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Population Based Analysis of Gender Disparities in 23,715 Percutaneous Endovascular Revascularisations in the Metropolitan Area of Hamburg

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WHAT THIS PAPER ADDS

This large population based study includes real world evidence from a long observation time between 2004 and 2015 and adds to the very limited knowledge base regarding gender disparities in peripheral arterial revascularisation practice. Females presented at an older age were more often treated for rest pain, and more often underwent revascularisations above the knee. Furthermore, major bleeding complications occurred more often in females, and the transferal rate to nursing homes was higher in female patients. These differences call for further research and gender related treatment recommendations in peripheral arterial disease revascularisations.

Background: The worldwide prevalence of peripheral artery disease (PAD) is increasing and endovascular revascularisation (ER) has become the primary invasive treatment option. This study aims to illuminate gender disparities in ER of PAD.

Methods: This is a retrospective, cross sectional study design. All inpatient invasive, percutaneous endovascular treatments of PAD conducted in the metropolitan area of Hamburg (Germany) were collected consecutively between 01/2004 and 12/2015. Relevant socio-demographic risk factors, technical assessments, procedural details, and in hospital outcomes were collected and subsequently analysed.

Results: A total of 23,715 ERs were identified (39.7% females). Female patients were older (74 vs. 70 years, $p < .001$) and more often suffered from rest pain (12.0% vs. 9.7%, $p < .001$) at the time of presentation. No differences were found for index lesion complexity (Trans-Atlantic Inter-Society Consensus classes) and the ankle brachial index was less often stated not to be valid in females (5.9% vs. 7.1%, $p = .005$ for intermittent claudication; 28.5% vs. 32.0%, $p = .001$ for chronic limb threatening ischaemia, CLTI). If the ER was performed for CLTI, crural vessels below the knee were less often revascularised in females (32.2% vs. 42.7%, $p < .001$). Peri-operative major bleeding complications including pseudoaneurysms occurred twice as often in females, and female gender was an independent predictor of bleeding complications in the adjusted analyses (OR 2.32, 95% CI 1.49–3.64, $p < .001$ for IC; OR 1.67, 95% CI 1.10–2.53, $p = .017$ for CLTI). Lastly, females were more often transferred to nursing homes when compared with males (0.3% vs. 0%, $p = .001$ for IC; 2.5% vs. 1.2%, $p < .001$ for CLTI).

Conclusion: In this study considering percutaneous ER for PAD, female patients were older, had different clinical symptoms, suffered more often from complications, and were at risk of social isolation after discharge when compared with their male counterparts. These results emphasise the need for further studies to evaluate a gender based treatment algorithm in PAD.

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INTRODUCTION

Peripheral artery disease (PAD) has become a global problem with significant impact on national healthcare systems.[1] With the rapid adoption of new techniques, endovascular revascularisations (ERs) for chronic limb threatening ischaemia (CLTI) increased by 46% between 2005 and 2009 in Germany.[2–4] Nevertheless, there remains an important evidence gap in valid practical guidelines requiring further research.[5,6] There is evidence of a higher radiation dose and more bleeding complications in females following percutaneous ERs conducted by various interventional medical specialties when compared with their male counterparts.[7,8] In another recently published study, the authors revealed remarkably high bleeding and transfusion rates in females following complex endovascular aortic repair when compared with males, underlining the need to look into this potentially underreported adverse event.[9] To date, gender disparities in multidisciplinary cardiovascular care are controversial but there is evidence of worse outcomes in females following various procedures.[9–15]

This study aims to describe gender disparities in presentation and short-term outcomes evaluating data from a large prospective, population based, multicentre, quality improvement registry in the metropolitan area of Hamburg, Germany.

METHODS

The statutory quality improvement registry (External Quality Insurance Hamburg, EQS registry) for PAD in the metropolitan area of Hamburg, Germany, was introduced in 2004 and prospectively records all percutaneous ERs performed for PAD. All medical specialties performing interventional procedures (vascular surgery, interventional internal medicine and cardiology, interventional radiology) are obligated to submit data to this registry.

The reporting of this study's results is in accordance with the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement in its latest version (www.strobe-statement.org).

