Operations, total hospital stay and costs of critical leg ischemia

A population-based longitudinal outcome study of 321 patients

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In a longitudinal analysis of all 321 patients in a defined population having surgery for critical leg ischemia during 1 year in Malmöhus county (0.53 million inhabitants), Sweden, we investigated all vascular procedures and amputations on both legs, total hospital stay and hospital costs from the first procedure in each patient until death or at follow-up at least 6 years postoperatively.

The first (key) operation during the inclusion year was a reconstructive vascular procedure in 96 patients, a restorative vascular procedure in 111 and a major amputation in 114 patients. One third of those with a reconstructive and half of those with a restorative key procedure had an ipsilateral major amputation. The mean number of surgical procedures and length of hospital stay among all patients were 3 (1–19) procedures and 117 (1–1097) days, respectively. Of the total number of days in hospital, less than half were in surgical departments, 10% in other acute-care departments and almost half in rehabilitation clinics and nursing homes. The total hospital and surgical costs among all patients were USD 15.1 million (mean USD 47,000/patient), with no significant differences in relation to the key operation.

We conclude that patients who have undergone surgery for critical leg ischemia accumulate very high total long-term hospital costs due to the need for repetitive surgery and long hospital stays. Our findings also show that a longitudinal study, including hospital stay in departments other than surgical, is necessary for a correct cost-and-outcome analysis.

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Critical leg ischemia (CLI) is limb- and life-threatening (Sec Eur Cons Doc 1991) and associated with very high treatment costs (Cheshire et al. 1992, Apelqvist et al. 1994, Johnson et al. 1995). Cost-effectiveness for primary revascularization versus amputation have been discussed in many articles (Callow and Mackey 1988, Raviola et al. 1988, Cheshire et al. 1992, The Vasc Surg Soc 1995, Johnson et al. 1995). However, long-term secondary expenses due to revisional procedures and hospitalizations also in departments other than surgical must be included as they may be considerably higher than those for the primary operation (Mackey et al. 1986, Cheshire et al. 1992). The longitudinal effects of repetitive surgery, hospital stay and costs are important, but have previously not been reported in a defined population.

We analyzed the long-term outcome in a defined population in southern Sweden having surgery for CLI including all surgical procedures, hospitalizations and hospital treatment costs from the first procedure in each patient until death or at least 6 years postoperatively.

Patients and methods

In Malmöhus county, Sweden, with a total population of 526,805 (end of 1987), there are 5 hospitals including the University Hospital of Lund, 1 county hospital and 3 municipal hospitals. 321 patients with surgery for CLI were consecutively included during 1 year (1987/88) in 2 prospective registration studies, one analyzing vascular procedures and the other major amputations in Malmöhus county, Sweden (VRISS 1989, Troëng et al. 1992, Eneroth et al. 1996). A retrospective analysis of each patient was added in 1994 concerning all surgical procedures in both legs, hospital admissions and length of hospital stay from the first operation for arterial occlusive disease until death or at least until 6 years after the first procedure for a longitudinal analysis. Data were obtained in a standardized manner on protocols. The outcome for these patients with regard to patient characteristics, ipsilateral reoperations and mortality was described in a previous study (Eneroth et al. 1996). Hospital admissions to the departments of general surgery, orthopedics, internal medicine, infectious diseases, reha-

bilitation clinics and nursing homes were included. In some cases, admissions to other acute somatic wards also occurred. These admissions were included in either of the above-described, most closely linked departments. Only admissions directly caused by arterial occlusive disease in the lower limbs were included. If the patient's hospital stay was prolonged because of a complication, such as pneumonia or myocardial infarction, the whole period was still included in the study. 52 patients lived in a nursing home before and returned to a nursing home after surgery. These patients were not included in the analysis of length of stay in nursing homes, whereas stays on acute somatic wards are included. All but 73 patients who were still alive in May 1994 were followed until death, resulting in a median follow-up time of 32 (0–88) months.

Cost calculation

All costs are quoted in USD in 1996 prices. 1 SEK equalled 0.15 USD. The direct costs for in-patient care and surgery were calculated according to an official price list of regional hospital fees for the southern part of Sweden in 1996. Treatment costs in nursing homes and long-stay wards were estimated according to official figures from the Federation of County Councils in Sweden 1991, in 1996 prices. The mean daily cost in nursing homes, long-stay wards and rehabilitation clinics was based on the proportion of the stay in different wards with varying costs. The approximate cost of surgery was based on a standardized fixed price per minute in the operating room, including staff and material costs, with the exception of implants (Table 2). The mean duration of use of the operating room for each procedure was not measured. Instead we employed a database, recording the length of time in the operating room for all vascular procedures and amputations performed during 1992–1995 at the University Hospital in Lund, Sweden. The costs of angiography, implants, intensive care, out-patient care, orthopedic appliances and indirect costs were not included.

