Outcome in octogenarian patients with lower extremity artery disease after endovascular revascularisation: a retrospective single-centre cohort study using in-patient data

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ABSTRACT

Objectives To investigate the clinical benefit of endovascular revascularisation (EVR) in octogenarian (aged ≥80 years) patients with lower extremity artery disease (LEAD).

Design Retrospective single-centre study.

Setting University hospital with a specialised centre for vascular medicine.

Participants 681 LEAD patients undergoing EVR between 2010 and 2016 were stratified by age.

Main outcome measure Technical success, complications and mortality.

Results The cohort comprised 172 (25.3%) octogenarian and 509 (74.7%) non-octogenarian patients. Despite higher LEAD stages and complexity of EVR in octogenarians, primary technical success rate (79% octogenarians vs 86% non-octogenarians, p=0.006) and 1-year survival (87% vs 96%, p<0.001) were overall on high levels. Especially for the octogenarians, 1-year survival depends on the presence of chronic limb-threatening ischaemia (CLTI) (octogenarians: non-CLTI 98%; CLTI 79% p<0.001 vs non-octogenarians: non-CLTI 99%; CLTI 91%, p<0.001). In octogenarians, female sex (HR 0.45; 95% CI (0.24 to 0.86); p=0.015), the intake of statins (HR 0.34; 95% CI 0.19 to 0.65; p=0.001) and platelet aggregation inhibitors (HR 0.10; 95% CI 0.02 to 0.45; p=0.003) were independently associated with improved survival after EVR.

Conclusion EVR can be performed safely and with sustained clinical benefit also in octogenarian patients with LEAD. After-care including medical adherence is of particular importance to improve long-term survival.

INTRODUCTION

Worldwide, the number of elderly people is rising caused by the demographic change and increased life expectancy. Older patients differ from younger patients in a multifaceted way regarding social and medical aspects. Commonly, multimorbidity, the frailty syndrome, cognitive limitations and a decrease in activities of daily living including impaired mobility are associated with higher age. Lower extremity artery disease (LEAD) as the manifestation of atherosclerosis in the peripheral arteries is likewise gaining ground, affecting globally 200 million people. Prevalence of LEAD is strongly increasing with age. At the age of 70 years, the prevalence of LEAD reaches 20% in the general population in high-income countries. However, particularly older patients are at risk of delayed diagnosis of LEAD as often other comorbidities limit these patients’ mobility. Furthermore, the need for medical aid for other reasons but LEAD, and cognitive impairment may result in withholding invasive therapeutic options. According to recent epidemiological research, especially patients with chronic limb-threatening ischaemia (CLTI) are approximately 3–5 years
older compared with that of lower LEAD stages.\textsuperscript{9} CLTI leads annually to over 210 000 in-hospital cases for LEAD, corresponding to 44% of total in-patient cases and with its share constantly increasing over the past decade (+32% in 2005–2009 in Germany).\textsuperscript{10} Overall, CLTI dramatically reduces the patients’ prognosis as every second patient deceases within 5 years.\textsuperscript{9,11,12} However, facing limited years of life ahead, the significance of revascularisation is not only to improve walking distance and quality of life (QoL)\textsuperscript{13} but also to retard progression of LEAD towards critical stages remains currently unclear in older patients. On the other hand, despite commonly regarded as a high-risk population, there is no evidence for less benefit or adverse outcome after endovascular revascularisation (EVR) in octogenarians.

The aim of our study is to investigate the benefit from EVR in octogenarians in comparison to non-octogenarian patients with LEAD. Therefore, aspects of EVR were analysed in consideration of patients’ individual risk profiles, EVR procedure characteristics and accompanying pharmacological treatment to further evaluate in-hospital and long-term outcome respective of age.

