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**THE COSTS OF ENDOVASCULAR IN-HOSPITAL TREATMENT
OF CRITICAL LIMB ISCHEMIA IN PATIENTS WHO FINALLY UNDERWENT
LEG AMPUTATION. A ONE-CENTER EXPERIENCE**

**KOSZTY SZPITALNEGO LECZENIA Z POWODU KRYTYCZNEGO NIEDOKRWIENIA
KOŃCZYN DOLNYCH U PACJENTÓW, U KTÓRYCH OSTATECZNIE
PRZEPROWADZONO AMPUTACJĘ KOŃCZYNY.
OBSERWACJE Z JEDNEGO OŚRODKA**

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S u m m a r y

B a c k g r o u n d . Currently, the average amputation free survival in patients with critical limb ischemia (CLI) amounts to 76% after one year of follow-up. Such poor prognosis raises the question: is revascularization in patients with CLI cost-effective? The aim of this study was to conduct a cost analysis of vascular care in patients with CLI.

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P a t i e n t s a n d m e t h o d s . A retrospective cost analysis of in-hospital endovascular treatment in 37 patients with CLI who underwent secondary leg amputation between January 2012 and June 2015.

R e s u l t s . The average length of time between the first endovascular procedure due to CLI and leg amputation amounted to 214 days (range 8-1088 days). The total cost of

hospitalizations before leg amputation amounted to 687 603.13 PLN, which is, on average, 18 583.87 PLN per patient, and 86.84 PLN per person per day for living with the preserved lower limb. The total costs associated with the patients who had undergone leg amputation amounted to 404 883.24 PLN, which is an average of 10 942.79 PLN per patient. Previous endovascular procedures accounted for 58.9% of this sum and 37.1% to total management costs for the patients.

C o n c l u s i o n s . The cost per day of endovascular treatment that makes it possible to live with two lower limbs did not exceed the established cost-effectiveness threshold. Lower limb amputation increases the costs of in-hospital patient care by 59%, represents financial wastage for the hospital, and incurs other costs not easily measured.

S t r e s z c z e n i e

W s t ę p . Obecnie około 76% pacjentów z krytycznym niedokrwieniem kończyn dolnych (KNKD) poddanych rewaskularyzacji przeżywa kolejny rok z zachowaną kończyną. Powstaje więc pytanie, czy zabiegi rewaskularyzacyjne u tych pacjentów są efektywne kosztowo, skoro 24% chorych nie korzysta z ich efektów dłużej niż przez rok? Celem niniejszej pracy była analiza kosztów opieki naczyniowej u pacjentów z KNKD.

P a c j e n c i i m e t o d y . Retrospektywna analiza kosztów szpitalnego leczenia angiologicznego KNKD u 37

pacjentów poddanych wtórnej amputacji kończyny w okresie 01.2012 - 06.2015.

W y n i k i . Średni okres między pierwszym zabiegiem rewaskularyzacyjnym a amputacją tej kończyny wynosił 214 dni (przedział 8-1088dni). Całkowite koszty hospitalizacji związanych z zabiegami wewnątrznaczyniowymi przed amputacją kończyny wyniosły 687 603,13 PLN, co średnio na pacjenta daje 18 583,87 PLN, 86,84 PLN za jeden dzień i 18 578,5 PLN za potencjalny rok życia z kończyną. Na koszty te składały się koszty stałe oraz zmienne, związane

głównie z liczbą implantowanych stentów (n=59) i leczeniem trombolitycznym (n=6). Natomiast całkowity koszt hospitalizacji związanych z amputacją kończyny dolnej wynosił w badanej grupie 404 883,24 PLN, co daje średnio 10 942,79 PLN na pacjenta. Suma ta stanowiła 58,9% kosztów wcześniejszych zabiegów rewaskularyzacyjnych oraz 37,1% całkowitych kosztów leczenia angiologicznego analizowanej grupy.