This study is a retrospective cross sectional study of procedures conducted between January 2004 and December 2015. The parameters collected by the EQS registry were defined a priori as a consensus by experts in 2004, with minor revisions in 2008. This EQS registry includes all inpatient procedures conducted at legally endorsed private or public hospitals within the metropolitan region of Hamburg, Germany (approximately 1.8 million inhabitants in Hamburg and 5.3 million inhabitants in the extended metropolitan region). The number of participating centres varied from 12 in 2004, to 17 in 2014. Each participating centre holds departments for vascular surgery, radiology, and interventional internal medicine. No hub and spoke model was deployed in the metropolitan area of Hamburg.[16]

Exclusion criteria were open surgery or hybrid cases and solely diagnostic angiograms. An external and internal validation is performed annually by random sample matching and cross checking with hospital diagnosis data from the German Bureau of Statistics. External validity was reported to be 91.8%—99.1% from 2010 to 2014.[7]

For this study, information was collected on patient age (in years), gender (female vs. male), coding of diabetes according to the World Health Organisation (WHO) International Classification of Diseases (ICD) codes (E10*, E11*, E12*, E13*, E14*), principal indication for the procedure, revascularisation (procedure) of crural vessels performed below the knee (BTK), disease severity score, treadmill test conducted before the procedure, ankle brachial index (ABI) before and after the procedure, ABI measured but stated as not valid, admission date, procedure date, early unsuccessful termination of the procedure, dose area product in Gy*cm,[2] discharge date and discharge destination, postoperative length of stay, and post-procedural complications.

The indication for the procedure was collected by Fontaine stages for intermittent claudication (IC, Fontaine stage II) and for CLTI (Fontaine stages III and IV).

The disease severity score was calculated as a summation of TASC classes as defined by the Trans-Atlantic Inter-Society Consensus for the Management of PAD (TASC II)[14] from TASC A (1 point) to TASC D (4 points).[17,18] Evaluations of all lesions in aorto-iliac, femoropopliteal vessels above the knee (ATK), and crural vessels BTK evaluated by preprocedural imaging or intra-procedural angiography were used as summands (0—12 points per leg). For bivariable analyses, TASC classes A/B vs. C/D were dichotomised. No follow up data were collected after hospital discharge.

Post-procedural complications included index lesion occlusion, pseudoaneurysm, revision or transfusion because of major bleeding, target vessel dissection, peripheral embolism, other complication (includes unplanned amputation, no further specification of complications), and in hospital mortality. Early unsuccessful termination of the procedure, considered as incomplete revascularisation, was stated if the procedure was aborted before successful revascularisation.

Ethical considerations

Informed consent was obtained for all cases prior to data submission to the EQS. As EQS is a regulatory statutory, quality improvement project of the Hamburg government, analysis of anonymised registry data without personal data could be executed without objections by the local ethics committee.

Statistical analysis

Depending on the distribution, data are presented either as mean and SD or as median and interquartile ranges (IQRs) for continuous variables. Proportions are reported by percentages and 95% CI. Bootstrapping was used to estimate the accuracy of given estimators such as standard errors and CI. The Mann Whitney *U* and Kruskal Wallis *H* tests were used for comparison of abnormally distributed data. Rates were compared with Fisher's exact test of independence or chi-square test. A multivariable logistic regression

approach was conducted to investigate the impact of female gender (versus male gender) on relevant outcomes. Multivariable analyses were adjusted for age, CLTI, involvement of crural vessels BTK, higher disease severity score, diabetes, and length of hospital stay. A p value of < 0.05 was regarded as statistically significant. No adjustment was performed for multiple testing. To handle missing values, missing data were deleted for an available case analysis. Statistical analyses were performed with IBM SPSS Statistics software version 25.0 (IBM, Armonk, NY, USA).

RESULTS

Patients and procedures

Baseline characteristics of the study population by gender are given in Table 1. A total of 23,715 admissions and ERs for PAD (39.7% females) were identified between 2004 and 2015 (Fig. 1). The annual number of treatments increased between 2004 and 2015 but no significant variation was identified in the proportion of females among all treatments (Fig. 2). Females were significantly older at the time of presentation when compared with male patients (74 vs. 70 years, $p < .001$). In analyses stratified between IC vs. CLTI, results of the ABI were less often stated to be not valid in females for elective treatment of IC (5.9% vs. 7.1%, $p = .005$) and for treatment of CLTI (28.5% vs. 32.0%, $p = .001$). A treadmill test was conducted in approximately 20% of the patients with no gender differences. Revascularizations of the crural vessels BTK were less frequent in females than in males (17.2% vs. 21.0%, $p = .001$). No gender differences were found regarding the general disease severity or the proportion of more complex lesions as measured by TASC classes (Table 1).

