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ABSTRACT

Critical leg ischaemia can be treated by amputation of the affected leg or by reconstruction of the arteries. Arterial reconstruction is perceived to be an expensive procedure, often requiring more than one operation, which does not always prevent amputation. However, amputation is associated with long term costs of rehabilitation and social support. A retrospective analysis was undertaken of 337 patients receiving initially arterial reconstruction or amputation between 1985 and 1989, a minimum of one year follow-up being obtained. Data were collected on the success of grafts, reoperation rates, type and rate of complications, hospital inpatient resource use and costs, subsequent rehabilitation and social support, and patient outcomes in terms of mobility and survival. A decision theoretic approach was used to assess the relative cost-effectiveness of distal reconstruction versus amputation, proximal reconstruction versus amputation and all reconstruction versus amputation. Overall, arterial reconstruction showed an expected net saving of £2730 per patient over amputation. Proximal grafts showed a saving of £3800 per patient and distal grafts a small net cost of £525. This net cost needs to be considered alongside any gains in mobility and quality of life. This approach can be used to develop guidelines for arterial construction and data on outcomes and cost from other units could be used to assess cost-effectiveness in different locations.

INTRODUCTION

In most developed countries the resources devoted to health care as a proportion of GDP have doubled in the last thirty years (Scheiber and Poullier, 1989). However, changes in health care technology and consumer expectations during this period have meant that the demands on available health care resources have also increased. Governments and third party payers have become increasingly concerned about the high level of expenditure on health care generally, and on new higher cost medical technologies in particular. As a result health care professionals have come under increasing pressure to demonstrate that new health care technologies are efficient and represent good value for money.

Critical limb ischaemia can be a fatal condition if left untreated. At present the disease can be treated by primary amputation of the affected limb, or by vascular surgery to reconstruct the arteries. Whether the patient is treated by amputation or arterial reconstruction it is estimated that between 40% and 75% of patients will be dead within 5 years (Dormandy and Thomas,1988). Arterial reconstruction of the larger proximal vessels is accepted by some to be an effective but costly procedure. There is more controversy about the usefulness and high cost of arterial reconstruction of the smaller distal vessels. Both proximal and distal reconstruction often require more than one operation and do not always prevent amputation. Long term limb salvage rates have been estimated at between 30% and 66% (Towne et al, 1981, Veith et al, 1981). Whether or not further interventions are required depends to a large extent on the success or failure of the graft itself. Furthermore, graft patency rates are likely to vary according to the indications for surgery, type of graft used and the number of arterial reconstructions performed at particular centres. In addition, it has been argued that those patients requiring secondary amputation following failed reconstruction may have a worse outcome than those having primary amputation (Dormandy and Thomas, 1988). There is little data available on the long term mobility of people having reconstruction, the costs of the initial and subsequent procedures or the long term costs of follow up and care.

Primary amputation is perceived by many to be a simpler and less costly procedure than arterial reconstruction. However, there are likely to be long term costs of rehabilitation and social support associated with amputation (Raviola et al, 1988). Furthermore those people undergoing amputation may be less likely to be fully mobile following the operation than those who have a successful arterial reconstruction. Various studies have estimated that between 30% and 85% of people having below knee amputation and 11% to 36% of people having above knee amputation regain full mobility (Cameron et al, 1964, Robinson, 1976, Jamieson and Ruckley, 1983). Additionally, these figures refer to best mobility achieved at the end of rehabilitation. Following the rehabilitation period mobility is likely to decline as patients stop using their prosthesis and the disease progresses.

However, differences in long term outcome may be due to differences in the severity of the disease for the two groups. People referred for primary amputation often have a poorer prognosis and higher operative and post operative mortality rates than those referred for arterial reconstruction (Dormandy and Thomas, 1988).

The current uncertainty about the long term costs and consequences of arterial reconstruction and primary amputation suggest a need for a detailed assessment of the comparative costs and effectiveness of the two interventions. This paper presents the results of a study to compare proximal and distal reconstruction with primary amputation, within a decision theoretic framework. The study used retrospective data on all patients receiving vascular surgery for critical limb ischaemia at a London hospital. The database included information on the type of procedure and graft used, indications for surgery and levels of patient mobility and independence before and after surgery. In addition, detailed data on the use of hospital resources and community based services were available. The availability of an extensive data set meant that it was possible to evaluate the long term costs and outcomes of the alternative procedures and the relative impact of variables such as graft patency rates on the success or failure of arterial reconstruction.

METHODS AND DATA

Study questions

The aims of the study were to assess the relative cost effectiveness of reconstruction and primary amputation, and to determine minimum graft patency rates at which arterial reconstruction would be of equal cost to primary amputation.

The study measured clinical outcomes (graft patency rates, number of secondary amputations and survival), the level of mobility and independence of the patient at discharge and follow up and the resources used for each procedure. Patient outcomes were combined with average life expectancy to estimate the number of years gained with full or limited mobility and independence. In addition, mobility and independence levels were combined with average life expectancy and health status utility weights to estimate the number of quality adjusted life years gained by each alternative (Gudex and Kind, 1988; Drummond, Stoddart and Torrance, 1987). The resource implications of reconstruction and amputation included both immediate resource utilization for the operation and clinical follow up, and the longer term costs of rehabilitation and social support.

