

**To Determine, Prevent and Manage Influence of Risk Factors  
Including Socio Economic Status on Prevalence of  
Cardiovascular Diseases in Indian Women**

*A Co-ordinated Proposal Submission by*

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# **To Determine, Prevent and Manage Influence of Risk Factors Including Socio Economic Status on Prevalence of Cardiovascular Diseases in Indian Women: Developing Guidelines**

## **Section – I : Basis of the Research Proposal**

### **Introduction**

In 2020, 2.6 million Indians are predicted to die of coronary heart disease which will constitute 54% of all cardiovascular disease (CVD) deaths.<sup>1</sup> Epidemiologic and clinical research suggests important gender-related differences in the prevalence, presentation, management and outcomes of patients with CVD. It appears that the disease in women evolves about 10 years later than in men, but after menopause the prevalence and mortality from CVD increases progressively with age.<sup>2</sup> It, however, remains unclear whether this menopause-associated higher prevalence of CVD that lasts for many years would eventually result in an equivalent incidence of CVD deaths in men and women in the later stages of life.<sup>3</sup> Gender differences in the clinical presentation of CVD are of particular relevance, because they contribute to a delay in the diagnosis in women resulting in adverse outcomes.<sup>4</sup> Despite the substantial risk of developing or dying from CVD, studies reveal that women with CVD or risk factors are less likely than men to receive recommended therapies.<sup>5</sup> Gender differences in the management of acute coronary syndrome with invasive strategy have been described in both observational and randomized clinical studies.<sup>6,7</sup> It has been suggested that women are less likely to undergo reperfusion therapy when they present with acute coronary syndrome.<sup>8</sup> Women are twice as likely to die of a myocardial infarction,<sup>9</sup> and have a less favorable long-term survival as compared with men. Further, it has been suggested that women have smaller coronary arteries than men, and are twice as likely to die as a result from coronary artery bypass surgery, and are more likely to need repeat revascularization.<sup>10</sup> It has also been shown that women's access to medical therapy and cardiac procedures such as cardiac catheterization, percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) is inappropriately restricted.<sup>11-15</sup> While Guidelines have been established in developed countries especially for women (ACC-2011), the situation of Indian women requires a unique solution.

### **Forecasting the prevalence rate of coronary heart disease in India**

Gender norms and roles influence the risk factors as women, in some contexts, do not have access to and control over resources that can diminish their exposure to the risk factors.

Year	Area	20–29 years		30–39 years		40–49 years		50–59 years		60–69 years	
		Male	Female								
2000	Urban	5.14	5.06	6.16	6.14	8.16	10.29	12.14	11.29	17.76	17.27
	Rural	1.80	1.30	3.10	2.90	3.17	6.55	4.64	10.38	10.21	9.67
2005	Urban	6.53	6.37	7.35	7.49	9.11	12.26	12.68	12.62	19.50	19.14
	Rural	1.80	1.30	3.78	2.90	3.55	7.39	4.93	11.88	11.24	11.02
2010	Urban	7.92	7.67	8.54	8.84	10.06	14.22	13.23	13.95	21.25	21.00
	Rural	1.80	1.30	4.45	2.90	3.94	8.23	5.22	13.38	12.28	12.37
2015	Urban	9.30	8.98	9.73	10.18	11.01	16.19	13.77	15.28	22.99	22.87
	Rural	1.80	1.30	5.13	2.90	4.32	9.08	5.50	14.89	13.31	13.71

The incidence and the progression rate of cardiovascular disease and hypertension is markedly higher in men than in age-matched, premenopausal women. After menopause, the incidences as well as the rate of progression of cardiovascular disease and hypertension are very similar in women and men. Other factors that are more prevalent among women and/or may make special contributions to CVD risk in women need further clarification in the context of defining effective interventions to improve CVD outcomes, as well as functional outcomes and adherence to therapy. These include depression and other psychosocial risk factors, as well as autoimmune diseases. Systemic lupus erythematosus and rheumatoid arthritis may be unrecognized risk factors in women and have been associated with a significantly increased relative risk for CVD. There may be certain differences in the clinical presentation of CVD in women leading to inadequate diagnostic and treatment interventions. Women with CVD living in developing countries experience specific challenges in accessing cost-effective prevention, early detection and treatment due to gender inequality, family responsibilities and the costs of seeking care. Numerous studies have examined gender difference in presentation, diagnosis, treatment and outcome among patients with acute coronary syndrome.<sup>16,17</sup> However, there are very few studies with small size determining gender differences in CVD in India, the outcome of which are not conclusive.

**Study Significance:**

Collection of data of over 50,000 CVD subjects will relate to many findings like influence of demographics, socioeconomic status, comorbidities, risk factors, lesion characteristics, treatment options, medications prescribed, pharmacoeconomic profile of treatment, medication adherence, adverse event reporting and many more. The data will be collected from outpatient department of CIMS hospital, besides through other related programs run by the hospital like “Hospital to Home visit Program (H2H)”. This visit reduces incidence of stent thrombosis as well as infection following cardiac surgery/intervention. During the visit besides monitoring of complains, medication adherence, development of adverse event, assessment of Quality of Life parameters

are also conducted. Along with it family counseling is done for post-menopausal women, smoking, alcohol, obesity and hypertension.

