

IMPACT OF A NUTRITIONAL INTERVENTION ON WAIST CIRCUMFERENCE REDUCTION

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ABSTRACT

Aim: This pilot study tested the hypothesis according to which it is possible to achieve a clinically relevant and sustainable reduction in waist circumference by means of an appropriate nutritional intervention.

Method: In this open, non-comparative study, patients consulting for weight excess followed a balanced diet, with a calorie restriction of one quarter the basal metabolism, along with a medical nutrition product under prescription (Stablor®).

Result: For the 64 participants, a mean reduction in waist circumference of 9.4% (-9.2 cm) was achieved over a 6-month period.

Conclusion: Nutritional intervention including a dietary supplement aimed at amplifying visceral fat metabolism and compensating for deficiencies allows, within 6 months, a mean waist circumference loss of nearly 10% to be achieved.

KEYWORDS: waist circumference, nutritional intervention, diet, visceral fat, cardio-metabolic risk, metabolic syndrome

INTRODUCTION

According to the World Health Organisation (WHO), 1.4 billion adults worldwide are overweight, including over 500 million who are obese¹. Excess weight exposes individuals to numerous co-morbidities, including type 2 diabetes and coronary disease; obese individuals, furthermore, possess an increased mortality rate^{2, 3}.

Fat mass distribution plays a key role in the onset of co-morbidities and visceral fat, which can be routinely determined by a simple waist circumference measurement, is an independent predictor of cardio-metabolic risk^{4, 5, 6}. When slimming, therefore, it is essential that weight loss be focused on a clinically relevant loss of visceral fat, i.e. on bringing the waist circumference below the recommended threshold, or reducing it by approximately 10%^{7, 8, 9, 10, 11, 12, 13}. This loss must be sustainable, with no associated vitamin or protein loss^{14, 15, 16}.

Research Aims

This pilot study was intended to test the hypothesis according to which it is possible to achieve, in less than 9 months, a clinically relevant and sustainable reduction in

waist circumference by means of a nutritional intervention specifically designed for this purpose. A concomitant improvement in risk factors was expected.

MATERIALS AND METHODS

Patient Selection Criteria

Patients consulting for excess weight were selected by their attending physician for their excessive waist circumference relative to International Diabetes Federation (IDF) standards (80 cm for women and 94 cm for men), along with the presence of at least two of the factors defined by the IDF worldwide consensus definition as presenting a cardio-metabolic risk: i.e. treated for or presenting high blood pressure, high blood glucose, dyslipidaemia (high triglycerides levels, high total cholesterol (TC), elevated low-density lipoprotein (LDL) cholesterol or low high-density lipoprotein (HDL) cholesterol.

Study Programme

The patients were monitored during outpatient nutrition consultations. During the initial visit, after signing the informed consent form, a clinical and biological assessment was performed and intensive nutritional care aimed at reducing waist circumference was implemented. Patients were seen in consultation at their discretion. At the end of this period, a new examination was performed, followed by a maintenance period of approximately 4 months, concluded by a clinical assessment (Table 1).

Nutritional Intervention Details

Upon completion of the initial consultation, the patients followed a diet adapted to their eating habits: balanced (50% carbohydrates, 35% lipids, 15% protein; carbohydrates with glycaemic charge less than 10), low-calorie (700 kcal restriction on base metabolism) and with a protein-based medical nutrition product under prescription (Stablor®) taken twice daily and contributing 360 kcal to the daily ration. This medical nutrition product intake was performed in the subject's actual situation. Physical activity of at least 5,000 steps (measured by pedometer) was prescribed. This intensive phase was to be

Stablor®: Nutritional composition: 15% carbohydrates, 15% lipids, 70% protein. Composition: whey protein concentrate, isolate and hydrolysate (emulsifier: soya lecithin); milk protein in calcium caseinate form; amino acids: L-glutamine, L-leucine, L-arginine, taurine, L-tryptophan; minerals: milk minerals and lactose, magnesium citrate, potassium phosphate, zinc gluconate, chromium chloride; fructooligosaccharides; maltodextrins; flavours; flax flour; wheat flour; thickeners: guar gum, carrageenans; acidity regulator: citric acid; salt; sweeteners: potassium acesulfame, sucralose; vitamins: D, B6, B9, E; colour: riboflavin; natural rosemary extract.

