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Research Article

Prevalence of Co-Morbidities and Clinical Coexisting Conditions among Post-Menopausal Women Affected by Coronary Artery Disease: Data from the "Real World"

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Abstract

Objectives: our study describes the prevalence of co-morbidity and clinical coexisting conditions in a population of post-menopausal women, partially affected by Coronary Artery Disease (CAD), with the specific purpose to lead to think over modifying clinical decision-making and potentially informing on the management of women on CAD affected by co-morbidity.

Patients and Methods: Among 8555 consecutive women, 6535(76,4%) were on menopause, clinical history was collected by trained nurses. Conditions that are likely to affect the clinical course or ability to treat CAD were considered, focusing on that which is relevant when making decisions related to prescribing medications or other treatments or achieving adherence. They were grouped into chronic disease as Congestive Heart Failure (CHF), stroke and Chronic Lower Respiratory Tract Disease (CRD); and clinical coexisting conditions as hypertension, diabetes mellitus, dizziness or falls, low Glomerular Filtration Rate (GFR), assumption of more than 4 medications, urinary incontinence and warfarin use. The diseases here studied are leading causes of death or morbidity and interacts with CAD, CAD treatments or their treatments interacts with CAD. About clinical conditions they may affect function and quality of life, affect a person's ability to adhere to therapy, and are often caused by several processes in post-menopausal women.

Results: 528 women (8,1%) were affected by CAD,6007 were not. People with CAD were more likely to be slightly older, but not in a statistical significant way. All co-morbid chronic diseases and two of clinical conditions considered were statistically significant and more prevalent for women with CAD than for their counterparts without CAD. The prevalence of diseases in postmenopausal women with CAD was for: CHF 9,1%($p<0,02$); stroke 6% ($p<0,01$) and CRD 6,5%($p<0,04$); the prevalence of coexisting clinical conditions, was for: hypertension 58.9% ($p<0,5$); diabetes 32,4%($p<0,1$); dizziness or falls 0,6 ($p<0,02$); low GFR 0,9%($p<0,004$); use of more than four medications 73,4%($p<0,2$); urinary incontinence 17%($p<0,2$) and for use of warfarin 2,3%($p<0,01$). 99 women affected by CAD had at least one more chronic disease (18,1%).

Conclusion: Complexity of clinical management for postmenopausal women with CAD is an ongoing rule. Guidelines focused on single diseases do not apply well to those with co-morbidity. Our findings support the idea that the complexity of a persons' health status can be better understood using a framework that incorporates all diseases paying attention to co-morbidities. Understanding how to, best care for women with CAD , in terms of all of their health needs, may lead to improvements in quality of life, use of health care, safety, morbidity, and mortality.

BACKGROUND

Coronary Artery Disease (CAD) is common among older adults, with a prevalence of 37% in men and 26% in women aged 65 and older [1]. It is negatively associated with quality of life and is the major cause of death [2,3]. In women with CAD, 79% have at least one additional major chronic disease [4]. There is increasing awareness that people with CAD and additional chronic disease experience high levels of healthcare use and poor outcomes [5,6]. A prior work in the Medicare population has found that many non cardiac co-morbidities increase the risk of hospitalizations and death in people with CAD and the awareness of them may help their prevention [7]. Conditions that affect negatively the specific physiopathology of CAD, thereby worsen its effects and interfere with CAD therapies modifying their actions, changing patients' or physicians' priorities for treatment; or function as competing demands, all situations that may cause adverse outcomes. This happens commonly among patients affected by CAD, among major chronic diseases [8]. It is important to consider co-morbidities in patients with CAD, because the prevalence and the potential

