■ 原　著　日血外会誌 13：663–666，2004

Epidemiological Aspects on Critical Limb Ischaemia in Europe

David Bergqvist

Abstract: The epidemiology of critical limb ischaemia (CLI) is presented from a European perspective. One problem in performing such a review is the various definitions used. However, there are large variations within Europe and within countries both regarding the incidence of the disease and regarding the number of arterial reconstructive procedures performed. An aggressive reconstructive approach to the problem seems to decrease the number of major amputations within the population.（J. Vasc. Surg., 13: 663–666, 2004）

Key words: Critical limb ischaemia, Vascular surgery, Europe, Epidemiology

Unfortunately critical limb ischaemia (CLI) has been defined in various ways over the years, which introduces some difficulties when comparisons are made—both temporal and geographical. In this paper we therefore have to stick to the definitions used by the various authors. From the clinical point of view, critical limb ischaemia can be defined as rest pain, ulcer and/or gangrene due to circulatory perfusion disease, arteriosclerosis being by far the dominating cause in Europe. Recent publications usually have referred to one of the definitions with a broad acceptance[1~3]. The reason is to be more specific that limb threatening ischaemia, indicating limbs, which without treatment will undergo amputation, has been considered too diffuse a definition. One difficulty in this respect is that not all patients with limb threatening ischaemia or even critical ischaemia will end up with an amputation.

This paper will deal with CLI from three aspects, all with a European perspective:

Department of Surgery, Uppsala University Hospital
（Tel: +46 18 611 46 33）
SE 751 85 Uppsala, Sweden.
Received: Aug. 16, 2004
Revision accepted: Aug. 31, 2004

- incidence
- reconstructive procedures
- the influence of arterial reconstruction on amputation within the population

Data on occurrence of critical limb ischaemia

Apart from the differences in definitions indicated above, there have been different ways to obtain data on CLI. Catalano[4] used three different approaches in a study on patients over 45 years of age in Northern Italy. Prospectively following claudicants over 7 years gave the incidence of 45 per 100,000 per year. Hospitalization for CLI in a sample of hospitals in Lombardy over a 3-month period gave the figure 65.2 and amputation for CLI 53.0 per 100,000 per year. This approach demonstrates that different incidence and interventions will be obtained depending on how the data are collected.

Figures on major amputation used to estimate the incidence of CLI data from various studies are summarized in **Table 1**. If only 25% of patients with CLI are supposed to require major amputation, the incidence of CLI can be calculated to be 50-100 per 100,000 per year. The above data from Northern Italy are well within this range. There is, however, a large variation in number of amputations among countries, with an extremely low incidence being reported from Iceland

Table 1 Number of major amputations /100,000 inhabitants/ year (due to ischaemia)

Liedberg[15]	Sweden	1983	32.0
Hoogendoorn[16]	Holland	1988	24.6
Norgren[17]	Sweden	1990	58.0
Ebskov[10]	Denmark	1994	25.0
Pell[8]	Scotland	1994	14.2
Luther[18]	Finland	1994	12.0
Myhre[19]	Norway	1995	20.0
Dormandy[20]	UK	1996	30.0
Jösson[21]	Sweden	1996	40.0

Table 2 European survey on vascular reconstructions 1999. Below-knee reconstructions per 100,000 inhabitants

	Population (million)	No. of procedures
Denmark	4.4	14.3
Finland	5.1	14.2
Sweden	8.9	12.4
Galicia, Spain	2.7	6.9
Slovakia	5.5	4.7
N. Ireland	1.7	4.5
St. Petersburg, Russia	4.5	2.6

From Paaske 2001[6]

Table 3 Interventions for CLI in Sweden (per 100,000 inhabitants and year)

County	OP	OP>65 years	%PTA
Stockholms län	20.3	143.1	25.6
Uppsala län	24.8	172.2	54.1
Södermanlands län	32.5	176.5	58.3
Östergötlands län	44.5	**251.3**	**48.9**
Jönköpings län	30.8	167.5	34.7
Kronobergs län	26.5	140.9	34.0
Kalmar län	**49.0**	241.2	33.0
Gotlands län	15.7	86.8	11.1
Blekinge län	26.8	131.5	53.8
Kristianstads län	18.6	94.0	38.9
Malmöhus län	20.3	119.2	45.7
Hallands län	27.3	154.2	47.4
Göteborgs och Bohus län	18.3	102.2	29.9
Älvsborgs län	22.4	202.0	24.7
Skaraborgs län	22.4	115.6	30.5
Värmlands län	31.1	154.1	52.9
Örebro län	11.0	59.9	50.0
Västmanlands län	34.0	191.0	42.2
Kopparbergs län	27.8	140.6	53.2
Gävleborgs län	25.3	127.0	**62.9**
Västernorrlands län	13.1	64.2	37.5
Jämtlands län	15.6	77.9	4.5
Västerbottens län	**1.8**	**8.9**	–

(43 per million according to Gislasson[5]).