stopped as soon as a 10% decrease in waist circumference was achieved, or once it returned to within IDF standards. It was also to be stopped if the goal was not achieved within 9 months. Upon completion of the intensive phase, a stabilisation phase was initiated, comprising a balanced diet without calorie restriction, with one packet of Stablor® taken in the morning. Dietary advice was systematically dispensed at the start of the intervention period and during the study, as required. In the event of early termination (before the waist circumference reduction aim was obtained), the patients were questioned concerning their reasons for leaving the programme.

RESULTS

Description of The Population

In total, 92 patients were included in the study: 28 (30%) dropped out after inclusion, 64 (70%) completed the intensive nutritional intervention phase and 34 (37%) took part in the stabilisation phase. The characteristics of the included population are described in table 2. It should be noted that the drop-out patients differed from those who completed the intensive phase by their lower degree of motivation, greater waist circumference (95.8 cm versus 94.2 cm) and greater number of family cardiovascular events (78% versus 41%). The reasons given for withdrawing from the study were: lack of motivation, cost deemed too high and intestinal discomfort. Patients who took part in the intensive phase were aware of their cardiovascular risk as they had a family history (41%) and had previously tried diets (68%); this could explain the large number of non-smokers (95%) amongst them.

Effects on Waist Circumference

Amongst the 64 patients who completed the slimming phase, 37 (58%) returned to within IDF waist circumference standards (Figure 1). The mean reduction in waist circumference for the 64 patients was of -9.2 cm (9.4%), the vast majority (56/64) having lost at least 5%. During the maintenance phase, attended by 34 patients and which lasted 4.1 months on average, the waist circumference decreased very slightly (-1%).

Secondary Outcome Measures

Weight loss (table 3) was of the same order of magnitude as waist circumference reduction, i.e. 9.2 kg. The number of patients with a BMI < 25 rose from 13 upon inclusion to 41 at the end of the study. The loss of fat mass relative to lean mass was preponderant, increasing the ratio of lean mass to total weight from 65% to 71%.

Blood pressure was normalised in all 17 hypertensive subjects.

Biological Parameters

Lipid profile: 11 out of 19 patients had normalised their LDL levels upon completion of the slimming phase. Inflammation

markers: the 11 patients with non-standard CRP levels upon inclusion had returned to normal values.

Blood glucose profile and insulin resistance: The preprandial blood glucose levels of 12 of the 22 hyperglycaemic patients upon inclusion had normalised; the significant drop in insulinaemia (-30.1%) led to a 35% decrease in insulin resistance, characterised by the calculated HOMA-IR¹⁷.

Creatinine dropped and urea remained stable, suggesting that the nutritional protocol used in the study had no detectable impact on renal function.

Tolerance

No adverse events were spontaneously reported. During the follow-up visits, the patients were questioned concerning the occurrence of adverse events since their last visit. Tolerance to Stablor® was assessed by means of a questionnaire focusing on digestive tolerance. The most frequently reported adverse events were minor gastrointestinal disorders (flatulence, constipation and diarrhoea).

DISCUSSION

A balanced low-calorie diet, supplemented twice daily with Stablor® resulted in a reduction in waist circumference of nearly 10% after 6 months on average. This reduction in waist circumference was associated with a weight loss due mainly to a loss of fat mass. This protocol led to a favourable progression of the cardio-metabolic risk profile, with in particular normalisation of blood pressure in the study patients and a distinct improvement in biological parameters. Stablor® appears to have had a particularly notable effect on metabolic inflammation and on the resulting insulin resistance. All patients with high CRP levels upon inclusion had normalised upon completion of the intensive phase; the two other most notably improved markers were HOMA-IR (35% reduction) and insulinaemia.

