





Abstract

Background: The metabolic syndrome (MetS) is associated with a high risk of cardiovascular or metabolic diseases. Multidisciplinary management with lifestyle changes (dietary, physical and psychological) is one strategy to treat MetS. The 3-week standard spa therapy approved for MetS in France is a moment when such intervention could be started as patients undertaking this are likely to be motivated to follow amultidisciplinary care program.

Objectives: To assess the maximum effect at one year of MetS multidisciplinary management initiated during spa therapy.

Methods: PriSMe was a prospective observational pilot study conducted in a spa therapy centre in France between July 2008 and December 2009 that included patients with MetS according to NCEP-ATP III criteria. Patients, identified by spa physicians, followed the spa therapy and associated multidisciplinary management. Patients whose general practitioner agreed to participate were followed 12 months without further intervention.

Results: Of the 145 included patients with MetS (3 NCEP-ATP III criteria), 75 patients were followed and 63 were analyzable. Their characteristics were: mean age 61 years, m/f sex ratio 0.31, mean BMI 32.5, and mean weight 90kg. At least four components defining MetS were present for 25% of patients. The waist circumference criterion was present in all patients, blood pressure (BP) in 78%, HDL-C in 41%, triglyceride (TG) in 59%, and fasting glucose (FG) in 32%. At end of follow-up, MetS was absent in 76% of patients: 18% no longer had the waist circumference criterion, 67% the BP, 30% the HDL-C, 35% the TG, and 16% the FG criterion. For each criterion, improvement was observed in absolute values for the majority of patients independently of persistent MetS. In a maximum bias analysis where all patients lost to follow-up were considered as having MetS, the syndrome was absent in at least 25% of patients.

Conclusions: This pilot study found that at least a quarter of patients undergoing multidisciplinary management of MetS no longer had the syndrome one year later.

Conflict of Interest Statement

This study was sponsored by an unconditional grant from AFRETh (Association Française pour la Recherche en Thermalisme).

Background

Metabolic syndrome has been defined as the association of several clinical and biological criteria (obesity, hypertension...) so as to better identify patients at high cardiovascular and metabolic risk. One of the strategies for the treatment of this syndrome consists of multidisciplinary intervention that includes nutritional, behavioural, psychological, and medial components. In France hydrotherapy in specific thermal institutions (spa therapy) may be prescribed and reimbursed. This may favourable for the initiation of such an intervention owing to the context and the motivation of patients who undertake such treatment.

Objectives

The objective of the PriSMe study is to determine the maximal effect of multidisciplinary management initiated during spa therapy on metabolic syndrome at one year.

Results of PriSMe, a French cohort study investigating multidisciplinary care on the one-year improvement of metabolic syndrome

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Methods

- > The PriSMe study is a prospective observational cohort pilot study.
- > The primary outcome was the persistence of metabolic syndrome according to the NCEP-ATP III criteria one year after spa therapy.
- > Physicians of the spa centre at Eugénie-les-Bains included, between July 2008 and December 2009, non-diabetic patients presenting with metabolic syndrome according to the NCEP-ATP III criteria.
- \succ The included patients participated in a multidisciplinary intervention that was associated with the spa therapy. Those whose general practitioner accepted to participate were then followed by both their general practitioner and the coordinating centre without additional intervention.
- Inclusion criteria: Patients should be adults able to complete the questionnaire and accepting to participate in the study. They should also:
 - Present metabolic syndrome according to the NCEP-ATP III criteria:
 - \checkmark Umbilical waist circumference >102 cm for men, 88 cm for women,
 - ✓ Triglycerides \geq 1.5 g/l,
 - \checkmark HDL-cholesterol <0.4 g/l for men, <0.5 g/l for women,
 - ✓ Fasting glycaemia \geq 1.1 g/l,
 - ✓ Blood pressure \geq 130/85 mmHg.
 - Have a BMI < 40,
 - Have fasting glycaemia < 1.26 g/l,
 - Initiate spa therapy for a metabolic indication.

Results

- > During the inclusion period, 145 patients presented at least three of the NCEP-ATP III criteria and were included in the PriSMe study.
- > Among these, 63 patients were followed and had sufficient data to be analysed at end of study (median follow-up: 10.4 months, Figure 1)



Figure 1. Patient flow

Results

- \succ Among the 63 patients followed and analysed, 76.2% were female, the mean (SD) age was 61.2 years (9.4), and over half were retired (60.3%). The mean (SD) weight for men was 98.6 Kg (15.3), and for women this was 86.6 Kg (11.9). All patients presented metabolic syndrome as defined by the NCEP-ATP III criteria; 74.6% presented three criteria, and 25.4% at least four. There were no medically-significant difference between the initial characteristics of the included patients and those followed and analysed.
- \succ The components of the metabolic syndrome are presented in Table 1, and the change in the parameters is presented in Table 2.

