70TH ESCVS CONGRESS & 7TH IMAD MEETING

20 I 23 JUNE 2022

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70th ESCVS
International congress of the European Society for Cardiovascular and Endovascular Surgery

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Gender related outcomes in asymptomatic patients undergoing carotid artery stenting (CAS)

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SPEAKER: Margot Ringold, MD

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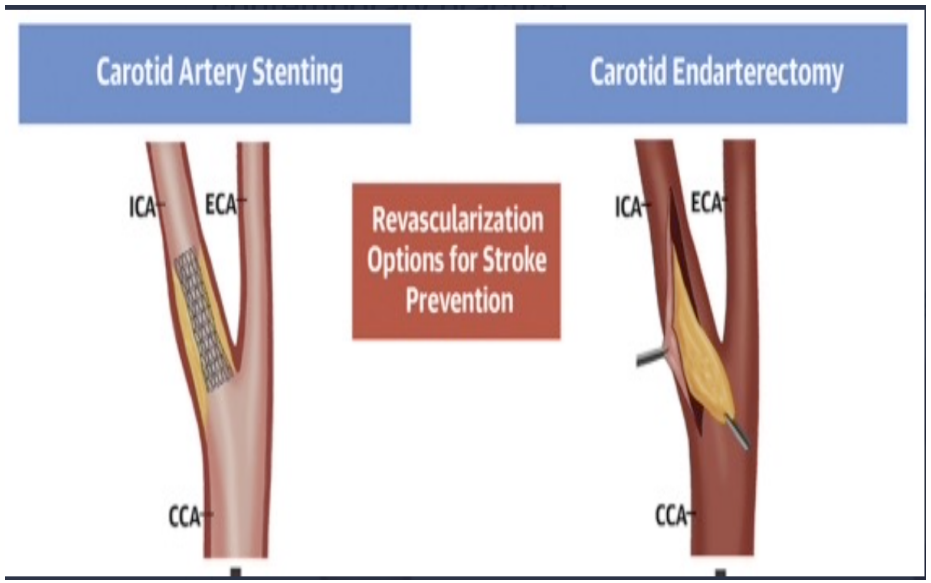
Background

CAS has been proposed as a potentially safe and less invasive therapeutic alternative compared to CEA mostly if associated with the use of EPDs



Recommendation 17	Class	Level	References
In "average surgical risk" patients with an asymptomatic 60–99% stenosis, carotid endarterectomy should be considered in the presence of one or more imaging characteristics that may be associated with an increased risk of late ipsilateral stroke,[a] provided documented perioperative stroke/death rates are <3% and the patient's life expectancy exceeds 5 years	IIa	B	13,35,54,84–94, 96,97
Recommendation 18			
In "average surgical risk" patients with an asymptomatic 60–99% stenosis in the presence of one or more imaging characteristics that may be associated with an increased risk of late ipsilateral stroke,[a] carotid stenting may be an alternative to carotid endarterectomy, provided documented perioperative stroke/death rates are <3% and the patient's life expectancy exceeds 5 years	IIb	B	80,84–98
Recommendation 19			
Carotid stenting may be considered in selected asymptomatic patients who have been deemed by the multidisciplinary team to be "high-risk for surgery" and who have an asymptomatic 60–99% stenosis in the presence of one or more imaging characteristics that may be associated with an increased risk of late ipsilateral stroke,[a] provided documented procedural risks are <3% and the patient's life expectancy exceeds 5 years	IIb	B	84–94,104,105

Naylor AR, Ricco JB, de Borst GJ, et al. Editor's Choice - Management of Atherosclerotic Carotid and Vertebral Artery Disease: 2017 Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS). *Eur J Vasc Endovasc Surg*. 2018;55(1):3-81. doi:10.1016/j.ejvs.2017.06.021

Background

May Gender influence CAS outcomes ?