Hence this proposal also aims at developing awareness about CVD prevention in India with diverse scientific and social contributing factors. By conducting this study at zonal levels, extending to countries and continents the results will be affecting and beneficial to global population at large. The proposal emphasizes reporting of all study results in a population-specific and gender-specific manner.

**Study Applicability:**

- The proposal highlights ongoing care of women heart disease, best practice disease-management models, including multidisciplinary teams, case managers, information technology that supports patient monitoring and follow-up, standing treatment orders, and patient self-management.
- This study will educate policymakers and public officials about the societal toll of heart disease in women. It will help develop and maintain an inventory of public and private policies that promote cardiovascular health; disseminate exemplary policies; identify policy gaps and suggest solutions.
- Indian guidelines will be developed for women with cardiovascular disease. Potential areas will emerge from assessment of the major causes of morbidity and mortality for women; uncertainty about the appropriateness of healthcare processes or evidence that they are effective in improving patient outcomes, or the need to conserve resources in providing care to them.
- A dialogue among clinicians, women subjects, and the potential users or evaluators of the guideline will be initiated and followed up. Discussions about the scope of the guideline will also take place within the guideline development panel.
- Data will be extracted from the relevant studies on the benefits, the harms, and (where applicable) the costs of the interventions being considered. Where appropriate, meta-analysis can be used to summarize results of multiple studies. Guidelines will receive external review to ensure content validity, clarity, and applicability. Using support from this phase, work will focus on Western India to prove concepts which later will expand to all of India and, subsequently, other developing countries.

## Section- II: Summary of Conducted Pilot Studies

### Study- I: Gender Disparity in Cardiovascular Risk Factors and Treatment Options

#### In Western States of India

**Objective** of this study was to determine gender differences in cardiovascular diseases (CVD) risk factors, and most importantly in treatment options offered in the Western states of India.

**Study Design:** All consecutive patients with CVD, over 18 years of age, visiting a tertiary care hospital Ahmedabad, India and undergoing coronary angiography from January 2008 to May 2012 formed the study population. Gender-based differences in clinical presentation and CVD related risk factors like hypertension, diabetes, obesity, family history and smoking were recorded. Patients were further categorized based on their primary residence in urban or rural areas. Data were collected relative to the number of coronary arteries affected by atherosclerosis and were categorized based on interventions like coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI), and medical therapy respectively for analyzing treatment options. Importantly, pregnant or lactating women were excluded. For statistical analysis continuous variables including age are presented as mean  $\pm$  SD. The categorical data, including place of primary residence (rural vs. urban), CVD risk factors, diagnosis of coronary disease, and coronary procedures performed are presented by frequency and percentage of patients. •p value  $<0.05$  were considered statistically significant.

**Results:** A total of consecutive 26971 coronary heart disease patients who underwent CABG, PCI or medical therapy were included in the study. Of these, 21266 (78.85%) were males and 5705 (21.15%) were females.

**Distribution of Patients:** Prevalence of CHD in male population was higher as compared to female population (78.85% vs. 21.15%,  $p<0.0001$  (Table 1)). This observation is similar to the INTERHEART study conducted in 52 countries, including India, wherein 76% of enrolled patients were males.

**Table 1. Distribution of Patients**

Variables	Male n(%)	Female n(%)	Total n(%)
Number of Subjects, n (%)	21266 (78.85)	5705 (21.15)	26971 (100)
Mean Age, (Years)	58.39 $\pm$ 11.45	57.85 $\pm$ 13.64	58.3 $\pm$ 11.84

**Influence of Habitat:** Present study showed higher prevalence of CVD in urban than rural female subjects, and the reverse was true in male subjects. The basis of this difference is not known but these findings are similar to the findings of studies conducted in urban Tanzanian and rural Chinese population.

**Table 2: Influence of Habitat**

Variables	Male n(%)	Female n(%)	Total n(%)
Urban Area	10544 (49.58)	3160 (55.39)*	13704 (50.81)
Rural Area	10722 (50.42)*	2545 (44.61)	13267 (49.19)

**Risk Factors:**

High prevalence of traditional risk factors, including hypertension, diabetes and obesity was observed in all patients with CVD with smoking more common in men. These data are similar to the results of the INTERHEART study that showed smoking, lipids, hypertension, diabetes and obesity account for about 80% of the population-attributable risk for acute myocardial infarction in a worldwide investigation.