Definitions

The definition of CLI was based on the European Consensus Document (Sec. Eur. Cons. Doc. 1991, Eneroth et al. 1996). The key operation was the first operation for CLI during the inclusion year. Surgical procedures for arterial occlusive disease in the other leg are referred to as contralateral operations. Follow-up was performed at death or in 1994 among survivors. Vascular surgery was divided into reconstructive, restorative and other procedures. Reconstructive vascular procedures include bypass surgery, thromboendarterectomy (TEA) and profundaplasty. Restorative vascular procedures include thromboembolectomy (TE), graft thromboembolectomy and percutaneous transluminal angioplasty (PTA). Other surgical procedures include exploration, simple suture, wound revision, sympathectomy, excision of graft and fasciotomy. A minor amputation was defined as an amputation distal to the ankle joint. A major amputation was defined as an amputation through or proximal to the ankle joint. Revision proximal to the ankle joint without shortening of bone was defined as a stump revision. Revision distal to the ankle joint after a minor amputation was included among minor amputations. Patients with dietary or medically-treated diabetes (n 118) were defined as diabetics.

Statistics

Cost and length of stay are given as mean, median and range. Differences between groups were calculated with the Mann-Whitney U-test and chi-square test, when applicable.

Results

Surgical procedures

The key operation was a reconstructive vascular procedure in 96 patients, a restorative or other vascular procedure in 111, and a major amputation in 114 patients. At follow-up, 978 surgical procedures had been performed (Table 2). Reconstructive procedures consisted of 217 bypass procedures (32 aortobifemoral, 28 to arteria femoralis, 104 femoropopliteal and 53 distal), 13 profundaplasties and 16 thrombendarterectomies. Of the restorative procedures 136 were thromboembolectomies, 69 percutaneous transluminal angioplasties and 59 graft thromboembolectomies. Of the amputations, 41 were minor, 209 transtibial, 18 knee disarticulations, 79 transfemoral, 2 hip disarticulations and 26 stump revisions. The mean number of surgical procedures was 3 (1–19). Among those with a reconstructive procedure as the key operation, 34% had an ipsilateral and 20% a contralateral major amputation. Among those with a restorative procedure as the key operation, 48% had an ipsilateral and 14% a contralateral major amputation. 58 patients became bilateral major amputees.

Length of hospital stay (Table 1)

The total length of hospital stay until follow-up in all 321 patients was 37,638 days, of which 44% were in surgical departments, 10% in other acute-care departments and 46% in rehabilitation clinics and nursing homes. The mean hospital stays were about the same

Table 1. Days in hospital, hospital cost/day and overall costs for hospital stay among all 321 patients until follow-up (excluding costs for surgery)

Department	Days in hospital Total	Days in hospital Mean (range)	Hospital cost/day (USD)	Overall cost for hospital stay (USD 1000)
General surgery	8,546	35 (1–210)	367	3,136
Orthopedic surgery	7,984	43 (1–262)	358	2,858
Internal medicine	2,483	33 (1–299)	336	834
Infectious diseases	1,342	30 (4–136)	603	809
Rehabilitation clinic /nursing home	17,283	159 (3–993)	303	5,236
All departments	37,638	117 (1–1,097)	–	12,873

Table 2. Mean time in operating room (OR), price per minute in OR and approximate costs per procedure and overall in 1996 prices among all 321 patients until follow-up. Implant costs are not included

Procedure	No.	Time in OR [a] (minutes)	Price/ minute (USD)	Mean cost/ procedure (USD)	Overall costs for surgery (USD 1000)
Reconstructive	246	310	13.5	4,185	1,029
Restorative	264		13.5	2,062	544
TE/Graft TE	195	160	13.5	2,160	421
PTA	69	–		1,785 [b]	123
Other vascular	93	106	13.5	1,431	133
Minor amputation	41	82	12	984	40
Major amputation	334	125	12	1,500	501
Total	978				2,247

[a] Mean values based on all similar procedures 1992–1995 at Lund University Hospital (n 1,612).
[b] Fixed price.

in all acute-care departments, whereas it was 5 times longer in rehabilitation clinics and nursing homes. The proportion of the stay in nursing homes versus in the rehabilitation clinics was about 3:1, with a mean daily cost of USD 303 (190–456). The overall cost for hospital stay, based only on hospital fees, was approximately USD 12.9 million, corresponding to mean individual costs of USD 40, 103 (356–341,248).

Patients who never became amputees had a mean hospital stay of 40 (1–590) days, while unilateral amputees had 139 (1–984) days and bilateral amputees had 207 (2–1,097) days. The mean hospital length of stay was not related to sex, but was inversely related to age (data not shown).