METHODS

Study population and parameters

The study was performed at a specialised vascular centre in Germany. The retrospective study comprises all octogenarian patients (aged ≥80 years at index), who received index EVR for symptomatic LEAD (Fontaine stages II–IV) between 1 January 2010 and 31 December 2016. LEAD was defined as ankle brachial index (ABI) <0.9. Stage of disease was obtained as recorded by detailed patient symptoms, wound status and apparatus diagnostic methods of both lower limbs (ABI, toe pressure, transcutaneous partial pressure of oxygen (tcpO2)), assessed by qualified physicians being specialised in vascular medicine. Detailed information on clinical and apparatus parameters were collected from the electronic patient file records (documentation system ORBIS). Baseline parameters include comorbidities, vascular status, wound status or previous amputation at index according to diagnostic findings and/or patients’ history. Detailed information on EVR procedure such as duration, volume of contrast medium, vascular access and sheath size, target vessel (pelvic, femoral, below-the-knee), applied devices or closing system were recorded. Furthermore, comprehensive laboratory parameters (eg, haemoglobin, creatinine, coagulation status) and medication (antiplatelet therapy, oral anticoagulation, statin) were assessed before, during and after index EVR as well as during follow-up.

Outcome parameters were defined as all-cause mortality, ipsilateral amputation and the composite endpoints major adverse limb event (MALE; ipsilateral amputation, re-EVR, peripheral vascular surgery) and major cardiac event (MCE; acute coronary syndrome, percutaneous coronary intervention, cardiac bypass surgery, stroke). Furthermore, technical success of EVR, perioperative and in-hospital complications (eg, bleeding, major adverse cardiac or limb events, bail-out procedures, amputation) were assessed during EVR procedure, postprocedural during in-hospital stay, and at 6-month and 12-month follow-up visits, which was the usual time of follow-up after EVR in this hospital setting. As a control, non-octogenarian LEAD patients receiving EVR between 2014 and 2016 were included in the analysis.

Patients not making use of follow-up visits, resulting in missing data at 6 and/or 12 months, were contacted personally in order to verify their vital status and to obtain clinical information.

Patient and public involvement

Patients or members of the public were not involved in the design of this study, nor in its implementation.

Statistical analyses

Relative frequencies were calculated for all categorical variables, differences between the two age groups were evaluated using two-sided Fischer’s exact test for binary variables and two-sided $\chi^2$ test for variables with more than two specifications. Descriptive analysis for all continuous variables was performed by determining median, average, variance, SD, IQR, minimum, maximum, 95% CIs and skewness. Differences between octogenarians and non-octogenarian patients were evaluated using two-sided Mann-Whitney U test. To evaluate the influence of LEAD stages at index EVR on the overall survival, a Kaplan-Meier estimate was determined and a log-rank test was performed. Furthermore, a multivariable Cox-regression analysis was performed and HRs with 95% CIs were presented. All analyses were exploratory, and an adjustment for multiple testing has not been performed. Two-sided p values <0.05 were considered to be statistically noticeable. SAS V.9.4 (SAS Institute, Cary (North Carolina), USA) and IBM SPSS Statistics V.25 (IBM Cooperation, USA) were used for statistical analysis.

RESULTS

In total, there were $n = 681$ LEAD patients receiving EVR during the study period, thereof, $n=172$ octogenarians (25%).

Baseline characteristics

Octogenarian patients were at median 84 years old. Compared with non-octogenarians (median age 70 years), the share of female patients was significantly higher with 47% versus 24% ($p<0.001$; table 1). Octogenarian patients were at higher LEAD stages compared with non-octogenarians: whereas two-thirds of octogenarian patients presented with CLTI (Fontaine stages III and IV), CLTI was present in 42% of non-octogenarians at index EVR ($p<0.001$). The rate of previous amputation was overall 10% with no difference between both age groups ($p=0.251$). Both, octogenarian and non-octogenarian patients presented frequently with arteriosclerotic...
comanifestation and risk factors (see table 1). Polyvascular disease (≥2 vascular territories affected) was present in 69% octogenarian versus 68% non-octogenarian patients (online supplemental figure S1).

**Determinants of EVR procedure and in-hospital outcome**

All EVR were performed by vascular specialists with long-term experience at a University Hospital setting. The procedural parameter use of contrast medium did not differ between octogenarian and non-octogenarian patients, EVR radiation dose and the duration of EVR were higher in octogenarian patients (table 2). The duration dose depends on the presence of CLTI (table 2).