**Table 3: Associated Risk Factors**

Variables	Males (n=21266) n (%)	Females (n=5705) n (%)	Total (n=26971) n (%)
Hypertension	7192 (33.82)	2546 (44.63)*	9580 (35.52)
Diabetes	5831 (27.42)	1728 (30.3)	7522 (27.89)
Obesity	4387 (20.63)	1157 (20.28)	5547 (20.57)
Family History	1469 (6.91)	1357 (23.79)*	2608 (9.67)
Smoking	3408 (16.03)*	29 (0.52)	3641 (13.5)

**Angiographic Impression of Patients:** Female patients were more likely to have single vessel coronary artery disease and male patients were more likely to have double or triple vessel coronary artery disease

**Table 4: Angiographic Impression of Patients**

Variable	Male (N=17127) n (%)	Female (N= 3033) n (%)	Total (N=16671) n (%)
Normal Coronaries	798 (4.66)	418 (13.78)*	990 (5.94)
Insignificant CAD	558 (3.26)	160 (5.29)	590 (3.54)
Single Vessel Disease	5610 (32.76)	1110 (36.60)	5551 (33.30)
Double Vessel Disease	4913 (28.69)	705 (23.26)	4656 (27.93)
Triple Vessel Disease	4798 (28.02)	585 (19.30)*	4467 (26.80)
Multiple Vessel Disease	447 (2.61)	53 (1.75)	415 (2.49)

**Treatment Options:** Treatment options of CABG and PCI were significantly higher in male patients as compared to female patients. On the other hand, medical therapy was the preferred treatment option in female patients. These results are in concordance with the report that

compared to men, high-risk women with ACS undergo less coronary angiography, angioplasty, and CABG surgery. GRACE registry also showed that women were less likely to undergo PCI (65% vs. 68%, P<0.001). This preferred treatment with CABG and PCI in men most likely represents a societal bias for aggressive therapy in favor of men, perhaps because they are often the bread winners. Whether, this difference holds true in urban women of equal socioeconomic class as men remains to be shown.

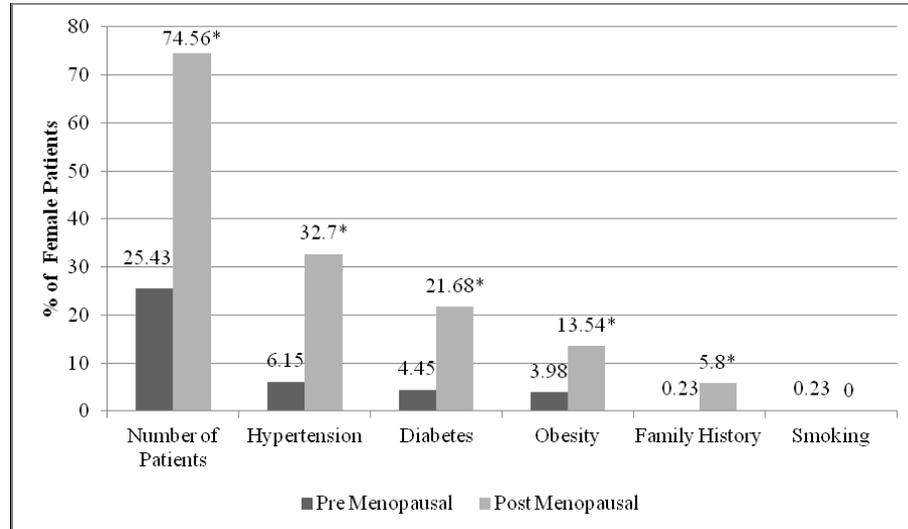
**Table 5: Treatment Options**

Variables	Male n(%)	Female n(%)	Total n(%)
CABG	3925 (18.45)*	709 (12.41)	4634 (17.18)
PCI	9580 (45.04)	2324 (40.72)	11904 (44.13)
Medical Therapy	7761 (36.49)	2672 (46.82)*	10433 (38.68)

**Comparative Characteristics in Pre and Post-Menopausal Female Patients**

Prevalence of risk factors was higher in post-menopausal women. Whether this higher prevalence is just a reflection of age-related disease in post-menopausal women, or implies some protective biological function in the pre-menopausal state is not known.

Nonetheless, we observed that more post-menopausal women underwent coronary angiography and PCI, which may be a reflection of recognition of higher prevalence of CHD in this age group.



**Conclusion**

Gender related differences with regard to extent of coronary disease and subsequent treatment options prevail in Western Indian patients with CVD. Treatment options like CABG and PCI are used more often in males than in females; in case of women medical therapy alone appears to be

the preferred option irrespective of the contributing/confounding factors. Further studies relating to the socioeconomic influence on the intervention and readmission or ongoing angina or mortality at large would aid in defining guidelines for Indian patients.

- 1) *Part of above mentioned study was presented by Dr.Parloop Bhatt at ACC 2012 (Control/Tracking Number: 9325) at USA and was published in Journal of American College of Cardiology [J Am Coll Cardiol 2012;59:(13):E1459].*
- 2) *Abstract Accepted and will be presented by Dr. Parikh at TCT 2012 Conference (Control/Tracking Number: 1328), Miami, FL, USA*
- 3) *Full Length Manuscript submitted to JACC*

## **Study II:Lack of Gender Disparity in DES versus BMS Penetration in Developing Countries despite Gender Disparity in Overall Coronary Intervention**

### **Background:**

Percutaneous coronary intervention (PCI) is increasingly being used for treatment of patients with acute coronary syndrome. However, females are less likely to have PCI compared to males. It is unclear whether such gender disparity extends to the implantation of the type of coronary stent.

### **Methods:**

Data from 2001 through 2012 were used to identify patients with stent implantation and type (DES versus BMS) of coronary stent implantation. We examined gender disparity in implantation of coronary stent in a consecutive cohort of 7830 patients undergoing percutaneous coronary intervention at our institute.

