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Design of the Middle East African Registry for Women's Cardiovascular Diseases (MEA-WCVD): Protocol for a Multicenter Observational Study

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Abstract

Background: Cardiovascular disease (CVD) is a leading cause of morbidity and mortality in the Middle East and Africa (MEA), with a rising incidence particularly among women. Despite this, women remain significantly underrepresented in cardiovascular research, and no large-scale, multicenter prospective trials have been conducted to provide national data. To address this gap, we established the Women CardioVascular Disease Middle East African Registry (MEA-WCVD) to create a comprehensive database on the epidemiological profile and management of heart failure (HF), atrial fibrillation (AF), ischemic heart disease (IHD), and valvular heart disease (VHD) in women.

Objective: The primary aim of this study is to compare the management of cardiovascular diseases in women and men across MEA countries in accordance with current practice guidelines. The study also seeks to identify gender-based disparities in healthcare insurance, income, and access to cardiovascular services.

Methods: The MEA-WCVD is a prospective, observational registry involving a one-time patient visit. Patients diagnosed with HF, AF, IHD, or VHD provide informed consent, and their clinical, demographic, and management data are collected in a centralized, certified database. The registry spans an initial 75-day data collection period, with an extended follow-up protocol planned to assess 1-year clinical outcomes.

Results: The MEA-WCVD study was funded in April 2023, and data collection began in May 2023. As of July 2023, 15,366 participants have been enrolled across 25 centers. A one-year follow-up is expected to be completed by July 2024. Data analysis is planned to commence in July 2024, with primary results anticipated for publication in March 2025. The study aims to establish the largest registry in the Middle East and Africa for HF, AF, IHD, and VHD, providing valuable insights into demographic trends, clinical management, and adherence to current guidelines

Conclusions: The MEA-WCVD registry will provide essential real-world data on the management and outcomes of the most prevalent cardiovascular diseases (HF, AF, IHD, VHD) in MEA regions. By directly comparing standard care management between men and women, this study will highlight gender disparities and inform future strategies for equitable cardiovascular care. The registry is expected to contribute to the largest contemporary cohort of CVD patients in the region, advancing knowledge in cardiovascular epidemiology and clinical practice.

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Design of the Middle East African Registry for Women's Cardiovascular Diseases (MEA-WCVD): Protocol for a Multicenter Observational Study

Abstract:

Background: Cardiovascular disease (CVD) is a leading cause of morbidity and mortality in the Middle East and Africa (MEA), with a rising incidence particularly among women. Regional factors such as limited healthcare access, cultural barriers, and sex-specific risk factors exacerbate this burden. Despite this, women remain significantly underrepresented in cardiovascular research, and no large-scale, multicenter prospective trials have been conducted to provide national data. To address this gap, we established the Women CardioVascular Disease Middle East African Registry (MEA-WCVD) to create a comprehensive database on the epidemiological profile and management of heart failure (HF), atrial fibrillation (AF), ischemic heart disease (IHD), and valvular heart disease (VHD) in women.

Objectives: The primary aim of this study is to compare the management of cardiovascular diseases in women and men across MEA countries in accordance with current practice guidelines. The study also seeks to identify gender-based disparities in healthcare insurance, income, and access to cardiovascular services.

Methods: The MEA-WCVD is a prospective, multicenter, observational registry enrolling consecutive patients ≥18 years with diagnosed HF, AF, IHD, or VHD across 25 tertiary care centers. Participants provided informed consent during a single visit, and trained investigators collected socio-demographic, clinical, and treatment data via electronic Case Report Forms (eCRFs). The eCRF captured general characteristics (age, gender, comorbidities) and diagnosis-specific details (imaging, guideline-based therapies, complications). Data were stored in a centralized, CRO-managed database (Eshmoun, Tunisia). An initial 75-day enrollment phase (May–July 2023) was followed by planned 1-year follow-up for outcomes analysis. Data will be analyzed using Statistical Package for the Social Sciences (SPSS) software (version 25) to compare gender disparities in management and outcomes, employing multivariable regression and survival analyses.

