GISE WOMEN

The Appropriateness of Medical Devices Is Strongly Influenced by Sex and Gender

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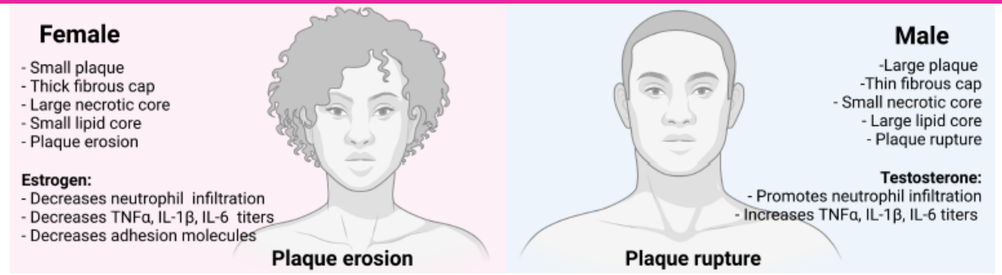
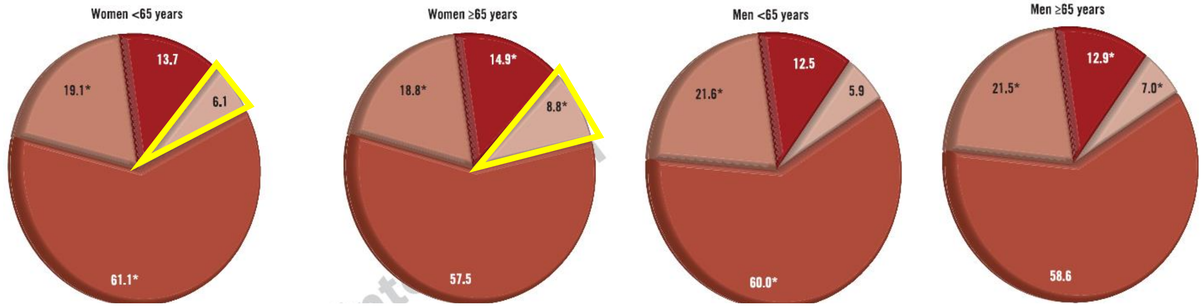
CARDIOVASCULAR DPT
AOU RUGGI D'ARAGONA -SALERNO

