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— REGENERATIVE MEDICINE INC. —

A Unique Disease in Women: Small Vessel Disease of the Heart

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Introduction:

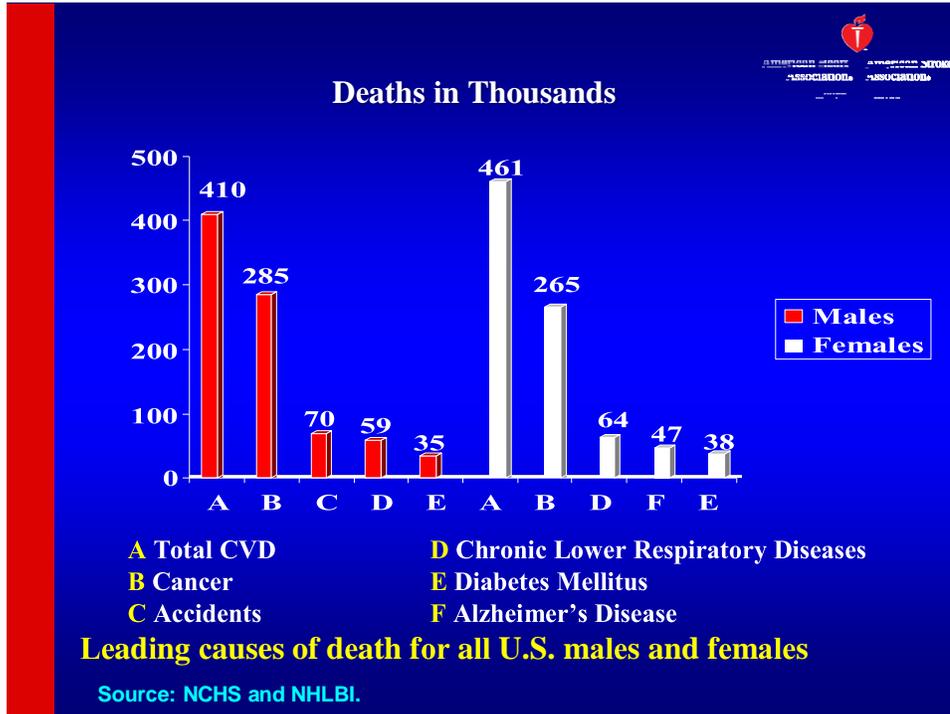
Heart disease is the leading cause of death of American women, accounting for 32 percent of all deaths per year. Nearly 366,000 women in America die every year of heart disease. The American Heart Association has been instrumental in publicizing the fact that coronary artery disease is as large a medical issue for woman as it is for men. Often in the past, coronary artery disease was misdiagnosed in woman, as they often have persistent angina, but in the absence of discernable blockages in their coronary arteries as visualized by coronary angiograms. It is now beginning to be appreciated that these women do have coronary artery disease, but it is affecting not the major coronary vessels, but a myriad of smaller coronary arteries in women's heart. Small vessel disease in women is a major unmet medical need, effecting women world-wide. This disease is not only a problem for women, but can affect populations that have smaller coronary arteries genetically, including both men and women from Arab countries and the Indian subcontinent.

I. The Problem:

Cardiovascular disease is the leading cause of death in women in the United States. As seen in Figure 1 below, which is data published by the American Heart Association, more woman than men die from cardiovascular disease. Here are some additional facts about women and heart disease that have been gathered from data released by the Centers for Disease Control in Atlanta, GA:

- 250,000 women die annually from ischemic heart disease and related conditions in the United States
- 38% of all women's deaths are related to coronary artery disease (CDC)

Figure 1: Leading Cause of Death for Males and Females in the U.S.