EVR was performed most commonly on the femoropopliteal vascular segment in both age groups; however, treatment of the infrapopliteal segment occurred more frequently in octogenarians (see table 2).

Primary technical success of EVR could be achieved in 84% of all patients, with somewhat lower success rates in octogenarians (79% vs 86%, p=0.006; table 2). However, periprocedural complications, including not only major adverse cardiac and/or limb events but also minor consistencies without clinical relevance (eg, bleeding at punction site), were not increased in octogenarian patients. Likewise, in-hospital ipsilateral amputation (overall 4%), MALE (7%), major cardiac event (2%) and in-hospital death (1%) did not differ between both age groups. However, length of hospital stay was on average 2 days longer in octogenarian patients (9 days vs 7 days, p<0.001).

**Medication**

At index EVR, 84% of all patients with LEAD received any kind of anticoagulating/antiplatelet medication. However, intake of antiplatelet medication was lower in octogenarians compared with younger patients (56% vs 70%, p=0.002), whereas the rate of oral anticoagulation was increased with higher age (35% vs 22%, p=0.003).
Furthermore, supply with statins was lower in octogenarians at index (62% vs 75%, \( p=0.005 \); online supplemental figure S2). At discharge, application rates blood thinning medication increased in both age groups reaching 100%, mainly driven by postprocedural increased intake of platelet inhibitors. However, octogenarians were persistently less frequent on statin therapy (71% vs 87%, \( p<0.0001 \)). Of those patients participating in follow-up visits at 6 and 12 months, approximately 100% of both age groups had any blood thinning medication. Furthermore, statin intake remained static at 87% at 6, and 88% at 12 months of follow-up.

Long-Term outcome

Ipsilateral amputation within 12 months from index was a rare event affecting only \( n=14 \) patients with LEAD, thereof, \( n=9 \) octogenarian patients (table 3). The combined limb-related endpoint (MALE) including amputation and/or endovascular and/or surgical reintervention was reached in about 16% of patients with LEAD in the first and second half-year after index EVR (0–6 months: 12% vs 17%; 6–12 months: 20% vs 16%). The rate of MALE was predominantly driven by around 10% reinterventions in either age group. Major cardiac event (MCE; acute coronary syndrome, percutaneous coronary intervention, coronary bypass grafting, stroke) occurred at low rates (0–6 months: 3% vs 4%; 6–12 months: 1% vs 7%). Survival rate at 1-year follow-up was 87% in octogenarian compared with 96% (\( p<0.001 \)) in non-octogenarian patients with LEAD. In octogenarians, overall survival was highly dependent on LEAD stage at index, resulting in 98% survival in claudicants compared with 79% in CLTI at 12-month follow-up (\( p<0.001 \)) (figure 1A). The impact of LEAD status on overall survival is less pronounced in the group of non-octogenarian patients (non-CLTI 99%)