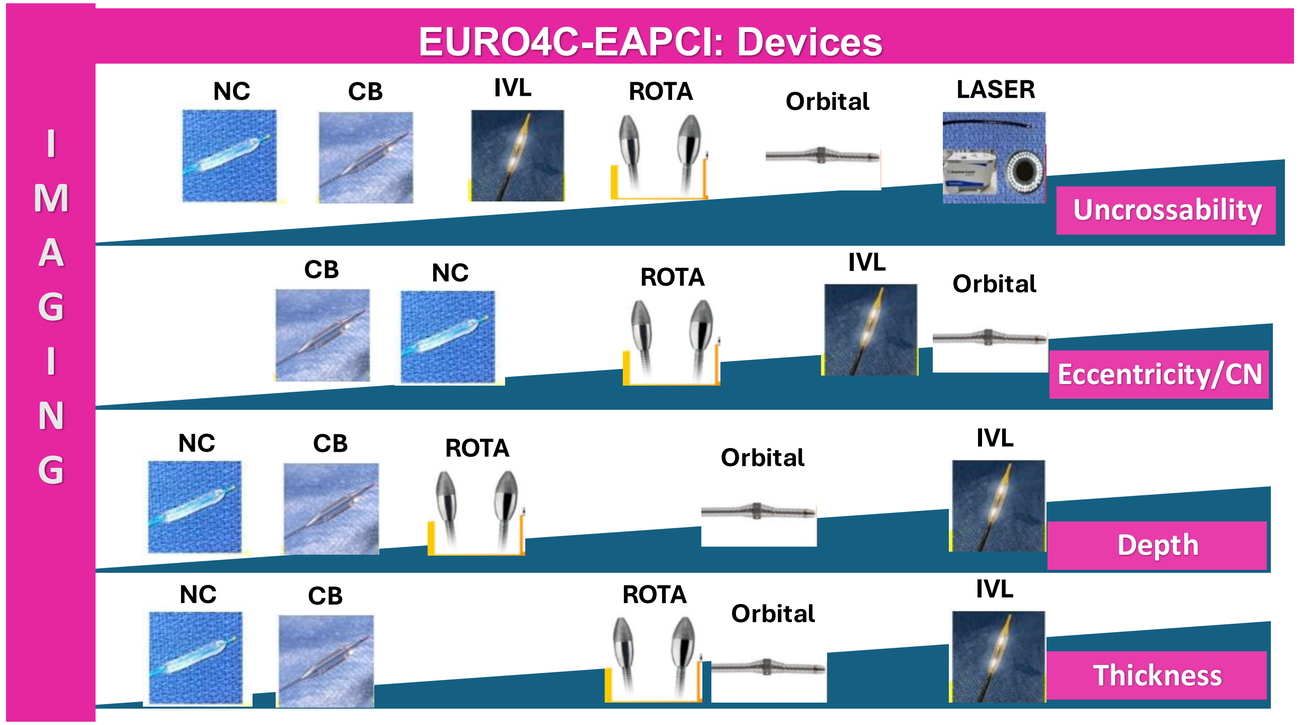
Nothing desclure to declare

Sex difference in coronary plaque composition





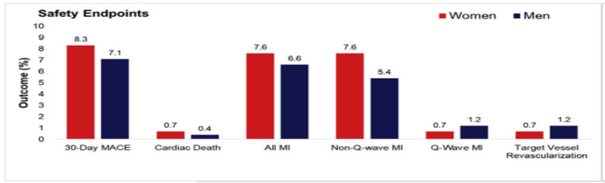
NC: necrotic core DC: dense calcium FF: fibro-fatty tissue FT: fibrous tissue

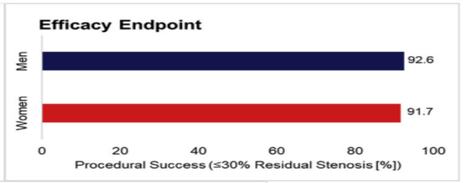

EURO4C-EAPCI: Devices
IMAGING
NC
CB
IVL
ROTA
Orbital
LASER
Uncrossability
CB
NC
ROTA
IVL
Orbital
Eccentricity/CN
NC
CB
ROTA
Orbital
IVL
Depth
NC
CB
ROTA
Orbital
IVL
Thickness

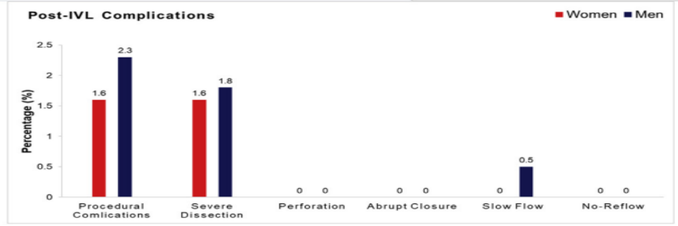
SEX and Calcium treatment: Lithotripsy (IVL)

Baseline Characteristics

Older Age
More Hyperlipidemia
More Renal Insufficiency
Shorter Lesion Length
Smaller RVD







SEX and Calcium treatment: Rotablator (RA)