More than half the patients wished to take part in the stabilisation phase. This phase demonstrated continued loss in waist circumference, resulting in particular in an additional 2.3% drop in total fat mass. The biological markers of cardio-metabolic risk were not reassessed at the end of this phase. The nutritional profile was well-tolerated and had no effect on renal function.

The analyses performed on obese subjects and women over the age of 50 in these groups, showed a progression comparable to that of the overall study population. The reduction of waist circumference, however, took longer to achieve, with respectively two and a half months and one additional month of intervention. These data confirm the greater difficulties experienced in shedding visceral fat mass in these populations. Some biological parameters progressed differently (slighter triglyceride drop in the two subgroups, blood glucose dropping more sharply in obese subjects and more slowly in women over the age of 50, HDL dropping in women over the age of 50). Considering the

small group sizes (15 and 27 individuals), additional studies would be of use for these specific populations.

CONCLUSION

This open study shows that calorie restriction by one quarter the basal metabolism, accompanied by a medical nutrition product amplifying the action on visceral fat loss and compensating for deficiencies, can lead to a nearly 10% reduction in waist circumference after 6 months on average. It provides a perspective of the possibility of private practice action to prevent cardio-metabolic diseases, as waist circumference measurement appears to be an efficient criterion for identifying and monitoring an at-risk population. Additional studies will be required to determine the specific role of Stablor® in the nutritional care for subjects with cardio-metabolic risk factors and to decipher the mechanisms regulating the adipocyte function that it appears to promote.

Abbreviations

BMI	Body mass index
BMR	Basal metabolic rate
CRP _{us}	Ultra-sensitive C-reactive Protein
HDL	High-Density Lipoprotein
HOMA-IR	Homeostasis model assessment for Insulin resistance
IDF	International Diabetes Federation
LDL	Low-Density Lipoprotein
SD	Standard deviation
TC	Total Cholesterol

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STATEMENT OF COMPETING INTERESTS

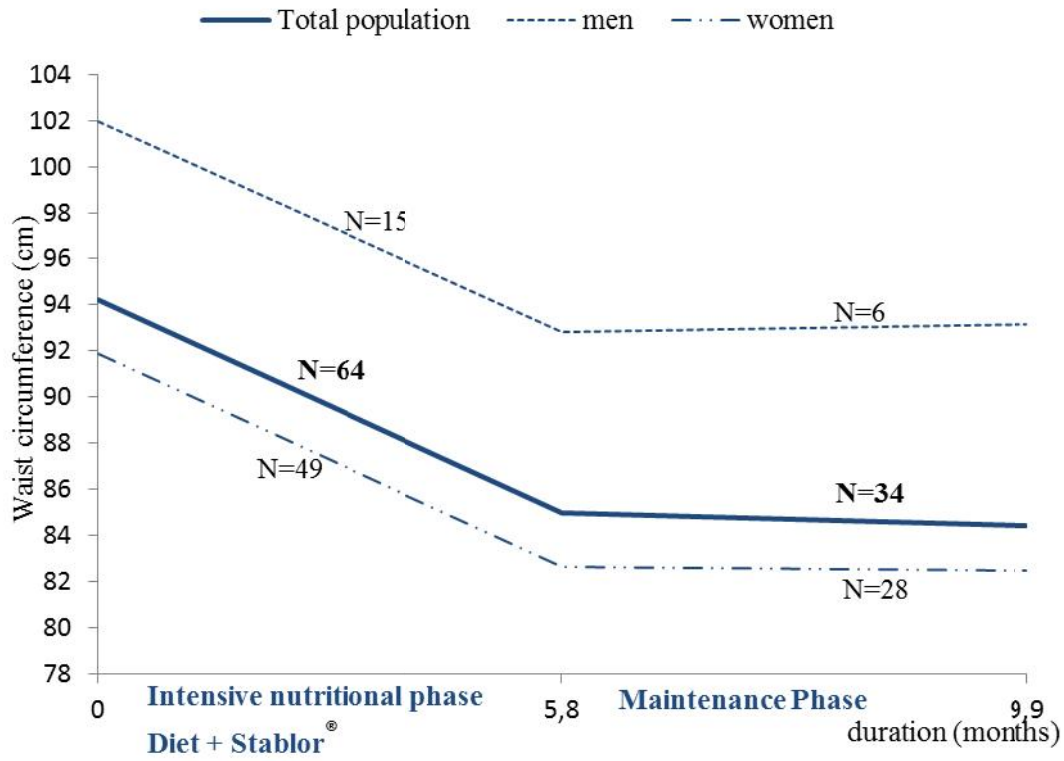
The author has no competing interests.

