ORIGINAL ARTICLE

Does the new vascular management of acute limb ischemia have effective results with lower treatment costs

Haris Vukas[1], Samra Kadić-Vukas[2], Senad Dervišević[1], Adis Salihbegović[3], Haris Vranić[4], Muhamed Djedović[4], Amel Hadžimehmedagić[4], Dragan Totić[4]

[1] Department of Surgery, [2]Department of Neurology; Cantonal Hospital Zenica, [3]Institute of Forensic Medicine and Forensic Toxicology, School of Medicine, University of Sarajevo, [4]Clinic of Cardio-Vascular Surgery, Clinical Centre of the University of Sarajevo; Bosnia and Herzegovina

ABSTRACT

Aim To compare hospital costs of acute limb ischemia treatment in two periods of time and to show evidence of long-term repercussions on reducing costs during successful treatment.

Methods Retrospective analysis of data obtained from 100 patients' medical history in the period 2000-2016 at the Clinic of Vascular Surgery Sarajevo: group A - 60 patients with acute limb ischemia in the period 2005-2016 and group B - 40 patients with acute limb ischemia (ALI) in the period 2000-2005. From 2000 to 2005 conservative treatment method was used, invasive diagnostic and surgical procedures were often delayed for a shorter or longer period of time. During the period from 2005 to 2016, the management model and safe practice included emergency diagnostic procedures, colour-Doppler, arteriography, emergency surgery (embolectomy by Fogharty and if necessary, vascular by-pass).

Results Better health service for the patients with acute limb ischemia was offered in the period 2005-2016, which relied on proven medical treatment trends. The largest share of the total costs of each patient included costs of hospital bed with significant difference between the period 2005-2016 and 2000-2005, mean of 1398.71 KM and 2480.45KM, respectively ($p < 0.0001$), indicating rationalization of time that patients spend at the Vascular Clinic.

Conclusion This trend of money/fund savings is an example of good practice, effectiveness and efficiency in the treatment of ALI and as such was used in patients with other vascular diseases.

Key words: acute limb ischemia, cost, embolectomy by Fogharty, vascular

Corresponding author:
Haris Vukas
Department of Surgery,
Cantonal Hospital Zenica
Crkvice 76, 72000 Zenica,
Bosnia and Herzegovina
Phone: +387 32 447 000,
Fax: +387 32 447 001;
E-mail: haris.vks77@gmail.com
ORCID ID: https://orcid.org/0000-0001-5061-6661

Original submission:
01 February 2019;
Revised submission:
26 March 2019;
Accepted:
13 May 2019.
doi: 10.17392/1004-19

Med Glas (Zenica) 2019; 16(2): 265-270

INTRODUCTION

In the developed countries of the world, especially in the United States, Canada and Australia, the processes of continuous improvement of health care quality started in the middle of the last century. Developed European countries began to introduce these strategies at the end of the last century. The World Health Organization for Europe (1), the Council of Europe and the European Commission (2) are the main makers of quality health care policies. The World Bank and other development agencies influence transition countries to develop national quality health policies (3).

The definition of quality in health care can be defined as "the degree to which health care and health services increase the likelihood of positive outcomes of treatment" (1).

The basic elements on which we determine the quality of medical services are indicators and standards. The indicator is defined as measurable facts within the treatment process such as success of treatment, patient satisfaction, mortality (e.g. after procedure, after surgery), frequency of individual complications, frequency of unsatisfactory treatment outcomes, hospital stay or cost per day. Standards are the values with which we compare the indicators. According to the International Quality Standard (ISQ) (4) and the International Standards for Health Standards (5) to be considered as quality health care services must be accessible, adequate, lasting, effective, cost-effective, safe and sustainable, they have to be able to provide them with competent, full-scale understanding. The content of standards to measure the quality of health services must be based on the stated quality dimensions, besides that the standards must contribute to the improvement of the quality and performance of patient care in health care institutions and the wider health care system they must be established with the support of management and infrastructure in the institution. The quality management system is described in the ISO 9001: 2000 standard (4). Applying this standard to a flexible system such as healthcare generally implies standardization of everyday common practices just as they are performed on a daily basis. In the overview of population studies, the incidence of acute limbs ischemia (ALI) was estimated to range from 4 to 17/100,000 (6). It is estimated that 10-20% of the vascular surgeon's practice in larger centres includes ALI treatment, the largest number being patients older than 70 years of age (6). The Swedish National Database reports that the most common cause of ALI was dominated by embolism, in 63% of cases, in the period 1987-1990, with mild drop in frequency up to 54% in the period 1991-1995 (6).