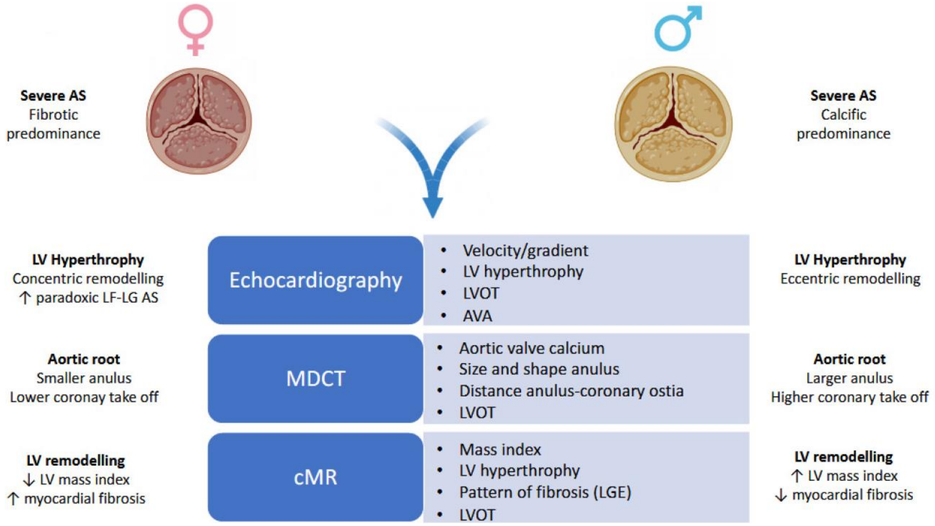
Effect of Sex on Outcomes of Coronary Rotational Atherectomy Percutaneous Coronary Intervention (From the European Multicenter Euro4C Registry)

Flavio Ribichini, MD, PhD
Emanuele Barbato, MD, Ph[P],

At 1 year follow-up, after complete adjustment on potential confounding factors, significant differences in disfavor of female patients were observed on cardio-vascular death (HR = 1, 96 [1.08 to 3.58] p = 0.028), stroke or TIA (6.27 [1.12 to 35.03] p = 0.036). Regarding MI, the difference was not significant, but a clear tendency could be observed (HR: 1.86 [0.99 to 3.49], p = 0.053). As a result, MACE were 1.8 times more likely to occur in female patient at 1 year. It is interesting to emphasize that this significant gender difference in MACE is driven by hard end points (death, stroke/TIA, MI) and not by TLR, which clearly does not differ between gender (1.02 [0.40 to 2.59]

Masiero ,Attisano *et al. Mini-invasive Surg* 2022;6:4

Different AV phenotypes in men and women



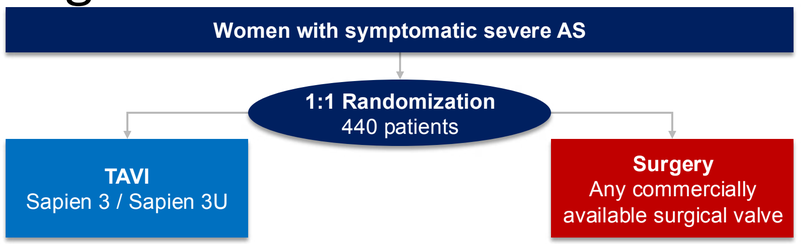
FEMALE SEX AND TAVI- MAIN CONCEPTS

1. Pathophysiology and clinical presentation of AS are influenced by sex
2. Women experience late referral to SAVR and worse outcomes
3. TAVI in female patients is associated with higher risk for vascular complications and bleeding
4. Female sex should be taken into account when planning TAVI strategy

RHEIA Trial Design

RHEIA

Investigator initiated, multicenter, international RCT to evaluate safety and efficacy of TAVI vs. Surgery in women with symptomatic severe AS



- Exclusion criteria:
- Bicuspid aortic valve
- Non-calcified aortic valve
- Complex coronary artery disease
- Other anatomical features increasing the risk of complications with TAVI or surgery

PRIMARY ENDPOINT
Composite endpoint at 1 year post procedure:
all cause MORTALITY, all STROKE and REHOSPITALIZATION