Costs of procedures were estimated by multiplying the amount of resources used by their unit costs. The outcome and cost data were then combined with probability data to calculate the expected costs and outcomes of arterial reconstruction and amputation.

Analytic framework

The framework of clinical decision analysis was used to assess the relative cost effectiveness of distal and proximal reconstructions versus primary amputation. A simplified version of the decision tree is shown in figure 1. Decision nodes are represented by boxes and chance nodes by circles. The flows are from left to right and the probabilities at any chance node sum to unity (Weinstein and Fineberg, 1980).

The analysis starts at the point when a patient has critical ischaemia of the leg. For patients with critical ischaemia the choice is between reconstruction of the artery or amputation of the limb (decision node A). (If the limb has not reached the critically ischaemic stage, other treatment options include chemotherapy, such as IV Naftidrofuryl, or less invasive surgical techniques such as angioplasty to improve blood flow through the affected vessels.) If reconstruction is chosen there is a chance that the graft will succeed or fail (chance node B). If the graft succeeds then there is a probability that the patient develops ischaemia in the second leg (chance node C). In this case it is assumed that the leg will either be amputated or arterial reconstruction will be attempted (chance node D). If the patient does not develop ischaemia in the second leg, there are assumed to be five possible outcomes: fully mobile and independent; limited mobility and independent; limited mobility and dependent; limited mobility only with a wheelchair and dependent and lastly, confined to bed (chance node E).

If however, the initial reconstruction fails, there are assumed to be three possible occurrences, one or more attempts to revise the graft, amputation or no further treatment (chance node F). If the patient receives no further treatment or has the limb amputated then there is a chance that they will have second leg ischaemia or not as above.

If the failed graft is revised then there is a chance that the revision will either succeed or fail. If the revision succeeds then the path of events is the same as that for a successful reconstruction. If revisions of the graft fail then the limb will either be amputated or no further treatment will be given. The sequence of events and final outcome will then depend upon whether the patient develops second leg ischaemia or not.

If primary amputation is chosen (decision node A), the amputation could be above or below the knee (chance node G). Again the sequence of events following amputation will depend upon whether the patient develops critical ischaemia in the second leg.

Whichever path is chosen, it is assumed that the sequence of subsequent events will take place within one year of the initial surgical intervention. The further assumption is made that all patients will also reach their final mobility and independence levels within this time period.

Data sources

The main source of data to estimate the probability of events occurring was a retrospective study of patients undergoing vascular surgery at St. Mary's Hospital, London, between 1985 and 1989. During this period complete records with at least one year follow up were available for 337 patients. The data included pre admission demographic and clinical status of patients; type of surgical procedure and graft; number of revisions and secondary amputations; pre operative, intra operative and post operative investigations; blood products used; concomitant or post operative medication; length of operation; professional staff time; length of inpatient stay for surgical procedures and length of inpatient stay for rehabilitation following amputation. In addition data were collected about method of discharge; the setting patients were discharged to; use of social support services and level of mobility and independence.

Information about the use of rehabilitation services, occupational therapy, home adaptations and walking aids, and supply and fitting of prostheses were collected by interview with the professional staff involved.

Sensitivity analysis

The base case estimates used to calculate expected costs and outcomes were calculated as the average (mean) values of the clinical and resource use variables in the retrospective study and published literature. Conservative assumptions in favour of primary amputation were used throughout. However, because of the problems of generalizing the results of an evaluation based on retrospective data, collected in one clinical setting, the evaluation also included a sensitivity analysis. By varying the values of key probability, cost, survival and health status utility parameters it was possible to assess their impact on the expected costs and outcomes of arterial reconstruction and primary amputation.

Minimum and maximum values for the probability estimates were generated from clinical and outcome data collected in the retrospective study and published literature where available. Minimum and maximum values for the cost estimates were derived from differences in resource use found in the retrospective study and from unit cost variations in the national data sources.

Threshold analysis

Threshold analysis was used to estimate the minimum values of key parameters at which the costs of arterial reconstruction and primary amputation would be equal. The parameters for threshold analysis were determined by the results of the sensitivity analysis.

The results of the sensitivity and threshold analyses could then be used to develop guidelines for the management of critical leg ischaemia in different settings, and to identify the key parameters which would affect the relative cost effectiveness of arterial reconstruction and primary amputation in other locations.

RESULTS

Demographic and clinical characteristics

Table 1 presents some of the demographic and clinical characteristics of patients followed in the retrospective study. The average age of patients was 60 years for the arterial reconstruction group and 63 years for those having primary amputation. Between 29% and 32% of those having arterial reconstruction lived alone, compared to 20% of those people having primary amputation. Most of the people in each study group were retired (72%-83%), although fewer people undergoing distal reconstruction were employed (12%) compared to proximal reconstruction (25%) and primary amputation (20%). A small percentage (4%-7%) of those having arterial reconstruction required some support from social services, compared to nearly half of those having primary amputation. Only 3% of the arterial reconstruction group and 9% of those undergoing primary amputation had full mobility before surgery. More of those having primary amputation had diabetes (25%), than those undergoing arterial reconstruction (12%). However, the proportions of those having other risk factors for atheroma, myocardial ischaemia or extracranial disease were similar in the two groups.