According to the ethiopathogenesis, embolism can be cardio-arterial and non-cardiac (7). Cardio-arterial embolism: atrial and ventricular (antechamber and chambers) embolus can occur in otherwise normal arteries. The most common cause is atrial fibrillation as a result of irregular contractions of the atrium and the ventricle (consequently with bloodstream in the left atrium resulting in thrombotic formation) (7). Mural thrombus, as a result of myocardial infarction or left ventricular aneurysm, is a particularly dangerous cause of embolism because the patient does not only have an ischemic endangered extremity but a high risk cardiovascular condition (8-11). Paradox embolus occurs when the clot from vein system, usually from deep venous thrombosis, travels through interseptal cardiac defect into the arterial system. A clinical sign is acute ischemia of the extremity in patients with deep vein thrombosis (12). Cardiac tumour, e. g. atrial myxoma, is a benign tumour of the left atrium that could be fragmented while increasing. Non-cardiac embolism includes atheroembolism in patients with extensive atherosclerotic aortic arch or descent thoracic aorta. Aortic mural thrombus, occasionally, in patients with hypercoagulable conditions, develops without pathological changes on the aortic wall (13). Acute arterial thrombosis usually occurs in the arteries with extensive atherosclerotic changes, with almost complete obliteration of lumen (7).

The aim of the study was to investigate positive outcome and contribution of newly-established management models, safe practices and protocols for patient treatment of acute limb ischemia comparing to the previous concept and its economic justification.

This type of study had never been performed in Bosnia and Herzegovina except once (14).

PATIENTS AND METHODS

Patients and study design

The retrospective, descriptive-analytical, comparative, randomized study was conducted at the Clinic of Vascular Surgery (CVS) of the Clinical Centre of the University of Sarajevo (CCUS) and included 100 patients. Medical records of patients from the period 2000-2016 were analysed in two periods: Group A - 60 patients with acute limb ischemia in the period from 2005 to 2016 (emergency non-invasive diagnostic procedure and surgical intervention) and Group B - 40 patients with acute limb ischemia in the period from 2000 to 2005 (time-delayed non-invasive and invasive diagnostic and treatment procedures). The study included patients who were hospitalized at the CVS because of the acute limb ischemia, hospitalized patients with a complication of the main disease in the form of acute limb ischemia, after-operative complications in the form of acute limb ischemia, complications of acute limb ischemia, e. g. bleeding, amputation, lethal outcome. Patients excluded from the study were the ones with terminal ischemia of the extremities caused by acute limb ischemia, and patients with no conservative or surgical treatment performed.

Methods

Economic and medical evaluation analysed an outcome of patients treated in two time periods. Management model and safe management practice of ALI from 2000 to the end of 2005 consisted of time-delayed non-invasive and invasive diagnostic procedures: colour Doppler, digital subtraction angiography (DSA), computerized tomographic angiography (CTA), echocardiography of heart (EHO), continuous heparin infusion of unfractionated heparin (UFH), which required increased use of laboratory findings and coagulation factors INR, APTT, blood analysis, D-dimer, urea, creatinine and continuous vasoactive infusion of iloprost or pentoxifylline. Surgical treatment (embolectomy by Fogarty, bypass with autologous or artificial graft) was done only in cases where conservative treatment failed and ischemic changes were not irreversible or at the border between reversibly-irreversible changes. Control invasive diagnostic procedures were not performed in patients who had no improvement of the local findings after drug therapy.

Management Model and Safe Practice of ALI management from 2005 to 2013 consisted of emergency non-invasive diagnostic procedure colour Doppler review (since 2009 at the Clinic of Vascular Surgery), emergency surgical intervention, embolectomy by Fogharty (after which the patient is subjected to a colour Doppler control review), invasive diagnostic procedures - digital subtraction angiography, that often suggested the necessity of percutaneous transluminal balloon dilatation angioplasty (PTA), PTA stenting, arterial reconstruction with bypass (autologous or artificial). Types of re-intervention, complications and costs for patients who had undergone unsuccessful treatment in both groups included revascularization (embolectomy, PTA, bypass), amputation of fingers, forearms, upper arms, toes, toes, feet, underknees and lower extremities.

The survey used a valid price list of the Clinic of Vascular Surgery Sarajevo services that had not been changed for the research period. The official Bosnian Herzegovinian currency, Convertible Mark, was used to calculate the treatment costs.