Results: The MEA-WCVD study was funded in April 2023, and data collection began in May 2023. As of July 2023, 15,366 participants have been enrolled across 25 centers. A one-year follow-up is expected to be completed by July 2024. Data analysis is planned to commence in July 2024, with primary results anticipated for publication in March 2025. The study aims to establish the largest registry in the Middle East and Africa for HF, AF, IHD, and VHD, providing valuable insights into demographic trends, clinical management, and adherence to current guidelines

Conclusions: The MEA-WCVD registry will provide essential real-world data on the management and outcomes of the most prevalent cardiovascular diseases (HF, AF, IHD, VHD) in MEA regions. By directly comparing standard care management between men and women, this study will highlight gender disparities and inform future strategies for equitable cardiovascular care. The registry is expected to contribute to the largest contemporary cohort of CVD patients in the region, advancing knowledge in cardiovascular epidemiology and clinical practice.

INTRODUCTION:

Numerous studies have uncovered substantial disparities in cardiovascular health between men and women, as well as among different subsets of women [1–3]. However, despite a growing global awareness, there remains a critical lack of region-specific data on the unique characteristics and management of cardiovascular diseases (CVD) in women across the Middle East Africa (MEA) Region [4]. This research gap is particularly concerning, as it contributes to the persistent underdiagnosis, undertreatment, and under-research of common cardiovascular conditions such as ischemic heart disease (IHD), heart failure (HF), valvular heart disease (VHD), and atrial fibrillation (AF) in women.

Compounding this issue, several studies indicate that women with suspected heart disease are less likely than men to undergo recommended diagnostic testing and receive evidence-based treatments [3,5]. These disparities are further exacerbated by ongoing sex-based biases in clinical decision-making and the underrepresentation of women in cardiovascular research. While global research has increasingly acknowledged the influence of sex-specific pathophysiological, hormonal, and psychosocial factors in cardiovascular disease, such insights are seldom translated into region-specific strategies, especially in low-resource settings.

In the MEA region, the challenges are magnified by limitations in healthcare infrastructure, sociocultural barriers, and insufficient awareness among both the public and healthcare professionals regarding the burden of CVD in women [1]. Moreover, existing prevention and treatment programs often fail to adequately address gender disparities, particularly in access to healthcare services, insurance coverage, and health education. These shortcomings are increasingly alarming given the demographic shift toward an aging population and the rising prevalence of cardiovascular risk factors in the region. This evolving epidemiologic landscape suggests a significant surge in CVD-related morbidity and mortality in the near future, with profound implications for public health systems.

In recent decades, Africa has seen a notable shift in the patterns of cardiovascular disease, marked by a decline in rheumatic heart disease and a rising prevalence of non-communicable conditions like

AF, HF, and IHD. While some national registries—such as those in Tunisia—have shed light on these trends [6,7] there remains a dearth of large-scale, gender-focused cardiovascular registries encompassing the broader MEA region. Notably, no comprehensive registry to date has centered on the cardiovascular health of women in this context, leaving an urgent need for sex-disaggregated data to inform health policy and clinical practice.

Research Gap:

There is a lack of robust, sex-disaggregated, and region-specific data on the clinical presentation, management, and outcomes of cardiovascular diseases in women within the MEA region. Existing studies and registries have largely overlooked gender-based analysis and fail to account for socioeconomic and structural determinants of health.

Registry objectives:

The primary goal of the Middle East African Registry Women Cardiovascular Disease (MEA-WCVD) registry is to compare the diagnosis, treatment, and outcomes of major cardiovascular diseases in women and men across participating MEA countries, in alignment with current clinical practice guidelines.