Clinical impact of sex on carotid revascularization

Age and gender disparities in the risk of carotid revascularization procedures

Sotirios Giannopoulos · Aristeidis H. Katsanos · Spyros N. Vasdekis · Efstathios Boviatsis · Konstantinos I. Voumvourakis · Georgios Tsivgoulis

Influence of sex on outcomes of stenting versus endarterectomy: a subgroup analysis of the Carotid

Carotid Artery Diameter in Men and Women and the Relation to Body and Neck Size

Jaroslaw Krejza, MD, PhD; Michal Arkuszewski, MD; Scott E. Kasner, MD, PhD; John Weigele, MD, PhD; Andrzej Ustymowicz, MD, PhD; Robert W. Hurst, MD, PhD; Brett L. Cucchiara, MD; Steven R. Messe, MD

Risk of periprocedural stroke F > M due to:

- soft plaques
- smaller carotid artery diameter
- calcified aortic arch
- less optimized statin therapy

Conflicting data from no-RCTs and from post hoc analysis of large RCT

Gender and Outcomes of Carotid Artery Interventions

Sex does not have an impact on perioperative transfemoral carotid artery stenting outcomes among octogenarians

Dania Mallick, MBBS, MSPH,[a] Courtenay M. Holscher, MD, PhD,[b] Joseph K. Canner, MHS,[c]

Female gender increases risk of stroke and readmission after carotid endarterectomy and carotid artery stenting

Steven Goicoechea [1], Martin Walsh [1], Michael Soult [2], Pegge M Halandras [2], Carlos Bechara [2], Bernadette Aulivola [2], Paul R Crisostomo [3]

F=M in terms of 30-day stroke, cardiac events or death rates

Aim of the study

Evaluate the influence of gender in asymptomatic patients undergoing CAS

Study design

Retrospective, observational, cohort study conducted in a single Italian tertiary referral center

Population

438 patients admitted to our department between January 2006 and December 2020 and affected by asymptomatic ICA stenosis > 60% underwent transfemoral CAS

INCLUSION CRITERIA

- **high carotid bifurcation**
- **previous neck irradiation / hostile neck**
- **plaque morphology (soft, ulcerated)**
- **controlateral nerve paralysis**
- **pts high risk for surgery**
- **previous CEA**

EXCLUSION CRITERIA

- **unfavorable aortic arch anatomy**
- **severe PAD**
- **markedly angulated or tortuous distal ICA**
- **unstable plaque, known allergies to Aspirin, Clopidogrel or contrast media and renal insufficiency**

462 procedures were performed (M, n=321, 69.4%, F, n= 124, 30,6%), 24 CAS were bilateral (5.5%)

Patients divided in 2 groups based on gender

132 FEMALES (F, 30,1 %)

306 MALES (M, 69,86%)

Statistical Analysis

- **The 2 groups were compared with the *log-rank test***
  - **All p values were 2-sided**
  - **p<0.05 was considered significant**

- **Follow-up outcomes were evaluated with Kaplan–Meier curves to estimate cumulative event-free survival and to compensate patient's dropouts**

- **All follow-up and periprocedural outcomes were analyzed in a subgroup analysis considering the gender variable**

Demographics and comorbidities

	MALES n=306 (69.9)	FEMALES n=132 (30.1)	*p**
Age	72.1±7.8	71.7±7.3	0.317
Abdominal Aneurysm	**26 (9.1)**	3 (2.5)	***0.010***
PAD	68 (23.9)	26 (21.3)	0.336
Family history of PAD	45 (15.7)	14 (11.5)	0.286
Dyslipidemia	206 (72)	94 (77.0)	0.328
Hypertension	255 (89.2)	107 (87.7)	0.733
Diabetes	118 (41.3)	55 (45.1)	0.104
Smoking habit	**170 (59.5)**	41 (33.6)	***0.001***

Baseline characteristics were homogeneous except for:

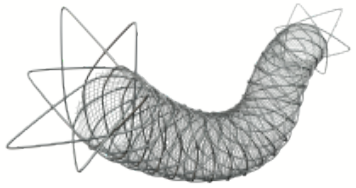
- **smoking habit**
- **coexisting abdominal aneurysm**