Probability of clinical events

The probability of events occurring are shown in Table 2 and on Figure 1. The graft patency rates of initial arterial reconstruction and revision following graft failure varied considerably between distal and proximal procedures. The probabilities of graft failure for distal reconstructions were 0.72 for the initial graft and 0.54 for graft revisions. In comparison the probabilities of graft failure for proximal reconstructions were 0.43 and 0.19 respectively. The probabilities that a failed graft would be revised were similar for both distal and proximal reconstruction (0.67 and 0.68 respectively). Patients were more likely to have a secondary amputation following failure of a distal graft (0.31) than after the failure of a proximal reconstruction (0.23). However secondary amputation following the failure of revised grafts was more likely for proximal grafts (1.00) than for distal grafts (0.89).

The probabilities of above and below knee amputation were roughly equal at 0.45 (above knee) and 0.55 (below knee). There was insufficient data to estimate the probability of revisions to the primary amputation. The conservative assumption was made that there would be no revisions to the stump. Of those having primary or secondary amputation the probability of them being fitted with a prosthesis was calculated to be 0.83.

It was estimated that the probability of second leg ischaemia would be the same for those people having primary amputation as for those having arterial reconstruction (0.14). This is a conservative estimate in favour of primary amputation. Although the rates of secondary leg ischaemia were equal in this study, evidence from other studies suggests that people having primary amputation have a poorer prognosis (Dormandy and Thomas, 1988). If this is the case then it may be expected that the probability of second leg ischaemia in these people would be higher than for those undergoing arterial reconstruction. For those having second leg ischaemia it was estimated that no one would have the second leg amputated as a primary procedure.

Probability of outcome: mobility and independence

Table 3 gives details of the likelihood of different mobility and independence levels following successful reconstruction (including successful revision of a failed graft), reconstruction followed by secondary amputation and primary amputation. As might be expected the outcome of successful reconstruction was better than that of reconstruction followed by amputation or primary amputation. There were also differences in outcome between primary amputation and secondary amputation following failed reconstruction. However, the assumption was made that the outcome of primary amputation would be the same as that of secondary amputation when calculating the expected costs and outcomes. This was due to the small sample size of the primary amputation group, and the likelihood that this group had a worse prognosis.

The probabilities of full mobility and independence for successful reconstruction were 0.65 (proximal) and 0.79 (distal) compared to 0.05 (above knee) and 0.09 (below knee) for amputation. Between 21% (distal) and 30% (proximal) of patients with a successful reconstruction had limited mobility and were independent. The corresponding figures for amputation were 29% (above knee) and 41% (below knee).

Following successful reconstruction the probabilities of a limited mobility and dependent outcome or being confined to a wheelchair were very low, (0 distal and 0.01 - 0.04 proximal reconstructions. In comparison, the probabilities of limited mobility and dependence for people with amputations were 0.33 (above knee) and 0.23 (below knee). Furthermore, the probability of confinement to wheelchair was 0.33 (above knee) and 0.27 (below knee) for amputations. None of the patients were confined to bed following successful reconstruction or primary and secondary amputation.

Full follow up data on length of survival was not available from the study. Therefore, average life expectancy was conservatively assumed to be 3 years for the base case with a range of 1 to 5 years for the sensitivity analysis.

Resource utilization

Details of the resources used for arterial reconstruction and amputation are given in Table 4. Table 5 presents the resource use for revision of failed grafts.

The resources used for arterial reconstruction varied between distal and proximal grafts. The main differences were in hospital length of stay (21 days distal graft, 16 days proximal graft), and length of operation, (4 hours distal graft, 3 hours proximal graft). The average number of revisions, for those patients having revision following a failed graft, were higher for proximal (1.58) than for distal grafts (1.31).

The main differences in resource use between reconstruction or revision and amputation were length of inpatient stay, length of operation and use of rehabilitation services (Table 5). The average length of hospital stay on a general surgical ward following amputation was 42 days (Table 4). In addition, 24% of patients were discharged to a rehabilitation ward or unit. The average length of stay for this subgroup of amputation patients was 130 days. All of those patients who had a leg amputated received occupational therapy (10.25 hours) and equipment such as bathboards, bathseats and kitchen aids. The majority of people (83%) were fitted and supplied with a prosthesis following primary or secondary amputation.

In addition long term resource use according to mobility outcome was estimated. The main service use was by people with limited mobility who were also dependent and by people confined to a wheelchair. Nearly one third of those with limited mobility used home help services (30%) compared to over half (55%) of those confined to a wheelchair. In addition those confined to a wheelchair had modifications to their home (20%) or were rehoused (20%).

Cost estimates

Details of the unit costs of preoperative investigations, operation and follow up for arterial reconstruction, revision, amputation and follow up are given in Table 6.

