Increased Detection of Acute Myocardial Infarction in Women Using Sex-Specific Upper Reference Limits in Clinical Pathways for Patients Presenting with Suspected Acute Coronary Syndrome

Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute, Mumbai, India

Sex differences are common across multiple aspects of cardiovascular care including diagnosis, treatment, and outcomes.¹⁻³ Large multi-centered randomized clinical trials have shown that women are under-recognized for acute myocardial infarction (AMI) and consistently have higher fatality rates compared to men, even following adjustments for age and comorbid conditions.¹ Women tend to have atypical symptoms when presenting to Accident and Emergency (A&E) and as such, tend not be recognized for experiencing AMI without male-patterned chest pain symptoms.² Thus, significant efforts across stakeholders have culminated in a greater awareness with improved measures to recognize and manage AMI and coronary artery disease (CAD) in women. Included in these measures are guideline recommendations for the implementation of sex-specific upper reference limits into clinical pathways for patients that present to A&E with suspected acute coronary syndrome.⁴⁻⁵ This is based on the fact that women tend to have smaller hearts with lower left ventricular mass compared to men, and consequently, have less circulating levels of cardiac troponin in the blood stream. Research suggests the differences between sexes in the upper reference limits (URLs) of seemingly healthy individuals can be as high as 50%.⁶ Recognizing that poorer outcomes for women vs. men post-intervention may result from delayed diagnosis of women, and with full appreciation that some men may be more aggressively treated based on use of lower upper reference limits that lack sex discrimination, the Biochemistry & Immunology Department at Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute (KDAH) team sought to investigate the opportunity to move from an overall URL to sex-specific URLs consistent with guideline-based care. This integrated clinical care team simultaneously sought to improve workflow efficiencies, leading to improvements across the care continuum. Site-wide education was crucial for physicians and patients to ensure earlier recognition of disease risk while maximizing treatment pathways for optimized patient care.
Acute myocardial infarction (AMI) is a leading cause of death worldwide. Early and accurate diagnosis of acute myocardial infarction is essential for successful treatment and improved outcomes. Women have been classically underdiagnosed and undertreated for AMI.

Data from the Accident and Emergency Department (A&E) of Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute indicate that men and women with suspected Acute Coronary Syndrome (ACS) present at comparable rates (50% +/-4%). Nevertheless, women are less likely to be diagnosed with AMI. This potential for under diagnosis may be explained by sex differences in the URL of seemingly healthy individuals, whereby women tend to have half the levels of circulating troponin compared to men.

The URL used in clinical care for troponin at Kokilaben Dhirubhai Ambani Hospital was 26 ng/L regardless of sex, whereas sex-specific URLs for this troponin method would be 16 ng/L for women and 34 ng/L for men based on manufacturing data.

HYPOTHESIS
Implementation of sex-specific upper reference limits with hs-cTn will help enable earlier and more sensitive detection of acute myocardial infarction in women.

PARTNERS
Changes to clinical care pathways are complex and require input and alignment across disciplines. Cardiac pathways involve diverse stakeholders with varying needs and expectations for optimal delivery of care. This clinical care project involved cross-functional discussions among A&E physicians, cardiology, laboratory medicine, and administrators to optimize and implement a new pathway for patients with suspected ACS that addressed all stakeholder needs, while maximizing patient care.
Validation of sex-specific upper reference limits in an Indian population

Education and stakeholder alignment for process mapping of a systemwide pathway change

Comprehensive workflow evaluation using lean-six sigma and DMAIC* principles for prioritized areas of improvement

*DMAIC = improvement cycle, stands for Define, Measure, Analyze, Improve, and Control

Algorithm alignment and implementation of a new ACS pathway

Implementation of education across all relevant stakeholders

Revised patient assessment pathway within A&E for faster clinical evaluation

Elimination of non-value added steps to improve workflow and turnaround time (TAT)

Cardiac troponin (cTn) is the preferred biomarker for the diagnosis of acute myocardial infarction.

High-sensitivity cardiac troponin (hs-cTn) assays enable accurate detection of low levels of circulating troponin, including the ability to distinguish differences between men and women.