### **Results:**

Of the total patients, 85.41% were males and 14.59% were females with mean age of 58.26±1.22 years. As compared to males, females had an increased prevalence of hypertension (p<0.0001) and diabetes (p=0.01); while males had smoking (p<0.0001) as a contributable risk factor. Females received preferentially more DES than BMS in last 2 years in same ratio (approximate 2:1) with males (Females: DES- 66.26%, BMS- 33.74%; Males: DES-65.97%, BMS-34.03%). There was no gender bias once the patient was taken for intervention between costlier DES versus less costly BMS (where 95% patients have out of pocket payment) however significant undertreatment of women was seen over one decade.

### **Conclusions:**

There is a consistent gender bias of "undertreatment" of females over males by ratio of 1:6.

However, surprisingly lack of gender bias was observed in DES (costlier) versus BMS (less expensive) implantation once the patient underwent interventional treatment.

### **Study III: Increasing Penetration of Drug Eluting Stent Use in Developing Countries**

#### **Background:**

The introduction of drug eluting stent (DES) led to dramatic changes in percutaneous practice with superior clinical outcomes compared to bare metal stent (BMS). However, the disparity in use of DES has been reported worldwide after the concern of late stent thrombosis raised globally. The current usage of DES in developing countries is not adequately reported. Hence, present study evaluated the contemporary trend of use of drug eluting stents in percutaneous coronary intervention.

#### **Methods:**

The data of patients implanted with DES or BMS (US FDA approved) was collected from hospital database in Ahmedabad, India. Between 2001 to 2012, total 7390 patients were implanted either with DES or BMS. We assessed DES utilization according to year of implantation with various clinical and procedural characteristics.

#### **Results:**

Of the total patients, 85.41% were males and 14.59% were females with mean age of  $58.26 \pm 1.22$  years. Of these, 84.07% patients had single vessel disease, 14.25% had double vessel disease and 1.68% had multi-vessel disease. Of these, 52.56% had left anterior descending coronary (LAD) artery lesion, 28.48% had right coronary artery (RCA) lesion and 18.96% had left circumflex (LCX) artery lesion. During this period, total number of stents used was 9100 including 4484 DES and 4616 BMS. In last 2 years, DES (60.17%) implantation has increased over BMS (39.83%) compared to initial years (DES: 23.05% vs. BMS: 76.95%) with last 1 year penetration of DES reaching over 70%.

#### **Conclusions:**

Although late stent thrombosis is a concern, the use of DES has been increasing in contemporary interventional practice in developing countries like India where despite out of pocket payment by patients (lack of insurance) DES (US FDA approved) intervention has risen significantly, suggestive of rapidly increasing DES acceptance and penetration.

#### **Study IV: Impact of Education and Socioeconomic Factors on Depression Associated with Cardiovascular Disease.**

A total of 948 consecutive coronary heart disease patients were enrolled in the study at CIMS hospital, Ahmedabad from Jan. 2011 to May 2011. Mean age was  $56.63 \pm 11.66$  years. Prevalence of depression was assessed by Montgomery-Asberg Depression Rating Scale (MADRS). In 374 (39.45%) patients MADRS score was greater than 6 depicting depression, while 574 (60.55%) had a MADRS score less than 6. Females (50.86%) had higher prevalence of depression compared to males (35.76%). Socioeconomic data of 710 patients revealed that depression was higher in uneducated (55.22% vs. 34.7%,  $p < 0.0001$ ), unemployed (45.82% vs. 33.59%,  $p < 0.0001$ ), rural subjects (42.41% vs. 37.30%,  $p < 0.0001$ ) and subjects with monthly income less than 10,000 rupees (45.06% vs. 32.62%,  $p < 0.0001$ ).

#### **Study V: A Prospective Study to Relate Gastrointestinal Distress with Depression and Quality of Life in Cardiovascular Disease Patients**

**OBJECTIVES:** Aim of the present study was to determine the correlation of gastric distress with depression, and quality of life in patients with cardiovascular disease (CVD).

**METHODS:** In this prospective study conducted at Care Institute of Medical Sciences (CIMS), Ahmedabad, India, a total of 644 CVD patients with either effort angina, unstable angina, myocardial infarction and left ventricular dysfunction were enrolled. All patients were assessed using Montgomery-Asberg Depression Rating Scale (MADRS) for depression and Hospital Anxiety and Depression Scale (HADS) for anxiety. SF-36 form assessed Quality of Life (QoL). Gastric distress was assessed with complains such as abdominal pain, vomiting, constipation, gas, abdominal tenderness and others.