The total cost of preoperative investigations, operation, inpatient stay and post operative follow up was £3449.00 per person for distal reconstructions and £2825.00 per person for proximal grafts (Table 7). The additional costs of revisions for those people with a failed graft were £4634 per person for revision of a distal graft and £3539 per person for revision of a proximal graft. The total costs of amputation were higher (£7434.00 per person) than for arterial reconstruction.

The annual long term costs of different levels of mobility ranged from £81.00 per person with full mobility/ independent to £1195.00 per person confined to a wheelchair (Figure 1).

Expected costs and outcomes

Table 8 presents the expected costs and outcomes per person of arterial reconstruction and primary amputation. The expected cost of arterial reconstruction ranged from £6590 per person for proximal grafts to £11000 per person for distal grafts. These included the costs of revision of failed grafts, secondary amputation and treatment of ischaemia of the second leg. Combining patient outcome with average life expectancy gave an expected gain of 2.61 years per person with full or limited mobility and independence for proximal grafts or 2.26 years per person for distal grafts. The number of quality adjusted life years gained per person was 2.96 (using the distress disability matrix) for proximal grafts and 2.92 for distal grafts.

The expected cost of primary amputation ranged from £10,400 to £10,850 per person with a gain of 1.26 years per person at full or limited mobility and independence or 2.82 quality adjusted life years per person. The variation in expected costs depended on whether the person had distal or proximal reconstruction following second leg ischaemia. Arterial reconstruction using proximal grafts resulted in a net saving of £3791 per person over amputation with a net gain of 0.14 quality adjusted life years per person. In contrast, distal reconstruction was associated with a net cost of £143 per person compared to amputation, with a net gain of 0.10 quality adjusted life years per person. The net cost per quality adjusted life year gained by distal reconstruction was £1430.

Sensitivity analysis

The expected costs and outcomes were recalculated using minimum and maximum values for each of the cost and probability estimates in turn. The results for proximal grafts compared to primary amputation were not sensitive to changes in any of the parameters. That is, proximal reconstruction showed a net saving over primary amputation under different assumptions about the likely value of each cost and probability variable. However the results for distal grafts were sensitive to changes in the costs of amputation, reconstruction and revision of failed grafts and the probability of graft patency. If the costs of amputation were assumed to be higher than assumed in the base case (due to a longer length of stay) there would be a net saving associated with distal reconstruction of £3027 per person (Table 9). Under the assumption that the costs of reconstruction, revision and amputation were all lower than estimated in the base case, (using lower costs per inpatient day), then the net saving of distal grafts would be £122 per person. Changing the probability that the first graft failed from 0.72 to 0.52 gives a net saving for distal reconstruction of £1505 per person. If the failure rate of graft revisions is reduced to 0.34 then there would be net savings of £675 per person associated with distal grafts.

Additionally, the sensitivity of the results to the health utility weights used was tested. Although using the multi attribute health utility rating scale reduced the quality adjusted years gained by each alternative, the overall ordering of the results was not affected (Table 8, Table 11).

Finally, the expected costs and outcomes were recalculated using different assumptions about average life expectancy. Again, only the expected costs and outcomes of distal reconstructions were sensitive to changes in this parameter (Table 9). Assuming a life expectancy of only 1 year meant that the expected cost of distal reconstruction was £806 per person higher than primary amputation, with a corresponding gain in quality adjusted life years of 0.03, or 11 days. This gave a net cost per quality adjusted life year gained of £23805 per person. In contrast, assuming an average life expectancy of 5 years resulted in an expected saving of £563 associated with distal reconstruction compared to primary amputation. This was due to the lower levels of mobility and correspondingly higher long term costs of care and support for the primary amputation group.

However, the results were not sensitive to the assumption that a higher percentage of those people having primary amputation (10%) died in the first year following the initial intervention, than those people undergoing arterial reconstruction (4%).

Threshold analysis

Threshold analysis was used to determine the maximum failure rates of initial and revised grafts at which the costs and outcomes of arterial reconstruction and amputation would be equal. The results of the threshold analysis are presented in Table 10. For proximal reconstruction, there were no threshold values for the initial graft failure rate, when base case assumptions for the probability of graft revision failure were used. If it were assumed that the failure rate of revised grafts were substantially higher (49%), then the threshold value for initial graft failure would be 87%. That is, if 87% of initial grafts and 49% of graft revisions failed, then the expected costs of proximal arterial reconstruction and primary amputation would be equal.

For distal grafts, the threshold value for the initial graft holding the graft revision failure rate constant was 0.70, slightly lower than that used in the base case. Table 10 also gives the results of a stepwise threshold analysis. Using this analysis the rates of graft revision failure were varied and the maximum failure rates for the initial graft were calculated.