Unadjusted group comparisons

In unadjusted bivariable analyses (Table 2) stratified between IC and CLTI, the rate of pseudoaneurysms was significantly higher in females than in males after treatment of IC (0.4% vs. 0.1%, $p = .003$) and CLTI (0.4% vs. 0.2%, $p = .043$). Major bleeding complications requiring transfusions or re-operations were more common in females following treatment of IC (0.6% vs. 0.2%, $p = .001$). Target vessel

Table 1. Unadjusted baseline characteristics of study population and procedural information

	Females	Males	p value
No. of procedures, (%)	9415 (39.7)	14,300 (60.3)	
Age, years, median (IQR)	74 (67–81)	70 (62–76)	< .001
Diabetes, % (CI)	10.3 (9.7–10.9)	14.7 (14.1–15.3)	< .001
Ischaemic rest pain, Fontaine stage III, % (CI)	12.0 (11.4–12.7)	9.7 (9.2–10.2)	< .001
Ulcer/gangrene, Fontaine stage IV, % (CI)	27.7 (26.8–28.6)	28.7 (28.0–29.5)	.084
Crural vessels, BKT involved in the procedure, % (CI)	17.2 (16.4–18.0)	21.0 (20.4–21.7)	< .001
TASC C/D lesions (aorto-iliac), % (CI)	7.6 (6.8–8.3)	8.5 (7.9–9.1)	.890
TASC C/D lesions (ATK), % (CI)	25.8 (24.8–26.8)	24.5 (23.7–25.4)	.530
TASC C/D lesions (BTK), % (CI)	25.6 (24.3–26.9)	28.1 (27.0–29.1)	.236
Treadmill test conducted, % (CI)	19.8 (19.0–20.7)	20.2 (19.5–20.9)	.518
Intermittent claudication (IC)	*n = 5591*	*n = 8643*	
Pre-op. measurement of ankle brachial index, % (*n*)	95.7 (5351)	96.1 (8307)	.240
Results of ankle brachial index not valid, % (*n*)	5.9 (315)	7.1 (591)	.005
Pre-operative ankle brachial index, median (IQR)	0.57 (0.41–0.70)	0.59 (0.44–0.73)	< .001
Post-operative ankle brachial index, median (IQR)	0.79 (0.60–0.93)	0.81 (0.62–0.95)	< .001
Peri-procedural increase in ankle brachial index, median (IQR)	0.18 (0.01–0.33)	0.17 (0.15–0.32)	.272
TASC C/D lesions (aorto-iliac), % (CI)	7.3 (6.4–8.2)	8.3 (7.6–9.1)	.831
TASC C/D lesions (ATK), % (CI)	21.9 (20.7–23.2)	21.6 (20.5–22.6)	1.000
TASC C/D lesions (BTK), % (CI)	15.1 (13.6–16.7)	16.9 (15.7–18.2)	.119
Crural vessels (BTK) involved in procedure, % (CI)	7.4 (6.7–8.1)	7.7 (7.1–8.3)	.559
TASC classes: Disease severity score, median (IQR) [min–max]	2 (1–3) [0–22]	2 (1–3) [0–22]	1.000
Dose area product in Gy*cm,^{2} median (IQR)	12.06 (3.69–33.80)	15.23 (4.80–42.44)	< .001
Chronic limb threatening ischaemia (CLTI)	*n = 3690*	*n = 5422*	
Preop. measurement of ankle brachial index, % (*n*)	82.6 (3048)	82.0 (4444)	.451
Results of ankle brachial index not valid, % (*n*)	28.5 (870)	32.0 (1424)	.001
Pre-operative ankle brachial index, median (IQR)	0.45 (0.23–0.64)	0.50 (0.28–0.73)	< .001
Post-operative ankle brachial index, median (IQR)	0.69 (0.50–0.88)	0.73 (0.50–0.92)	< .001
Increase in ankle brachial index, median (IQR)	0.17 (0.00–0.38)	0.17 (0.00–0.37)	.395
TASC C/D lesions (aorto-iliac), % (CI)	8.3 (7.0–9.8)	8.7 (7.6–10.0)	.856
TASC C/D lesions (ATK), % (CI)	32.0 (30.3–33.7)	29.8 (28.3–31.2)	.583
TASC C/D lesions (BTK), % (CI)	37.0 (34.9–39.1)	39.9 (38.2–41.6)	.644
Crural vessels (BTK) involved in procedure, % (CI)	32.2 (30.7–33.8)	42.7 (41.4–44.1)	< .001
TASC classes: Disease severity score, median (IQR) [min–max]	3 (2–4) [1–24]	3 (2–4) [0–24]	1.000
Dose area product in Gy*cm,^{2} median (IQR)	10.89 (3.39–29.80)	10.72 (3.80–30.45)	.329