Statistical analysis

The results were analysed using t-test and, $\chi 2$ test for comparison and association between the investigated groups. The degree of correlation was tested using the correlation coefficient Pearson or Spearman (according to data distribution). It applied appropriate models of regression analysis to determine the independent association of variables. Values of $p<0.05$ were considered as statistically significant

RESULTS

The medical records of 100 patients in the period from 2000 to 2016 were analysed in two periods: Group A - 60 patients with acute limb ischemia in the period from 2005 to 2016 and Group B - 40 patients with acute limb ischemia in the period from 2000 to 2005. There were 26 males and 34 females in the group A, mean age of 65.35 years (min. 38 and max. 86 years) and in the group B 18 males and 22 females with mean age of 62.97 years (min, 34, max. 82 years)

There was significant difference between mean of hospitalization days of group A vs group B,

11.23 vs 20.85 days, and mean time that spent in admission-revascularization in group A vs group B, 2.31 vs 3.32 (Table 1).

Table 1. Hospitalization, first symptoms-hospital admission and admission-revascularization period of 100 patients with acute limb ischemia

Group (period)	Variable	Min.	Max.	Mean	SD
A (2005-2016) (N=60)	Hospitalization (days)	1.0	30.0	11.23	6.54
	First symptoms- hospital admission (hours)	0.0	110.0	28.93	34.07
	Hospital admission -revascularization (hours)	0.0	8.0	2.31	1.48
B (2000-2005) (N=40)	Hospitalization (days)	1.0	90.0	20.85	17.49
	First symptoms - admission (hours)	0.0	216.0	35.22	51.41
	Admission-revascularization (hours)	0.0	12.0	3.32	2.93

There was no significant difference between groups in comorbidity (Table 2).

Table 2. Comorbidity frequency of 100 patients with acute limb ischemia

Comorbidity	No (%) of patients in the group (period)	
	Group A (2005-2016) (N= 60)	**Group B** (2000-2005) (N= 40)
Diabetes	16 (26.7)	5 (12.5)
Myocardial infarction in hospital	3 (5)	1 (2.5)
After myocardial infarction	10 (16.7)	20 (50)
Cardiac arrhythmia	41 (68.3)	30 (75)
Condition after coronary bypass	0	1 (2.5)
Cardiac Pace maker	0	1 (2.5)
Cardiac Failure	36 (60)	32 (80)
Compensated heart	50 (83.3)	29 (72.5)
Decompensated heart	5 (8.3)	7 (17.5)
Arterial hypertension	58 (96.7)	32 (80)
State after stroke	8 (13.3)	8 (20)
Stroke in hospital	3 (5)	1 (2.5)
Paraplegia (on admission)	3 (5)	0
Quadriplegia (on admission)	0	1 (2.5)
Verified cancer	7 (11.7)	3 (7.5)

T-test for independent samples of colour Doppler exams between the groups showed that there was a statistically significant difference between the cost (in KM) of colour Doppler group A, mean= 60.8, and group B, mean= 4.8 ($p<0.0001$).

Cost difference in DSA after surgery was found statistically significant between group A (mean=331.73, SD=312.72) and group B (mean=31.25, SD=137.25); t=5.71; $p<0.0001$ and after surgery CTA between group A (mean=21.08, SD=70.51) and group B (mean=12.00, SD=0.00); t=2.31; p=0.02 (significant), which explains the change in the safety management model of AIE. The newly introduced method allowed to confirm the success of performed surgery in a short period and the need for further vascular surgical treatment.

There was significantly more use of LMWH in group A and pentoxifilin infusions in group B during hospitalization (Table 3).

Table 3. Acute limb ischemia drug therapy cost

Treatment	Mean cost at the group (period) (KM)		p
	A (2005-2016)	**B** (2000-2005)	
UFH	0.30	5.85	0.000
LMWH	203.50	41.25	0.00
Coumarin derivatives	1.14	2.73	0.023
Antithrombotics	1.13	5.05	0.003
Iloprost infusion	23.33	0.00	0.310
Pentoxifilin infusion	3.00	80.25	0.000

UFH, unfractionated heparin; LMWH, low molecular weight heparin

More performed embolectomies resulted in more cost in group A vs group B (523.58 vs 334.75 mean in KM) and more cost due to general endotracheal anaesthesia in group B vs group A (173.00 vs 77.85 mean in KM) (Table 4).