| Table 2 | EVR parameters and in-hospital outcome |
|--------|--------------------------------------|
|        | Octogenarians | Non-octogenarians | Total | P value |
| EVR technical parameters—median (IQR) | | | | |
| EVR duration total—minutes | 95.0 (59.0) | 87.0 (50.5) | 89.0 (55.0) | 0.039 |
| EVR duration patients with CLTI—minutes | 107.5 (60.8) | 97.0 (51.3) | 99.5 (55.8) | 0.081 |
| EVR duration claudicants—minutes | 77.5 (46.0) | 81.5 (48.0) | 81.0 (48.3) | 0.657 |
| EVR contrast medium—millilitre | 119.4 (55.3) | 125.3 (55.0) | 123.8 (51.4) | 0.226 |
| EVR radiation dose total—cGy*cm\(^2\) | 3067.5 (4611.8) | 2370.0 (3552.3) | 2825.0 (4429.3) | 0.010 |
| EVR radiation dose patients with CLTI—cGy*cm\(^2\) | 2261.5 (3429.8) | 2232.5 (3895.3) | 2261.5 (3571.0) | 0.963 |
| EVR radiation dose claudicants—cGy*cm\(^2\) | 3027.0 (4112.0) | 3767.0 (5553.0) | 3658.0 (5067.0) | 0.032 |
| Treated arterial segments—n (%) | | | | |
| Aorto-iliac level | 21 (12.3) | 147 (29.0) | 168 (24.7) | \(<0.001\) |
| Femoro-popliteal level | 131 (76.2) | 384 (75.7) | 515 (75.8) | 0.993 |
| Infrapoliteal level | 85 (49.7) | 187 (36.8) | 272 (40.1) | 0.004 |
| Usage of devices—n (%) | | | | |
| Bare-metal stent | 104 (61.5) | 322 (63.8) | 426 (63.2) | 0.670 |
| Drug-eluting stent | 22 (13.0) | 37 (7.3) | 59 (8.7) | 0.034 |
| Plain old balloon angioplasty | 165 (97.6) | 481 (95.8) | 646 (96.3) | 0.399 |
| Drug-coated balloon | 32 (18.9) | 200 (39.7) | 232 (34.4) | \(<0.001\) |
| In-hospital outcome | | | | |
| EVR primary technical success rate—n (%) | 135 (78.9) | 437 (86.0) | 572 (84.2) | 0.006 |
| Complications periprocedural—n (%) | 20 (11.8) | 100 (19.9) | 120 (18.7) | 0.024 |
| Complications before discharge—n (%) | 35 (21.0) | 85 (17.2) | 120 (18.1) | 0.332 |
| Amputations, ipsilateral—n (%) | 10 (5.9) | 15 (3.0) | 25 (3.8) | 0.142 |
| MALE—n (%) | 11 (6.5) | 32 (6.4) | 43 (6.5) | 1.000 |
| MCE—n (%) | 3 (1.8) | 11 (2.2) | 14 (2.1) | 0.961 |
| Mortality—n (%) | 4 (2.3) | 4 (0.8) | 8 (1.2) | 0.226 |
| Length of hospital stay—days—arithmetic mean (±SD) | 8.7 (±11.2) | 7.0 (±12.8) | 7.4 (±12.5) | \(<0.001\) |

Statistically significant values are in bold.

*Periprocedural complications: includes (micro-)embolism, any bleeding, paravasat, emergency surgery, amputation, death.
†Complications before discharge: includes local bleeding, false aneurysm, arteriovenous fistula, surgery, blood transfusion, MCE, MALE.
CLTI, chronic limb-threatening ischaemia; EVR, endovascular revascularisation; MALE, major adverse limb event; MCE, major cardiac event (ACS, stroke, PCI, and/or CABG).
vs CLTI 91%, p<0.001; **Figure 1B**). After adjustment for selected baseline risk factors, CLTI turned out as a major independent predictor of death (HR 4.38, p<0.001; **Figure 2**). The presence of polyvascular disease did not further affect mortality risk in octogenarians, whereas female sex was associated with slightly lower mortality risk (HR 0.45, p=0.015). Furthermore, intake of statin (HR 0.34, p=0.001) and platelet aggregation inhibitors (HR 0.10, p=0.003) were associated with higher survival during follow-up.

**DISCUSSION**

Our study represents the unadorned daily care of patients with LEAD treated with EVR. In line with epidemiological data, octogenarian patients were more frequently women (47%) and a high proportion of patients presented with polyvascular disease and traditional cardiovascular risks. Therefore, octogenarian age frequently implies aspects of risk management that need to be considered during treatment and thereafter.