**RESULTS:** From a total of 644 patients, 560 were males and 84 were females with a mean age of  $58.7 \pm 10.22$  years who underwent coronary artery angiography (21.98%), percutaneous transluminal coronary angioplasty (40.29%) and coronary artery bypass graft (37.33%). As per MADRS score, 247 patients (38.35%) had depression (MADRS score  $> 6$ ) and 205 patients (31.83%) had anxiety (HADS score  $> 8$ ). GI distress was depicted in 58.97% patients. Most common GI distress symptoms reported were abdominal pain (32.81%), constipation (33.12%) and gas (34.07%). Mean MADRS score ( $7.3 \pm 5.12$  v/s  $3.38 \pm 5.36$ ) and HADS score ( $7.48 \pm 3.24$  v/s  $3.94 \pm 3.34$ ) were significantly higher in patients with GI complains. QoL as assessed by Physical Component Summary scores ( $68.42 \pm 26.23$  v/s  $75.68 \pm 26.17$ ) and Mental Component Summary scores ( $71.04 \pm 23.62$  v/s  $79.82 \pm 23.54$ ) were significantly lower in patients with GI distress as compared to subjects without GI distress.

**CONCLUSION:** A strong association exists between GI distress and affective disorders affecting Quality of Life in CVD patients.

**Presented at Cardiology Society of India Conference held in Dec.2012**

### **Study VI: A Prospective Study to Evaluate Correlation between Depression and Cardiovascular Disease and its Effect on Clinical Outcomes**

**OBJECTIVE:** To evaluate correlation between depression and cardiovascular disease (CVD) and its effect on clinical outcomes of the disease.

**METHODS:** A prospective study was conducted at Care Institute of Medical Sciences (CIMS), Ahmedabad in which the subjects were drawn from a population of patients with CVD based on well-defined inclusion and exclusion criteria. Incidence and severity of depression in these patients was assessed by MADRS (Montgomery-Asberg Depression Rating Scale). The end point was to determine occurrence of Major Adverse Cardiac Event (MACE) and Quality of Life (QoL) at 6 months follow up.

**RESULT:** A total of 1648 consecutive CVD patients were enrolled in the study with a mean age of  $56.63 \pm 11.66$  years. Out of these 39.8% were depressed (MARDS score  $> 6$ ) and 60.2% were non-depressed (MARDS score  $\leq 6$ ). Depression was higher in uneducated (54.22% vs. 40.95%,  $p < 0.0001$ ), unemployed (36.45% vs. 22.10%,  $p < 0.0001$ ), rural subjects (42.41% vs. 37.30%,  $p < 0.0001$ ) and subjects with monthly income less than 10,000 rupees (39.16% vs. 33.14%,  $p < 0.0001$ ). Marital status and number of family members did not affect the depressive state in CVD patients. QoL data of 600 patients at 6 months revealed that QoL was poor in depressed (61.33% vs. 84.92%,  $P < 0.0001$ ) as compared to non-depressed patients. Rehospitalization (27.56% vs. 3.47%,  $P < 0.0001$ ), revascularization (7.09% vs. 0.58%,  $P = 0.0055$ ), and mortality rate (3.94% vs. 1.73%,  $P = 0.4171$ ) were higher in depressed as compared to non-depressed patients.

**CONCLUSION:** There is a strong association between depression and cardiovascular disease and its outcomes.

**Presented at Cardiology Society of India Conference held in Dec.2012**

### **Study VII: Influence of Gender on Risk Factors, Treatment Options and Outcomes in Coronary Heart Disease in India**

At CIMS a total of consecutive 26971 CVD (unstable and stable angina and acute coronary syndrome) patients who underwent coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI) or medical therapy were included in the study. Of these, 21266 (78.85%) were males and 5705 (21.15%) were females. Prevalence of CVD was higher in urban female subjects ( $p < 0.0001$ ) whereas, it was higher in males in rural areas ( $p < 0.0001$ ). As compared to males, female patients had higher prevalence of hypertension ( $p < 0.0001$ ), diabetes ( $p = 0.01$ ) and family history of CVD ( $p < 0.0001$ ); while male patients had smoking ( $p < 0.0001$ ) as a major contributing risk factor. Post-menopausal women had higher prevalence of CVD and associated risk factors. Treatment options like CABG (18.45% vs. 12.41%,  $p < 0.0001$ ) and PCI (45.04% vs.

40.72%, $p=0.001$ ) were used more often in males as compared to females where medical therapy was the preferred option(36.49 % vs. 46.82%,  $p<0.0001$ ). A total of 9100 stents (Drug eluting stents (DES)-4484; Bare metal stents (BMS)-4616) were implanted during this period.

***This study was awarded as the top 25 poster award at TCT 2012 conference, held at Florida,USA.***

### **Study VIII: Non-Adherence to Prescribed Antihypertensive Drug Treatments: Causes, Interventions and Outcomes**

Of the 1000 enrolled patients at CIMS, 416 (41.6%) patients exhibited non adherence to antihypertensive medications as determined by MMAS. Medication non-adherence was higher in males as compared to females ( $P<0.0001$ ). Non adherence was higher in the age group 45-65 years, <1 year treatment duration, when >2 drugs were prescribed, and subjects with rural background, and low levels of education, employment and income. Patients prescribed a single morning dose showed lower non adherence than multiple dosing. Common causes of non-adherence included forgetfulness (43.6 %), side effects (13.8%), lack of medication understanding (12.01%), too many medications (10.9%), change of routine (5.45%), travelling (3.63%), misplacing of drug (1.81 %) and cost of medications (1.6%). Behavioral interventions were most effective (58%) in improving non adherence followed by technical (19%) and educational (23%).

