

Determination of Cardiovascular Status in Menopausal Women included in a Substitution Hormonal Therapy Feasibility Study

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SUMMARY

Background: In feasibility study concerning the effects of substitution hormonal therapy (SHT) on the cardiovascular status in the post-menopausal women (pmw) was analysed the rate of participation of Romanian women, the reasons for abandon to participation etc., in a multicentric international study.

Objectives: This study has intention to analyse the cardiovascular status of the pmw proposed for STH.

Material and Methods: Only 120 women, which accepted all conditions for participation to study, was included in this study. Mean age was 55+/-5 years (45-64 years), 84 women was in natural and 36 in surgical menopause. The study protocol included analysis of: 1) the coronary risk factors (arterial hypertension, diabetes, smoking, dislipemia, etc.), 2) inflammatory syndrome (fibrinogenemia, C reactive protein), 3) presence of osteoporosis (osteodensitometry DEXA), 4) cardiovascular status (clinical data, ECG).

Results: 1) Incidence of essential hypertension was 23%; type II diabetes 17%; smoking 15%; hypercholesterolemia was presented in 82%; hyperlipemia in 56%; hypertriglyceridemia in 35%; HDL was reduced in 56%. 2) Hyperfibrinogenemia was detected in 20% and CPR in 20%; 3) Only 12 pmw was analysed by DEXA: all have diverse grades of osteopenia. 4) ECG was altered in 30% (HVS, ST-T modifications). Only 20% from pmw with alterations of ECG have not presented coronary risk factors or inflammatory syndrome.

Discussion: It is a feasibility study in a domain very extended actually by many multicentric clinical trials. The problem of the effects of SHT on cardiovascular system is still in dispute, and our study appreciates the preliminary data at beginning of a trial. These data show a high percent of pmw with a concurrency of coronary risk factors and inflammatory indices which have already alterations of ECG. The effects of SHT in these women necessitate still a study on long time interval. For Romanian pmw, these data indicate the importance of the precocious investigations and detection of all coronary risk factors concerning the correct indications of SHT and its effects.

[Top](#)

BACKGROUND

Actually there are some clinical ample studies in course concerning substitution hormonal therapy (SHT) in postmenopausal women. The WISDOM study, for example, is in work in United Kingdom under coordination of Prof. TW Meade from Wolfson Institute - London and aims to the following of the effects of substitution hormonal therapy on the cardiovascular disease of the postmenopausal women, in a 10 years following period.

Our work is the first study from Romania on this topic. Initially, we collaborated with WISDOM study, but, subsequently, establishing the existence of significant differences in the content of the hormonal therapy, we agreed to continue independently and to maintain our collaboration by mutual information. In the first part of this work, communicated and published on Internet at "First Virtual Congress of Cardiology" in 1999-2000, we analysed the possibilities of recruitment of the women patients for the study, respecting the rules of good practice in clinical study.

OBJECTIVES

This work aims to analyse cardiovascular status in postmenopausal women on a little preliminary sample from Romanian population, which constituted the cases base of the feasibility study of the SHT.

MATERIAL AND METHODS

The cases study group contain 120 women in physiological or surgical menopause. This population sample represents the women which have accepted to participate at study and which have conformed to pre-established criteria of the protocol used with English partner. This analyse of cardiovascular status exclusively refers to the beginning of the study, to the first clinical investigation and to the first collect of the blood in conformity with the

protocol.

The specific features of the analysed group of postmenopausal women are reproduced in [Table 1](#).

Table 1. Clinical data of the all study group.

ANALYZED SPECIFIC FEATURES	NR.	%
Mean age. (years)	55.5	-
Natural menopause.	92	77
Surgical menopause.	28	23
Civil status:		
Married	83	69
Spinsters	12	10
Divorced	7	6
Separates	4	3
Widows	14	12
Age of first menstruation (years)	13.4	-
Nr. of births:		
No birth	30	25.0
1 birth	28	23.0
2 births	46	38.5
3 or over	16	13.5
Professional state:		
Professional actives	35	29
Pensioners and other	85	71

The method consisted from filling and application of an ample investigation protocol which contains: history, clinical examination, laboratory analyses, electrocardiography record, mammography and, in a little subgroup of the patients, bone mass density determination (DEXA). The entrance in the study was permitted only after writing accept of the patient, after a good information of the study and conforming to rules of the good clinical practice.