Key words: assessment, communication, brain injury, disorders of consciousness, assistive technology

Słowa kluczowe: przewlekłe niedokrwienie kończyn dolnych, krytyczne niedokrwienie kończyn dolnych, amputacja kończyn dolnych, analiza kosztowa

INTRODUCTION

The costs of therapy for peripheral artery disease (PAD) concerning the lower limbs continue to increase [1]. The costs result mainly from the increasing rate of revascularization interventions [2, 3]. According to the REduction of Atherothrombosis for Continued Health (REACH) Registry, the annual costs of vascular-related hospitalizations were estimated in the US to be \$21 billion in 2004 [2]. In spite of continuing advances in the possibilities and outcomes of endovascular treatment, some patients with critical limb ischemia (CLI) need primary or secondary leg amputation due to vascular causes. According to data presented in the Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease (TASC-II) [4], such a procedure is required in 30% of patients with CLI annually. Moreover, over a one-year period, 25% of patients with CLI die and only 45% of patients remain alive with both lower limbs. Thus, a high percentage of CLI treatment fails and the lack of at least one-year of benefits from lower limb revascularization in 55% of patients with CLI may suggest that interventional therapy in patients with CLI is not cost-effective and leads only to ineffective resource utilization. In this context, in spite of endovascular therapy for lower limb ischemia being recognized as a significantly less costly procedure than surgery without significant differences in amputation-free survival [5], primary leg amputation in CLI patients might seem to be a better option for patients with CLI, especially in individuals for whom there are risk factors for poor treatment outcome [6]. However, such risk-factor scores for CLI have still not been published [7].

Moreover, leg amputation is associated with high perioperative mortality, which ranges from 2.8% to 30% of in-hospital deaths, with 2.2% of deaths occurring within 30 days and 45% within 12 months,

Wnioski. Koszt rewaskularyzacji wewnątrznacynowej umożliwiającej 1 dzień życia bez amputacji nie przekraczał aktualnego proggu efektywności kosztowej, dlatego leczenie to powinno być dostępne dla prawie wszystkich pacjentów z KNKD (14% wymagało pierwotnej amputacji). Wykonanie amputacji o 59% zwiększało koszty szpitalnego leczenia angiologicznego chorych z KNKD, generowało ujemny bilans przychodów dla szpitala oraz dalsze, nieanalizowane straty.

as well as increased risk of myocardial infarction and stroke [8]. Lower limb amputation is also linked with additional costs resulting from prosthetic, orthopedic and rehabilitation services and absence from work. Therefore, every patient with CLI needs proper therapy in accordance with advances in the medical care for limb ischemia, especially that in recent report amputation free survival concerned 76.8% patients with CLI after one year of follow-up [9]. On the other hand, it is worth knowing how much this costs.

The aim of this study was to determine the real-life costs in one angiology center of amputation-free survival in patients treated endovascularly due to CLI and who finally required leg amputation.

PATIENTS AND METHODS

The analysis included 37 patients who underwent leg amputation between January 1, 2012 and June 30, 2015 in our angiology center. All of these patients had been treated endovascularly as a first approach due to CLI before being admitted for leg amputation. CLI was defined by meeting the criteria for Classes IV-VI of the Rutherford classification, a decrease an ankle-brachial index (ABI) value below 0.3, as well as an ankle pressure below 30 mmHg in patients with rest pain (IVth class) and below 50 mmHg in individuals with ischemic ulcers [4].

A retrospective analysis of the demographic and clinical data, as well as the costs of their vascular management, was performed for all the patients included in the analysis. All hospitalizations of the respective patients between the first endovascular therapy in our clinic and later leg amputation were taken into account. The costs of hospitalizations associated with endovascular interventions before leg amputation were calculated according to the hospital price list. The actual, constant and variable costs were estimated and compared with prices refunded by the National Health Foundation.

BIOETHICS

The analysis was performed on the basis of permission from the local Bioethical Commission on February 18, 2014 (KB 139/2014) and an annex on April 21, 2015 to conduct analyses of the outcomes of the endovascular procedures. The study was conducted in accordance with the Revised Declaration of Helsinki.

RESULTS

Between January 1, 2012 and June 30, 2015, 43 lower limb amputations due to CLI were performed in our center. These procedures comprised 43/1 282 (3.4%) of all vascular procedures on lower extremities made in our clinic between January 1, 2012 and June 30, 2015. Primary amputations were undertaken for 6/43 (14%) of these patients. In the remaining 37/43 (86%) of patients, lower limb amputation was preceded by 64 endovascular interventions, including 27 rescue procedures (target lesion revascularization [TLR]), the aim of which was the restoration of secondary stent patency. None of the patients had surgical revascularization performed as a first approach. Where endovascular revascularization procedures were performed, 59 involved the implantation of bare metal stents and six concerned local transcatheter thrombolyses were done. The mean duration of the period between the first endovascular procedure and target leg amputation amounted to 214 days (range 8-1088 days). The demographic and clinical characteristics of these patients are presented in Table 1.