ATK: above the knee; BTK: below the knee; CI: confidence interval, in this context 95%; CLTI: chronic limb threatening ischaemia; IQR: interquartile range; IC: intermittent claudication; TASC: Transatlantic Society Consensus for the Management of Peripheral Arterial Disease.

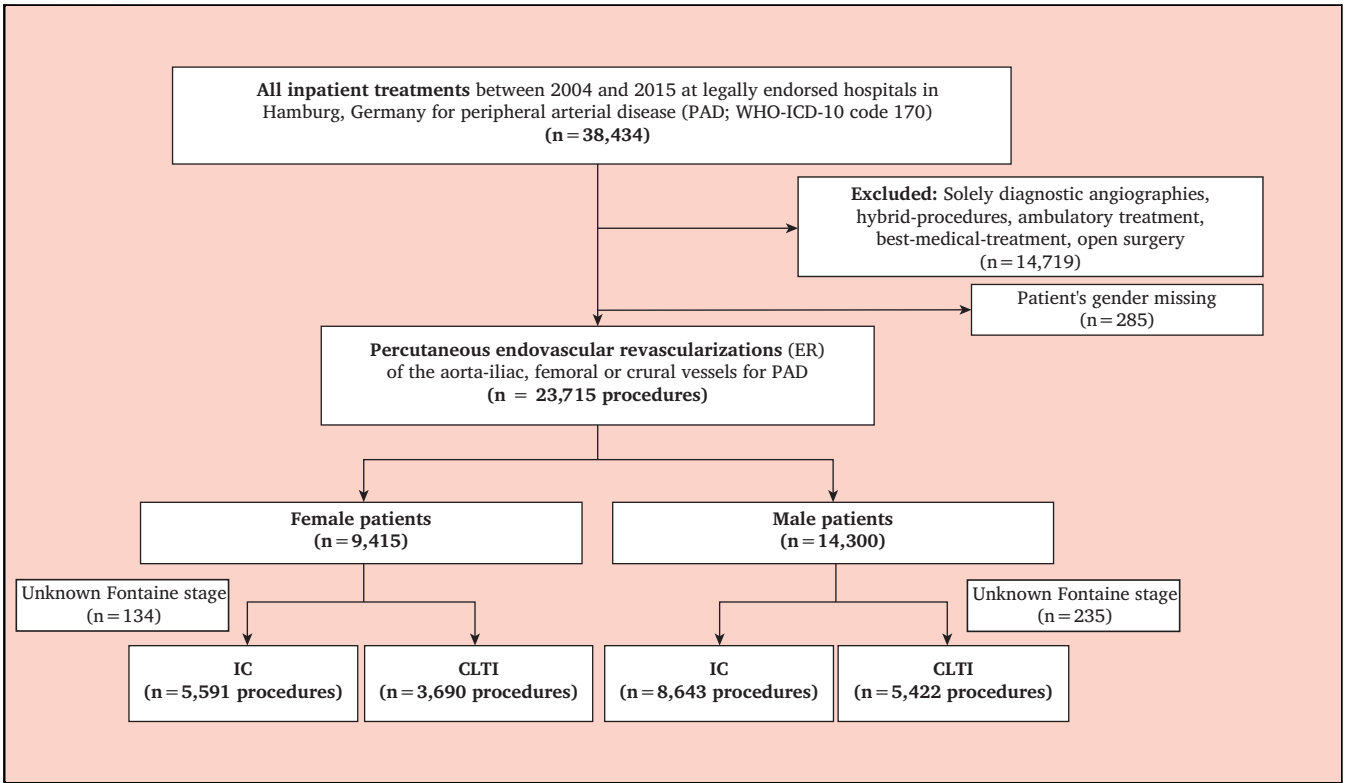

Figure 1. Flow chart: 23,715 percutaneous endovascular revascularisations included in this study between 2004 and 2015. PAD = peripheral arterial disease; IC = intermittent claudication; CLTI = chronic limb threatening ischaemia; WHO-ICD = World Health Organization-International Classification of Diseases.