Used medication was supplied by Schering firm: Climen (estrogens and ciproteronate), Progynova (only estrogens), or *Placebo*. The study groups for active medication or for *Placebo* were selected by randomisation. The details on the methods were presented in the first part of this work.

RESULTS

The analyse of the results includes more objectives : a) Cardiovascular risk factors; b) Lipidemic profile; c) Inflammation syndrome presence.

- a) Cardiovascular risk factors: ([Table 2](#))
- b) Lipids profile: ([Table 3](#))
- c) Inflammatory syndrome: ([Table 4](#))

Table 2. The incidence of the risk cardiovascular factors in the women population studied: all women, women with natural and women with surgical menopause

FACTORI DE RISC	UTERUS+ (n=92)		UTERUS- (n=28)		All women (n=120)	
	Nr.	%	Nr.	%	Nr.	%
Age (years)	55+/-3		52+/-5		55.5+/-5	
Weight index	25.6+/-3.5		25.8+/-4.0		25.6+/-4.5	
Systolic AT (mm Hg)	132.0+/-24.9		133.8+/-25.0		132.7+/-24.7	
Diastolic AT (mm Hg)	85.0+/-14.5		82.6+/-12.0		83.3+/-13.2	
Smoke	21	13	6	23	18	15
Diabetes	2	0.02	1	0.3	20	17
Altered ECG	34	36	2	6	36	30

Table 3. Lipids alterations in all menopausal women, with and without uterus

BLOOD LIPIDS	Mean values +/- Std. Dev.		ALL
	UTERUS+	UTERUS-	
Lipidemia (mg)	845.0+/-167.3	941.3+/-151.2	867.9+/-166.6
Cholesterol total (mg)	274.2+/-66.3	318.1+/-69.6	284.5+/-66.30
HDL (%)	47.8+/-16.0	45.7+/-17.2	47.0+/-16.0

Table 4. The presence of the elements noting the inflammation syndrome in all women studied

INFLAMMATORY SYNDROME	Mean values +/- Std. Dev.	Increased values (%)
Fibrinogen (*)	461.5+/-132.8	21.8
Increased RCP (%)	-	20.0 %

(*) We not founded significant differences on the fibrinogen levels between the physiological and surgical menopausal groups.

DISCUSSION AND CONCLUSIONS

Our study presents an analysis of a postmenopausal women sample selected in a feasibility study begun with intention to extend the cases number and to follow evolution, tolerance of the drugs, and overall effects on the coronary disease, because these problems are disputing in cardiology literature. We appreciate the data at beginning of the trial.

All data show that in postmenopausal women are present the coronary risk factors: dislipidemia, arterial hypertension, smoke. We detected the presence of an inflammatory syndrome consisting from increased in fibrinogen serum level, and a significant increase of the incidence of the reactive C protein (RCP). This inflammatory syndrome presence seems to be connected at ECG alterations. (Table 5)

Table 5. Alteration of ECG and association of coronary risk factors or inflammatory syndrome.

ECG	Coronary risk factors and/or inflammatory syndrome	
	0 or 1	2 or more
Altered ECG	7 (20%)	29 (80%)
Normal ECG	80 (87%)	12 (13%)

All coronary risk factors have more increased levels in the women with surgical menopause, probably because of a more long time interval of menopause, comparing with the women with physiological menopause at the comparable ages.

We detected also the presence of a concurrency of coronary risk factors and inflammatory syndrome in the women with altered ECG, and our conclusions are in concordance with the Ridker's point of view which concludes, in his study on postmenopausal women: "...the addition of C-reactive Protein to screening based on lipid levels may provide an improved method of identifying women at risk for cardiovascular events."

REFERENCES

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2. Ridker PM, Hennekens CH, Buring JE, Rifai N: C-Reactive Protein and Other Markers of Inflammation in the Prediction of Cardiovascular Disease in Women. N Engl J Med 2000; 342/12: 836-843.

[Top](#)

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