

Design of The Middle East African Registry for Women's CardioVascular Disease (MEA-WCVD)

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Abstract

Background: The escalating incidence of cardiovascular disease (CVD) in the general population, particularly among women, has resulted in increased morbidity and mortality in the Middle East and African (MEA) Regions. Despite this concerning tendency, women remain significantly underrepresented in cardiovascular research, with no large-scale prospective multicenter trials reflecting national data published to date. To address this gap, we initiated the "Women CardioVascular Disease Middle East African Registry (MEA-WCVD)" to establish a comprehensive database on the contemporary epidemiological profile and management of Heart Failure (HF), Atrial fibrillation (AF), ischemic heart disease (IHD) and Valvular Heart disease (VHD) in women.

Objective: This study aims to compare the management of cardiovascular diseases in women and men in a MEA countries sample, according to the current practice guidelines and encompass the identification of gender-based disparities, specifically examining healthcare insurance, income, and access to healthcare services.

Methods: This prospective observational study involves a one-shot visit where patients diagnosed with HF, AF, IHD, or VHD provide informed consent, and their data are collected in a centralized certified database. The registry spans 75 days, with plans for an extended protocol to assess 1-year clinical outcomes.

Results: The study's findings, expected at the conclusion, will include a comprehensive evaluation of the demographic profile and care management practices for the most prevalent cardiovascular diseases in women worldwide, aligned with current guidelines. The MEA-WCVD registry is anticipated to become the largest database for Middle East African patients monitored for HF, AF, IHD, and VHD.

Conclusions: The MEA-WCVD registry will provide unique and necessary data on the management and outcomes of the most common CV diseases (AF, HF, IHD and VHD) while comparing standard care management in women to men in MEA regions. This study will yield the largest contemporary cohort of patients with cardiovascular diseases in MEA countries and would provide valuable answers about real-world cardio-vascular clinical epidemiology and management.

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Conflict of interest: None

Keywords: cardiovascular disease, cardiovascular risk factors, women

Abstract:

Background: The escalating incidence of cardiovascular disease (CVD) in the general population, particularly among women, has resulted in increased morbidity and mortality in the Middle East and African (MEA) Regions. Despite this concerning tendency, women remain significantly underrepresented in cardiovascular research, with no large-scale prospective multicenter trials reflecting national data published to date. To address this gap, we initiated the "Women CardioVascular Disease Middle East African Registry (MEA-WCVD)" to establish a comprehensive database on the contemporary epidemiological profile and management of Heart Failure (HF), Atrial fibrillation (AF), ischemic heart disease (IHD) and Valvular Heart disease (VHD) in women.

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This study will yield the largest contemporary cohort of patients with cardiovascular diseases in MEA countries and would provide valuable answers about real-world cardio-vascular clinical epidemiology and management.



Background:

Numerous studies have uncovered substantial disparities in cardiovascular health between men and women, as well as among different subsets of women (1–3). Despite this, a lack of data exists regarding the distinct features of cardiovascular disease in women within the Middle East Africa (MEA) Region (4). This research gap has led to the underdiagnosis, undertreatment, and under-research of prevalent cardiovascular diseases, such as coronary heart disease, heart failure, valvular heart disease, and atrial fibrillation, specifically in women.

Compounding this issue, studies indicate that women with suspected heart disease are less likely to undergo necessary diagnostic tests and treatments than male, and persistent sex-based biases continue to influence cardiovascular disease management (3,5). Additionally, women remain notably underrepresented in cardiovascular research, despite a growing body of literature highlighting factors such as sex-based physiology, and psychosocial influences.

Addressing these challenges necessitates a heightened focus on public awareness and the education of healthcare professionals regarding the burden of cardiovascular diseases in women (1). Risk factor control programs should be integrated into the health research agenda in the MEA Region, accompanied by enhancements in health services for women, ensuring equitable and effective cardiovascular disease prevention and treatment.

Given the aging population and the increased prevalence of cardiovascular risk factors, there is a projected surge in the burden of cardiovascular diseases, including Heart Failure (HF), Atrial Fibrillation (AF), Ischemic Heart Disease (IHD) and valvular heart disease (VHD) leading to significant morbidity and mortality. This escalation carries substantial public health implications.

Over the last few decades, Africa has witnessed a noteworthy shift in the epidemiologic and etiologic patterns of cardiovascular diseases, marked by a decline in rheumatic heart disease and a concurrent rise in AF, HF and IHD. Previous registries focused on the specificities of these diseases in some Africa countries such as Tunisia (6,7) but there is no african reliable data focusing on women.

Registry objectives:

The primary goal of the Middle East African Registry Women CardioVascular Disease (MEA-WCVD) registry is to compare the management of cardiovascular diseases in women and men in a MEA countries sample, according to the current practice guidelines.