The prognosis for patients with CLI is poor. According to the Transatlantic Inter-society Consensus[3] the one year fate is 20% mortality, 35% are alive but amputated and 45% are alive without amputation.

Data on reconstructive surgery due to CLI

One difficulty is that the indications for various types of procedures are not always reported. **Table 2** shows data from a European survey of vascular interventions 1999[6]. In below-knee reconstructions it is assumed that the majority are performed because of CLI and only a few because of intermittent claudication. The variations are considerable and what is even more surprising are the variations within countries, exemplified by Sweden (**Table 3**). There could be several explanations such as differences in indications, in reconstructive aggressiveness as well as in true differences in disease pattern—not only CLI but also diabetes mellitus. From various national vascular data bases it is possible to obtain detailed information. Of infrainguinal bypass procedures around 60% are performed because of CLI (**Table 4**). The 30-day postoperative mortality is around 5%.

Influence of reconstruction for CLI on the amputation rate within the population

Every vascular surgeon can report on many individual patients with CLI who have benefited from vascular reconstructions, relieving rest pain, healing their ulcers and stopping the development of gangrene. However, there are also failures, involving reconstruction, occlusion, reopening, infection, prolonged hospitalization and sad stories of prolonged suffering ending with an amputation. One epidemiological problem has been to show whether or not the amputation rate

Table 4 Indications for infrainguinal bypass reconstructions from theVascular Surgical Society of Great Britain and Ireland (n=673, 2002) and the Swedish Vascular Registry (n=3,218, 2001).

	VSGBI	Swedvasc
CLI	60%	62%
Claudication	26%	37%
Aneurysm	7%	1%
Others	7%	–
Crude 30-day mortality	5.5%	4.8%

Table 5 Effect of vascular reconstruction on amputation rate at the district hospital of Varberg, Sweden (125,000 inhabitants).[22)]

	Vascular reconstruction		Amputations	Limb salvage at 30 months
	Total	CLI		
1985–1988 (no vascular surgeon)	408	104	114	37%
1989–1992 (full-time vascular surgeon)	672	154	79	53%
Percent change	+64	+54	−44	+43

within a defined population is influenced by an aggressive reconstructive attitude in patients with CLI. As shown by Luther et al.[7)] it is important that such analyses are made on a defined population. Otherwise referral patterns may influence the results. In that study it was shown that at a university hospital an increasing number of reconstructions because of CLI did not reduce the number of amputations, which could be explained by referral of many difficult cases, whereas in a county with a stable population and only one hospital performing reconstructive surgery the increased number of reconstructions for CLI coincided with a decrease in number of amputations. This pattern has also been reported by others[8~14)]. **Table 5** shows the amputation rate in a district hospital in Sweden before and after the employment of a vascular surgeon in the hospital. From that study it could be concluded that a greater awareness and a higher reconstructive activity did decrease the number of amputations within the catchment area of the hospital.

Discussion

Europe is not a uniform entity concerning CLI. Although there are several difficulties because of various definitions and insufficient data from the different countries, there seem to be large variations in reported incidence of CLI. This is true between countries but is also obvious within countries. A similar pattern is seen regarding numbers of reconstructive procedures. Whether it is possible in the future to improve limb salvage by technical innovations (more distal reconstructions, combinations between open and endovascular treatment options, more use of microvascular techniques, combinations of invasive interventions and new pharmacological treatments, etc.) remains to be seen. In such analyses it will be increasingly more important to answer the question whether a more aggressive policy will influence the amputation rate within the population. When analysing the influence of reconstructive procedures on amputation rate and pattern it is also important to include methods to quantify the effect on health economy and quality of life. As patients with CLI have very advanced general atherosclerotic disease it is also important to take this into account and optimise pharmacological treatment, not least concerning the cardio- and cerebrovascular part of their atherosclerotic process. If and when

the survival is still shortened it is important to give patients good palliation, and that could indeed be a successful reconstruction without the need for amputation. This could mean the difference between living the remaining time of life at home or in an institution.

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