PROPORTION OF WOMEN AND REPORTING OF OUTCOMES BY SEX IN CONTEMPORARY CLINICAL TRIALS OF ATRIAL FIBRILLATION

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Background: Underrepresentation of women in randomized clinical trials (RCTs) limits the generalizability and the quality of the evidence guiding the treatment of women.

Objective: To measure the sex disparities in participants' recruitment and determine associated factors, and to describe the frequency of the reporting of outcomes by sex.

Methods: MEDLINE was searched to identify RCTs of AF published between January 1, 2011, and November 20, 2021 in 12 top tier journals. We measured the enrolment of women using the enrolment disparity difference (EDD) which is the difference between the proportion of women in the trial and the proportion of women with AF in the underlying general population (obtained from the Global Burden of Disease). Random-effects meta-analyses of the EDD were performed, and multivariable meta-regression was used to explore factors associated with disparity estimates. We also determine the proportion of trials that included sex-stratified results.

Results: Out of 1133 records screened, 142 trials were included, reporting on a total of 133,532 participants. The proportion of women in trials ranged from 10.0% to 72.8% (median 30.9%), interquartile range [IQR] 24.6%-38.1%), whereas the their proportion in the general population ranged from 34.7% to 55.9% (median 45.3%, IQR 40.6%-47.2%) (Figure 1). The random-effects summary EDD was −0.125 (95% CI, −0.143 to −0.108), indicating that women were underenrolled by 12.5 percentage points. Subgroup analyses are presented in Figure 2. Women enrolment was higher in trials published in 2020-2021 compared to those published in 2011-2013 (adjusted odds ratio [aOR] 1.058, 95% CI: 1.004-1.115), higher in trials with higher sample size (≥250 vs 750>, 1.065, 95% CI: 1.008-1.125), higher mean participants' age (per 1 year increase, aOR 1.006, 95% CI: 1.002-1.009), and lower in trials conducted in Northern America compared to Europe (aOR 0.945, 95% CI: 0.898-0.995). Only 36 (25.4%) reported outcomes by sex, and of these, 29 (80.6%) included sex-stratified results.

Conclusion: Women remain substantially less represented in RCTs of AF, and sex-stratified reporting of primary outcome is infrequent. These findings call for actions to improve sex equity in enrollment and sex-stratified outcomes' reporting in RCTs of AF.

NEW-ONSET BLEEDING AND SUBSEQUENT RISK OF CARDIOVASCULAR OUTCOMES IN ANTICOAGULATED PATIENTS WITH ATRIAL FIBRILLATION

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Background: The use of oral anticoagulation for stroke prevention in patients with atrial fibrillation (AF) increases their risk of bleeding. The prognosis of AF patients who experience a bleeding event is not well studied.

Objective: To assess the subsequent risk of cardiovascular outcomes and death in AF patients who experience bleedings.

Methods: AF patients taking oral anticoagulation were prospectively followed in a large multicenter cohort study. Information on bleedings was systematically collected during yearly follow-up visits; bleedings were adjudicated as major or clinically relevant non-major bleeding (CRNMB). Adverse outcomes were a composite of stroke, myocardial infarction and all-cause death, its individual components, and cardiovascular death. Bleeding was used as a time-updated covariate in multivariable Cox models to estimate the risk of cardiovascular outcomes in patients after a bleeding event compared to those without a bleeding.

Results: Of the 3,279 patients included (mean ± SD age 72±9 years, 28.5% women), 297 patients (9.1%) developed a major bleed and 418 (12.7%) experienced a CRNMB during a median follow-up of 4.1 years. The incidence of the composite outcome was 26.71 and 4.07 per 100 person-years in patients with and without a major bleeding, respectively, while the incidence of stroke was 4.10 versus 0.82. The adjusted hazard ratios (aHRs) were 5.16 (95% confidence interval [CI], 4.24-6.26) for the composite outcome; 4.49 (95% CI, 2.80-7.18) for stroke; 2.57 (95% CI, 1.39-4.74) for myocardial infarction, and 6.42 (95% CI, 4.91-8.39) for cardiovascular death. In patients with and without CRNMB, the incidence of the composite outcome was 10.24 and 6.42 per 100 person-years, respectively, and for stroke it was 1.41 and 0.92. The aHRs were 2.01 (95% CI, 1.63-2.47) for the composite outcome; 1.39 (95% CI, 0.82-2.36) for stroke; 1.67 (95% CI, 0.96-2.81) for...
myocardial infarction, and 2.01 (95% CI, 1.50-2.71) for cardiovascular death. Discontinuation of oral anticoagulation after the bleeding event was observed in 22.6% of patients who had a major bleeding and in 11.2% who experienced a CRNMB. **Conclusion:** Patients with AF who experience a major bleed during follow-up have a greatly increased risk of cardiovascular outcomes after the event. This excess risk was much lower in patients who had a CRNMB.