Operative data

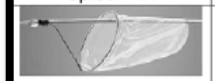
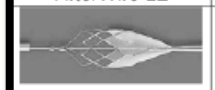
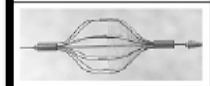
	MALES n=321 (69.4)	FEMALES n=141 (30.6)	p*
Open cell stent	276 (86)	121 (85.8)	0.534
Closed cell stent	22 (6.9)	10 (7.1)	0.533
Micromesh stent	20 (6.2)	7 (5)	0.384
Hybrid stent	3 (0.9)	3 (2.1)	0.297
Stent Diameter (mm)			
10	5 (1.6)	2 (1.4)	0.636
9	3 (0.9)	0 (0)	0.556
8	166 (51.7)	61 (43.3)	0.106
7	131 (40.8)	62 (44)	0.540
6	13 (4)	15 (10.6)	*0.010*
5	3 (0.9)	1 (0.7)	0.643
Stent Length (mm)			
20	6 (1.3)	1 (0.7)	0.681
25	5 (1.6)	3 (2.1)	0.705
30	65 (20.2)	35 (24.8)	0.272
40	244 (76.0)	101 (71.6)	0.353
50	1 (0.3)	1 (0.7)	0.518
Distal EPDs	318 (99.1)	139 (98.6)	0.483
Proximal EPDs	3 (0.9)	2 (1.4)	0.483

2006 – 2016 : Precise (open cell) and Wallstent (closed cell)

2016 - 2020 : C – Guard and Roadsaver (micromesh)



EPDs always employed

DPD	Pore Size, μm	Device Size, mm
 Spider RX	70–200	3, 4, 5, 6, 7
 FilterWire EZ	110	3.5–5.5 (one size fits all)
 RX Accunet	115	4.5, 5.5, 6.5, 7.5
 Emboshield	140	3, 4, 5, 6
 Angioguard XP	100	4, 5, 6, 7, 8

No significant differences in stent devices,

lengths and EPDs employed between the groups.

Post-operative data

- **Access site related complications**

3 cases (0.6%: M, n=1, 0.3%; F, n=2, 1.4%; *p*= .155)

all CFA pseudoaneurysms

- **Systemic complications**

10 cases (2.2%: M, n=5, 1.6%; F, n=5, 3.5%; *p*= .155)

mild (n= 5)

chest pain without any evidence of electrocardiographic signs of ischemia or an elevation of cardiac enzymes

moderate (n=2)

non-fatal pulmonary embolism treated with anticoagulant therapy

severe (n = 3)

- **1 case of bowel ischemia followed by death**
- **2 cerebral hemorrhages with permanent disability and prolonged convalescence**

- **Type of antiplatelet therapy**

ASA 100 mg + Clopidogrel 75 mg for 1 month followed by single lifetime antiplatelet therapy)

Outcomes

PERIPROCEDURALS (30-DAY)

❖ **STROKE**

- **ipsilateral ischemic minor stroke (3 M)**
- **ipsilateral hemorragic major stroke (3 F and 2 F)**

1.7 % (n=8) → ***p*=.462 ns**

❖ **MYOCARDIAL INFARCTION** → **0 events**

❖ **DEATH**

- **1 sepsis secondary to pneumonia**
- **1 bowel perforation**
- **1 ruptured cerebral aneurysm**