The secondary objectives are to identify gender-based disparities in healthcare access, including differences in insurance coverage, income level, and healthcare utilization, as well as to highlight any deviations from guideline-recommended care based on sex.

Hypothesis:

We hypothesize that women in the MEA region with cardiovascular diseases are less likely than men to receive appropriate diagnostic evaluation and evidence-based treatment, resulting in suboptimal clinical outcomes. Furthermore, we expect that socioeconomic factors such as limited healthcare coverage and reduced access to specialized services disproportionately affect women's cardiovascular care.

METHODS:

Study design

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

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.

Individuals were excluded if they presented with cardiovascular diseases other than the four target conditions. Additionally, patients who were unable to provide informed consent—due to cognitive impairment, communication barriers, or other medical or legal reasons—or those who explicitly refused to participate in the study, were also excluded.

Clinical assessment and data collection:

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

To ensure the accuracy and completeness of the data, all centers involved in data collection will adhere to standardized protocols for data entry, with regular training sessions provided to research personnel.

The eCRF was structured into two main sections :

- The first was a common data module that included a comprehensive set of items pertaining to each patient's sociodemographic profile and general clinical background. This encompassed variables such as age, sex, level of education, type of health insurance, socio-economic status, degree of financial or physical dependency, and smoking status. Additionally, it recorded information on cardiovascular risk factors (e.g., hypertension, diabetes, dyslipidemia), past cerebro-cardiovascular events (such as stroke or myocardial infarction), coexisting pulmonary diseases, thyroid disorders (hypothyroidism or hyperthyroidism), as well as any history of cancer and related treatments. Key laboratory data such as creatinine and hemoglobin levels were also collected to assess renal function and anemia status, both of which are important prognostic factors in cardiovascular care.
- The second part of the eCRF was diagnosis-specific and tailored according to the patient's primary inclusion diagnosis (HF, AF, IHD or VHD). For each condition, this section captured detailed clinical information including the etiology, findings from relevant imaging and laboratory investigations, the use of guideline-directed medical therapy, occurrence of complications, as well as aspects related to medication adherence and reported side effects. This diagnostic-specific approach allowed for a nuanced evaluation of each disease entity and facilitated meaningful comparisons between male and female patients across the MEA region.

The study began with an initial 75-day enrollment phase, which took place from May to July 2023. During this phase, eligible participants were identified and enrolled into the study. After the enrollment phase, a planned 1-year follow-up period will be conducted to analyze the outcomes associated with the treatment. This follow-up will be carried out through patient visits to healthcare centers. The 1-year follow-up period will allow for the evaluation of both short-term and long-term treatment effects, contributing to a more comprehensive understanding of the study's outcomes.

Ethical Considerations

This study was conducted in compliance with the principles outlined in the Declaration of Helsinki. The MEA-WCVD registry (ClinicalTrials.gov ID: NCT05869214) received ethical approval from the South Tunisian Persons' Protection Committee (PPC SUD N°0496/2023). The protocol was reviewed and approved as a multicenter study involving both hospital-based and private-practice cardiology consultations.

All eligible participants were enrolled only after providing written informed consent during a single outpatient cardiology visit. Investigators ensured that participants fully understood the objectives of the registry, the voluntary nature of their participation, and their right to withdraw at any time without any impact on their medical care.

Data collected via the electronic eCRF included anonymized and pseudonymized identifiers. No identifiable personal data (e.g., names, addresses, or national IDs) were stored in the analysis database. All data were securely transferred and stored in a centralized, certified, and encrypted database managed by the Contract Research Organization (Eshmoun, Tunisia).

No financial or material compensation was provided to participants. Participation in the study was voluntary, and no incentives or reimbursements were offered to avoid coercion or bias.

No identifiable photographs, images, or multimedia files of participants are included in this manuscript.

Statistics:

Data will be analyzed using Statistical Package for the Social Sciences (SPSS) software in its 25th version. To explore gender disparities in cardiovascular health outcomes and treatment effectiveness, data will be stratified by gender during analysis.

