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Gender Differences in High-risk CAS through Radial Access

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Abstract

AIMS: Transradial (TR) carotid artery stenting (CAS) has been established as an acceptable alternative to carotid endarterectomy, especially in patients with a high risk for surgery. The purpose of this study was to evaluate the gender differences of radial access CAS in high-risk patients.

MATERIALS AND METHODS: This was a prospective analysis which included 54 consecutive patients in the period from December 2020 to January 2022. According to the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy study for high-risk CAS, patients with at least one anatomic or comorbid factor associated with increased surgical risk were included in the study. Subjects were divided into two groups according to sex. Follow-up assessments included neurological exams, 12-lead electrocardiogram, and duplex ultrasound (DUS). The primary endpoint was 30-day composite rate of stroke, death, and myocardial infarction. Secondary endpoints included procedure success, access site complications according to Early Discharge after TR Stenting of Coronary Arteries (EASY) score classification, target lesion revascularization, and in-stent restenosis evaluated with DUS.

RESULTS: The study population was predominantly male 37 (61.1%) and females were 17 (38.9%). Mean age in the women group was 64.4 ± 7.43 years, and in men, it was 69.1 ± 8.01 years (p = 0.0223). From risk factors for coronary artery disease, hypertension and smoking were more frequent in the male group and hyperlipidemia and diabetes in the female group. Most of the male patients were symptomatic compared to the female group (p = 0.0151). Procedural success was obtained in all cases. Transient vasospasm induced by the distal protection device was present in one male patient. No 30-day major adverse events were recorded between the two groups. Minor access site bleeding complications according to EASY score (Easy type 1) were recorded in 4 patients (3 males vs. 1 female). There were no cases of hand ischemia after procedure or follow-up. None of the patients had in-stent restenosis >70% on DUS during 1-year follow-up.

CONCLUSION: Results from this study demonstrate no gender-related differences in radial access CAS for high-risk patients.

Introduction

Carotid artery stenting (CAS) is a safe and effective alternative to carotid endarterectomy (CEA) in the treatment of carotid stenosis [1], [2]. In the last decade, with the increasing age of the population as well as its comorbidities, a transition from CEA to CAS is evident. This is especially true for high-risk patients as well as symptomatic patients previously deferred from surgical treatment. Stroke imposes a high socioeconomic burden and is among the three leading causes of death. Approximately 7–12% of all strokes and 9–15% of all ischemic strokes are the result of significant carotid stenosis [3]. Studies show that women have a higher risk of stroke compared to the male population [4]. The role of gender in choosing the appropriate access and type of carotid artery intervention is still a topic of debate. The benefit of CEA in women remains questionable, leading to uncertainty about the influence of female gender on the effectiveness of endovascular treatment. Several studies have associated female gender with negative outcomes, such as an increased risk of perioperative stroke in CEA [5], restenosis, or reintervention [6]. Some characteristics may negatively affect the prognosis in this group such as the size of the blood vessel, the morphology of the plaques, the sensitivity to antiplatelet therapy, as well as the influence of sex hormones [7]. Other authors of gender studies did not show an association between these adverse events and the female gender [8], [9]. However, gender is still considered an independent risk factor in carotid stenting, potentially limiting immediate and long-term benefits.

The aim of this study was to evaluate gender differences in patients with CAS through radial access who are at high risk for CEA.

Materials and Methods

This is a single-center prospective study that included 54 patients undergoing carotid stenting, at a high risk for CEA, performed through a transradial (TR) approach between December 2020 and January 2022.

High-risk patients were defined as those who met at least one of the high-risk criteria according to the Study: Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE). According to North American Symptomatic Trial Collaborators (NASCET) criteria [10] and recommendations from the European Association [11], symptomatic patients with stenosis ≥50% or asymptomatic patients with stenosis ≥70% were suitable for an interventional procedure. Patients were divided and analyzed in two groups according to gender. All patients underwent clinical and neurological examination, a 12-lead electrocardiogram, and duplex ultrasound (DUS) were performed to assess the degree of carotid stenosis. According to our routine procedures, they were given dual antiplatelet therapy, aspirin 100 mg and clopidogrel 75 mg daily, 7 days before the intervention. Patients were scheduled for a regular appointment for carotid stenting and signed informed consent before the procedure. After radial puncture, pre-procedural angiography of the arteries of the arm was performed, which is a routine procedure in our center and allows insight into the anatomy of the arteries, their caliber, possible spasm, or anatomical variations [12]. Initial angiography is performed through a 5 French (Fr) diagnostic catheter, most commonly Simmons 2 dedicated catheter. After diagnostic angiography confirmed the degree of stenosis according to NASCET criteria and review of the aortic arch, we selected one of two main strategies for cannulation, anchoring, or telescopic technique [13], [14]. Different approaches for cannulation (direct cannulation, “simple loop,” and retrograde cannulation “deep loop”) are directly related to the degree of the angle between the arm and the common carotid artery and depend on the classification of the carotid arteries: right, left “bovine,” and left “non-bovine” subgroup. Distal embolic protection device (EPD; Emboshield NAV 6; Abbott Vascular, Santa Clara, California) was used and placed distal to the lesion. Depending on the stenosis, pre-dilatation or direct stenting is performed. After placement of the stent, post-dilatation was performed in most of the cases. After final angiographic control, the whole system was removed, and hemostasis was obtained by the application of TR Band (Terumo Medical, Leuven, Belgium) Figures 1 and 2.