0.6% (M, n=3) → ***p*=.334 ns**

Cumulative peri-operative stroke/death rate was 2.3% (n=11, M 8/11) *p*=.554

Follow up

364 CAS procedures included in follow up(78.7%: M n=255, 79.5%; F n=109, 78%)

PRIMARY OUTCOMES

- Survival

- Stroke free survival

SECONDARY OUTCOMES

- Freedom from restenosis

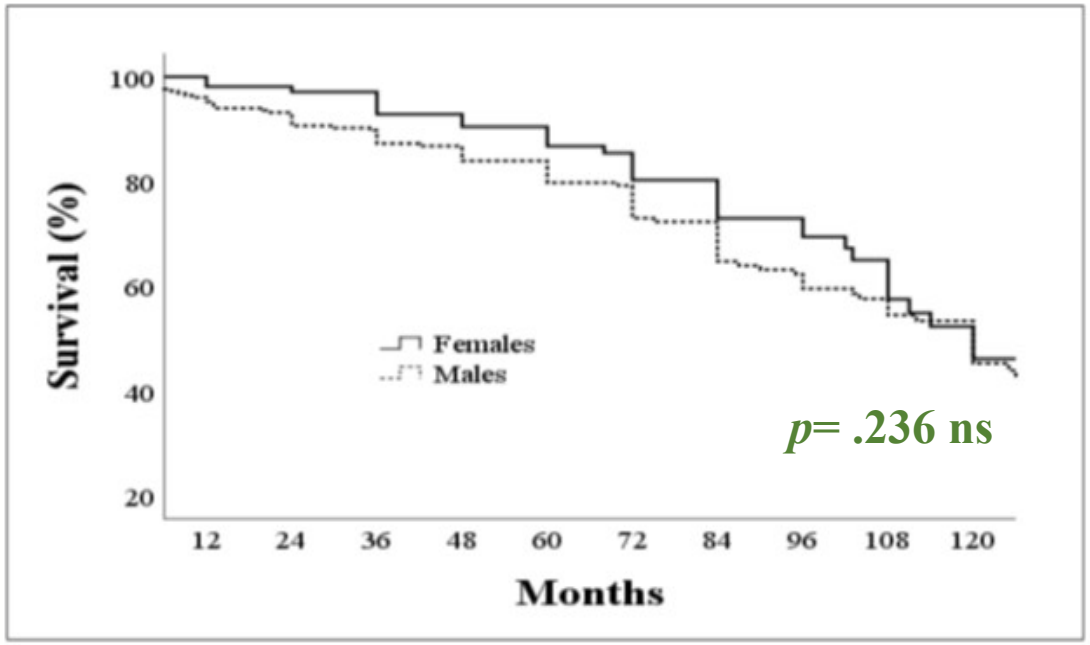
- Reintervention rates

	POPULATION	FEMALES	MALES
@ 1 YEAR	N = 334 (91,7%)	N = 101, 92.6%	N =231, 90.5%;
@ 5 YEARS	N = 211 (57.9%)	N = 144, 56.4%	N = 67, 61.4%
@ 10 YEARS	N = 50, 13,7%	N = 37, 14.5 %	N = 13, 11.9%

MEAN FOLLOW UP : 73.66 ± 40.83 months

(M, 72.66; F, 76.01 months; *p*=.246)

Primary outcomes



N @ risk	0	1 year	5 years	10 years	SE (%)
Males	255	243	209	166	4.5
Females	109	107	97	76	7.4