**Conclusion:**

**Patients with AF who experience a major bleed during follow-up have a greatly increased risk of cardiovascular outcomes after the event. This excess risk was much lower in patients who had a CRNMB.**

**HP-574-04**

**ASSOCIATIONS BETWEEN OBESITY PARAMETERS AND THE RISK OF INCIDENT ATRIAL FIBRILLATION AND ISCHEMIC STROKE IN DIFFERENT AGE GROUPS: A NATIONWIDE POPULATION-BASED STUDY**

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**Background:** Atrial fibrillation (AF) and ischemic stroke (IS) are two representative cardiovascular diseases. They share common metabolic risk factors such as obesity and ageing is an important predisposing factor. Limited data comprehensively evaluated the relationship between obesity measurements - body mass index (BMI) and waist circumference (WC) - and incident AF and IS in the different age groups.

**Objective:** We investigated the risk of AF and IS according to body mass index (BMI) and waist circumference (WC) stratified by age.

**Methods:** We included 9,432,332 adults who underwent a health examination in 2009 from the Korean National Health Insurance Service database. The age of individuals was categorised into six subgroups by an increase in every decade from the twenties. In each age group, BMI (kg/m²) was categorised into five groups: underweight (<18.5), normal (18.5-22.9), overweight (23-24.9), obese class I (25-29.9), and obese class II (≥30). WC was categorised into six groups with distinctive points of 80, 85, 90, 95, and 100 cm for men and 75, 80, 85, 90, and 95 cm for women. Primary outcomes were incident AF and IS.

**Results:** Across age, BMI-AF presented a J-shaped association. The hazard ratio (HR) of obese class II was the highest in subjects aged 30-39 years (HR 1.80, 95% confidence interval (CI) 1.63 to 1.98, p<0.001). The increased risk of AF in the underweight group was only statistically significant in adults over 60 years of age. The risk of IS increased in those with a BMI over the normal range in early and midlife, but was not significant in adults aged ≥60 years. The highest HR of obese class II was observed in subjects aged 20-29 years (HR 3.00, 95% CI 2.34 to 3.84, p<0.001). Positive linear correlations of WC-AF and WC-IS were observed, but the WC-IS association was weak in the population aged ≥40 years.

**Conclusion:** There was a J-shaped association between BMI-AF and BMI-IS, and a positive linear correlations between WC-AF and WC-IS. The higher risks of AF and IS according to an increment of BMI and WC were more apparent among the young ages; hence, more attention should be directed to weight management in early life. The association between IS and obesity was not significant in the elderly, implicating that several other factors contribute to IS in this age group.

**ABSTRACT AP-518:**

Optimizing care of the SICD patient: Special programming and management strategies

Saturday, April 30, 2022
3:30 PM - 4:30 PM

**AP-518-01**

**SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SMART DEACTIVATION INCREASES INAPPROPRIATE SHOCKS, A REAL-WORLD SINGLE CENTRE EXPERIENCE**

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**Background:** The SICD has been increasingly used with its addition to the HRS guidelines in 2017. A question mark remains around the burden of inappropriate therapy (IT), which, in PRETORIAN had an IT in 9.6% of patients over 4 years. Importantly, this trial was conducted using devices without the SMART pass (SP) algorithm installed. SP (Boston Scientific Corporation, Natick, MA) is a bandpass filter has been shown to reduce inappropriate therapy. However, a key area under-investigated is the algorithms’ ability to deactivate itself in community.

**Objective:** We aimed to assess: the effect of SP, with clinical variables, on inappropriate therapies and oversensing; why the