We monitored the clinical and procedural characteristics, bleeding complications at the puncture site, and failure of the primarily chosen TR approach in both groups of patients. Both groups were followed up at day 30, 6 months, and 1 year postoperatively with DUS to assess carotid artery flow, as well as physical examination to assess neurological status. The primary endpoint was to compare the 30-day rate of major adverse events (MAE), defined as the cumulative incidence of any periprocedural (≤30 days post-procedure) complication including death, stroke, or myocardial infarction (MI) between the two study groups. The secondary end goal included (1) success of the procedure; defined as successful carotid stent implantation, with ≤50% residual angiographic stenosis determined by angiographic finding of the target lesion; (2) late ipsilateral stroke (31–365 days); (3) repeat revascularization of the target lesion; (4) in-stent restenosis on DUS (peak systolic velocity (PSV) >300 cm/s at internal carotid artery/common carotid artery ratio PSV ratio >4.0); and (5) access site complications according to Early Discharge After TR Stenting of Coronary Arteries (EASY) Study score classification [15], major vascular or ischemic complications at follow-up.

Statistical analysis

Simple descriptive statistics were used. For normally distributed numeric variables, data were expressed as mean ± standard deviation and for continuous variables not fitting a normal distribution as median (minimum-maximum). Percentages were used to express categorical variables. Student’s t-test was used to compare differences between two groups. The Fisher’s exact test was used for categorical variables. A $p < 0.05$ was considered statistically significant.

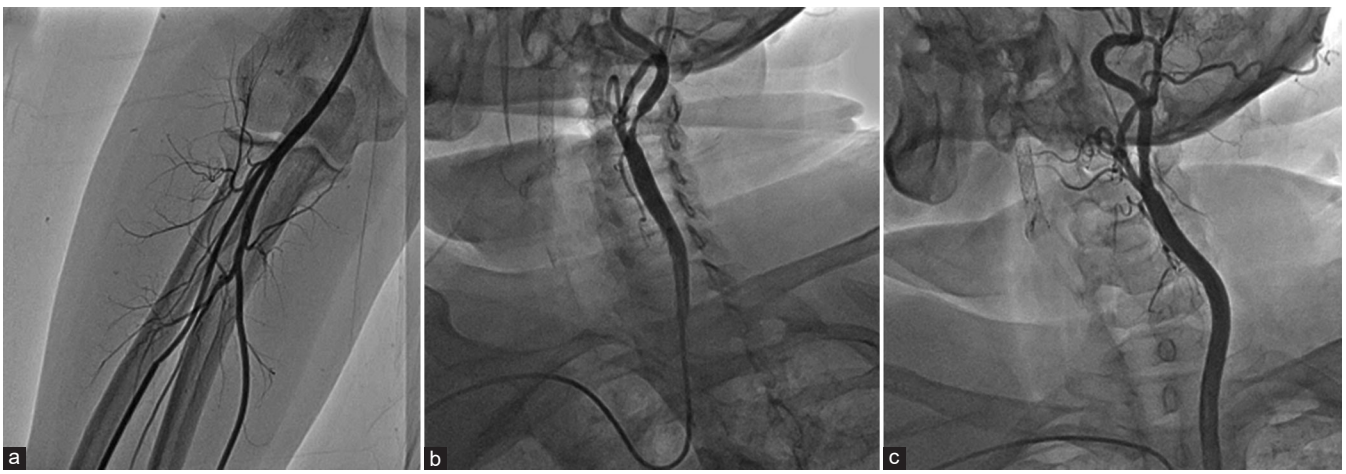


Figure 1: Carotid artery stenting (CAS) in a female patient. (a) Forearm arteriography in female patient. (b) Destination sheath 5 French in left common carotid artery. (c) Result after CAS of left internal carotid artery. Please note previous stent in right internal carotid artery



Figure 2: Carotid artery stenting (CAS) in a male patient. (a) Forearm arteriography in male patient. (b) Shuttle sheath 6 French in right common carotid artery. (c) Result after CAS of right internal carotid artery

Statistical analyses were performed with JMP 16.O for Windows (SAS, Cary, NC, USA).