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.

RESULTS:

The MEA-WCVD study was officially funded in April 2023, with data collection commencing in May 2023. By July 2023, a total of 15,366 participants had been enrolled across 25 centers. The study plans to complete a one-year follow-up by July 2024, after which data analysis will begin in July 2024. The primary results are expected to be published in March 2025.

This study seeks to establish the largest registry in the Middle East and Africa for HF, AF, IHD, and VHD. By examining these conditions, the study aims to provide valuable insights into regional demographic trends, clinical management practices, and patient adherence to current medical guidelines. The findings will be pivotal in shaping future healthcare strategies and improving the management of cardiovascular diseases in the region.

DISCUSSION:

This registry is expected to reveal significant sex-based disparities in the management and outcomes of cardiovascular diseases among patients in MEA countries. The MEA-WCVD registry will thus fill a critical data gap by offering region-specific, sex-disaggregated insights into four major cardiovascular conditions: HF, AF, IHD and VHD [4].

Principal findings :

The primary analyses are expected to confirm disparities in cardiovascular care and outcomes between men and women, particularly in diagnostic approaches, therapeutic interventions, and access to care. For instance, we hypothesize that fewer women will undergo advanced imaging, invasive procedures, or receive guideline-directed medical therapy compared to men. Furthermore, socioeconomic and healthcare access factors—such as insurance status and financial dependency—may further exacerbate these disparities in women. This comprehensive analysis will offer a deeper understanding of the structural and systemic barriers affecting cardiovascular care for women in the MEA region.

Comparison to prior work

While previous registries and studies conducted in high-income countries have shown persistent sex-based differences in cardiovascular health, such investigations remain scarce in the MEA region [1–3]. Existing studies from North Africa, such as those from Tunisia, have primarily focused on single diseases and lacked large-scale, sex-disaggregated data. The MEA-WCVD registry is unique in its multicntric, multisite approach and its focus on capturing real-world clinical practices in both men and women across a wide range of healthcare settings [6,7].

Strengths and limitations:

A major strength of this study lies in its prospective design and standardized electronic data collection, which enhances the accuracy and consistency of the data across sites. In addition, the focus on sex-disaggregated outcomes and the inclusion of social determinants of health will allow for a multidimensional understanding of gender disparities in cardiovascular care.

However, limitations may include potential selection bias, differences in healthcare infrastructure between participating countries, and challenges related to the availability and interpretation of diagnostic tests across diverse settings. Although the current study provides valuable insights based on a one-year follow-up, extending the follow-up period in future research would be essential to better capture the long-term effects of cardiovascular treatments, monitor chronic disease progression, and assess the sustainability of treatment outcomes, particularly among women.

The inclusion of genetic data or biomarkers could have further enhanced our ability to identify populations at higher risk and support the development of personalized treatment strategies. However, the integration of genetic or molecular data presents significant challenges, including logistical and financial constraints, which prevented their inclusion in the current analysis.

Future directions:

The MEA-WCVD registry has the potential to inform future health policies, educational initiatives, and targeted interventions aimed at reducing gender inequities in cardiovascular care. The findings may also serve as a foundation for the development of regional clinical guidelines that better reflect the realities of healthcare delivery in MEA countries. Additional longitudinal follow-up could be considered to assess the impact of interventions over time and to explore outcomes such as rehospitalization and mortality.

Dissemination plan:

All collected data are pseudonymized to ensure patient confidentiality and will be analyzed centrally before being shared in aggregate form. The results of the registry will be compiled into a comprehensive study report and disseminated through peer-reviewed publications and conference presentations. Importantly, participating investigators will have access to the final analyses, and efforts will be made to share findings with local health authorities, medical societies, and advocacy groups to support evidence-based decision-making and gender-sensitive healthcare planning.

