the 1-year local data input of one major centre to the same data input of the central unit.

Results: The rate of missing registrations was 19% ranging from 0–47%. The data of the re-registered forms were in agreement with the original data in 93% of all data points, the range being from 81–100%. There was a difference of 1.5% in the data between the major centre and the central unit.

Conclusions: The Finnvasc registry makes it possible to audit vascular surgery nationally, although a potential limitation is centres with low registration rates.

Key Words: Vascular registry; Audit; Quality control; Data validation.

Introduction

In an era of increasing demands and diminishing resources it is of utmost importance to know how to divide up the money offered for health services and how efficiently the money provided is used. The variation in the quality of medical treatment is also an increasing concern and the need for a continuous audit is paramount. Therefore, monitoring and critical analysis of routine medical care have been discussed increasingly in recent years. Vascular surgery is particularly well suited for such an audit because the clinical problems are often well defined, and the outcomes are mostly easy to characterise and identify. A systematic register of vascular procedures and their outcomes is one method of quality assessment.

The registry creates an instrument for quality measurement and assurance and it provides a basis for optimal health care planning and appropriate use of financial resources. It elucidates the volume of vascular surgery and provides a true picture of vascular surgical practice, the prevalences of the vascular diseases, and the prognosis of various therapies in the presence of different risk factors. For any surgeon or department dealing with vascular surgery it is essential to be able to compare its own results with the average results of other centres. The registry makes it possible to follow changes in vascular practice such as the adoption and results of new technologies. The registry serves as a source of observational or retrospective studies and also serves educational purposes. Furthermore, registry data can be used as a logbook for vascular trainees.

The Cleveland Vascular Society in the U.S.A. established a vascular registry in 1975 and reported more than 8000 registered cases in 1979. In the Nordic countries, the first vascular registry was established and commenced in 1987 in Southern Sweden (VRISS).
Validity of a Vascular Registry

Materials and Methods

The Finnvasc registry embraces a total of 5.1 million inhabitants, i.e. the whole population of Finland. The country is served by 16 central hospitals and six surgical departments at the Universities of Helsinki, Kuopio, Oulu, Tampere and Turku serving as their referral centres. Four large district hospitals are also included in the registry. Three private hospitals and 18 small district hospitals with little provision for vascular surgery do not participate in the registry. A common record form has been modified from those used by Karmody et al.16,17 and by VRSS-Swedvasc.10,18 The data consists of the patient’s identification, procedure indications and risk factors, the operation code with the anatomy and possible graft materials, the preoperative and discharge status of the patient and 30-day follow-up; including ankle brachial pressure indices when appropriate (Table 1). All data are recorded on paper forms, in binary form, absolute values, or as code numbers and mailed regularly to the central registry at Tampere University Hospital, where the data is fed into the computer by a single secretary. The record forms are filled in by the surgeons or residents in charge of the patient and checked in every centre by the vascular surgeon responsible for the collection of the data and the local register, called Minivasc. Patient identification information is only included in the Minivasc data, whereas in the central registry it is done by a code given in the treatment hospital. This is to assure patient privacy regulations. A number of local registries also enter the data into their own files.

The software package Paradox 4.0 is used as the database program and SPSS for statistical analysis. A total of 17,465 records were mailed to the central registry during the years 1991–1994. Fifty three per cent of the procedures were performed in the university hospitals, 44% in the central hospitals and only 3% in the district hospitals. The surgical operations constituted 67% and endovascular procedures 33%. Cross validation of the Finnvasc data was carried out by checking the initial data against computerised hospital records, which were a combination of data retrieved from anaesthesia and discharge records.

To assess the validity of the Finnvasc registry the surgeon responsible for data collection in each centre was asked to refill Finnvasc forms of randomised cases. This included every fiftieth case of the records during years 1991–1994 giving 349 forms, of which 319 (91%) were returned for analysis. The new forms were compared to the primary Finnvasc data. The number of achieved data points, in which the primary and refilled protocols were in agreement, were related to the total number of possible data points. The total number of possible data points of each protocol depended on the type of operation, the number of positive alternatives in different variables in the refilled protocol, possible reoperations and the completeness of the follow-up. The maximum comparable data points thus ranged from 17–42.