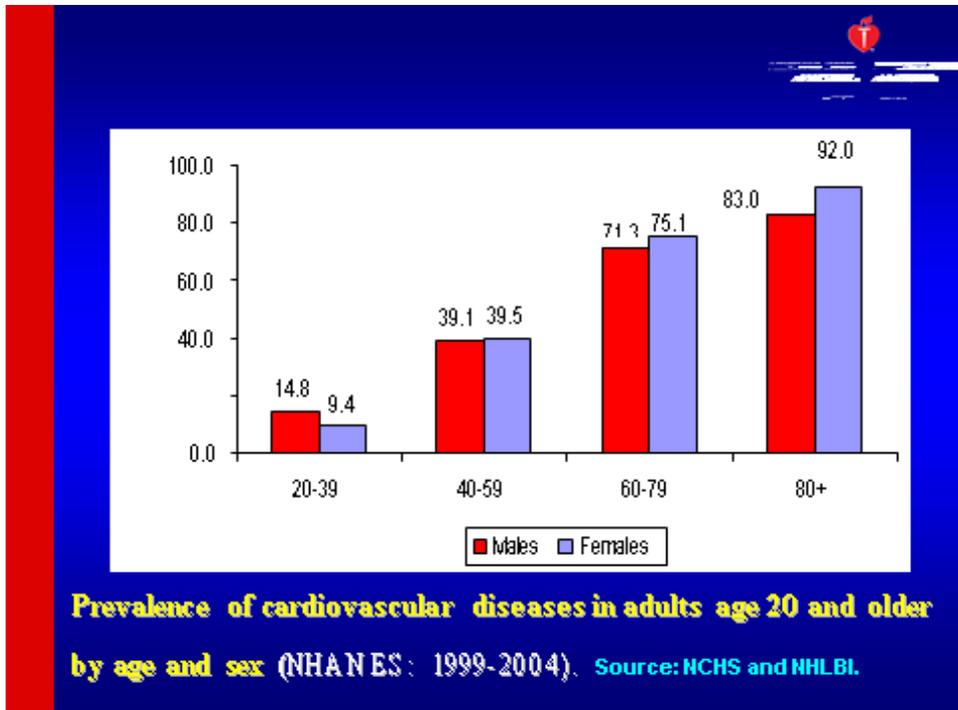


When compared to men:

- As shown in Figure 2 below, women after the age of 40 always have a higher incidence of cardiovascular disease compared to men
- More women have chest pain; 60% of all angina cases are in women, yet women have a lower prevalence of coronary artery disease than men (6% vs. 7%)
- Fewer women have heart attacks. Woman experience only 30% of all total myocardial infarctions recorded in the United States

- Women's heart attacks are more frequently fatal, despite less severe obstructive disease in their larger coronary arteries and better left ventricle function
- Women with coronary artery disease have more disability and heart failure, and have worse outcomes when intervention is attempted with either coronary bypass procedures or stenting operations.¹

Figure 2: Prevalence of Cardiovascular Disease as a Function of Age



It is known that post-menopausal women have a higher prevalence of traditional risk factors to develop coronary artery disease with more clustering of several risk factors in an individual, and at a generally higher level of severity than in the male population. Women develop coronary artery disease at a later age than men, with the threshold for increased risk at 55 years of age as compared to men's 45 years of age. In addition, women experience ischemic disease differently than men, with more complaints of fatigue, sleeplessness, and shortness of breath which are all early warning signs of a potential heart attack.

Previously, because men's experiences with heart diseases have been the basis for evaluation and treatment, women with chest pain in the absence of CAD were not considered to have significant heart disease. Women were not appropriately evaluated and generally not offered treatment other than reassurance that their heart condition was not a serious medical problem and suggestions that perhaps they should seek a psychological evaluation. If medication was offered it was generally pain medications and nitrates, which typically gave a poor response in women. And even after ineffectual treatment, women were just not considered to have compromised outcomes by their heart disease.¹

Figure 3: Coronary Angiograms of Healthy Adult Female and Male



Figure 3 above shows a coronary angiogram of a healthy male and female subject. It is readily apparent that the angiogram of the male subject on the right displays larger diameter coronary arteries. Women have smaller coronary arteries which no doubt contributes to small vessel disease, but other factors also contribute to this syndrome. In particular, the pathology of the atherosclerotic process appears to be different between men and woman.

II. Small Vessel Disease in Woman: Pathology and Physiology

Typically, coronary artery disease occurs when part of the smooth, elastic lining inside a coronary artery develops atherosclerosis. With atherosclerosis, the artery's lining develops hard plaques that fill with calcium and fat deposits, and are infiltrated by inflammatory cells to form a plaque. Plaques protrude into the channel of an artery, causing a partial obstruction to blood flow. Patients with coronary artery disease might have just one or two plaques, or might have dozens distributed throughout their coronary arteries.²



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