**Presented at Indian Pharmacology Society, Gujarat chapter, March 2013.**

### **Study IX:A Prospective Study to Evaluate Correlation between Coronary Heart Disease and Depression and Its Influence on Quality of Life and Clinical Outcomes**

**Background:** A correlation exists between depression and coronary heart disease (CHD), affecting quality of life and clinical outcomes.

**Methods:** A prospective study was conducted on CHD patients at Care Institute of Medical Sciences (CIMS), Ahmedabad, India. Incidence and severity of depression in these patients was assessed by Montgomery-Asberg Depression Rating Scale (MADRS). The end point at 12 months was to determine the influence of depression on clinical outcomes and Quality of Life(QoL) as assessed by SF 36 Health Survey.

**Results:** A total of 1648 patients (mean age of 56.63 • }11.66 years) undergoing percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass graft (CABG) were enrolled in the study. Of these 39.8% (n=655) patients were depressed, MARDS score > 6. Prevalence of depression was higher in hypertensive (62.04 %) and diabetic (35.77%) patients as compared to those with smoking (16.42%), or alcohol (6.2%). Cardiac procedure (PTCA or CABG) did not influence the prevalence of depression which was higher ( $p<0.0001$ ) in males as compared to females (68.45 vs. 31.55 %), less educated (54.22 vs. 40.95 %), unemployed (36.45 vs. 22.10%), rural subjects (42.41 vs. 37.30%), and in those with monthly income <INR10,000 (39.16 vs. 33.14%). Marital status and number of family members did not affect the frequency of depression. At 12 months QoL was poor in depressed (61.33 vs. 84.92%,  $P<0.0001$ ) than in non-depressed patients in terms of reduced physical functioning (62.86 vs. 89.83%), physical well-being (35.24 vs. 84.94%), emotional stability (53.27 vs. 88.7%), emotional well-being-(61.31 vs.

72.83%), social functioning (85.14 vs.95.11%), perception of pain (88.23 vs. 97.29%) and general health (41.59 vs. 69.65%). At 12 months rates of re-hospitalization (18.59 vs. 3.47%,  $p<0.0001$ ), revascularization (8.54 vs. 0.16 %  $p<0.0001$ ), and mortality (4.77 vs. 1.66%,  $p<0.005$ ) were higher in depressed as compared to nondepressed patients.

**Conclusion:** There is a significant association between depression and CHD, which is influenced by socioeconomic factors. Presence of depression adversely affects clinical outcome and quality of life in CHD patients.

**Presented at ACC, San Francisco US, Mar 2013; JACC March 12, 2013 Volume 61, Issue 10, E1478.**

## Section III

### **Short Term Objectives:**

- 1: Improve prevention, early detection, treatment, and management of risk factors for heart disease specially in women
- 2: Eliminate gender related disparities in prevention, management and treatment of CVD
- 3: Decrease death and disability from heart disease through early detection, treatment, and management of acute events in women

### **Long Term Objectives:**

- 1: Develop guidelines in cardiovascular disease in Indian women
- 2: Decrease death and disability from heart disease through public education and health care professionals
- 3: Improve chronic disease management of heart disease in women
- 4: Expand data acquisition and surveillance of cardiovascular disease in women, including evaluation of programs targeting heart disease, and related risk factors
- 5: Improve quantity and quality of research on heart disease in women and related risk factors
- 6: Improve cardiovascular health and quality of life through legislation and policy.

### **Elements of the Strategic Proposal**

#### **Goal 1: Improve prevention, early detection, treatment, and management of risk factors for heart disease specially in women**

##### ***Recommendations for achieving it:***

- Increase number of women who undergo regular screening and follow-up for high blood pressure and high cholesterol thereby educating about abnormal levels and their manifestations.
- Educate and counsel to increase the number of women who achieve and maintain recommended normal levels for blood pressure and cholesterol.

#### **Goal 2: Eliminate gender related disparities in prevention, management and treatment of CVD**

##### ***Recommendations for achieving it:***

- Through public education using appropriate language and culturally sensitive educational materials establish equal respect for either gender.

- Within communities, assure accessible screening and follow-up for high blood pressure and cholesterol.
- Promote quality improvements in health care for women by recommending changes at the systems level (e.g., preprinted treatment orders, standard protocols).
- Improve cultural competency among health care professionals, so as to communicate effectively.

**Goal 3: Decrease death and disability from heart disease through early detection, treatment, and management of acute events in women**

***Recommendations for achieving it:***

- Educate women to recognize signs and symptoms of heart attack and call emergency service immediately when symptoms occur.
- Continue development of specialty centers for CVD.
- Improve the women's ability to respond to sudden cardiac arrest by promoting cardiopulmonary resuscitation training, as well as placement of automated external defibrillators in public places.

**Goal 4: Decrease death and disability from heart disease through public education**

***Recommendations for achieving it:***

- Target educational efforts for high-risk groups (e.g., post-menopausal women, women of low socioeconomic status, urban women, and women with MADRS scale > 6).
- Present education and counseling in a variety of venues throughout the community and use multiple communication channels (e.g., mass media, provider/patient education, camps, etc.).