CONCLUSION:

The MEA-WCVD registry represents a major step toward addressing the significant lack of sex-specific cardiovascular data in Middle East and African countries. By providing real-world, region-specific evidence on the management and outcomes of AF, HF, IHD and VHD, this study is expected to uncover critical disparities in care between women and men. The anticipated findings will not only contribute to a better understanding of the epidemiologic profile of cardiovascular disease in the MEA region but will also help inform more equitable and guideline-oriented clinical practice. Ultimately, this large-scale registry has the potential to guide policy, optimize resource allocation, and foster gender-sensitive improvements in cardiovascular health systems across the region.

Data Availability

The data sets generated and analyzed during the current study are available from the corresponding author on reasonable request. In line with our commitment to transparency, we encourage data sharing in appropriate cases. Data that can be shared publicly will be deposited in a publicly accessible repository.

For data and code that cannot be publicly shared due to privacy or other concerns, access can be requested by contacting the corresponding author directly. A reasonable request will be reviewed, and steps for data access will be provided accordingly.

In cases where data sharing is not possible, a detailed explanation is provided.

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(STCCCV)

Funding:

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Conflict of interest:

The authors declare no financial or non-financial competing interests related to this work. No funding sources had any role in study design, data collection/analysis, or manuscript preparation.

Oversight and leadership:

The protocol of MEA-WCVD was approved by the STCCCV and coordinated by a team headed by two expert women cardiologists.

Author Contributions:

Author contributions are detailed in the metadata of the manuscript, including author names and affiliations

REFERENCES:

1. Bairey Merz CN, Andersen H, Sprague E, et al. Knowledge, Attitudes, and Beliefs Regarding Cardiovascular Disease in Women: The Women's Heart Alliance. *J Am Coll Cardiol*. 2017;70(2):123-132. doi:10.1016/j.jacc.2017.05.024

2. Vaccarino V, Badimon L, Corti R, et al. Ischaemic heart disease in women: are there sex differences in pathophysiology and risk factors? Position paper from the working group on coronary pathophysiology and microcirculation of the European Society of Cardiology. *Cardiovasc Res*. 2011;90(1):9-17. doi:10.1093/cvr/cvq394

3. GBD 2016 Causes of Death Collaborators. Global, regional, and national age-sex specific mortality for 264 causes of death, 1980-2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet Lond Engl*. 2017;390(10100):1151-1210. doi:10.1016/S0140-6736(17)32152-9

4. Damasceno A, Mayosi BM, Sani M, et al. The causes, treatment, and outcome of acute heart failure in 1006 Africans from 9 countries. *Arch Intern Med*. 2012;172(18):1386-1394. doi:10.1001/archinternmed.2012.3310

5. Mosca L, Hammond G, Mochari-Greenberger H, Towfighi A, Albert MA, American Heart Association Cardiovascular Disease and Stroke in Women and Special Populations Committee of the Council on Clinical Cardiology, Council on Epidemiology and Prevention, Council on Cardiovascular Nursing, Council on High Bloo. Fifteen-year trends in awareness of heart disease in women: results of a 2012 American Heart Association national survey. *Circulation*. 2013;127(11):1254-1263, e1-29. doi:10.1161/CIR.0b013e318287cf2f

6. Abid L, Charfeddine S, Kammoun I, et al. Epidemiology of heart failure and long-term follow-up outcomes in a north-African population: Results from the NAtional TUnisian REgistry of Heart Failure (NATURE-HF). *PloS One*. 2021;16(5):e0251658. doi:10.1371/journal.pone.0251658

7. Ouali S, Ben Halima A, Chabrak S, et al. Epidemiological characteristics, management, and outcomes of atrial fibrillation in TUNISIA: Results from the National Tunisian Registry of Atrial Fibrillation (NATURE-AF). *Clin Cardiol*. 2021;44(4):501-510. doi:10.1002/clc.23558

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

• PPC : Persons’ Protection Committee

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