Costs for surgery (Table 2)

Based on all similar procedures in the period 1992–1995 at Lund University Hospital (n 1612), the surgical cost for a reconstructive procedure was twice that of a restorative and 3 times higher than for an amputation, implant costs not included. The overall cost for surgery was approximately USD 2.25 million, corresponding to individual costs of USD 7050 (1,426–43,310). The cost for surgery accounted for 15% of all hospital costs.

Costs for hospital stay and surgery (Table 3)

Patients with an amputation as the key operation underwent fewer surgical procedures than those with a vascular key operation ($p = 0.0001$), whereas the hospital length of stay until follow-up was longer among patients with an amputation as the key operation ($p = 0.01$). The key operation accounted for only one third of all procedures, whereas ipsilateral operations before and after the key operation accounted for 43% and operations on the other leg for 24% of all procedures.

The mean hospital stay among all patients was almost twice the median length of stay. The mean hospital and surgical costs until follow-up were USD 46,000 among those with a reconstructive procedure, USD 41,000 among those with a restorative procedure and USD 54,000 in patients with an amputation as the key operation, with no significant differences.

Table 3. Surgical procedures, mean (median) hospital stay in days and hospital costs until follow-up in relation to the key operation

Key operation	Reconstructive vasc. procedure	Restorative vasc. procedure	Amputation	Total
Surgical procedures (n)	335	404	239	978
Key operation (patients)	96	111	114	321
Other ipsilateral [a]	154	217	55	426
vascular	103	139	28	270
amputation	51	78	27	156
Contralateral	85	76	70	231
vascular	59	54	13	126
amputation	26	22	57	105
Hospital stay (days)				
Mean (median)	101 (51)	96 (46)	152 (96)	117 (65)
Range	8–455	1–590	1–1097	1–1097
Hospital costs (USD 1000)				
Total	4,385	4,593	6,142	15,120
surgery	995	878	374	2,247
daily hospital fees	3,390	3,715	5,768	12,873
Mean (median)	46 (29)	41 (27)	54 (37)	47 (32)
Range	7–172	2–208	2–344	2–344

[a] Before or after the key operation.

Hospital stays in rehabilitation wards and nursing homes accounted for half of all hospital costs among patients with an amputation, compared to one fourth for patients with a vascular procedure as the key operation.

Diabetes mellitus

The 118 patients with diabetes had a longer mean hospital stay (134 vs 108 days; $p = 0.009$) and a higher mean total hospital cost (USD 52,000 vs 44,000; $p = 0.01$) than patients without diabetes. Both groups had the same mean number of operations (3) performed, with no differences regarding reconstructive or restorative procedures, whereas patients with diabetes had a higher mean number of amputations ($p = 0.01$). Diabetic patients more often than non-diabetic patients had an amputation as the key operation (50 vs 27%; $p < 0.0001$) and more often became bilateral major amputees than did non-diabetics (28 vs 12%; $p = 0.0004$).

Discussion

Our study is the first to report a longitudinal analysis of all surgical procedures, total hospital stay and hospital and surgical costs among patients with surgery for critical leg ischemia in a defined population. The poor outcome among these patients, of whom fewer than one third were alive with an intact ipsilateral leg one year after surgery has previously been reported (Eneroth et al. 1996). The findings in the present study, with an average of 3 surgical procedures, a mean hospital stay of 117 days and a mean hospital cost of USD 47,000 further emphasizes the risk of repetitive surgery, long hospital stay and high costs in patients with CLI. These findings are even more remarkable regarding the high mortality.

In Sweden, the nationalized hospital health care system provides all hospital medical care. Until 1994 it had been almost impossible to obtain treatment at hospital other than that providing care in the community or county where the patient lived. Almost all patients with vascular disease in Malmöhus County, needing hospital care or operation were therefore treated in one of the 5 hospitals included in our study. Only a few patients were treated at other hospitals. These patients' hospital stays and operations were also included. We are therefore certain that all hospitalizations and surgical procedures performed were included.

The choice between revascularization or major amputation in patients with CLI has been discussed in many articles (Scher et al. 1986, Callow and Mackey 1988, Gupta et al. 1988, Ouriel et al. 1988, Cheshire et al. 1992, Bunt and Malone 1994). Proponents of primary revascularization say the advantages are better mobility, lower mortality and lower costs (Ouriel et al. 1988, Allen et al. 1990, Cheshire et al. 1992, Johnson et al. 1995), while other authors found no differences in costs (Mackey et al. 1986, Callow and Mackey 1988, Gupta et al. 1988, Raviola et al. 1988). However, a comparison of outcome or costs between revascularization or major amputation in patients