REFERENCES

- World Health Organization. Fact file on obesity and overweight. Reviewed March 2013
- Després JP, Lemieux I, Bergeron J, Pibarot P, Mathieu P, Larose E, Rodés-Cabau J, Bertrand OF, Poirier P. Abdominal obesity and the metabolic syndrome: contribution to global cardiometabolic risk. *ArteriosclerThrombVasc Biol.* 2008 Jun; 28(6): 1039-49. Epub 2008 Mar 20. Review. Erratum in: *ArteriosclerThrombVasc Biol.* 2008 Jul; 28(7): e151
- Guize L, Thomas F, Pannier B, Bean K, Jégo B, Benetos A. All-cause mortality associated with specific combinations of the metabolic syndrome according to recent definitions. *Diabetes Care.* 2007 Sep; 30(9): 2381-7. Epub 2007 Jun 11
- Pischon T, Boeing H, Hoffmann K, Bergmann M, et al. General and abdominal adiposity and risk of death in Europe. *N Engl J Med.* 2008 Nov 13; 359(20): 2105-20.
- Dallongeville J et al. Abdominal obesity is associated with ineffective control of cardiovascular risk factors in primary care in France. *Diabetes & Metabolism,* 2008; 34: 606-11.
- Cornier MA, Deprés JP, Davis N, et al. Assessing adiposity: a scientific statement from the American Heart Association. *Circulation.* 2011 Nov 1; 124(18): 1996-2019.
- Klein S, Allison DB, Heymsfield SB, Kelley DE, Leibel RL, Nonas C, Kahn R; Association for Weight Management and Obesity Prevention; NAASO; Obesity Society; American Society for Nutrition; American Diabetes Association. Waist circumference and cardiometabolic risk: a consensus statement from shaping America's health: Association for Weight Management and Obesity Prevention; NAASO, the Obesity Society; the American Society for Nutrition; and the American Diabetes Association. *Diabetes Care.* 2007 Jun; 30(6): 1647-52.
- Ishizaka N. Association between changes in waist circumference versus in body mass index and changes in cardiometabolic risk factors. *Ningen Dock* 2011; 25:1-5.
- Balkau B, Picard P, Vol S, Fezeu L, Eschwège E; DESIR Study Group. Consequences of change in waist circumference on cardiometabolic risk factors over 9 years: Data from an Epidemiological Study on the Insulin Resistance Syndrome (DESIR). *Diabetes Care.* 2007 Jul;30(7):1901-3
- Pataky Z, Bobbioni-Harsch E, Golay A. Cardio-metabolic profile is influenced by modest modifications of body weight. *Rev Med Suisse.* 2012 Mar 28; 8(334):670-2.
- Katsoulis K, Blaudeau TE, Roy JP, Hunter GR. Diet-induced changes in intra-abdominal adipose tissue and CVD risk in American women. *Obesity.* 2009 Dec; 17(12):2169-75.
- Lovegrove JA, Griffin BA. Can dietary modification reduce the cardiovascular complications of metabolic syndrome? 'All for one' or 'one for all'? *Expert Rev CardiovascTher.* 2011 Apr; 9(4):413-6.
- IDF (International Diabetes Federation). The IDF consensus. Worldwide definition of the metabolic syndrome. 2005
- Xanthakos SA. Nutritional deficiencies in obesity and after bariatric surgery. *PediatrClin North Am.* 2009;56:1105-1121. doi: 10.1016/j.pcl.2009.07.002.
- Treyzon L, Chen S, Hong K, Yan E, Carpenter CL, Thames G, Bowerman S, Wang HJ, Elashoff R, Li Z. A controlled trial of protein enrichment of meal replacements for weight reduction with retention of lean body mass. *Nutr J.* 2008 Aug 27;7:23.
- Pieterse Z; Jerling JC; Oosthuizen W; Kruger HS; Hanekom SM; Smuts CM; Schutte AE. Substitution of high monounsaturated fatty acid avocado for mixed dietary fats during an energy-restricted diet: effects on weight loss, serum lipids, fibrinogen, and vascular function. *Nutrition.* 2005 ; Jan. 21(1): 67-75
- Katsuki A; Sumida Y; Gabazza EC; Murashima S; Furuta M; Araki-Sasaki R; Hori Y; Yano Y; Adachi Y. Homeostasis model assessment is a reliable indicator of insulin resistance during follow-up of patients with type 2 diabetes. *Diabetes Care.* 2001, Feb; 24(2): 362-5