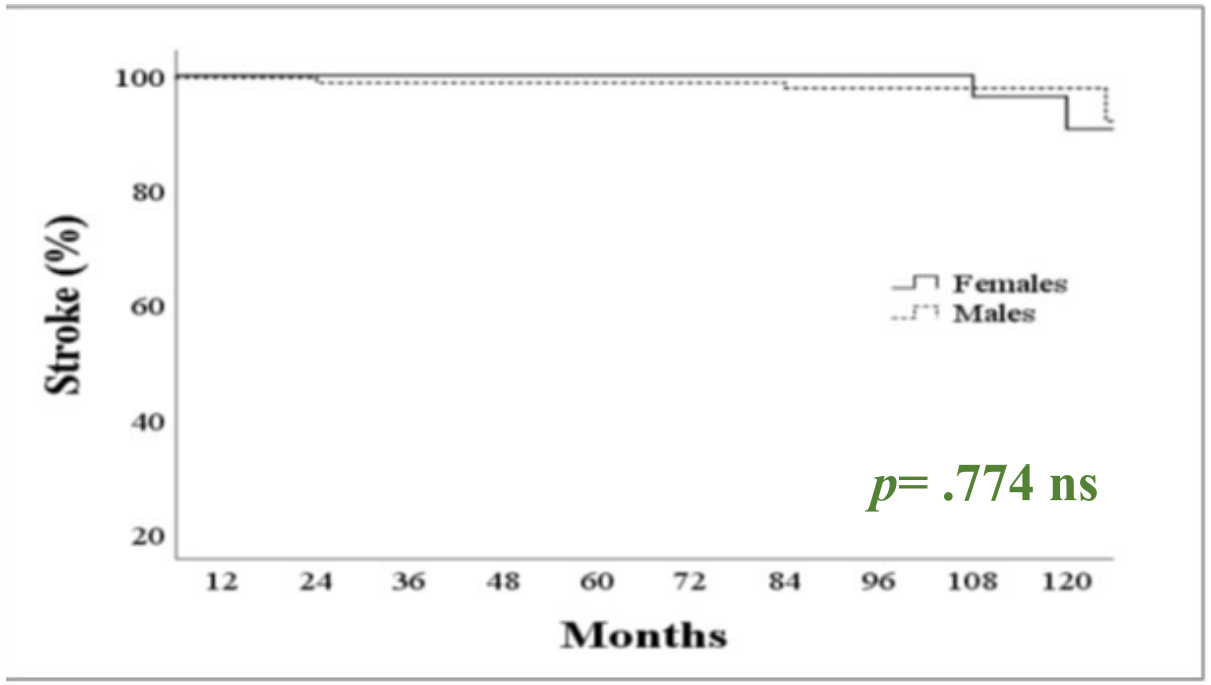
Overall survival rate for all-cause mortality:

- **96.1% at 1 year**
- **81.8% at 5 years**
- **45.5% at 10 years**

Univariate analysis found that overall survival rate was significantly influenced by:

- **dyslipidemia *p*= .045**
- **peripheral arterial disease *p*= .003**

Primary outcomes



N @ risk	0	1 year	5 years	10 years	SE (%)
Males	255	254	252	251	1.2
Females	109	109	109	107	6.5

8 strokes (M, n=6; F, n=2):

5 ipsilateral and 3

controlateral

Overall stroke rate:

0.3% at 1 year

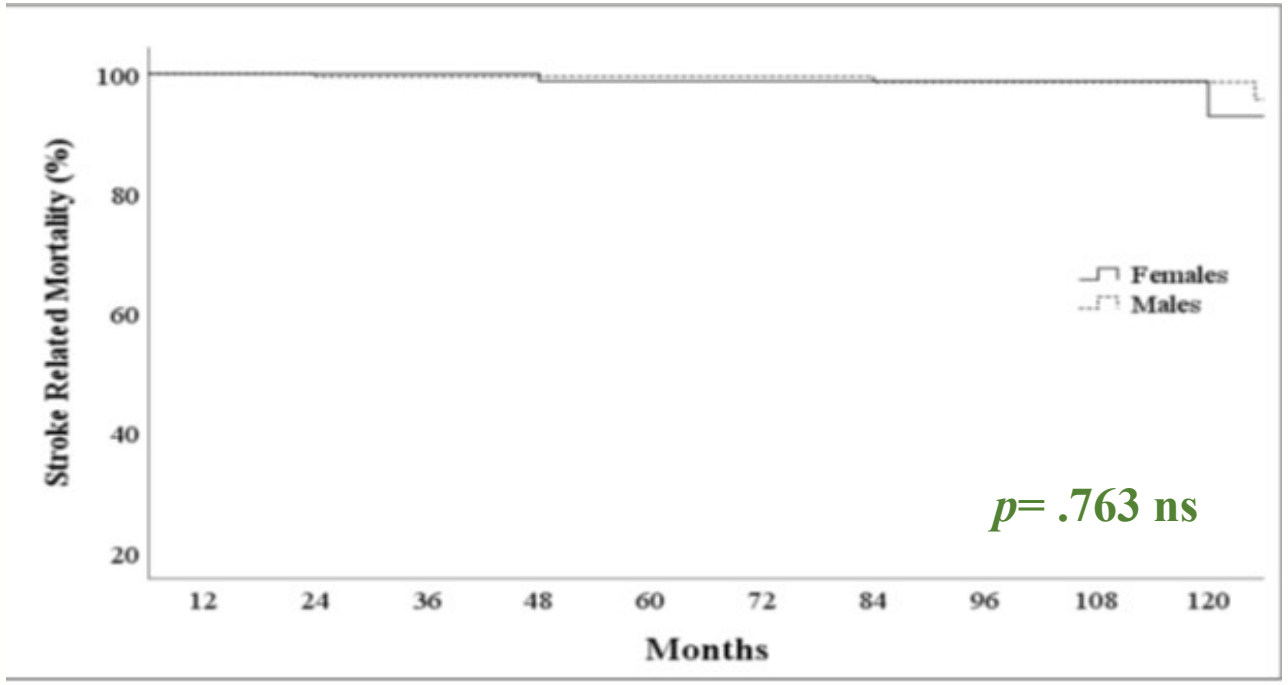
0.9% at 5 year

4.3% at 10-years

F group: stroke-event was less often observed

during the first 5-years period

Primary outcomes



N @ risk	0	1 year	5 years	10 years	SE (%)
Males	255	254	252	251	0.4
Females	109	109	108	107	5.8

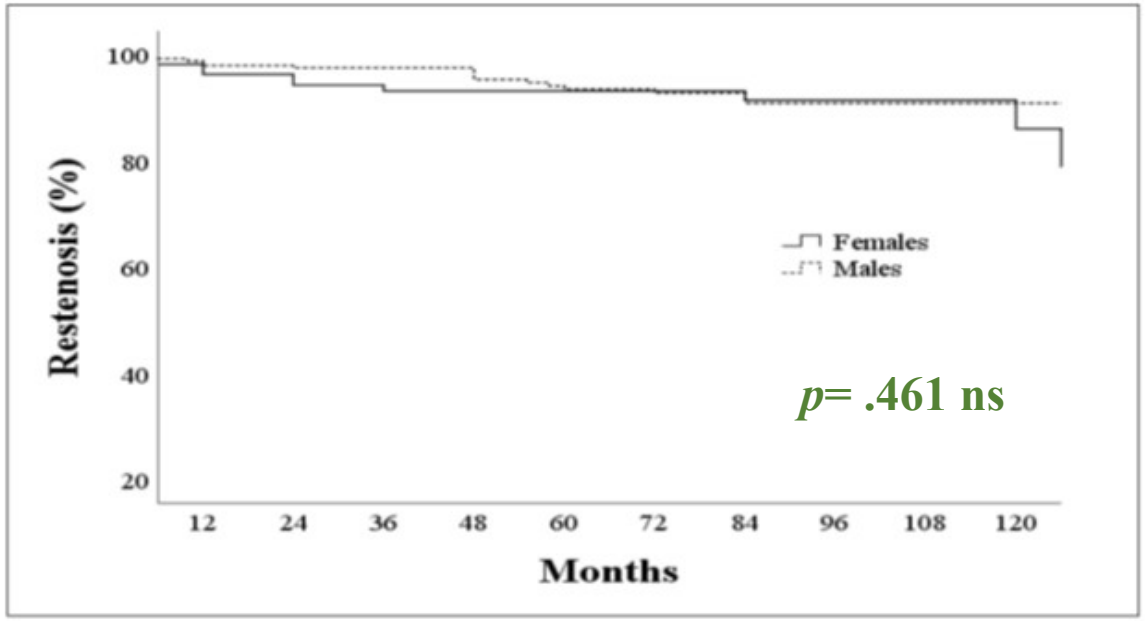
In 6 cases stroke caused death (M, n=4; F, n=2)

No stroke-related deaths during the 1st year

Stroke-related mortality rate:

- **0.7% at 5 years**
- **2.9% at 10-years**

Secondary outcomes



p= .461 ns

N @ risk	0	1 year	5 years	10 years	SE (%)
Males	255	250	242	239	2.3
Females	109	105	102	99	5.9

M group: 2 reinterventions for severe restenosis (>80%)

Overall freedom from restenosis rate was:

- **97.4% at 1 year**
- **93.4% at 5 years**
- **89.5% at 10-years**

Univariate analysis found that freedom from restenosis rate was significantly influenced by

active smoking *p*= .033

Overall freedom from reintervention rate was

- **99.7% at 1 year and 5-years**
- **99% at 10-years of follow-up**

p= .322 ns

→ **Re - PTA**

Study limitations

- **retrospective and not randomized → potential confounding variables such as selection bias and data collection**

- **monocentric experience with a limited sample size and without any head-to-head comparison on different types of surgical approach to carotid stenosis.**

HOWEVER

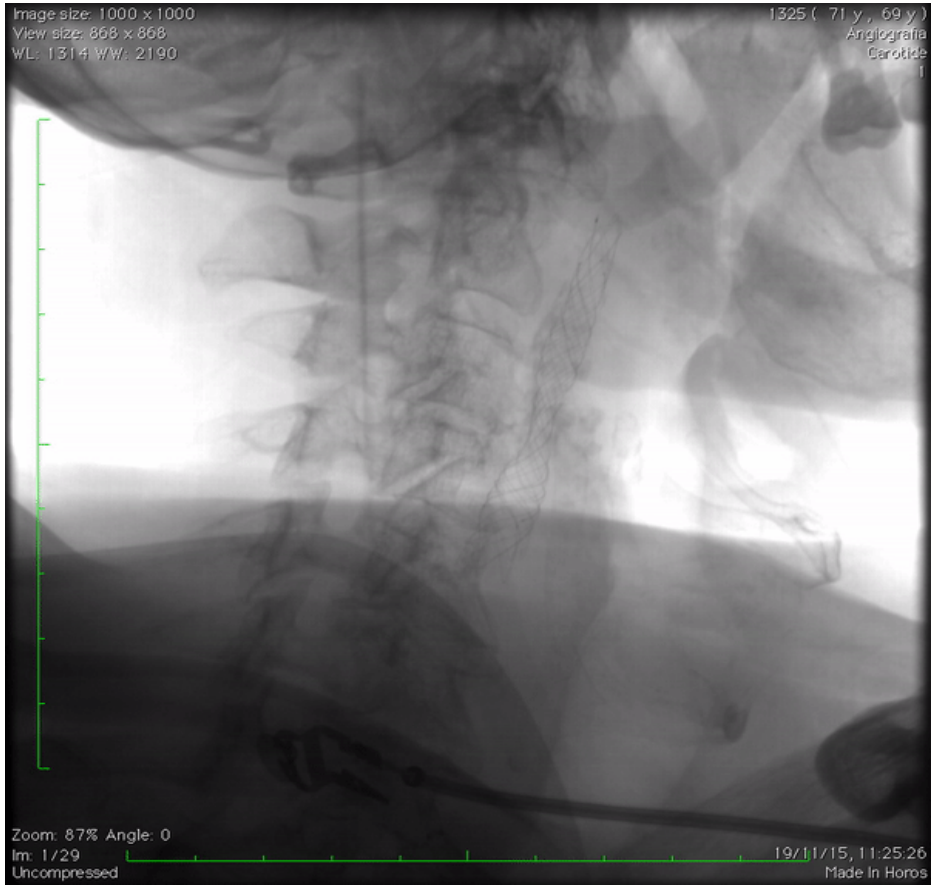
this kind of study provides real-world data with a long time of observation

Conclusions

In our experience gender does not influence the outcomes of CAS in asymptomatic patients at early and late follow-up

CAS may be safely proposed but …

A careful patient's selection and standardized procedural protocols are crucial to obtain satisfactory results




THANK YOU FOR
YOUR ATTENTION!