STUDY VISITS
Screening, procedure, post-procedure, discharge, 30 days, and 1 year

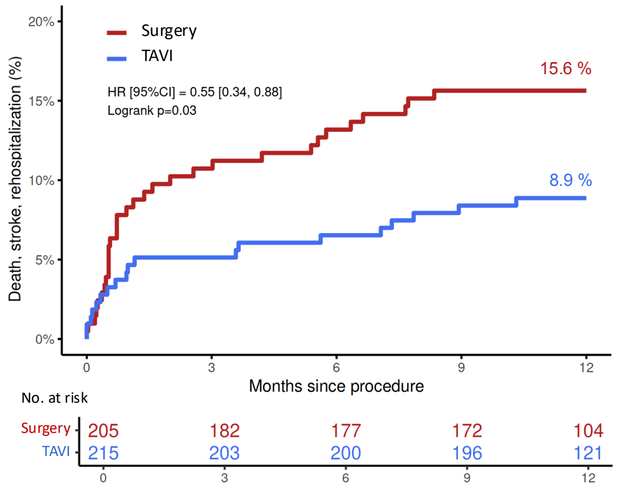
Eltchaninoff H. & Tchétché, D. *Transcatheter versus surgical aortic valve replacement in women*. ESC 2024 Satellite Symposium, sponsored by Edwards Lifesciences, 31.08.2024

Primary Endpoint Kaplan–Meier Estimate

RHEIA

NON-INFERIORITY ✓

SUPERIORITY ✓



Eltchaninoff H. & Tchétché, D. *Transcatheter versus surgical aortic valve replacement in women*. ESC 2024 Satellite Symposium, sponsored by Edwards Lifesciences, 31.08.2024

TAVI IN SMALL ANNULUS

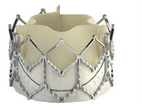
Herrmann, H, et al, *N Engl J Med* 2024;390:1959-1971

SMART Trial

Women (86.7%)
Mean age 80 y
Mean STS 3.3%

Patients (n=737) with severe AS and small aortic annulus (<430 mm2 by MDCT)

or

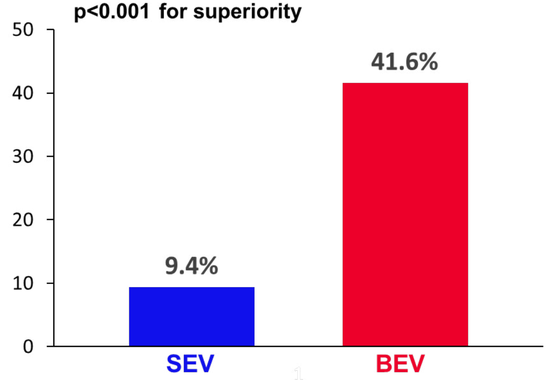


Medtronic
Evolut PRO/PRO+/FX
Supra-annular
Self-expanding

Edwards
Sapien 3/SAPIEN3 Ultra
Intra-annular
Balloon-expandable

Co-Primary Endpoint 2
Bioprosthetic Valve Dysfunction

Difference, -32.2% (95% CI -38.7%, -25.6%)
p<0.001 for superiority



BVF was defined as Hemodynamic structural valve dysfunction: Mean gradient ≥20 mmHg; Nonstructural valve dysfunction: Severe PPM (VARC-3), ≥moderate total AR; Clinical valve thrombosis (VARC-2); Endocarditis (Duke criteria); Aortic valve reintervention

7. Take Home Message

This review has highlighted that sex and gender gaps are present in all processes, from ideation to commercialization, and seeks to encourage us to have a greater awareness of the impact of sex and gender on MDs. To do so, the creation of multidisciplinary team which adopts a sex- and gender-sensitive approach to ensure more rigorous sex–gender data in the field of MDs is an essential requirement for the personalization of prevention and care following the principle of the health equity.