**Table 3** Long-term outcome

|                | 0–6 M          |          | 6–12 M          |          |
|----------------|----------------|----------|----------------|----------|
|                | Octogenarian   | Non-octogenarian | Total | Octogenarian   | Non-octogenarian | Total |
|Patients        | 168            | 505      | 673            | 151      | 496            | 647   |
|MALE*—n (%)     | 14/114 (12.3)  | 64/386 (16.6) | 78/500 (15.6) | 18/91 (19.8) | 48/299 (16.1) | 66/390 (16.9) |
|Amputation, (ipsilateral)*—n (%) | 3/126 (2.4) | 8/406 (2.0) | 11/532 (2.1) | 1/95 (1.1) | 2/308 (0.6) | 3/403 (0.7) |
|Re-intervention*—n (%) | 13/163 (0.8) | 59/503 (11.7) | 72/666 (10.8) | 17/145 (11.7) | 49/494 (9.9) | 66/639 (10.3) |
|Vascular surgery*—n (%) | 0/133 (0.0) | 2/382 (0.5) | 2/495 (0.4) | 0/92 (0.0) | 1/280 (0.3) | 1/372 (0.2) |
|MCE*—n (%)      | 3/112 (2.7)   | 15/356 (4.2) | 18/468 (3.8) | 1/87 (1.1) | 17/263 (6.5) | 18/350 (5.1) |
|Reported death*—n (%) | 17/168 (10.1) | 9/505 (1.8) | 26/673 (3.9) | 5/151 (3.3) | 11/496 (2.2) | 16/647 (2.5) |
|Survival rate†—% | 0.9027 (0.856, 0.950) | 0.981 (0.968, 0.993) | 0.961 (0.946, 0.977) | 0.868 (0.815, 0.922) | 0.956 (0.937, 0.975) | 0.934 (0.915, 0.954) |

*Number of events relative to patients alive with completed information on the respective variable.  †Survival rate per Kaplan-Meier estimate at 6 and 12 months.

MALE, major adverse limb event: ipsilateral amputation, re-intervention, and/or peripheral vascular surgery; MCE, major cardiac event: ACS, stroke, PCI, and/or CABG.
In octogenarians, a higher percentage of patients was treated for critical stages of disease (CLTI 67% vs 42% in non-octogenarians, p<0.001). This may be driven by a potentially higher rate of CLTI among the older patients as LEAD onset and progression is strongly dependent on age. Otherwise, this trend may hint at a more restrained indication for invasive therapy in the older patient subset. Endovascular treatment for improved walking distance and associated gain of mobility may be restricted depending on physicians’ impression on overall health status. However, the treated patients in our subset did not differ in terms of severe and commonly lifetime reducing comorbidities such as diabetes, chronic kidney disease and chronic heart failure. Furthermore, the rate of complex interventions of the lower limb including below-the-knee reconstruction was even higher compared with non-octogenarians (50% vs 37%, p=0.004). Due to the presence of a higher percentage of CLTI in octogenarians, EVR duration time is higher in octogenarian patients. It may, therefore be questioned, if indication for EVR may also be driven by subjective parameters on the part of practitioners and patients (eg, reduced self-assertion).

Apart from benefits in mobility, mitigating progress of LEAD to critical stages remains a primary goal across all age groups. Hence, performance of EVR has significance in lower LEAD stages weighing risks and benefits in view of the circumstances of the individual case. In this context, safety and efficacy of EVR in octogenarians are of particular importance. Our data show that high primary technical success rates are achievable also in octogenarian age groups. Compared with younger patients, the higher rate of infrapopliteal interventions in octogenarians may have contributed to the somewhat lower technical success. However, as far as observed, primary technical success translated well into a very low percentage of ipsilateral amputation after 6 and 12 months in octogenarians and into an acceptable rate of reintervention after 6 and twelve months. In line with this Dua et al could also show, that an aggressive tibial and pedal revascularisation in patients with CLTI may lead to a lower amputation rate after 6 months. Importantly peri- and post-procedural complications were not increased in octogenarians, and therefore substantiate EVR safety irrespective of age.