CONCLUSIONS

Under base case assumptions, proximal arterial reconstruction was cost effective compared to primary amputation and distal reconstruction was cost neutral. Both methods of arterial reconstruction showed a net improvement in mobility and dependency outcomes. This resulted in a small net gain in estimated quality adjusted health years. Sensitivity analysis was undertaken to explore the impact on the results of differences in the values of key parameters (eg graft failure rates and resource costs) that might occur in alternative settings. The sensitivity analysis indicated that distal reconstruction would be associated with net savings under different assumptions about graft failure rates, and the resource costs of amputation. However, the expected costs and outcomes of proximal reconstruction were not sensitive to changes in any of the parameters.

In addition, conservative assumptions in favour of primary amputation were used throughout the analysis. These included the use of lower estimates of inpatient stay for the operation and rehabilitation and higher estimates of the probability that patients would have full or limited mobility and be independent. These conservative estimates were based on the results found for people having secondary amputation, who had a higher probability of full or limited mobility than those having primary amputation. The group undergoing secondary amputation had a higher sample size, and may have had a better prognosis than the primary amputation group. Furthermore, it was assumed that the one year mortality rates were equal between those having primary amputation and those people undergoing arterial reconstruction. The literature suggests that the one year mortality rate associated with primary amputation may be more than twice that of arterial reconstruction.

Nonetheless, the expected costs and outcomes reported in this paper were based on data from a retrospective study of vascular surgery in one hospital, where the surgeons favoured arterial reconstruction wherever possible. Out of 337 cases, only 11 people had primary amputation. This means that vascular practice and the results of this study may not be representative of the costs and outcomes that could be expected in other settings. Factors which affect the generalisability of results to other localities include: patient case mix and severity of disease; graft failure rates; the management and rehabilitation of amputees and the availability of modern rehabilitation services for those having amputation. There is some evidence to suggest that aggressive and intensive management of amputation can result in better mobility and independence at lower costs (Aristides, 1989).

The probability of full mobility and independence following amputation calculated in this study was at the lower end of the range reported in the literature. However, the proportion of people with limited mobility following amputation in this study was higher than that found in previous studies. Furthermore the proportion of people confined to a wheelchair or bed was lower than that reported elsewhere (Dormandy and Thomas, 1988). Additionally, sensitivity analysis of the probability of different mobility rates following amputation indicated that even if 80% of those having amputation had limited or full mobility following the operation, there would still be a net saving associated with proximal reconstruction and a gain in quality adjusted life years. There would be a net cost associated with distal reconstruction of £428 per person, with a net gain in quality adjusted life years of 0.09. This would give a cost per quality adjusted life year of £4755.

The sensitivity analysis indicated that graft patency rates were a key determinant of the expected costs and outcomes of arterial reconstruction, particularly distal reconstruction. Threshold analysis was used to determine the combination of graft patency rates for the initial procedure and subsequent revisions at which the expected costs and outcomes associated with arterial reconstruction would be equal to those of primary amputation. This gives some indication of the range of graft patency rates at which arterial reconstruction would be a relevant option to consider in terms of costs and mobility outcomes. The analysis indicated that the failure rates of initial and revised grafts would have to be substantially higher than those assumed in the analysis before the costs of proximal reconstruction would be as high as those of primary amputation. Indeed, if it were assumed that the failure rate of revised grafts was 20%, then the failure rate of the initial graft could be as high as 100% and still lead to small net savings and an increase in mobility levels associated with proximal grafts.

The threshold value for the failure rate of initial distal grafts was slightly lower than that used in the base case. However there was still a net gain in quality adjusted life years associated with distal grafts.

The threshold and sensitivity analyses, combined with the use of conservative assumptions throughout suggest that the results of the study presented here are robust, and can be used to determine guidelines for vascular practice in other settings. In particular, the results suggest that there is no economic argument against proximal reconstruction. Whether distal reconstruction should be attempted will depend on the probability of graft failure in different settings. However, even if the graft failure rate is as high as that used in this study, distal reconstruction may still be a relevant option. This will depend upon the value attached to the small gains in mobility and independence associated with distal reconstruction compared to the small net cost of the procedure. Furthermore, the decision theoretic model presented in this paper can be adapted to other hospitals to assess the expected costs and outcomes of arterial reconstruction and primary amputation in different situations.