for the condition to affect real-world clinical decision-making are likely to determine the highest priorities. Co-morbidity has been defined as "any distinct additional clinical entity that has existed or may occur during the clinical course of a patient who has the index disease under study" [9]. Co-morbidity has been studied for prognostic stratification, risk adjustment, and more recently, understanding heterogeneity of treatment effect [10,11], but there are few experiences to understand how co-morbidities may affect health status complexity, and, at the patient level, affect clinical decision-making [12]. Usually co-morbid conditions are underestimated among post-menopausal women because of a low awareness of their existence. Co-morbid conditions are often ignored in the development of more relevant clinical practice guidelines, because people affected by co-morbidity are excluded from the largest trials for statistical reasons. At the opposite our study describes the prevalence of co-morbidity and clinical coexisting conditions in a population of post menopausal women, partially affected by CAD, representative of Southern Italy, with the specific purpose to lead to think over modifying clinical decision-making and potentially informing on the management of women on CAD affected by co-morbidity. This manuscript describe a population of consecutive women, enrolled by our Heart Station, to estimate the above mentioned prevalence to increase the awareness of post-menopausal women health status and improve the complexity of management of CAD as a basis for deciding which clinically important factors should be studied and incorporated into management for people with CAD.

PATIENTS AND METHODS

Our population consists of 8555 consecutive women, send to our Heart Station by General Practitioners because suspected to be affected by cardiovascular disease, suspect based on high risk status according to major risk factors or based on symptoms. 6535(76,4%) were on menopause, 2020 were menstruate. We considered women on menopause only after, at least, twelve consecutive months of amenorrhea. In this study we will consider post-menopausal women. Our collection of information concerning clinical history was performed by four trained nurses. Conditions that are likely to affect the clinical course or ability to treat CAD were considered, focusing on that which are relevant when making decisions related to prescribing medications or other treatments or achieving adherence. Although health system and social factors are also significant, these factors were beyond the scope of this study. We consider only conditions that physiologically interact with recommended therapies or that alter a patient's ability to achieve treatment benefit. These factors were grouped into chronic disease and clinical coexisting conditions to reflect a progressively widening scope from classic disease definitions to clinical conditions predisposing to chronic diseases (Table 1). The diseases here studied are considered of major importance because they are established as leading causes of death or morbidity and because there are known interactions between each disease and CAD, between CAD treatments and each disease, between one of their treatments and CAD, or between treatments for both conditions.

It is useful to remember that some clinical conditions should be weighed when prescribing therapies because they may be a contraindication or relative contraindication (i.e. complaints of dizziness when considering the use and dose of therapy to lower blood pressure) and also that they may affect function and quality of life, are likely to affect a person's ability to adhere to therapy, and are often caused by several processes in postmenopausal women.

Diseases

Co-morbid disease status was ascertained through specific and validated questions and diagnosed by documentation containing instrumental examination reports for heart failure, stroke, CAD, angina pectoris or a heart attack. The same was for diagnosis of chronic lower respiratory tract disease included emphysema, chronic bronchitis, or current asthma or a history of asthma.

Clinical conditions

Participants were diagnosed as diabetic if they took insulin or a pill for diabetes mellitus and hypertensive if they took therapy to lower blood pressure. GFR was calculated using the Modification of Diet in Renal Disease equation based on serum creatinine and age, normal value more than 60mL/min [13,14]. Urinary Incontinence (UI) was ascertained according to self-report of leaking urine at least a few times a month. Individuals who reported dizziness or imbalance lasting at least 2 weeks or for an unknown duration or having fallen in the last year were counted as having problems with dizziness or falls. Using more than four medications was defined following a previously established cut-point [15] and from inspection of prescribed medications and over-the-counter analgesics used daily. Use of warfarin was defined after inspection of prescribed medications.

Statistical analysis

It was performed by statistical software designed to conduct subpopulation analysis, baseline characteristics were summarized using means and standard deviations. Differences in these variables between subjects with and without CAD were compared using a two-sided t-test for continuous variables and the chi-square test for categorical data. A $p < 0,05$ was considered statistically significant

RESULTS

Table 1 describes the baseline demographic and complexity factors according to CAD status.