Table 4. Acute limb ischemia surgical procedure cost of 100 patients with acute limb ischemia

Treatment	Mean cost at the group (period) (KM)		p
	A (2005-2016)	**B** (2000-2005)	
Embolectomia by Fogharty	523.58	334.75	0.00
Vein Bypass	111.06	0.00	0.025
Dacron Bypass	57.01	0.00	1.00
Therapy with blood derivatives	2.80	2.80	1.00
General endotracheal anaesthesia (GET)	77.85	173.00	0.00
GET preparation	88.65	197.00	0.00
Local anaesthesia	17.56	0.42	0.00
Reanimation	6.13	6.90	0.874

More hospital days in group B vs group A resulted in significant difference in costs (2480.45 vs 1398.71 mean in KM) (Table 5).

Table 5. Hospitalization cost of 100 patients with acute limb ischemia

Hospitalization	Mean cost at the group (period) (KM)		p
	A (2005-2016)	**B** (2000-2005)	
Intensive care	116.73	226.60	0.111
Semi-intensive care	28.00	204.70	0.058
Hospital department	1398.71	2480.45	0.000

Total costs of AIE hospitalization in group A: min. 1260.00 KM, max. 8473.00 KM per patient, mean=3422.36 (SD=1535.58); in group B: min. 1276.00 KM, max. 16633.00 KM, mean=4142.08 (SD=2927.39).

DISCUSSION

Compared with the management of critical limb ischemia, the investigations and treatments of

ALI have been subjected to very few economic analyses in BiH, possibly because the urgency and limited number of therapeutic options.

The study which was carried out on Vascular Institute in Sheffield has explained in details the costs of treating patients with acute limb ischemia. From the total number of acute limb ischemia, in 69% there was attempted revascularization, 13 revascularizations failed (of which 4 were completed with a fatal outcome); in 21 patients, with attempted rescue of limbs, there was a fatal outcome within one year. Percentage of limb salvage was 67% of the total number of patients who attempted revascularization. Total costs during the 12-month follow-up in primary amputations were far greater than the total costs from costs of attempting limb salvage with threatening ischemia. Increased costs were in direct correlation with the length of hospitalization. Attempted limb salvage costs are significantly lower in ALI caused by embolization compared to ALI as exacerbation of CLI. There were no significant differences in the cost of treatment in patients with ALI who had undergone surgical or endovascular treatment. Unsuccessful revascularization significantly increased the total cost of the treatment even above the total costs of primary amputation. The largest single factor in the cost of treatment was the length of hospitalization, which was often extended due to slow rehabilitation or delayed because of inadequate patient's home conditions and support. Reducing the cost of treatment can be achieved by transferring patients to less expensive (compared to clinical treatment) rehabilitation centres. Patients who had primary surgery required fewer visits to the operating theatre than those who had primary thrombolysis, but there was no difference in the total time that the theatre or radiology suite was occupied: median 2.3 (10th centile range 1.5-5.0) h and 3.0 (2.0-5.0) h respectively. Median (range) cost of disposables for performing surgery was 82.00 pounds (58.00-169.00) and for thrombolysis was 407.00 pounds (252.00-596.00). When the costs of using the theatre or radiology suite were included, the costs of both treatments were similar: surgery 683.00 pounds (309.00-1438.00) and lysis 861.00 pounds (611.00-1244.00). Median (10th centile range) inpatient stay for surgical patients was 9 (3-18) days and for those having thrombolysis 11 (2-29) days. Median (10th centile range) costs for bed occupancy were similar in both groups: surgery 2497.00 pounds (643.00-9.115.00) and lysis 2.189.00 pounds (902.00-6.020.00). Mean cost for attempting limb salvage by surgery was 3.429.00 pounds (1.094.00-10.065.00) compared with 3.230.00 pounds (1.543.00-8.353.00) for thrombolysis (15,16)

Lurie et al. found in 205 patients treated with catheter directed thrombolysis (CDT) alone, with angioplasty, open surgery, endovascular and with hybrid procedures no significant difference was found in clinical outcome among the groups, reintervention rates during hospital stay, readmission rates, and costs were highest in the CDT group. Reintervention was required in 62% of patients after CDT compared with 7% after open surgery, and 16% of the CDT patients needed more than one reintervention. The mean total hospital cost was $34.800.00 per patient in CDT group compared with $10.677.00 in open surgery group (17). Comparing with the price list which is valid at the Sarajevo Cardiovascular Clinic (CCUS), we can notice a huge difference in the price list of services. It is also noticeable that the services that are charged in the World Vascular Centres in B&H are conducted as part of the daily duties of medical personnel (e. g. recovery, operation blocks, etc.).

In the light of new procedures the study that was performed in four ProMedica community hospitals in the Northwest Ohio from January 2009 to December 2012 showed that total costs per patient were $17.163.47 after surgery, $20.620.39 after endovascular, $21.277.61 after hybrid, and $30.675.42 after catheter directed thrombolysis, suggesting that in comparison with other available alternatives, endovascular treatment is cost-effective in healthcare resources (18).