**Goal 5: Improve chronic disease management of heart disease in women**

***Recommendations for achieving it:***

- To reduce disability, increase availability of in-hospital rehabilitative care units, as well as long-term community rehabilitation for survivors.
- To reduce the risk of a recurrent heart attack, systematize the application of proven therapies (e.g., use of medications and lifestyle changes); beginning in the hospital setting.
- For ongoing care of heart disease women, apply best practice disease-management models, including multidisciplinary teams, case managers, information technology that

supports patient monitoring and follow-up, standing treatment orders, and patient self management.

**Goal 6: Decrease death and disability from heart disease through the education of health care professionals**

*Recommendations for achieving it:*

- Increase awareness of and adherence to evidence-based international guidelines and established protocols for prevention and management of heart disease especially women.
- Provide continuing education to inform practicing health care professionals of updates to evidence-based guidelines for heart disease prevention and treatment in women.
- Develop and disseminate health education resources on heart disease to health care professionals, including emergency medical services providers

**Goal 7: Expand data acquisition and surveillance of cardiovascular disease in women, including evaluation of programs targeting heart disease, and related risk factors**

*Recommendations for achieving it:*

- Maximize the use of existing data sources, including the patient discharge file, and hospital databases.
- Evaluate the feasibility of an outpatient reporting system for heart attack, including rehabilitation and its outcome.
- Evaluate the feasibility of statewide registries for acute coronary syndrome.
- Outreach to academic institutions globally to identify and collaborate with researchers who have experience in evaluating programs that address heart disease related risk factor.

**Goal 8: Improve quantity and quality of research on heart disease in women and related risk factors**

*Recommendations for achieving it:*

- Identify effective strategies for reducing prevention, management and treatment disparities among gender groups.
- Examine the correlation between psychosocial conditions and behaviors and the risk of heart disease.
- Increase awareness of the need for including priority populations in research.
- Encourage participation by women in clinical studies.
- Encourage reporting of all study results in a population-specific and gender-specific manner.

**Goal 9: Improve cardiovascular health and quality of life through legislation and policy development**

***Recommendations for achieving it:***

- Educate policymakers and public officials about the societal toll of heart disease in women.
- Develop and maintain an inventory of public and private policies that promote cardiovascular health; disseminate exemplary policies; identify policy gaps and suggest remedies.

**The Need of Developing Indian Guidelines for Cardiovascular Disease in Women**

Based on statistics of rising CVD in Indian women, it stands as a priority. In a first-of-a-kind presentation of data at the World Congress of Cardiology on April 20, 2012 in Dubai, the Indian Heart Watch (IHW) study has revealed the truth behind the prevalence, awareness, treatment and control of key risk factors that are driving the country's growing cardiovascular disease (CVD) epidemic. "India has the dubious distinction of being known as the coronary and diabetes capital of the world," said Chairman Prof. Prakash Deedwania, University of California, San Francisco, USA. "These results show why - and must prompt the government to develop public health strategies that will change lifestyles, if these risk factors are to be controlled." Overweight and obesity was reported in 45 per cent of women. High blood pressure was reported in 30 per cent of women, while high cholesterol was found in one-quarter of all men and women. Diabetes (and or metabolic syndrome) was also reported in 37 per cent of women. The lack of knowledge and subsequent action by people to take responsibility for their own health is shocking and demands

government intervention, education and publicity to curb the epidemic of CVD in India. Previous research conducted at CIMS([www.cims.me](http://www.cims.me)) a tertiary care hospital has helped disseminate CVD preventive actions to achieve institute goal by bringing a paradigm shift from the “treatment of risk factors in isolation” to “comprehensive cardiovascular risk management”. Besides, CIMS Ahmedabad, India has joined as one of the first participants of the PINNACLE INDIA HEALTHCARE QUALITY IMPROVEMENT PROGRAM (PIQIP) a program undertaken by American college of Cardiology(ACC). With more than 4 million patient records, the PINNACLE Registry® has become cardiology's largest ambulatory quality improvement registry in the USA(Attached invitation).

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**SECTION IV**  
**CASE REPORT FORM FOR THE PROPOSED STUDY**

**1. Demographic details:**

Patient ID: \_\_\_\_\_ Name of patient: \_\_\_\_\_

Sex: M / F Age: \_\_\_\_\_ yr. Height: \_\_\_\_\_ cm. Weight: \_\_\_\_\_ kg

BMI: \_\_\_\_\_ Kg/m<sup>2</sup>

Address: \_\_\_\_\_

Contact No: \_\_\_\_\_

**2. Socioeconomic status**

**a. Marital status**

- Single
- Married
- Divorced
- Widow

**b. Family members**

- 1 member
- 2 members
- 3 members
- 4 or more members

**c. Education**

- None
- School
- High school
- Graduate
- Post-graduate

**d. Occupation**

- Working full time
- Working part time
- Student
- Unemployed
- Retired

**e. Living location**

- Rural area
- Urban area

**f. Living place**

- Private apartment
- Live in apartment with paying rent
- Govt. paid apartment
- Other