Among our 6535 postmenopausal women 528 (8,1%) were affected by CAD, 6007 were not. People with CAD were more likely to be slightly older, but not in a statistical significant way. All co-morbid chronic diseases and all clinical conditions considered were statistically significant and more prevalent for women with CAD than for their counterparts without CAD.

The prevalence of in postmenopausal women with CAD was: 9,1% for congestive heart failure versus 1,6% in their counterparts($p<0,02$); for stroke 6% versus 0,6%($p<0,01$) and for chronic lower respiratory tract disease 6,5% versus 5,4%($p<0,04$). Among postmenopausal women the prevalence of coexisting clinical conditions, adding to complexity of clinical decision-making for CAD was: 58.9% for hypertension in affected by CAD versus 58,4% in their counterparts($p<0,5$); for diabetes 32,4% versus 14%($p<0,1$); for dizziness or falls 0,6% versus

1,6%(p<0,02); for low GFR 0,9% versus 0,6%(p<0,004); for use of more than four medications 73,4% versus 46,6%(p<0,2); for urinary incontinence 17% versus 18%(p<0,2) and for use of warfarin 2,3% versus 2%(p<0,01).

Table 3 depicts the prevalence of women experiencing at least two chronic disease, 7 of them were affected by CHF (1,3%), 1 were not(0,2%). 99 women affected by CAD had at least one more chronic disease(18,1%).

DISCUSSION

Our study illustrate an innovative and easily replicable approach to evaluate considering clinical complexity that may assist in choosing conditions to be considered in clinical trials, guideline development and implementation, and therefore eventually in clinical decision-making with patients affected by co-morbidity. We found that 99 postmenopausal women (18,8%) have one major disease, in addition to CAD, 8 (1,5%) more than one, contributing to status of co-morbidity (Table 2 and 3)(Figure 1&2) . We found an elevated rate of clinical coexisting conditions too (Table 2) (Figure 1).

The high prevalence of co-morbidity of diseases and clinical coexisting conditions in people with CAD, which has not been previously identified or quantified, underscores the importance of recognizing all of them in the conduct of research and clinical practice and the development and application of clinical practice guidelines for adults with CAD. Clinical coexisting conditions and major chronic diseases are often present and strongly associated with repeated hospitalization. These findings suggest that efforts to reduce hospitalizations of people with CAD should potentially target interventions at conditions that classic disease labels do not capture and focus on other clinical factors. It is likely that the mechanism by which coexisting diseases and clinical conditions influence an outcome such as repeated hospitalization is complex, dependent on specific diseases and conditions, and influenced by social and health system factors that were not examined here.

Table 1: Definitions of Factors adding to complexity.

Diseases	
Arthritis	Arthritis
Chronic lower respiratory tract	Emphysema
	Chronic bronchitis
	Disease Asthma now or had in past and refused to say
Congestive heart failure	Congestive heart failure
Stroke	Stroke
Clinical conditions	
Hypertension	Hypertension and take a pill
Diabetes mellitus	Diabetes mellitus
	Borderline diabetes mellitus and take a pill or insulin
	Borderline diabetes mellitus and retinopathy or leg ulcer
Dizziness or falls	Dizziness or imbalance lasting 42 weeks
Low glomerular filtration rate	<60 mL/min, Modified Diet based on serum creatinine and age
> 4 Medications	Inspection of prescribed medications
Urinary incontinence	Leak urine a few times a month or more
Warfarin use	Inspection of medications

Table 2: Baseline Characteristics (Demographics, Diseases and Clinical Conditions) overall and According to Coronary Heart Disease Status.