Sex-specific upper reference limits based on the 99th percentile of seemingly healthy individuals is recommended for established cardiology and laboratory medicine guidelines for the diagnosis of AMI.

Education across disciplines is crucial for systemwide implementation of new clinical pathways.

From Left to Right: Mr. Sufiyan Tamboli, Ms. Vishakha Tawde, Ms. Vrushali More, Ms. Rashma Morajkar, Ms. Poornima Shetty, Ms. Alisha Tauru, Dr. Barnali Das, Ms. Deane Maria Dmello, Ms. Rashmi Patil, Mr. Prashant Korpe, Ms. Poonam Mandavkar Pal, Mr. Sayyadain Raza Khan.

INCREASED DETECTION OF ACUTE MYOCARDIAL INFARCTION IN WOMEN USING SEX-SPECIFIC UPPER REFERENCE LIMITS IN CLINICAL PATHWAYS FOR PATIENTS PRESENTING WITH SUSPECTED ACUTE CORONARY SYNDROME

EXECUTION

Implementation efforts involved multistep processes including strategic assessment and enactment of a new clinical pathway, as well as operational workflow changes.

PROOF OF VALUE

WITHIN LABORATORY METRICS

One Sigma Improvement in Quality

5.62 Minute Improvement in Cardiac Troponin Turnaround Time

OUT OF LABORATORY METRICS

Detection of AMI in Women

Comparative Rates of AMI Detection of Patients Suspected with ACS Post-Implementation

Detection of AMI in Men

SUCCESS FACTORS

- Cardiac troponin (cTn) is the preferred biomarker for the diagnosis of acute myocardial infarction.
- High-sensitivity cardiac troponin (hs-cTn) assays enable accurate detection of low levels of circulating troponin, including the ability to distinguish differences between men and women.
- Sex-specific upper reference limits based on the 99th percentile of seemingly healthy individuals is recommended for established cardiology and laboratory medicine guidelines for the diagnosis of AMI.
- Education across disciplines is crucial for systemwide implementation of new clinical pathways.
SPOTLIGHT ON STAKEHOLDER SUCCESS

INCREASED PATIENT WELLNESS
“Earlier detection of women for acute myocardial infarction enables faster treatment, increasing the likelihood of better outcomes.”
— Dr. Barnali Das, Consultant, Laboratory Medicine
Reduced the potential of unnecessary invasive procedures for men by 2.9%.

EARLIER DIAGNOSIS
Implementation of sex-specific upper reference limits identified an additional 14% of at risk women with potential acute myocardial infarction.

INCREASED PATIENT EXPERIENCE
“Any time we are able to offer personalized care to our patients they feel cared for and are more likely to be compliant in treatment. Reference intervals by sex enables personalized care.”
— Dr. Sanjay Sm Mehta, Director, Accident & Emergency Department

INCREASED CONFIDENCE
“Troponin is a significant tool in diagnosing AMI. With sex-specific criteria, I am even more confident that I am making the right decisions for my patients.”
— Dr. Jamshed Dalal, Director, Cardiology Sciences

INCREASED SATISFACTION
“The workflow improvements and the personalized approach that we offer in A&E enables me to better care for my patients.”
— Sameer Rathi, Consultant, Emergency Medicine

ENHANCED REPUTATION
Media recognition in two leading local newspapers recognized this site’s leadership in implementing a novel clinical pathway for patients with suspected acute coronary syndrome.

RISK MITIGATION
“Risk mitigation with earlier and accurate diagnosis and treatment enables improved outcomes and reduces risk of long-term complications.”
— Santosh S. Shetty, Executive Director & Chief Operating Officer

3. Merz, Noel. Women experience different MI causes, symptoms than men https://www.healio.com/cardiology/chd-prevention/news/print(cardiology-today%7B3c7963c41-f8a-468b-b45e-9fd3e6992624%7D)women-experience-different-mi-causes-symptoms-than-men
13. ARCHITECT STAT High Sensitive Troponin-I Package Insert G45454/R03.

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