Results

The study included 54 patients with carotid stenosis and high risk for CEA undergoing a carotid procedure between December 2020 and January 2022. Thirty-seven (63%) of these patients were male and 17 (37%) were female. According to age, the men group was older than the female group (69.1 ± 8.01 years vs. 64.4 ±7.43 years, p = 0.0223) Figure 3. Demographic variables were comparable between the sexes and did not differ significantly Table 1. The rate of hypertension (67% vs. 33%) and previous MI (37% vs. 17.6%) was higher in men and the rate of diabetes was higher in women (35% vs. 20%), but both differences were not statistically significant. Symptomatic carotid stenosis was more frequent in men rather than women (p = 0.0151), as was also the rate of previous ischemic stroke (p = 0.0114). Procedural success with primary chosen TR access was 100%. In relation to radial artery anatomy, the overall incidence of radial anomalies and tortuosity was higher in the female group (p = 0.0415 and p = 0.0235, respectively). In 28 patients (male 48% vs. female 58%), the target lesion was on the left carotid artery, and in 26 (male 51% vs. female 41%) in the right internal carotid artery. In 37% of cases with CAS, distal protection device was used. Several types of stents were used during the interventional procedure. Closed cell self-expanding stents Wallstent™ (Boston Scientific) was implanted in 14 patients and Xact (Abbott Vascular) in 4, double-mesh stents Roadsaver® (Terumo Corporation, Tokyo, Japan) in 25 patients, whereas Neuroguard IEP System (Contego Medical, Raleigh, NC) in 11 cases. The mean procedural time was 24.1 ± 10.9 min and mean fluoroscopy time 10.1 ± 7.4 min, volume of contrast used was 168 ± 61 mL. (100–200 mL), and these procedural characteristics did not differ between groups. Anatomical and procedural characteristics from both groups are presented in Table 2. We also did not register any statistically significant lesion characteristics difference according to gender, even though men had more calcific lesions, bilateral carotid disease, and string sign documented, and women had more frequent tortuous internal carotid anatomy Table 3. Procedural success was obtained in

Table 1: Demographic characteristics

Demographic characteristics	Total (n = 54) *n* (%)	Men (n = 37) *n* (%)	Women (n = 17) *n* (%)	p*
Average age ± SD	67.66	69.1 ± 8.01	64.4 ± 7.43	0.0223
Symptomatic	32 (59.2)	26 (70.3)	6 (35.3)	0.0151
Asymptomatic	22 (40.8)	11 (29.7)	11 (64.7)	
BMI	26.10	25.75	26.45	0.8101
Hypertension	51 (94.4)	34 (67)	17 (33)	0.2270
Previous ischemic stroke	16 (29.6)	15 (40.5)	1 (5.8)	0.0114
Transient ischemic attack	6 (11.1)	6 (16.2)	0 (0)	0.0637
Diabetes mellitus type 2	14 (26)	8 (20)	6 (35)	0.2452
Smokers	18 (33.3)	13 (35.1)	5 (29.4)	0.0509
Hyperlipidemia	23 (42.5)	15 (40)	8 (47)	0.6741
Previous Myocardial Infarction	17 (31.4)	14 (37)	3 (17.6)	0.1379
Previous PCI	11 (20.3)	8 (20)	3 (17.6)	0.7363
Bilateral carotid disease	5 (9.2)	4 (10)	1 (5.8)	0.5617
Contralateral occlusion	3 (5.5)	2 (5.4)	1 (5.8)	0.9433
LV Ejection fraction EF < 30%	5 (9.2)	4 (10)	1 (5.8)	0.5617
Previous aorta coronary bypass	3 (5.5)	3 (8.1)	0 (0)	0.2270
High cervical lesion	3 (5.5)	1 (2.7)	2 (11.6)	0.1731
Creatinine > 177 mmoL/	15 (27.7)	10 (27)	5 (29.4)	0.8510
Recent heart surgery	1 (1.8)	1 (2.7)	0 (0)	0.3496
HOBB	9 (16.6)	7 (18.9)	2 (11.6)	0.5124

BMI: Body mass index.