with CLI, especially with a short follow-up are not adequate, as it would probably reflect differences in the severity of leg ischemia, patient characteristics, patient selection and treatment strategy rather than the type of treatment efficacy. Long-term secondary procedures and expenses must therefore also be included in the comparison of outcome as well as in the calculation of mean reconstruction and amputation costs as they may amount to considerably more than the primary operation (Mackey et al. 1986, Cheshire et al. 1992). In the present longitudinal study with a long follow-up, we could find no significant differences in hospital and surgical costs between patients with regard to the key procedure, when classifying key procedures into three groups, i.e., reconstructive and restorative vascular procedures and amputations. However, when evaluating the results within the vascular groups, the heterogeneity of patient characteristics, of type of interventions and the mixture of acute or chronic CLI within groups has to be considered. Patients having a successful arterial reconstruction, without the need for a secondary intervention or amputation, had a significantly shorter hospital stay than amputees.

Apelqvist et al. (1994) found, in an economic analysis in the same area as in the present study, that the average in- and out-patient care cost for diabetic patients who had an amputation was SEK 345,000 (USD 52,000), of which four fifths of the costs were for hospital treatment. On the basis of that study, and due to the difficulties of a retrospective analysis of out-patient care costs, we chosed to include only hospital treatment costs.

The majority of hospital costs in our study were due mainly to long hospital stay, especially in rehabilitation clinics and nursing homes. Previous studies reporting duration of hospital stay among patients with peripheral vascular disease often are restricted to a selection of patients with a short- or medium-term follow-up (Cheshire et al. 1992, Gibbons et al. 1993, The Vasc Surg Soc 1995, Johnson et al. 1995). Although differences in patient characteristics, variations in the prevailing hospital care system and the possibilities of discharging patients to less costly care facilities make comparisons between different series difficult (Rhodes et al. 1986, Moher et al. 1992, Creditor 1993, Gibbons et al. 1993, Kalman et al. 1994), duration of hospital stay has been shown to be the major determinant of hospital costs in lower limb ischemia (Mackey et al. 1986, Callow and Mackey 1988, Cheshire et al. 1992, Gibbons et al. 1993, Solomon et al. 1994, Johnson et al. 1995).

We found that the mean hospital stays among patients with vascular procedures as well as major amputations were much longer than previously described (Cheshire et al. 1992, Gibbons et al. 1993, Johnson et al. 1995, The Vasc Surg Soc 1995). The long-term follow-up including all departments responsible for hospital treatment as well as the inclusion of all procedures even in the other leg probably explain these differences.

When reporting hospital stay and costs of in-patient care in this category of patients, not only admissions to surgical departments must be included but also those to other medical and rehabilitation departments as well as nursing homes. These findings are in agreement with a study of diabetic amputees (Apelqvist et al. 1994), in which two thirds of the average treatment days in hospital after amputation took place in departments other than the department of orthopedics—e.g., the departments of internal medicine, infectious diseases—or in nursing homes.

Patients with diabetes mellitus more often became major amputees, had a longer hospital stay and higher hospital costs than non-diabetics. The reason for the higher frequency of amputations may have been that distal bypass surgery was considered unsuitable for many diabetics during the study period, making an amputation the first choice. The reduction in the number of major amputations in recent years, possible because of achievements in diabetes foot care (Gibbons et al. 1993, Larsson et al. 1995) and distal vascular bypass surgery (Shah et al. 1992, Pedersen et al. 1994, Budd et al. 1995, Pomposelli et al. 1995) may favorably have changed the overall outcome compared to that in our study, since the majority of operations in the present study were performed in the late eighties. However, due to an increasing mean age at surgery (Eneroth and Persson 1992, Sayers et al. 1993, Green et al. 1995), a slower rehabilitation and a higher prevalence of complications and associated morbidities are likely to result in longer hospital stays.

A cost analysis consists of approximations to the true costs. The actual costs are very hard to evaluate, even in prospective studies, since the daily hospital fees, operation costs and especially out-patient care costs are only approximations to the true costs. Bearing these shortcomings in mind, the mean total hospital treatment cost of USD 47,000 we found, by far exceeded those described in patients with other orthopedic disorders, such as total hip prosthesis (Lavernia et al. 1995, Levine et al. 1995) and hip fractures (Borgquist et al. 1991). The total hospital cost we described is probably an underestimate of the true costs, especially among those with a reconstructive key procedure since the mortality in that group is lower than in the other two (Eneroth et al. 1996), with a higher risk of further surgical procedures and hospitaliza-

tions. If those who lived in nursing homes before and returned to nursing homes after surgery had been included in the analysis of hospital stays, the total hospital costs would have been higher. Inclusion of the costs for implants, intensive care and angiography, as well as out-patient care costs and costs for orthopedic appliances among amputees, would have resulted in even greater costs.

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