The total cost of all hospitalizations prior to leg amputation due to lower limb revascularization of all 37 patients amounted to 687 603.13 PLN (an average of 18 583.87 PLN per patient). The sums were related to the constant and variable costs, the latter resulting mainly from the costs of stents and thrombolytic therapies. Another perspective on our calculations is that the average cost of living with a lower extremity for one day amounted to 86.84 PLN (the equivalent of \$ 22.27, according to an exchange rate of \$1 = 3.9 PLN), and the annual cost per patient of salvaging limb is on average 18 578.51 PLN (which is the equivalent of \$4 763.72). This sum is lower than the current threshold for the cost-effectiveness of medical procedures proposed by the Polish Agency of Health Technology Assessment, which proposed 125 955 PLN for one quality-adjusted life year (QALY) as determined on January 8, 2016.

Table 1. Demographic and clinical data of the 37 patients with CLI studied who underwent leg amputation after the performance of endovascular treatment

Tabela 1. Dane demograficzne i kliniczne analizowanych pacjentów poddanych amputacji kończyny dolnej po wcześniejszym przeprowadzeniu przynajmniej jednej interwencji wewnątrznaczyniowej

| Parameter Parametr | Value Wartość |
|--|-----------------------------------|
| Age (years) Wiek (lata) | 66.5 ± 9.9 |
| Male gender (n, %) Płeć męska (n, %) | 23 (62%) |
| History of coronary artery disease (n, %) Wywiad choroby niedokrwiennej serca (n, %) | 18 (49%) |
| History of stroke (n, %) Przebyty udar mózgu (n, %) | 6 (16%) |
| Diabetes mellitus (n, %) Cukrzyca (n, %) | 22 (59%) |
| Hypertension (n, %) Nadciśnienie tętnicze (n, %) | 29 (78%) |
| Smoking habit (n, %) Palenie tytoniu (n, %) | 22 (59%) |
| Dyslipidemia (n, %) Dyslipidemia (n, %) | 22 (59%) |
| Statins use (n, %) Leczenie statynami (n, %) | 35 (95%) |
| ACEI use (n, %) Leczenie ACEI (n, %) | 25 (68%) |
| Aspirin use (n, %) Leczenie kwasem acetylosalicylowym (n, %) | 37 (100%) |
| Clopidogrel 1 month after stenting (n, %) Zalecenie klopidogrelu na miesiąc po zabiegu (n, %) | 37 (100%) |
| β-blockers (n, %) terapia blokerem receptorów adrenergicznych β (n, %) | 22 (59%) |
| Calcium channel blockers (n, %) Terapia blokerem kanałów wapniowych (n, %) | 7 (19%) |
| The average Rutherford class during first intervention Średnia klasa Rutherforda podczas pierwszego zabiegu rewaskularyzacyjnego | 5.0 ± 0.7 |
| Target lesion classification according to TASC (femoropopliteal level) (A/B/C/D) during the first intervention Klasyfikacja zaawansowania angiograficznego zmian podczas pierwszego zabiegu wewnątrznaczyniowego wg TASC-II (n, %, A/B/C/D) | 4 (11%)/6 (16%)/13 (35%)/14 (38%) |
| Necessity of intervention in BTK arteries during the first procedure (n, %) Konieczność rewaskularyzacji wewnątrznaczyniowej na tętnicach poniżej szpary stawu kolanowego (n, %) | 23 (62%) |
| Number of stents per procedure (BMS) (n) Średnia liczba stentów implantowanych podczas jednej procedury | 1.2 ± 1.1 |
| Sum of stent lengths (mm) Suma długości implantowanych stentów (mm) | 239.5 ± 175 |
| TLR (n, %) | 27 (73%) |
| The mean number of interventions per patient Średnia liczba interwencji u jednego pacjenta | 1.5 ± 0.8 |
| The level of limb amputation (n, %) (forefoot/calf/above the knee) Poziom amputacji kończyny (n, %) (przodostopie/podudzie/udo) | 21 (57%)/2 (5%)/14 (38%) |

Abbreviations: ACEI = angiotensin-converting-enzyme inhibitor; TASC = Trans-Atlantic Inter-Society Consensus; BTK = below the knee; BMS = bare metal stent; TLR = target lesion revascularization. **Skróty:** ACEI = inhibitory enzymu konwertującego angiotensynę; TASC = Trans-Atlantic Inter-Society Consensus; BTK = procedura wewnątrznaczyniowa wykonana na tętnicach poniżej szpary stawu kolanowego; BMS = stent nieuwalniający leku; TLR = ponowny zabieg rewaskularyzacyjny w miejscu poprzedniego.