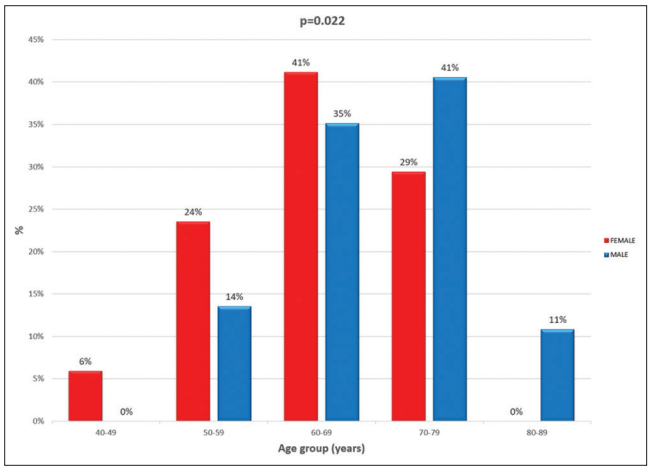


Figure 3: Age distribution of the patients included in the study by sex

Table 2: Anatomical and procedural characteristics

Variable	Total (n = 54) n (%)	Men (n = 37) n (%)	Women (n = 17) n (%)	p-value
Localization of target lesion				
Right internal carotid artery	26 (48.1)	19 (51)	7 (41)	0.4871
Left internal carotid artery	28 (51.9)	18 (48)	10 (58)	
Aortic arch type				
Type 1	3 (4.7)	2 (67)	1 (33)	
Type 2	43 (79.6)	30 (69.7)	13 (30.3)	
Type 3	6 (11.1)	3 (50)	3 (50)	
"Bovine"	2 (3.7)	1 (50)	1 (50)	
Lesion characteristic				
Bilateral carotid disease	5 (9.2)	4 (10.8)	1 (5.8)	0.5617
Calcium lesion	6 (11.1)	5 (13.5)	1 (5.8)	0.4073
Tortuous CA	4 (7.4)	2 (5.4)	2 (11.7)	0.3735
String sign	14 (26)	11 (29.7)	3 (17.6)	0.3467
Contralateral occlusion	3 (5.5)	2 (5.4)	1 (5.8)	0.9433
Access site characteristics				
RA anomalies	4 (7.4)	1 (2.7)	3 (17.6)	0.0415
RA spasm	2 (3.7)	0 (0)	2 (11.7)	0.0235
Procedural				
5F Guiding sheath	23 (42.5)	15 (40)	8 (47)	0.7134
*Destination	20 (37)	13 (35)	7 (41)	0.6694
*Shuttle sheath	3 (5.5)	2 (5.4)	1 (5.8)	0.9433
6F Guiding sheath	26 (48.1)	19 (51)	7 (41)	0.7432
*Destination	18 (33.3)	12 (32)	6 (35)	0.8359
*Shuttle Sheath	8 (14.8)	7 (18.9)	1 (5.8)	0.2104
Sheathless	5 (9.2)	3 (10.8)	2 (11.9)	0.8199
ACC Cannulation Technique				
"Anchoring"	44 (81.5)	30 (81)	14 (82)	0.9110
"Telescopic"	11 (20.3)	8 (21)	3 (17)	0.7363
Direct cannulation	10 (18.5)	9 (24)	1 (5.8)	0.1052
Simple loop cannulation	38 (70.4)	25 (67)	13 (76)	0.5058
Deep loop cannulation	6 (11.1)	3 (8)	3 (17.6)	0.3002
Distal embolization protection filter				
Emboshield NAV 6	20 (37)	14 (37.8)	6 (35)	0.8573
Stent type				
Wallstent	14 (25.8)	10 (27)	4 (23.5)	
Roadsaver	25 (46.3)	16 (43.2)	9 (25.9)	
Neuroguard IEP System	11 (20.4)	8 (21.6)	3 (17.5)	
Xact	4 (7.4)	3 (8.1)	1 (5.8)	
Direct Stenting	43 (79)	31 (83)	12 (70)	0.2635
Procedural characteristics				
Procedural time (min)	24.1 ± 10.9	25 ± 11.6	22.1 ± 9.4	0.1903
Fluoroscopy time (min)	10.1 ± 7.4	10.8 ± 8.8	8.7 ± 2.1	0.1740
Contrast volume (ml)	168 ± 61.9	176 ± 64.2	150 ± 54.7	0.1224
Filter time (min)	2.2 ± 2.8	2.2 ± 2.9	2 ± 2.7	0.3658

all cases. Transient vasospasm induced with wire from the EPD was present in one male patient. No 30-day MAEs were recorded between the two groups. Minor access site bleeding complications according to EASY score [15] (EASY type 1) were recorded in 4 patients (3 males vs. 1 female). There were no cases of hand ischemia after procedure or follow-up. Furthermore, there was no cases of in-stent restenosis >70% on DUS during 1-year follow-up Table 4.