dissections (0.7% vs. 0.2%, $p < .001$) and distal embolisms (1.1% vs. 0.5%, $p < .001$) were more common in females after ER of CLTI. Female patients were more often transferred to another hospital after a median post-operative hospital stay of one day for IC (0.8% vs. 0.4%, $p = .005$). The same gender related difference appeared regarding transfer to a nursing home (0.3% vs. 0%, $p = .001$ for IC; 2.5% vs. 1.2%, $p < .001$ for CLTI).

Adjusted multivariable analyses

In multivariable analyses stratified for IC and CLTI, the independent impact of female gender on the occurrence

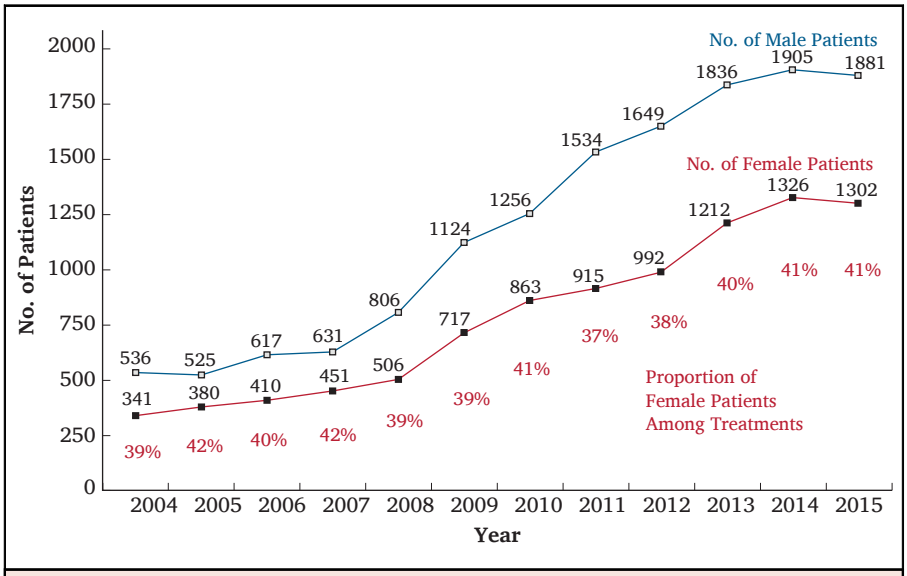

Figure 2. Annual numbers and proportions (%) of male (blue) and female (red) patients included in this study between 2004 and 2015.

Table 2. In hospital outcome (unadjusted) by gender of intermittent claudication (above) and chronic limb threatening ischaemia (below)