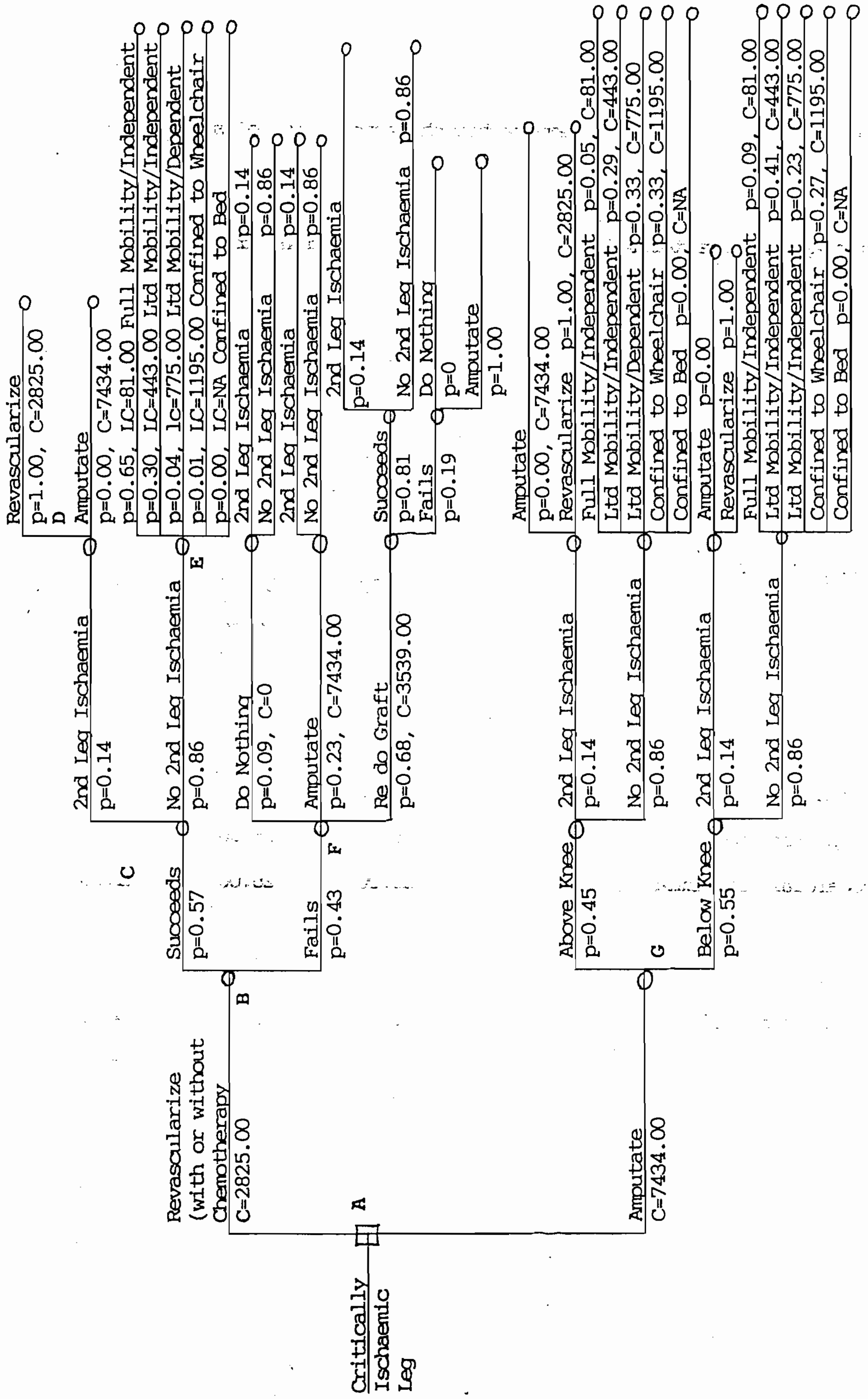
Critically Ischaemic Leg
A
Revascularize (with or without Chemotherapy
C=2825.00
Amputate
C=7434.00
B
Succeeds
p=0.57
Fails
p=0.43
C
2nd Leg Ischaemia
p=0.14
No 2nd Leg Ischaemia
p=0.86
D
Revascularize
p=1.00, C=2825.00
Amputate
p=0.00, C=7434.00
E
p=0.65, LC=81.00 Full Mobility/Independent
p=0.30, LC=443.00 Ltd Mobility/Independent
p=0.04, LC=775.00 Ltd Mobility/Dependent
p=0.01, LC=1195.00 Confined to Wheelchair
p=0.00, LC=NA Confined to Bed
F
Do Nothing
p=0.09, C=0
2nd Leg Ischaemia p=0.14
No 2nd Leg Ischaemia p=0.86
Amputate
p=0.23, C=7434.00
2nd Leg Ischaemia p=0.14
No 2nd Leg Ischaemia p=0.86
Re do Graft
p=0.68, C=3539.00
Succeeds
p=0.81
2nd Leg Ischaemia
p=0.14
No 2nd Leg Ischaemia p=0.86
Fails
p=0.19
Do Nothing
p=0
Amputate
p=1.00
G
Above Knee
p=0.45
2nd Leg Ischaemia
p=0.14
Amputate
p=0.00, C=7434.00
Revascularize p=1.00, C=2825.00
No 2nd Leg Ischaemia
p=0.86
Full Mobility/Independent p=0.05, C=81.00
Ltd Mobility/Independent p=0.29, C=443.00
Ltd Mobility/Dependent p=0.33, C=775.00
Confined to Wheelchair p=0.33, C=1195.00
Confined to Bed p=0.00, C=NA
Below Knee
p=0.55
2nd Leg Ischaemia
p=0.14
Amputate p=0.00
Revascularize p=1.00
No 2nd Leg Ischaemia
p=0.86
Full Mobility/Independent p=0.09, C=81.00
Ltd Mobility/Independent p=0.41, C=443.00
Ltd Mobility/Independent p=0.23, C=775.00
Confined to Wheelchair p=0.27, C=1195.00
Confined to Bed p=0.00, C=NA