**g. Personal monthly income**

- < 5000
- 5000-10000
- 10000-20000
- 20000-40000
- > 40000
- Answer denied

**h. Receiving financial support from others**

- Yes
- No
- Answer denied

**3. Complaints:** \_\_\_\_\_

**4. Cardiac Risk Factors:**

Hypertension: Yes/No      Dyslipidemia: Yes/No  
Diabetes:      Yes/No      Obesity:      Yes/No  
Smoking:      Yes/No      Tobacco:      Yes/No  
Alcohol:      Yes/No

**5. Past History:**

Unstable Angina    MI    CHF    CAG    PTCA    CABG    Other

**6. Family History:**

Cardiac disease    Psychiatric illness    Other

**7. Vital Signs:**

Heart Rate : \_\_\_\_ /min Systolic BP: \_\_\_\_\_ mmHg  
Diastolic BP: \_\_\_\_ mmHg Respiratory Rate: \_\_\_\_ /min  
Temp: ° F

**8. 12 lead ECG:**

HR: / min QT: \_\_\_\_\_ QRS: \_\_\_\_\_ PR: \_\_\_\_\_ P: \_\_\_\_\_ T: \_\_\_\_\_

**9. Echo:**

LVEF: \_\_\_\_\_ %

**10. Diagnosis:**

Chronic stable angina    Unstable Angina    MI    CHF    Other

**11. Type of Coronary Artery Disease**

Single vessel disease    Double vessel disease    Triple vessel disease    Multi-vessel disease

**12. Angiography Procedure done:**

Yes    No

**13. Treatment Options:**

PCI    CABG    Medical Therapy

## 14. SF36 Health Survey

Instructions for completing the questionnaire: Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

1. In general, would you say your health is:
  - Excellent
  - Very good
  - Good
  - Fair
  - Poor
  
2. Compared to one year ago, how would you rate your health in general now?
  - Much better now than a year ago
  - Somewhat better now than a year ago
  - About the same as one year ago
  - Somewhat worse now than one year ago
  - Much worse now than one year ago
  
3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?
  - 3(a) Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.
    - Yes, limited a lot.
    - Yes, limited a little.
    - No, not limited at all.
  
  - 3(b) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?
    - Yes, limited a lot.
    - Yes, limited a little.
    - No, not limited at all.
  
  - 3(c) Lifting or carrying groceries.
    - Yes, limited a lot.
    - Yes, limited a little.
    - No, not limited at all.
  
  - 3(d) Climbing several flights of stairs.
    - Yes, limited a lot.
    - Yes, limited a little.
    - No, not limited at all.
  
  - 3(e) Climbing one flight of stairs.
    - Yes, limited a lot.
    - Yes, limited a little.

- No, not limited at all.

3(f) Bending, kneeling or stooping.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

3(g) Walking more than one mile.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

3(h) Walking several blocks.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

3(i) Walking one block.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

3(j) Bathing or dressing yourself.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

4(a) Cut down the amount of time you spent on work or other activities?

- Yes
- No

4(b) Accomplished less than you would like?

- Yes
- No

4(c) Were limited in the kind of work or other activities

- Yes
- No

4(d) Had difficulty performing the work or other activities (for example, it took extra time)

- Yes
- No

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?
  - 5(a) Cut down the amount of time you spent on work or other activities?
    - Yes
    - No
  - 5(b) Accomplished less than you would like
    - Yes
    - No
  - 5(c) Didn't do work or other activities as carefully as usual
    - Yes
    - No
6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
  - Not at all
  - Slightly
  - Moderately
  - Quite a bit
  - Extremely
7. How much bodily pain have you had during the past 4 weeks?
  - Not at all
  - Slightly
  - Moderately
  - Quite a bit
  - Extremely
8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
  - Not at all
  - Slightly
  - Moderately
  - Quite a bit
  - Extremely
9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.
  - 9(a) did you feel full of pep?
    - All of the time
    - Most of the time
    - A good bit of the time
    - Some of the time
    - A little of the time
    - None of the time
  - 9(b) have you been a very nervous person?
    - All of the time
    - Most of the time
    - A good bit of the time
    - Some of the time

- A little of the time

9(c) have you felt so down in the dumps nothing could cheer you up?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

9(d) have you felt calm and peaceful?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

9(e) did you have a lot of energy?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

9(f) have you felt downhearted and blue?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

9(g) did you feel worn out?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

9(h) have you been a happy person?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

9(i) did you feel tired?

- All of the time

- Most of the time
  - A good bit of the time
  - Some of the time
  - A little of the time
  - None of the time
10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?
- All of the time
  - Most of the time
  - Some of the time
  - A little of the time
  - None of the time
11. How TRUE or FALSE is each of the following statements for you?
- 11(a) I seem to get sick a little easier than other people
- Definitely true
  - Mostly true
  - Don't know
  - Mostly false
  - Definitely false
- 11(b) I am as healthy as anybody I know
- Definitely true
  - Mostly true
  - Don't know
  - Mostly false
  - Definitely false
- 11(c) I expect my health to get worse
- Definitely true
  - Mostly true
  - Don't know
  - Mostly false
  - Definitely false
- 11(d) My health is excellent
- Definitely true
  - Mostly true
  - Don't know
  - Mostly false
  - Definitely false