Clinical Stage	Female Patients	Males Patients	*p* value
Intermittent claudication (n = 14,234)	*n = 5591*	*n = 8643*	
Early unsuccessful termination of procedure, *n* (%)	296 (3.1)	478 (3.3)	.561
Occlusion, *n* (%)	18 (0.3)	19 (0.2)	.243
Pseudoaneurysm, *n* (%)	**23 (0.4)**	**12 (0.1)**	.003
Major bleeding, *n* (%)	34 (0.6)	21 (0.2)	.001
Dissection, *n* (%)	28 (0.5)	29 (0.3)	.135
Embolism, *n* (%)	37 (0.7)	52 (0.6)	.667
Other complications (incl. amputation), *n* (%)	25 (0.4)	36 (0.4)	.797
Median length of post-operative hospital stay, days (IQR)	1 (1–2)	1 (1–2)	1.000
In hospital mortality, *n* (%)	6 (0.1)	10 (0.1)	1.000
Transferred to another hospital, *n* (%)	43 (0.8)	35 (0.4)	.005
Transferred to rehab, *n* (%)	20 (0.4)	32 (0.4)	.996
Transferred to nursing home, *n* (%)	14 (0.3)	4 (0.0)	.001
Chronic limb threatening ischaemia (n = 9112)	*n = 3690*	*n = 5422*	
Early unsuccessful termination of procedure, *n* (%)	138 (3.7)	244 (4.5)	.079
Occlusion, *n* (%)	28 (0.8)	42 (0.8)	1.000
Pseudoaneurysm, *n* (%)	16 (0.4)	10 (0.2)	.043
Major bleeding, *n* (%)	35 (0.9)	33 (0.6)	.082
Dissection, *n* (%)	25 (0.7)	11 (0.2)	.001
Embolism, *n* (%)	42 (1.1)	27 (0.5)	.001
Other complications (incl. amputation), *n* (%)	36 (1.0)	45 (0.8)	.496
Median length of post-operative hospital stay, days (IQR)	4 (2–12)	4 (2–12)	1.000
In hospital mortality, *n* (%)	119 (3.2)	139 (2.6)	.062
Transferred to another hospital, *n* (%)	293 (7.9)	539 (9.9)	.001
Transferred to rehab, *n* (%)	55 (1.5)	77 (1.4)	.789
Transferred to nursing home, *n* (%)	91 (2.5)	67 (1.2)	< .001

IQR: interquartile range.

Table 3. Independent impact of predictors on the likelihood that any bleeding complication occurs following percutaneous endovascular revascularisation of intermittent claudication (left) and chronic limb threatening ischaemia (right) in adjusted multivariable analysis (adjusted for female gender, disease burden by TASC classes, length of hospital stays, diabetes and age)

Endpoint: Any bleeding complication including major bleeding or pseudoaneurysm	Intermittent claudication			Chronic limb threatening ischaemia		
	OR	95% CI	*p* value	OR	95% CI	*p* value
Female gender (vs. male gender)	2.46	1.58–3.84	< .001	1.66	1.09–2.51	.018
Higher age (increase by one year)	1.03	1.01–1.05	.017	1.01	0.99–1.04	.199
Higher plaque burden (increase by one score point)	1.06	0.99–1.14	.097			

TASC: Transatlantic Society Consensus for the Management of Peripheral Arterial Disease. OR = Odds Ratio. CI = Confidence Interval.

Table 4. Independent impact of predictors on the likelihood that the patient is transferred to a nursing home following percutaneous endovascular revascularisation of intermittent claudication (left) and chronic limb threatening ischaemia (right) in adjusted multivariable analysis (adjusted for female gender, disease burden by TASC classes, length of hospital stays, diabetes and age)

Endpoint: Transfer to nursing home	Intermittent claudication			Chronic limb threatening ischaemia		
	OR	95% CI	*p* value	OR	95% CI	*p* value
Female gender (vs. male gender)	3.93	1.26–12.25	.018	1.53	1.10–2.13	.012
Higher age (increase by one year)	1.12	1.05–1.18	< .001	1.06	1.04–1.08	< .001
Below the knee procedure performed				1.27	0.92–1.75	.142
Diabetes coded	9.01	3.34–24.27	< .001			

TASC: Transatlantic Society Consensus for the Management of Peripheral Arterial Disease. OR = Odds Ratio. CI = Confidence Interval.

of any bleeding complication and transfer to nursing homes remained statistically significant (Table 3 for IC, Table 4 for CLTI).

DISCUSSION

In this German investigation of gender disparities in 23,715 ERs for PAD conducted between 2004 and 2015, considerable differences were found between genders deserving further reflection. Females were significantly older and more often suffered from rest pain at the time of presentation when compared with males. Although no differences appeared in lesion complexity or disease burden, crural vessels were less often revascularised in females than males. Interestingly, bleeding complications and transfer to nursing homes were more common in female patients and the independent effect of female gender remained statistically significant in multivariable analyses. Although these gender disparities seem to underline the ongoing debate in vascular medicine, it must be highlighted that differences in outcomes were mainly accounted for by numerically small differences. It is for the vascular community to ponder statistical significance vs. clinical relevance.

Some epidemiological prospective trials are available to illuminate gender disparities among PAD patients, but they are usually limited to an age of 74 years while approximately 38% of the study cohort were 75 years or older. There are certainly discrepancies between target populations underlining the importance of investigating hospitalised cohorts.