Demographic variables	**All**	**CHD free**		**CHD prone**		
Age (%)	64±9	63±8		66±5		
Postmenopausal women	6535	6007		528		
Diseases						
Congestive heart failure	141	93	1.60%	48	9.10%	p<0,02
Stroke	68	34	0.60%	32	6%	p<0,01
Chronic lower respiratory tract disease	299	265	5.40%	34	6.50%	p<0,04
Clinical Conditions						
Hypertension	3822	3511	58.40%	311	58.90%	p<0,5
Diabetes mellitus	1990	1819	14%	171	32.40%	p<0,1
Dizziness or falls	101	98	1.60%	3	0.60%	p<0,02
Low glomerular filtration rate	28	23	0.60%	5	0.90%	p<0,004
> 4 Medications	3178	2790	46.40%	388	73.50%	p<0,4
Urinary incontinence	1167	1082	18%	85	17%	p<0,2
Warfarin use	130	118	2%	12	2.30%	p<0,01

Table 3: Comorbidity rate: Diseases and Clinical Conditions).

Diseases	CHD prone	
Congestive heart failure (CHF)	41	7.70%
Stroke (S)	26	4.90%
Chronic lower respiratory tract disease (CLRTD)	32	6%
CHF + S	6	1.10%
CHF + CLRTD	1	0.20%
S + CLRTD	1	0.20%
All	99	18.10%

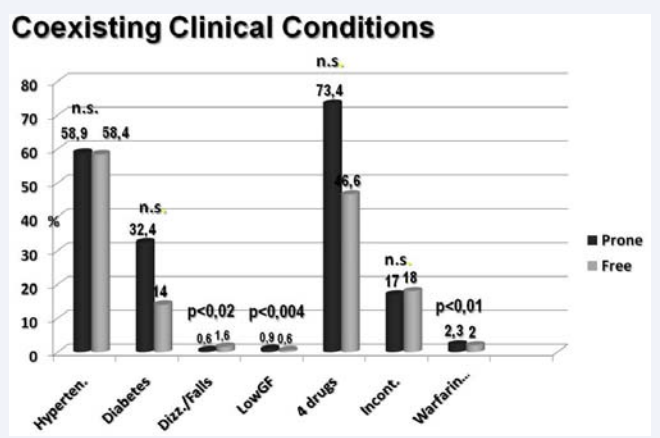

Figure 1 Clinical coexisting condition rate in our population.

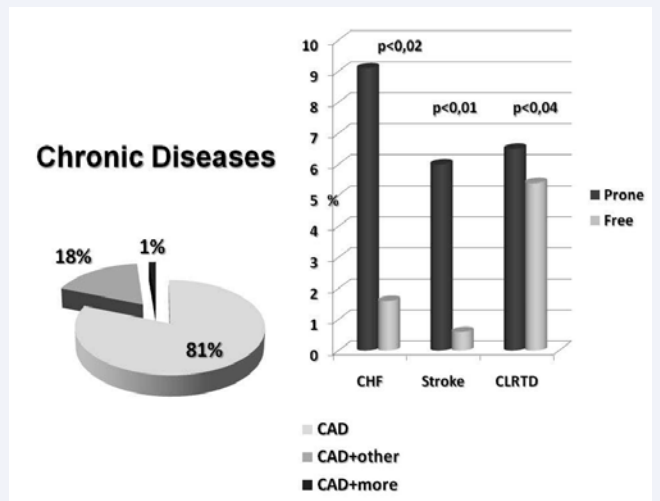

Figure 2 Correlation between CAD and Chronic Diseases.