Table 1. Description of the metabolic syndrome criteria at inclusion and end of study

	Total population N = 145 $(108 \bigcirc -37 \checkmark)$	Analysed patients N = 63 (48 ♀ - 15 ♂)	
	At inclusion	At inclusion	At end of study
Umbilical waist circumference ^a			
Men, cm - mean (SD)	113.0 (9.0)	111.6 (10.7)	108.2 (14.3) ^b
Women, cm - mean (SD)	115.8 (9.6)	116.0 (10.2)	101.7 (10.3) ^b
Presence of the criterion, n (%)	145 (100.0)	63 (100.0)	45 (71.4) ^b
Triglycerides			
g/l, mean (SD)	1.68 (0.77)	1.68 (0.70)	1.38 (0.53) ^b
Presence of the criterion, n (%)	79 (54.5)	37 (58.7)	19 (30.2) ^b
HDL-cholesterol			
Men, g/l - mean (SD)	0.45 (0.12)	0.49 (0.14)	0.49 (0.12)
Women, g/l - mean (SD)	0.46 (0.11)	0.47 (0.12)	0.53 (0.10) ^b
Presence of the criterion, n (%)	94 (64.8)	37 (58.7)	20 (31.7) ^b
Fasting glycaemia			
g/I, mean (SD)	1.02 (0.13)	1.00 (0.13)	1.01 (0.21)
Presence of the criterion, n (%)	51 (35.2)	20 (31.7)	14 (22.2)
Blood pressure			
Presence of the criterion, n (%)	115 (79.3)	49 (77.8)	8 (12.7) ^b

a: missing data at end of study for 7 patients (1 man, 6 women); b: comparison between inclusion and end of study p<0.05

Table 2. Change in metabolic syndrome parameters between inclusion and end of study according to the thresholds of NCEP-ATP III criteria

	Absence of criterion at inclusion and at end of study N (%)	Disappearance of criterion N (%)	Persistence of criterion N (%)	Appearance of criterion N (%)
Umbilical waist circumference*		11 (17.5)	45 (71.4)	0
Triglycerides	22 (34.9)	22 (34.9)	15 (23.8)	4 (6.3)
HDL-cholesterol	24 (38.1)	19 (30.2)	18 (28.6)	2 (3.2)
Fasting glycaemia	39 (61.9)	10 (15.9)	10 (15.9)	4 (6.3)
Blood pressure	13 (20.6)	42 (66.7)	7 (11.1)	1 (1.6)





- > At the end of the study, the majority of patients reduced the number of NCEP-ATP II criteria they presented, and 76.2% of the 63 patients followed and analysed no longer presented metabolic syndrome (Figure 2).
- > Independently of the persistence or not of metabolic syndrome, an improvement in absolute values was observed for the majority of patients (Table 3).
- > A maximal bias sensitivity analysis was performed considering all non-followed patients as having had metabolic syndrome at end of study. According to this hypothesis at least 25.4% of patients no longer had metabolic syndrome (the lower-limit of the 95% confidence interval).



Figure 2. Presence or absence of metabolic syndrome at end of study in patients followed and analysed (n=63) and the total population (n=145). The maximal bias hypothesis considers all patients not followed as having metabolic syndrome at end of study.

Table 3. Change in metabolic syndrome parameters between inclusion and end of study independently of persistence or not of metabolic syndrome (Change in relation to 0 for waist circumference and triglycerides, 0.05 for HDL-cholesterol, and 0.1 for fasting glycaemia)

	Missing data N (%)	Better N (%)	No change N (%)	Worse N (%)
Umbilical waist circumference	7 (11.1)	51 (81.0)	1 (1.6)	4 (6.3)*
Triglycerides	_	44 (69.8)	2 (3.2)	17 (27.0)*
HDL-cholesterol	_	29 (46.0)*	29 (46.0)	5 (7.9)
Fasting glycaemia	_	6 (9.5)	50 (79.4)	7 (11.1)*
* missing data at end of study for 7 patients				

Conclusions

- > At least one quarter of patients having benefited from this multidisciplinary management no longer presented metabolic syndrome at the end of study. \succ The results of this study will allow the calculation of the number of subjects needed
- to identify the best methodology for an ulterior multicentre study investigating the same type of intervention.