Several studies mainly focussing on clinical cohorts have reported similar proportions[3,21,22] and a higher age of females when compared with males at the time of hospital admission.[8,22–24] Well known demographic developments may cause an increasing proportion of ageing female patients[25] in the future and there is already a verifiable trend when reviewing women in cardiovascular clinical trials between 1994 and 2017.[26]

As a possible side effect of these demographic developments, it was found that female gender was an independent predictor of being transferred to a nursing home after revascularisation. It seems likely that a higher life expectancy of females when compared with males leads to differences in ambulatory care. Women outlive their husbands and care for their disabled spouses. However, there is also evidence that women with PAD are subject to a greater degree of functional impairment and lower quality of life when compared with males suffering from PAD.[27] Unfortunately, no information about the ambulatory setting or care was collected in this study. Thus, future studies should illuminate differences in the level of frailty, ambulation, and social isolation of these patients.

Regarding differences in clinical presentation, it was found that female patients more often suffer from ischaemic rest pain when compared with males. This finding confirms prior results from disease registries[8,22,28] and cross sectional studies where women with PAD were more likely than men to have exertional leg pain that sometimes begins at rest.[23] Others have found women to be more prone to present with no symptoms when compared with their male counterparts.[29,30] Studies have shown gender specific differences in clinical presentation among patients with cardiovascular disease in that women more often present with atypical symptoms of angina. This fact has been regarded as responsible for a deficient awareness and underutilisation of early treatment options in female gender.[31,32] The question arises of whether disparities in clinical symptoms between genders may have an impact on the referral practice of general practitioners and on the female patient's consent to be revascularised.[20] Among all patients with CLTI in the study cohort, female patients were significantly less often revascularised BTK compared with their male counterparts. This finding confirms results from three studies where females had a higher incidence of femoropopliteal disease when compared with males.[22,33,34] A higher rate of diabetes with corresponding non-valid ABI values in males seems to support the conclusion that male patients more often suffer from atherosclerotic diseases BTK while females primarily suffer from lesions ATK.

Another important research question of this study was to illuminate differences in bleeding rates between genders. This study revealed a two- to threefold higher rate of pseudoaneurysms and major bleeding complications in female patients compared with males, confirming prior reports concerning complex endovascular aortic repair and percutaneous ERs.[8,9] Anatomical differences such as smaller vessel diameter in females often serve as a possible explanation. These anatomical differences might also explain the higher rate of target vessel dissection or distal embolism in females following CLTI. Unfortunately, to date, there is no commonly accepted definition of bleeding complications. Furthermore, there are various closure devices commercially available, ERs are often performed under platelet inhibitors or anticoagulants, and this complication is likely to be under diagnosed or under reported in real world evidence. However, although comparatively rare, it is possible that major bleeding requires an unplanned open surgical revision or re-intervention with possible impact on outcomes and quality of life emphasizing the need for further reflection.

This study has limitations. First, it is limited to inpatient treatments and in hospital outcomes and there is no information on long-term patency or target limb revascularisation as commonly consented indicators of outcome quality for PAD treatment.[35] To date, no valid data are available including the outpatient treatments of PAD patients in the metropolitan area of Hamburg. Although the fee for service reimbursement system in Germany probably motivates interventionalists to perform inpatient procedures rather than outpatient procedures, there might be another target population not included in this study. However, it is believed that gender distribution is comparable and that there is no relevant selection bias limiting the results of this study. Second, no information regarding admission mode is collected in the EQS and this applied to both genders. Third, the adjusting covariable of diabetes

was extracted from ICD-10 codes used for hospital reimbursement and it is possible that this risk factor is under reported in this database. However, this would have an impact on both groups equally.[36] Lastly, there are possibly some confounders making the conclusions arising from outcome differences merely speculative. For instance, the sheath size, puncture direction, or closure devices used might have an impact on complication rates. Unfortunately, this information was not available within the study data. Future prospective trials, such as the IDOMENEO study in Germany (ClinicalTrials.gov NCT03098290), should illuminate the impact of access related details on outcomes.

CONCLUSIONS

In this study considering percutaneous ER for PAD, female patients were older, had different clinical symptoms, more often suffered from complications, and were at risk of social isolation after discharge when compared with their male counterparts. These results emphasise the need for further studies to evaluate a gender based treatment algorithm in PAD.

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CONFLICTS OF INTEREST

None.

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