The total expenditure of hospitalizations associated with 37 leg amputations amounted to 404 883.24 PLN (an average of 10 942.79 PLN per patient). The sum of the costs linked to leg amputations amounted to 37.1% of the total cost of the patients' vascular treatment (previous endovascular procedures plus leg amputation), and 58.9% of the expenditure for vascular patients' management before leg amputation.

The reimbursement provided by the National Health Foundation for the above patient hospitalizations amounted to 233 399 PLN (an average of 6 308.08 PLN per patient). In this way, every patient who underwent lower limb amputation incurred a loss for clinic an average 4 634.71 PLN.

DISCUSSION

The most important observation resulting from our study is that among patients with CLI treated endovascularly in whom, after an average of 214 days the first or repeated revascularization procedures failed and leg amputation was eventually undergone, the average cost of one day of living with a lower limb between the first endovascular intervention and lower limb amputation amounted to 86.84 PLN (equivalent to \$22.27). Compared to the data reported by Krzanowski et al. [9], in whose center the first year of treatment of patients with CLI amounted to \$3 804.25 per patient (about \$10.42 per day), our costs were higher, but our hospital covers a larger area than the referenced center in Cracow and our patients were initially in a more advanced clinical condition, which in all of them resulted in leg amputation. In the investigation by Krzanowski et al. [9], amputation-free survival during the first year after leg revascularization amounted to 76.8%. On the other hand, our average in-hospital costs of endovascular treatment for CLI (\$4 763.72 per year and \$13.05 per day), resulting in individually different amputation-free survival periods, were lower than the threshold for the estimation of the cost-effectiveness of medical intervention for one QALY, as determined in Poland in January 2016 at the level of 345.08 PLN (\$88.48) per day. This means that lower limb revascularization and salvation, even for a limited amputation-free survival period, should be recognized as a worthwhile and cost-effective procedure, which is supported by other authors [5, 9-13]. The resource expenditure linked with endovascular procedures might be further decreased by the selective use of stents and other expensive devices [9, 14]. The other potential way to reduce resource utilization in patients with lower limb ischemia is the recommendation of appropriate pharmacotherapy in accordance with the

requirements for the prevention of secondary cardiovascular disorders and supervised exercise training in patients with intermittent claudication (not with CLI), which appear to be more cost-effective in such disease advancement than endovascular revascularization [15].

The second important finding of our study was that the leg amputation procedure incurs a loss of resources for a hospital, in addition to further resource utilization, and entails sacrifices for the patient that are impossible to evaluate in financial terms [16]. This observation is the opposite of the general medicinal opinion in Poland that lower limb amputation is a more cost-effective procedure than revascularization.

In our study, we also found that the percentage of patients with CLI who underwent lower limb amputation having undergone a endovascular revascularization procedure (85%) was more frequent than previously reported (50%) [4]. This suggests that the availability of revascularization procedures in the area surrounding our clinic is good and physicians and patients have better knowledge of alternative forms of CLI treatment other than primary amputation. Such observations have also been pointed out by angiologists in Cracow [9]. However, it is known that leg amputation without the performance of basic diagnostic procedures is not rare, and that this is not only the case in Poland. It was reported that in the US amputation was the first choice of treatment in as many as 67% of patients with CLI. In 31.8-50% of patients with CLI, leg amputation was undergone without earlier diagnostic procedures which might otherwise have shown the potential of revascularization [17]. For example, arteriography was performed in 16% of them, ABI was measured in 35% of patients, and only 26% of patients were consulted by a cardiologist and 21% by a vascular surgeon. These data show that CLI is still not diagnosed and managed correctly [3].

In summary, it should be stated that our study, as with others, has some limitations. The study group was small and the cost of lower limb revascularization and amputation were calculated according to local appraisal, which may be different in other hospitals. Nonetheless, our analysis shows that the resource expenditure on endovascular procedures prolonging the amputation-free survival period in patients with CLI did not exceed the threshold for the estimation of the cost-effectiveness of therapeutic methods, which is accepted by institutions responsible for medical care reimbursement in Poland. Therefore, in almost all patients suffering from CLI, endovascular therapy using the currently available techniques should be recommended to avoid leg amputation.

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