The third task was to find out the numbers of errors in the feeding of the data into the computer. Therefore the data input from one major centre, the Division of...
Vascular Surgery, Department of Surgery in Helsinki University Central Hospital, as recorded in its MiniVasc register, and the corresponding data from the Tampere central unit were compared. The data of the same paper forms had been entered into different computers by two separate secretaries. This comparison included 539 procedures, performed in 1994.

Results

The hospital records were only received from 15 of the 26 hospitals. However, their vascular surgical activity corresponded to 81% of the whole Finnvasc volume. When comparing the number of cases between the Finnvasc registry and hospital records, the mean percentage of missing cases in the Finnvasc registry was 19%, ranging from nil to 47%. In two centres the Minivasc register was more complete than the hospital registers. The completeness of the data varied considerably between the centres. In six of the 15 centres the number of missing cases exceeded 20%, whereas in five centres 10% or less were missing (Fig. 1). The operations most often missing were those performed as emergencies and endovascular procedures.

Refilled forms were returned from 20 centres, corresponding to 91% of the random sample. When comparing the originally recorded data with the set of recorded forms refilled later, an overall agreement of 93% was seen (Fig. 2). Only 38% of all Finnvasc forms contained no differences. The maximum number of differences in one Finnvasc form was 14 (Fig. 3). Regarding specific variables in the registry, the risk factors and the operation code were the variables differing most. The follow-up data was lacking in 18% of the cases, and the number of differences in the follow-up data was 6% in the function and patency, and 8% in the ankle brachial index (ABI) (Table 2).

![Graph](image)

**Fig. 1.** Agreement between the number of procedures registered in the hospital records and in the Finnvasc registry. The numbers inside the columns indicate the total vascular case load per hospital during years 1991–1994.
Fig. 2. Reproducibility per cent in different hospitals. The comparison was made between the primary data and number of positive alternatives in refilled protocols. One difference lowered one data point. The numbers inside the columns indicate the total vascular case load per hospital during the years 1991–1994.

Fig. 3. The distribution of number of differences between 319 original and refilled Finnvasc forms.
Table 2. Number of differences in each variable when comparing the primary data to the positive alternatives in refilled forms.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Differences (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Binary data (checklist: answer each question)</td>
<td></td>
</tr>
<tr>
<td>Risk factors (10 questions)</td>
<td>15</td>
</tr>
<tr>
<td>Surgical complications (14 questions)</td>
<td>5</td>
</tr>
<tr>
<td>Non-surgical complications (11 questions)</td>
<td>3</td>
</tr>
<tr>
<td>Non-vascular reoperations (11 questions)</td>
<td>2</td>
</tr>
<tr>
<td>Binary data (choose 1-3 of the available alternatives)</td>
<td></td>
</tr>
<tr>
<td>Operation classification (6 alternatives)</td>
<td>9</td>
</tr>
<tr>
<td>Operation type (13 alternatives)</td>
<td>6</td>
</tr>
<tr>
<td>Graft (11 alternatives)</td>
<td>6</td>
</tr>
<tr>
<td>Function and patency (7 alternatives)</td>
<td>6</td>
</tr>
<tr>
<td>Coding (choose 1-4 code numbers)</td>
<td></td>
</tr>
<tr>
<td>Indication (40 alternatives)</td>
<td>8</td>
</tr>
<tr>
<td>Surgeon (personal codes)</td>
<td>5</td>
</tr>
<tr>
<td>Operation codes (Finnish coding system)</td>
<td>10</td>
</tr>
<tr>
<td>Anatomy (35 alternatives)</td>
<td>6</td>
</tr>
<tr>
<td>Numerical data (give pressure indices)</td>
<td></td>
</tr>
<tr>
<td>Preoperative ABI</td>
<td>10</td>
</tr>
<tr>
<td>Postoperative ABI</td>
<td>10</td>
</tr>
<tr>
<td>Follow-up ABI</td>
<td>8</td>
</tr>
</tbody>
</table>

Differences less than 0.10 in ankle brachial index (ABI) and minor differences in anatomical level were accepted.

When comparing the data of the Minivasc register of one major centre with the same data of the Tampere central unit we found 98.5% agreement, i.e. a 1.5% data input error.

