Patients Not Included in Medical Audit Have a Worse Outcome Than Those Included

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The aim of the present investigation was to analyse a clinical database in order to see how many patients were not included in medical audit and to see whether the outcome of the non-registered patients differed from that of the registered patients. Two independent surgeons studied the records of all infrainguinal bypass operations performed at six vascular surgical departments over a three-year period. A total of 684 bypass operations was reported to the register, of which 636 could be reviewed. One-hundred and twenty-eight cases that had not been reported were found from other sources. The outcome variables were mortality, amputation rate and patency. Sixteen per cent of eligible cases had not been reported. Mortality and amputation rate were twice as high among the missing cases as among the reported cases. There was no difference in patency. Overall judgement of the performance of an individual department may be impaired by cases not included in the register. Copyright © 1996 Elsevier Science Ltd.

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INTRODUCTION

Various systems are used for measuring outcome and quality. Patient outcome data are most often used by departments themselves in the process of improving quality. There is, however, a growing interest from financing organizations and from government departments to know what results may be expected [1]. External revision for such purposes requires a register which includes patient groups from several hospitals covering a large area.

When comparing the results and quality of individual departments, certain methodological problems arise:
1. The annual numbers of cases, and especially complications, per department are often small, which leads to wide confidence intervals.
2. Composition of the patient groups, the "case-mix", and thereby the possibility of attaining good results, may vary,
3. Registration of patients and data may be incomplete, and the results recorded may thus give a false impression of the actual outcome.

The aim of the present investigation was to compare six Swedish vascular surgical departments in order to see how many patients and operations were lost to medical audit, and to see whether the outcome of the non-registered patients differed from that of the registered patients.

MATERIAL

During the years 1988–1990, all hospitals in southern Sweden with a vascular surgical de-
partment took part in the "SWEDVASC" register. This register, which, since 1994, includes all Swedish vascular surgical departments, records vascular operations and interventions, and their results after 30 days and after one year [2]. Six of these hospitals were chosen for analysis. These were the hospitals with the largest number of operations. Two were university hospitals and four were district hospitals. All infrainguinal bypass operations performed during this period were included in the study. The material consisted mainly of the cases reported to the register by the surgeons. Forty-five records could not be found. Therefore, 636 cases constitute the "reported and documented group". Another 128 unreported cases were obtained from other registers at the National Board of Health and at anesthesiological departments. These were called the "missing group". The sum of these groups was called the "total group" (764). All these cases were the target for the audit.

METHODS

The vascular register, SWEDVASC, records data from the patient, the operation and information about the results at 30 days and at one year, a total of 44 variables. Normally, the surgeon in charge of the patient is responsible for collecting the data, which are then sent to a central office for analysis. In this investigation, a new set of data was produced by two surgeons, not affiliated to any of the six departments, who studied the patient records from the surgical, medical and orthopaedic departments. All variables were coded in the same manner as with the ordinary register without the knowledge of what had previously been reported by the original surgeon. This new set of data was the basis of the analysis.

A subset of the variables was used in the analysis. The outcome variables were mortality, amputation rate, patency (all measured both at 30 days and at one year). Patency was defined as the percentage of grafts remaining open during the observation period. Mortality and amputation could be determined exactly. Dates of death were obtained from the national Swedish population register.

Patency was more difficult to define exactly from data in the records. Ankle blood pressure was used, if recorded. An increase of >10% associated with symptom relief was taken as an indication of patency. Apart from this, we had to rely on statements in the notes made by the examining surgeon, such as palpable pulses and other observations. The graft was considered patent if the patient died without symptoms. Secondary patency was accepted when only minor revisions, thrombectomy or thrombolysis had been performed. Had a new bypass been performed, total or partial, or a procedure of similar magnitude, the original bypass was considered to be a failure. Some other variables were used to characterize the patient groups, namely age, sex, indication for operation, medical risk factors, location of distal anastomosis and graft material.

Comparisons were made in three ways. First the cases which had been reported to the register and documented by the examiners were compared to those not reported. The SWEDVASC register requires a report of the outcome at 30 days and at one year. Patients with a 30-day report may have escaped registration of the outcome at one year. Therefore, in the second round in the "reported and documented group", we compared the cases without a one-year report to the remainder. In a third analysis the "reported and documented group" was compared with the "total group". This was done to study how much the missing cases would have influenced judgement of the performance originally made from the reported cases only.

Statistical methods

Data were stored and processed with the SPSS-package. Proportions were analysed using Chi-square.

RESULTS

Six-hundred and eighty-eight bypass operations were registered in SWEDVASC. The records of 45 patients could not be found. The "reported and documented group" therefore comprised 636 cases. One-hundred and twenty-eight new cases were found from the other sources. Thus, 16% of eligible cases were not reported.