We emphasize that although ultrasound of the heart was indicated, it was not performed during hospitalization at the CVS, among other things, due to limited resources of the Clinical Centre of the University of Sarajevo in a given moment, immobility of patients, or short time of hospitalization. However, all patients after discharge from the CVS had a recommendation to contact relevant specialists of cardiology in order to have ultrasound examinations of the heart and obtain further correcting cardiac therapy.

If we look at the overall picture of improving management models, safe practices economic rationalizations, we concluded that in the period of 2005 to 2016 better health service were offered to the patients relying on medically proven trends of ALI treatment. While we should not forget responsibility towards the entire society which provides funding, improving medical treatment and lifelong education of medical staff is crucial for quality health care.

FUNDING

No specific funding was received for this study

TRANSPARANCY DECLARATION

Competing interest: None to declare.

REFERENCES

1. World Health Organization for Europe. Health 2020: the European policy for health and well-being. http://www.euro.who.int/en/home (24 March 2019)
2. European Union. Supporting public health in Europe. https://europa.eu/european-union/topics/health_en (24 March 2019)
3. Syed SB, Leatherman S, Mensah-Abrampah N, Neilson M, Kelley E. Improving the quality of health care across the health system. Bull World Health Organ 2018; 96:799.
4. International Organization for Standardization. https://www.iso.org/home.html (24 March 2019)
5. World Health Organization., Management of quality of care: Standards https://www.who.int/management/quality/standards/en/ (24 March 2019)
6. Aune S, Trippesrad A. Operative mortality and long term survival of patients operated on for acute lower limb ischemia. Eur J Vasc Surg 1998; 15:143-46.
7. Haimovici H, Peripheral arterial embolism: a study of 330 unselected cases of embolism of the extremities. Angiology 1950; 1:2-45.
8. Abbott WM, Maloney RD, McCabe CC, Lee CE, Wirthlin LS. Arterial embolism: a 44 year perspective. Am J Surg 1982; 143:460-4.
9. Haridas AK, Bhat BS. Peripheral vascular thrombo-embolism and the role of various fogarty arterial thrombo-embolectomy catheters: a comparative prospective study and its result. J Vas Dis Treat 2018; 2:3-6.
10. Mohamed AM, Tawil A, Al Salihi M, Mattos M. Left atrial myxoma embolization presenting as Acute limb ischemia: an unusual presentation. Cureus 2018; 10:e2764.
11. Wu MY, Lee LC, Lin CH, Chen TY, Tsai YW, Chen YL, Shen TY, Yiang GT. Atrial myxoma inducing acute stroke and mimicking ST-elevation myocardial infarction: a case report. Biomedical Research 2018; 29:2773-5
12. Mirijello A, D'Errico MM, Curci S, Spatuzza P, Graziano D, La Viola M, D'Alessandro V, Grilli M, Vendemiale G, Cassese M, De Cosmo S. Paradoxical embolism with thrombus stuck in a patent foramen ovale: a review of treatment strategies. Eur Rev Med Pharmacol Sci 2018; 22:8885-90
13. Tuzovic M, Herrmann J, Iliescu C, Marmagkiolis K, Ziaeian B, Yang EH. Arterial thrombosis in patients with cancer. Curr Treat Options Cardio Med 2018; 20:40
14. Vukas H, Kadić-Vukas S, Salihbegović A, Djedović M, Totić D, Vranić H, Hadžimehmedagić A. Cost-effectiveness analysis of treatment acute deep vein thrombosis in Clinic of Vascular Surgery Sarajevo. Open Access Maced J Med Sci 2017; 5:681–5.
15. Singh S, Evans L, Datta D, Gaines P, Beard JD. The costs of managing lower limb-threatening ischaemia. Eur J Vasc Endovasc Surg 1996; 12:359-62.
16. Braithwaite BD, Jones L, Heather BP, Birch PA, Earnshaw JJ. Management cost of acute limb ischaemia. Br J Surg 1996; 83:1390-3.
17. Lurie F, Vaidya V, Comerota AJ. Clinical outcomes and cost-effectiveness of initial treatment strategies for nonembolic acute limb ischemia in real-life clinical settings. J Vasc Surg 2015; 61:138-46.
18. Vaidya V, Gangan N, Comerota A, Lurie F. Cost-effectiveness analysis of initial treatment strategies for nonembolic acute limb ischemia using real-word data. Ann Vasc Surg 2017; 39:276-83.