Table 3: Lesion characteristics

Lesion characteristics	Male n = 37 n (%)	Female n = 17 n (%)	p-value
Bilateral carotid disease	4 (10.8)	1 (5.8)	0.5617
Calcium lesion	5 (13.5)	1 (5.8)	0.4073
Tortuous CA	2 (5.4)	2 (11.7)	0.3735
String sign	11 (29.7)	3 (17.6)	0.3467
Contralateral occlusion	2 (5.4)	1 (5.8)	0.9433

Discussion

Carotid revascularization is the treatment of choice in patients with significant carotid disease. Initially, the superiority of CEA over medical treatment was proven [13], but over the years, carotid stenting has been shown to be a safe and effective alternative method [16], [17], especially with new devices being developed in recent years [18], [19], [20]. Gender

Table 4: Secondary end-point outcomes

Variable	Male n = 37 n (%)	Female n = 17 n (%)	p-value
Procedural success	37 (100)	17 (100)	NS
Technique success	37 (100)	17 (100)	NS
Radial access success	37 (100)	17 (100)	NS
Late ipsilateral stroke	0 (0)	0 (0)	NS
TVR	0 (0)	0 (0)	NS
In-stent restenosis on DUS	0 (0)	0 (0)	NS
EASY type 1 hematoma	3 (8.1)	1 (5.8)	NS

plays an important role in cardiovascular events. Men have a higher prevalence and incidence of stroke, but women tend to have a more severe clinical state and prognosis [21]. This raises the question of whether the post-operative success of CAS may differ between the sexes. Initially, female gender is associated with a higher rate of stroke occurrence after CEA [5]. Most of the clinical studies targeting CEA were limited by the small percentage of female patients included, and the long-term benefit was influenced by perioperative comorbidity in women. The SAPPHIRE study [10] was the first to show that CAS was non-inferior to CEA, but no comparison was made between genders. Several years later, a higher rate of restenosis, stroke, or reintervention was reported in females after CEA and CAS [6], [22]. Some of the authors in other studies did not confirm these results [23], [24]. A sex-specific subgroup analysis from the CREST (Carotid Revascularization Endarterectomy Versus Stenting Trial) study [25] reported a higher periprocedural risk for any stroke, MI, or death for women randomized to CAS compared with women randomized to CEA, with little difference for men. No difference in risk by treatment was detected for women relative to men in the 4-year primary outcome [25]. Even though radial artery anomalies were more frequently found in the female group of patients, they did not seem to influence any of the procedural characteristics or access site complications that were the same between both sexes. In this prospective study, we examine the influence of gender in patients at high risk for endarterectomy, on the safety and success of carotid stenting performed through radial approach. All procedures in our study were successfully performed using right radial approach without switching to femoral, although it is important to note that our center is an experienced radial center where 99% of all procedures are performed using wrist approach [12], [26], [27]. Postoperative adverse events in women compared to men had no significant differences in the rate of stroke, MI, and mortality. With long-term clinical monitoring of patients and with duplex ultrasonography, we concluded that gender does not affect the success of the procedure and the occurrence of adverse events. Significant restenosis due to neointimal proliferation up to 1 year of follow-up of patients showed no statistically significant difference between the sexes during this period. Several recent studies have also shown that there is no greater risk of complications associated with the female sex. The results of Jim *et al*. [23] involving 9865 patients did not show an increased risk of adverse events during a 30-day follow-up in women. Furthermore, the results

obtained by Goldstein *et al*. [28] did not show gender differences in the rate of mortality and adverse events at 30 days or 1–5 years. It is possible that some of the differences in literature are due to follow-up criteria (30–60 days post-procedure or 1–5 years), improvement in carotid revascularization technique, and best medical treatment.

Limitations of the study

This is a single-center non-randomized clinical study involving a small number of patients; further multicenter studies are needed to establish the generalizability of our results.

Conclusion

Carotid stenting can be safely and effectively performed in women as well as in men, without significant differences between sexes. Our results did not show a significant influence of gender on the results and outcome of patients at high risk for CEA, in whom CAS was performed through radial approach.

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