Table 1 **Demographic characteristics of study group**

Demographic characteristic	**Patient group**		
	Distal graft n=72 %	Proximal graft n=254 %	Primary amputation n=11 %
Age	60.20	60.20	63.10
Living alone	31.88	29.53	20.00
Employment status			
- employed	11.59	25.38	20.00
- retired	82.61	71.54	80.00
- unemployed	5.80	3.08	0.00
Requires social services	8.69	3.94	40.00
Risk factors for atheroma			
- diabetes	12.00	12.00	25.00
- hyperlipidaemia			
- smoking	65.00	65.00	62.00
- family history			
- hypertension	38.00	38.00	37.00
Myocardial ischaemia	26.00	26.00	21.00
Extracranial disease	8.00	8.00	4.00
Mobility			
- fully mobile	2.82	2.66	9.09
- limited mobility	45.07	60.08	54.54
- confined to wheelchair	50.70	37.26	18.18
- confined to bed	1.41	0.00	18.18

Table 2 Probability of events: arterial reconstruction

Event	Probability (range) Distal graft p=	Proximal graft p=	Amputation p=
1st graft fails	0.72[1] (0.52[2]-0.72)	0.43[1] (0.23-0.70[3])	na
Graft revision fails	0.54[1] (0.34[2]-0.72)[1]	0.19[1] (0.00-0.49)	na
Revision following 1st graft failure	0.67[1] (0.47-0.87)[1]	0.68[1] (0.40-0.80)[1]	na
Amputation following 1st graft failure	0.31[1] (0.11-0.51)[1]	0.23[1] (0.11-0.51)[1]	na
Do nothing following 1st graft failure	0.02[1]	0.09[1] no range	na
Amputation following revision graft failure	0.89[1] (0.69-1.00)[1]	1.00[1] (0.553-1.00[1])	na
Do nothing following revision graft failure	0.11[1]	0.00[1] no range	na
Above knee amputation	na	na	0.45[1] (0.24-0.69)[3]
Below knee amputation	na	na	0.55[1] (0.31-0.76)[3]
Prosthesis supplied and fitted		na	0.83[1] (0.29-0.83)[4]
Ischaemia second leg	0.14[1] (0.00-0.30)[1]	0.14[1] (0.00-0.30)[1]	0.14[1] (0.00-0.3)[1]
Arterial reconstruction of second leg	1.00[1]	1.00[1]	1.00[1]

Notes
1. Retrospective study
2. Auer et al,1983
3. Dormandy and Thomas, 1988
4. Malone et al, 1979

Table 3 **Probability of outcome: mobility and independence, arterial reconstruction and amputation**

Outcome	Probability (range)[1]			
	Successful reconstruction		Amputation	
	distal	proximal	above knee	below knee
Full mobility + independent	0.79 (0.65-0.89)	0.65 (0.55-0.79)	0.05 (0.00-0.30)[2]	0.09 (0.00-0.69)[2]
Limited mobility + independent	0.21 (0.11-0.30)	0.30 (0.21-0.40)	0.29 (0.09-0.29)[2]	0.41 (0.11-0.41)[2]
Limited mobility + dependent	0.00 (0.00-0.10)	0.04 (0.00-0.10)	0.33 (0.09-0.33)[2]	0.23 (0.11-0.41)[2]
Confined to wheelchair	0.00 (0.00-0.04)	0.01 (0.00-0.1)	0.33 (0.33-0.61)[2]	0.27 (0.19-0.27)[2]
Confined to bed	0.00 (0.00-0.05)	0.00 (0.00-0.05)	0.00 (0.00-0.05)	0.00 (0.00-0.05)

Notes
1. retrospective study
2. Dormandy and Thomas, 1988 (probabilities for full and limited mobility reduced by 30% to take account of reduced prosthesis use.)

Table 4 **Resource utilization: initial operation and follow up primary reconstruction**

Procedure	Average resource use[1]		
	Distal	Proximal	Amputation
Preoperative investigations			
- general exam	1.00	1.00	1.00[2]
- treadmill	0.34	0.34	0.00[2]
- IVDSA	0.28	0.28	0.18[2]
- IADSA	0.74	0.74	0.73[2]
- duplex	0.02	0.02	0.00[2]
Inpatient stay (days)			
- general surgical ward	21.00	15.73	42.00
- ITU	0.00	0.16	0.10
Operation (hours)	4.00	3.18	1.25
Blood products			
- FFP (units)	0.00	0.07	0.00
- Red cell concentrate (units)	0.80	1.16	1.82
- Dextran (mls)	71.54	82.06	506.41
- Haemmacel. (mls)	55.38	171.76	83.33
Intra operative investigations			
- duplex	0.00	0.01	0.16
- arteriogram	0.42	0.33	0.41
Postoperative follow up			
- general exam	0.21	0.37	0.09[2]
- treadmill	0.02	0.03	0.00[2]
- IVDSA	0.03	0.01	0.00[2]
- IADSA	0.00	0.00	0.00[2]
- duplex	0.02	0.02	0.00[2]
Rehabilitation			
- rehabilitation ward (days)			130.00
- occupational therapy (hrs)			10.25
- bathboard			1.00
- bathseat			1.00
- kitchen aids			1.00
- prosthesis			0.83