The first comparison was made between the "reported and documented group" (636 oper-
TABLE 1. Comparison of outcome between cases in the “reported and documented group” and the “missing group”. Number of cases (per cent) in each outcome measure

<table>
<thead>
<tr>
<th></th>
<th>Reported group</th>
<th>Missing group</th>
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<tbody>
<tr>
<td></td>
<td>n = 636</td>
<td>n = 128</td>
</tr>
<tr>
<td>Mortality (30 days)</td>
<td>27 (4.3)</td>
<td>16 (13)</td>
</tr>
<tr>
<td>p&lt;0.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amputation (30 days)</td>
<td>36 (5.7)</td>
<td>17 (13)</td>
</tr>
<tr>
<td>p&lt;0.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mortality (1 year)</td>
<td>128 (20)</td>
<td>36 (28)</td>
</tr>
<tr>
<td>p&lt;0.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amputation (1 year)</td>
<td>88 (14)</td>
<td>28 (22)</td>
</tr>
<tr>
<td>p&lt;0.05</td>
<td></td>
<td></td>
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<tr>
<td>Patency (1 year)</td>
<td>408 (64)</td>
<td>80 (63)</td>
</tr>
<tr>
<td>n.s.</td>
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</tbody>
</table>

Age, sex, risk factors, indication and type of bypass and other background variables did not vary between the two groups. There were differences in outcome variables, however (Table 1). At 30 days, the mortality and amputation rate among the missing cases were twice as high as among the reported cases. At one year, the differences were less, but still significant. Concerning patency, there was no significant difference between the two groups.

Eighty-three patients (13%) in the “reported and documented group” did not have their outcome at one year reported. These were compared to the remainder of the reported and documented group (Table 2). The one-year mortality and patency were significantly different, being worse among those with no one-year report. There was no significant difference in amputation rate.

In the third analysis, the “reported and documented group” was compared with the “total group”. This was done to study how much judgement of the performance of each department and of the whole hospital group was influenced when the missing cases were added to those listed in the SWEDVASC register. In this comparison, it was found that outcome measures did not differ whether or not the missing cases were included (Table 3). The figures in the register thus give a reasonably accurate picture of the performance of each department.

DISCUSSION

This investigation has shown that, despite maintenance of a clinical database, a certain number of cases are not included in medical audit and that these patients have a worse outcome than those in the register. Judgement of the performance of an individual department might thus be misleading, although in this investigation, only to an insignificant degree. Judgements of the performance of a group of hospitals seemed to be unaffected by these cases lost to follow-up.

Several approaches to outcome measurement have been used. These include the use of administrative databases, peer reviews, patient satisfaction questionnaires and clinical databases. All of these have their advantages and disadvantages. It is of paramount importance that complete data are obtained. All patients must be registered, and all relevant data for each patient must be collected. Administrative databases are probably the most complete. Peer reviews often have their source of information in the administrative databases and are therefore almost as complete [3]. If, however, the patient records have to be studied, a certain loss is inevitable, because the records are not always accurate.
at hand at any given moment. In our investigation, 6% could not be found. If the peer review is performed soon after discharge from hospital, there is a risk of systematic errors. The notes might be missing because a complication has occurred. The method associated with the greatest losses is the patient questionnaire, which is a well-known problem [4].

No study reporting the outcome of patients not registered in clinical databases could be found in the Medline database. The risk of bias due to incomplete data has, however, been addressed [5,6]. The agreement of data between a clinical and an administrative database for coronary bypass surgery patients has been studied [7], but the article did not mention whether the number of cases differed.

There are several reasons why patients are not registered in clinical databases. If discharge abstracts are used as the basis for the registration, unintentional losses may occur when patients are transferred to another department, e.g. due to myocardial infarction or amputation. Systematic errors may also occur if, for instance, patients of different ages or various types of operations are treated differently. Another possibility is that unfavourable cases are deliberately withheld and not reported. There are, of course, also truly random causes, i.e. forgetfulness.

The SWEDVASC register is characterized by voluntary participation, and no department has been subjected to audit on the basis of the reported figures. We do not therefore believe that the surgeons are inclined to adjust their results. Moreover, patency did not differ, which would have been likely if cases were deliberately withheld. On the other hand, the data are mostly collected by the surgeons themselves without the help of specially designated staff and without access to administrative databases. This means that both random and systematic causes may play a role. The fact that the characteristics of the patient groups were similar indicates that factors related to the patient and the operation were of little importance. The outcome differed, and we therefore believe that transfer to another department due to a complication was the main systematic reason for the faulty registration. Since not all missing cases were failures, random losses must also play a part.

Even if the outcome of the “missing group” was inferior to the “reported and documented group”, the error in judgement of the performance of individual departments was small. The influence on analysis of the results of all hospitals together was even less. Therefore, the SWEDVASC register in this investigation was sufficiently accurate to serve as the basis for analysis of the outcome of infrainguinal bypass surgery. However, this conclusion is not necessarily valid for the rest of the register or for other registers. Both the number of cases not included and the size of the difference in outcome have influence and have to be measured. Without knowing these figures, the accuracy of the register is open to doubt. From this discussion, we conclude that all efforts must be made to ensure that databases, which are compiled from discharge abstracts, are complete. One way to attain this is to arrange an automatic link to an administrative database. Specially trained personnel, employed to maintain the registers, may also facilitate the collection of data.

One may also conclude that clinical databases are not suitable for review by health authorities.
Patients lost to databases

There is another reason for this, apart from the doubtful accuracy discussed above. If a process of external review is announced in advance, departments may change their behaviour in order to receive a high rank in the outcome measurements in question. If, for instance, a 10% mortality is said to be the accepted maximum, some patients with a 50% chance of survival may be refused the operation. The consequences for those patients denied a useful treatment must be taken into consideration. This kind of register should probably include patients left without treatment or should make use of an epidemiological outcome measure. This delicate medical, ethical and health policy problems must be addressed.

REFERENCES