Many of the clinical coexisting conditions may function as competing demands for physicians, patients, and family or friends [16,17]. Sometimes it is possible that having more chronic diseases is not associated with worse performance on disease-specific process measures, perhaps in part because of more-frequent contact with the health system [18,19]. But also when it happen and disease-specific process measures are used in patients with co-morbidity, there is no consensus on what the best quality measures for the population with co-morbidity are [20]. We think that this study is particularly useful to induce a rethink on the use of guidelines, drawn by clinical trials, into clinical practice to guide management of chronic medical conditions, where co-morbidity often are present among the exclusion criteria of the same trials. Implementation of guidelines into clinical practice so is difficult, but often it is used to define quality standards and provide focus for quality improvement effort [18,21-24]. Commonly guidelines have been developed with a focus on specific chronic conditions and their application to the management of people with co-morbidity is an ineffective procedure [1,25,26]. Our data suggest that strict adherence to guidelines, in women with CAD and co-morbidity, may be associated poor outcomes. For example, following the recommendations of guideline for CAD may lead to taking more medications and could result in medication side effects such as dizziness or falls, all factors demonstrated to be associated with discomfort and low quality of life. In addition, taking more medications can lead to poorer adherence and influence patient safety and clinical outcomes [27]. Guideline use in the clinical setting requires a substantial effort by the clinician to prioritize and make choices about all possible recommendations for CAD and other conditions [1,28,29]. Clinicians are without explicit guidance or evidence as to how to approach care decisions for such patients. A first step toward developing such guidance is to understand the common patterns of coexisting conditions relevant to clinical decision-making for women with CAD. Neglect of the coexisting conditions that may add to complexity of clinical decision-making in the design, conduct, and reporting of clinical and health services trials raises serious concerns about external validity of most guidelines in clinical practice. The patients studied in clinical trials that form the basis of guidelines do not adequately reflect the true population in terms of burden of co-morbidity [30-33]. Post-menopausal women with CAD and major co-morbidities are not considered by clinical trials. By providing a framework for evaluating complexity along with empirical data for CAD, it may be possible to find a balance between trial safety and the need to include adequate representation of the targeted population. As a first step toward improving the ability to assess external validity, this study has provided an Italian representative estimates for CAD and factors that may add to the complexity of clinical decision-making. Studies of CAD report on the prevalence of a small number of conditions. To develop guidelines useful in clinical practice for women with CAD and co-morbidities, first it must be decided what the common and clinically relevant conditions to consider are. The current study has considered these on two levels: conditions and treatments that interact with CAD or its treatments and chronic diseases that may make the implementation of guidelines more challenging. It described how common these conditions are in people with CAD to have this inform the processes that CAD guideline developers will undertake during development of new or revised CAD guidelines. This article does not mandate a specific set of conditions that should be considered in the development of clinical practice guidelines. This choice will need to be part of priority setting at the outset of guideline development to be applied in clinical practice.

Limitations

Also if the finding of this study can be extended to all Italian

postmenopausal women, we know that the study doesn't assess fully all factors that would add to complexity of management of CAD, including depression and other diagnosed mental illnesses. The prevalence of low glomerular filtration rate is lower than expected, we can only suppose that it is due to low proteins dietary in our region. Sometimes mental distress or rarely true mental illness are present in women affected by CAD. Similarly, there are many conditions that would greatly add to complexity of management of a person with CAD that our study did not assess, including active cancer, aspirin sensitivity, and many others. Despite these limitations, our data on the burden of complexity experienced by adult women with CAD provided is useful and is more than has been previously recognized in clinical practice.

CONCLUSION

Complexity of clinical management for post-menopausal women with CAD is an ongoing rule. One every five women have one or more chronic diseases, more than half have hypertension, more than one third have diabetes and three quarters assumes more than 4 medications. Nevertheless the current paradigm of evidence-based medicine and healthcare quality focuses largely on osteoporosis and breast cancer prevention about menopause without consider others comorbidities [34-39]. Data are very limited, so there is a limited knowledge base to guide clinicians on how to deliver the best-quality care to these patients [40]. Guidelines focused on single diseases do not apply well to those with co-morbidity. Describing the complexity of women with CAD is a necessary first step toward developing evidence and strategies to guide the care of these patients. The findings presented here support the idea that the complexity of a persons' health status can be better understood using a framework that incorporates all diseases paying attention to co-morbidities. Understanding how to best care for women with CAD in terms of all of their health needs may lead to improvements in quality of life, use of health care, safety, morbidity, and mortality.

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