Notes
1. Retrospective study
2. Excludes secondary amputees

Table 5 Resource utilization: operation, revision of graft

Procedure	Average resource use[1]		
	Distal	Proximal	All
Average number of revisions	1.31	1.58	1.60
Inpatient stay			
- general surgical ward	33.00	24.81	25.01
- ITU	0.09	0.11	0.10
Operation (hours)	3.67	2.03	2.35
Blood products			
- FFP (units)	0.00	0.07	0.06
- Red cell concentrate (units)	0.87	0.94	0.93
- Dextran (mls)	184.78	157.22	162.50
- Haemmacel. (mls)	86.96	146.91	135.42

Notes
1. Retrospective study

Table 6 **Unit costs of resources: 1988/89**

Procedure/item	Unit cost (£'s)
Inpatient stay 'hotel' cost/day	
- general surgical ward	61.23[1] (38.38-94.88)[2]
- rehabilitation ward	65.00[3] (50.00-117.00)[2]
- ITU	330.00[4]
Staff/hour	
- consultant surgeon/anaesthetist	21.26[5]
- senior registrar	12.13[5]
- registrar	10.00[5]
- senior house officer	9.09[5]
- sister	7.55[6]
- state registered nurse	5.81[6]
- state enrolled nurse	5.03[6]
- paramedical professions	5.40[7]
- home help	4.46[8]
Operating theatre + recovery room/hour	297.00[4]
Operating theatre supplies/operation	63.00[4]
Blood products	
- FFP/unit	12.00[9]
- red cell concentrate/unit	14.00[9]
- dextran/500 mls	4.50[9]
- haemaccel/500 mls	3.80[9]
- haematology staff/operation	12.00[10]
Prosthesis	2500.00[11]

Notes
1. DHSS performance indicators, 1984, converted to 1989 prices using NAHA inflator, NAHA, 1990
2. CIPFA, 1989
3. Based on staffing and hotel service costs of a rehabilitation ward
4. Nuffield Hospital, 1989
5. Wilkins, 1989
6. Cleminson, 1989a
7. Cleminson, 1989b
8. Davies et al., 1990
9. Blood transfusion service charges
10. Knill Jones et al, 1990
11. Aristides, 1989.

Table 7 **Costs of arterial reconstruction: initial operation and follow up, 1988/89**

Procedure	Average cost per person				
	Distal		Proximal		Amputation
	1st graft	revision	1st graft	revision	
Pre operative investigations	43.00	0.00	43.00	0.00	34.00
Operation	2118.00	2583.00	1764.00	1984.00	570.00
Post operative investigations and follow up	2.00	0.00	2.00	0.00	0.00
Inpatient stay	1286.00	2051.00	1016.00	1564.00	2605.00
Rehabilitation					
- inpatient stay	na	na	na	na	2028.00
- equipment/OT	na	na	na	na	122.00
Prosthesis	na	na	na	na	2075.00
TOTAL	3449.00	4634.00	2825.00	3539.00	7434.00

Table 8 **Expected costs and outcomes per person of arterial reconstruction and primary amputation**

Procedure	Expected cost per person	Expected years at full/ltd mobility independent	Expected QALY's distress/ disability matrix	MAU health state
Distal reconstruction	10996.00	2.26	2.92	1.87
Proximal reconstruction	6590.00	2.61	2.96	2.08
All reconstruction	7743.00	2.45	2.94	1.98
Primary amputation				
- distal graft, 2nd leg	10853.00	1.26	2.82	1.23
- proximal graft, 2nd leg	10381.00	1.26	2.82	1.23
- all grafts, 2nd leg	10470.00	1.26	2.82	1.23

Table 9 **Sensitivity analysis: distal reconstruction**

Parameter	Net saving (cost)/person	QALY's gained/person
Cost of amputation = 12306	3027	0.10
Cost of graft = 2699 and cost of revision = 3880, cost of amputation = 6011	122	0.10
Probability 1st graft fails = 0.52	1505	0.12
Probability revision fails = 0.34	675	0.12
Life expectancy = 5 years	563	0.17

Table 10 **Threshold analysis for cost equivalence of arterial reconstruction and primary amputation: graft patency**

Parameter	Joint threshold values for graft patency rates					
Distal grafts						
- 1st graft fails	0.60	0.63	0.68	0.70	0.78	0.92
and revision fails	0.80	0.72	0.60	0.54	0.40	0.20
QALY's gained = 0.09						
Cost = 10850						
Proximal grafts						
- 1st graft fails	0.69	0.81	0.79	0.87	0.92	n a
and revision fails	0.80	0.70	0.60	0.49	0.40	0.19
QALY's gained = 0.07						
Cost = 10830						
All grafts						
- 1st graft fails	0.64	0.72	0.77	0.84	0.91	0.99
and revision fails	0.80	0.60	0.50	0.40	0.30	0.20
QALY's gained = 0.08						
Cost = 10850						

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