The secondary objectives encompass the identification of gender-based disparities, specifically examining healthcare insurance, income, and access to healthcare services.

Methods:

The MEA-WCVD is a prospective observational multicentric international study. This publication will focus on the available Tunisian cohort across all governorates of Tunisia, encompassing both public and private health sectors.

Enrolment for the MEA-WCVD registry ClinicalTrials.gov ID NCT05869214 was conducted in Tunisia from May 10, 2023, to July 25, 2023, and involved a one-shot visit wherein patients were screened for eligibility upon presentation to a cardiologist, either in a hospital or private medical center.

Eligible patients provided informed consent, and their data, as outlined in the electronic Case Report Form (eCRF), was meticulously collected and stored in a centralized certified database handled by our Contract Research Organization (CRO) (Eshmoun, Tunisia).

The data collection process, including patients' demographics, diagnoses, medical history, and treatments, was carried out by local investigators and trained staff.

Study protocol was in accordance to the Helsinki convention and the ethical considerations and registry approval were obtained from the south Tunisian Persons' Protection Committee (PPC) PPC SUD N°0496/2023.

The study aimed to enroll at least 2000 female patients from Tunisia, with the participation of hospital-and private cardiologists who agreed the study protocol.

Inclusion and exclusion criteria :

Patients (men and women) were officially enrolled in MEA-WCVD only if they were older than 18 years old and they have at least one of the following 4 diagnoses: HF, AF, IHD or VHD. Exclusion criteria were diseases other than the 4 previously mentioned.

Clinical assessment and data collection :

During the office visit, the physician had to complete the eCRF of the registry after the patient's approval according to the inclusion criteria.

The eCRF included:

- a common section of items about socio-demographic and general clinical characteristics (age, gender, education level, health insurance, socio-economic level, financial or physical dependency, smoking, cardiovascular risk factors, cerebro-cardiovascular history, pulmonary diseases, hypothyroidism or hyperthyroidism, history of cancer and cancer treatment, creatinine and haemoglobin levels).
- specific data according to the primary inclusion diagnosis (HF, AF, IHD or VHD): aetiology, imaging and laboratory tests, guidelines-oriented treatment, complications, drug adherence and side effects.

Statistics:

Data will be analyzed using Statistical Package for the Social Sciences (SPSS) software in its 25th version.

For the descriptive analyses, the Kolmogorov Smirnov normality test will be performed for quantitative variables. Means and standard deviations will be used to describe quantitative variables when they are normally distributed. Otherwise, medians and interquartile ranges (IQRs) will be used. Qualitative variables will be presented as numbers (N) and proportions (%).

To compare frequencies according to gender, the "Pearson Chi squared" test will be used when the application conditions are verified. Otherwise, the "Fisher exact" test will be used. To compare means according to gender, the "Student" test for independent samples will be used when the two quantitative variables are normally distributed. If at least one variable is not normally distributed, the "Mann-Whitney U" test will be used. p values less than 0.05 will be considered statistically significant.

Expected implications:

The MEA-WCVD is the first large-scale investigation in MEA countries aiming to report area-specific contemporary demographic data, guidelines-oriented management and outcomes of these main 4 diagnoses (HF, AF, IHD or VHD), frequency and quality of treatment in this population.

The main purpose of this registry is to find whether women are as well treated as men and if not how deep this gap is?

The primary analysis will be descriptive of CV risk factors, demographic and clinical data followed by analytic analysis.

Collected data will be analysed and compiled in a study report and presented in a paper for publication.

All collected data is pseudonymized, it's analysed and shared as a study report and publication with all investigators.

Oversight and leadership:

The protocol of MEA-WCVD was approved by the Tunisian society of cardiology and cardiovascular surgery (STCCCV) and coordinated by a team headed by two expert women cardiologists.

Conclusion:

MEA-WCVD will fill a significant gap and address the lack of data concerning cardiovascular disease care and research in women in MEA countries. It will provide unique and necessary data on the management and outcomes of the most common CV diseases (AF, HF, IHD and VHD) while

comparing standard care management in women to men in MEA regions.

This study will yield the largest contemporary cohort of patients with cardiovascular diseases in MEA countries and would provide valuable answers about real-world cardio-vascular clinical epidemiology and management.

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Abbreviations :

- AF: Atrial fibrillation
- CV: Cardiovascular
- DPC: Data Protection Committee
- eCRF: electronic Case Report Form
- GCP: Good Clinical Practices
- HF: Heart Failure
- IRB: Institutional Review Board
- IHD: Ischemic Heart Disease
- LPLV: Last Patient Last Visit

- MEA: Middle East Africa
- MoH: Ministry of Health
- VHD: Valvular Heart disease
- LVEF : left ventricular ejection fraction