Particularly major events such as amputation, MCE and in-hospital mortality were extraordinarily rare. Long-term survival rate was comprehensibly lower in octogenarians, most likely as an effect of high patient age itself, but also due to the higher proportion of patients with CLTI, which could be identified as a major risk factor of death. However, under optimal care of the university setting, survival rates in octogenarians were comparably high, reaching almost 98% in claudicants and even 79% in patients with CLTI at 1 year. In comparison, the national average survival rates of CLTI patients after EVR range around 70% at 1 year over all ages. Nevertheless, the difference in 1 year outcome for claudicants vs CLTI is smaller in the control group. Thus the impact of the presence of CLTI in octogenarian patients could be described as more important for overall survival. Surprisingly, the presence of polyvascular disease did not further deteriorate survival in octogenarians as an independent risk factor, which is in contrast to data on younger age groups. Possibly, the impact of polyvascular disease takes full effect over several years ahead. Moreover, octogenarians can be regarded as survivors and therefore traditional risk factors may weight differently compared
with younger patients. Moreover, the intake of statins and platelet aggregation inhibitors each were associated with a survival benefit in LEAD even at octogenarian patient age. Supporting guideline-recommended pharmacotherapy including statins and blood thinners remained at high levels in the subset of patients who took part in regular aftercare appointments. Given the importance of physician contacts in terms of medical aftercare, assessment of long-term results and medical adherence action should be taken for octogenarians to recognise and overcome potential obstacles of follow-up visits.

Strengths and limitations
The work underlies the typical constraints of retrospective data assessment based on a hospital information system. Importantly, results of the study should be regarded as hypothesis generating. However, data documentation was performed in a standardised way by specialised physicians and data assessment was conducted conscientiously for further analysis. Moreover, the observational analysis reflects the standard of care of a university hospital setting, and, therefore, may not be representative for other medical care units. Data on non-octogenarian control is somewhat more recent because of octogenarians represent a smaller percentage of the annual patients treated with EVR. In order to acquire sufficient patient number and to keep the target population balanced with the control group of younger patients, the prior years 2012–2014 were enrolled to the study. This may have introduced a certain bias upfront; however, standard of care (guideline recommendation, technical supply, interventional team) remained constant over the entire period of study. Furthermore, underlying reasons for lack of guideline adherence in terms of secondary preventive medication are not known but may have an impact on outcome. Finally, a deficit of follow-up visits could be identified as a major issue in octogenarian patients, resulting in limited clinical long-term information. However, all patients were contacted to capture their vital status or date of death. Therefore, by all means, mortality as the primary outcome should be correct.

CONCLUSION
In this single-centre university setting, EVR could be performed with good technical success and low rate of major complications in patients of octogenarian age. CLTI turned out as frequent condition and major risk factor of death, while the importance of other traditional risk factors stepped into the background in light of high patient age. The intake of statins and platelet aggregation inhibitors were each independently associated with improved long-term survival irrespective of octogenarian patient age. We identified an under-supply with preventive pharmacotherapy at index; however, adherence could be sustainably improved in patients participating in follow-up visits. In this context, deficit in follow-up contacts turned out as major issue in octogenarians, and further research is needed to dismantle potential barriers of aftercare.

Contributors AL collected primary data, contributed to data analysis, interpreted the data and wrote the manuscript. JK performed the statistical analysis and critically reviewed the manuscript. HB collected data and critically reviewed the manuscript. KV collected data and critically reviewed the manuscript. JF performed the statistical analysis and critically reviewed the manuscript. LM contributed to data analysis and critically reviewed the manuscript. CE contributed to data analysis and critically reviewed the manuscript. HR contributed to discussion and critically reviewed the manuscript. MMM interpreted the data, contributed to discussion and critically reviewed the manuscript. EF designed the study, contributed to data analysis and interpretation, contributed to discussion and critically reviewed the manuscript. All authors approved the final version of the manuscript. HR serves as guarantor.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests AL was supported by a grant of the German Society of Vascular Medicine (Deutsche Gesellschaft für Angiologie e.v.). CE and LM received travel support from Bayer Vital outside this work. HR reports personal fees from Daiichi, grants from BMS/Pfizer, personal fees from Medtriflpdate, personal fees from DiaPlan, personal fees from Neovasc, grants and personal fees from Pluristem, grants from Bard, grants from Biotronik, personal fees from NovoNordisk, outside the submitted work. EF received grants from BAYER outside this work.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The study was approved by the Ethics Committee of medical board Westfalen-Lippe and of Westfälische Wilhelms-University Munster (File number: 2019-362-1-S).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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