Discussion

In a review on the Swedvasc experience Bergqvist et al.6 pointed out that a registry should fill certain minimum criteria; i.e. the amount of information must be large enough to give a meaningful database, the registry must be simple enough to keep the compliance high and to maintain it on a population basis, and all hospitals within the geographical area of the registry should participate. These criteria are met by the Finnvasc registry.

The principal claim for any registry should be that the data collected is valid.15 This validation should be a continuous process. Running a registry covering a whole country certainly brings difficulties. One problem is the number of cases not registered; this has an effect on whether or not the vascular procedures included in the registry reflect the true number of the procedures. Cross-checking with hospital records may reveal missing data, but hospital records are not free of omissions either, and therefore cannot be an absolute reference. The weakness of hospital records as trustworthy references was highlighted by the observation from two central hospitals in which the Minivasc register included more registrations than the hospital records. The accuracy of the hospital records might improve, because today the hospital charges are based on the surgical procedural code registered in the patient file. To use the total number of cases, i.e. those in hospital records only, plus overlapping cases, plus registry cases only, as a standard for comparison would have been more clear, but the number of overlapping cases was not available in our study.

The function of the registry is to a large extent dependent on the responsible surgeons of each unit and their dedication to the task.6 All entry forms should be checked by an experienced person, preferably one of the surgeons, and the data should be fed into the computer by a person specially trained for this purpose. Errors may occur due to mistakes in entering the data on the form as well as mechanical mistakes in entering the data into the computer.19 The agreement of the different variables can be improved if the data is directly entered into the database, without any intervening use of paper forms. Some of the errors may be eliminated by computer warning messages if logical errors or improbable values are attempted when entering the data into the computer.19 In the present study the errors related to the mechanical input of data into the computer appear to be of no major importance.

The collection of the follow-up data may be difficult because not all patients are able to revisit the hospital. Some of the patients are transferred to other institutions, and some others simply are not willing to attend the outpatient clinic. In the present study the errors related to the mechanical input of data into the computer appear to be of no major importance.

The collection of the follow-up data may be difficult because not all patients are able to revisit the hospital. Some of the patients are transferred to other institutions, and some others simply are not willing to attend the outpatient clinic. In the present study the follow-up data was missing in 18% of cases. In the follow-up section the surgeon in charge states whether the treatment has resulted in an improvement or not. This is a method with several possibilities for bias.5
Validity of a Vascular Registry

Objective criteria such as ankle pressure measurements are available only for lower extremity surgery and can be misleading as well. So far the registry deals with procedures available only for lower extremity surgery and can be misleading as well. However, in our case vascular surgical manpower is a serious limiting factor. Having the registry linked to the registry for vital statistics could ease evaluation of long-term survival analysis.

The methods and results of the present study are comparable to those reported from Swedvasc by Bergqvist et al. The control of reproducibility was done in our study by refilling a 2% random sample of case forms instead of the 5% done in the Swedvasc registry, but the total annual number of re-registered cases was 80 in the Finnvasc and 50 in Swedvasc evaluation. Furthermore, the number of returned recorded forms from the random sample was 91% in our study instead of 83% in the Swedvasc registry. In the Swedvasc registry more than 90% agreement for most of the variables was recorded. In an early assessment of the validity of the Finnvasc data, 21% of the operations were missing during the first registration and there was a 92% agreement for most of the variables. That was interpreted to be due to the late start of some centres. The present results were, however, almost equal to those results. The lack of improvement may be due to the fact that some centres are less interested in participating in the data collection and the time-consuming task of filling in the forms properly. This is compensated only by the knowledge of own results and the overall data from the whole of the country. No monetary compensations are available. A potential problem arises from the fact that the registration rate differs strongly between different centres. Suspicions may be raised that the centres with low registration rates possibly tend to forget reporting unsuccessful cases more often than the centres with high registration rates. Problematic areas like the repair of ruptured aneurysms and embolectomies at night need further scrutiny, as do those procedures performed in the angiography suite.

Combining the number of missing cases, erroneously recorded and typed cases, up to 26% of data may be considered to be deficient in some respect. There may be some overlapping in erroneously recorded and typed cases, but in any case the accuracy should be higher. Of these factors the number of missing cases are, of course, of major concern, and this should be lower than 19%. In conclusion, population-based monitoring of vascular surgery seems to be possible with a reasonable validity of data. However, the problem of missing forms needs to be addressed.

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References


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