Figure

Figure 1. Changes to waist circumference during the study



Tables**Table 1. Study assessments**

	Initial visit	End of the intensive nutritional intervention phase	End of the maintenance period
Informed consent signed	X		
Motivations, weight loss history, smoking, current medication, family history of cardiovascular events, height	X		
Clinical examination, weight, waist circumference, BMI	X	X	X
Lean mass, fat mass (impedance measurement)	X	X	X
Diastolic and systolic blood pressure	X	X	X
Biological profile: - Inflammation and coagulation markers: CRP; fibrinogen - Lipid profile: triglycerides, total cholesterol, HDL cholesterol and calculated LDL cholesterol - Glycaemic profile and insulin-resistance: fasting blood glucose, insulinaemia, calculated HOMA-IR - Renal function: creatinine and urea	X	X	

Table 2. Baseline characteristics of patients included in the study and patients who completed the intensive nutritional phase

	Patients who completed the intensive nutritional phase (mean \pm SD, or number of patients) N=64		Patients included in the study (mean \pm SD, or number of patients) N=92	
	Men	Women	Men	Women
	15	49	18	74
Mean age (years)	53.7 \pm 11.1	53.0 \pm 11.	54.5 \pm 11.0	51.9 \pm 12.5
Waist circumference (cm)	101.9 \pm 7.3	91.9 \pm 10.2	103.5 \pm 7.7	92.6 \pm 10.8
Height (cm)	177.8 \pm 4.9	163.6 \pm 6.1	178.1 \pm 5.1	164.0 \pm 7.0
Weight (kg)	92.3 \pm 8.6	74.3 \pm 11.5	93.6 \pm 9.0	76.2 \pm 12.5
BMI (kg/m ²)	29.2 \pm 2.6	27.8 \pm 4.9	29.5 \pm 2.7	28.4 \pm 5.0
with BMI<25	0	13	0	18
with BMI>25	36	15	18	56
including obese subjects ((BMI> 30)	4	11	6	20
BMR, basal metabolism rate (kcal)	1745 \pm 272	1367 \pm 110	1781 \pm 264	1393 \pm 136
<i>Motivation</i>				
strong	2	30	2	35
moderate	12	15	15	33
low	1	2	1	3
<i>Reasons for consultation</i>				
Health	14	32	17	50
Appearance	2	43	2	64
Compelled by friends and family	0	2	0	2
<i>Co-morbidities</i>				
Diabetes	1	2	1	2
Sleep apnoea	0	1	0	1
<i>Concomitant treatment:</i>				
Central antihypertensive	2	4	2	4
Diuretic	1	0	1	0
Oral antidiabetic	1	2	1	2
Smokers	1	2	2	4
Family history	8	18	11	37
Previous diet	1	39	1	58

Table 3. Results for the 64 patients who completed the intensive nutritional phase

	Initial value (mean ± SD)	Final value	Change (mean ± SD)	% change
BMR (kcal)	1455 ±227	1439.5 ±201.5	-15.8 ±117	-0.6
Waist circumference (cm)	94.2 ±10.5	85.0 ±7.5	-9.2 ±6.8	-9.4
Weight (kg)	78.5 ±13.3	69.3 ±10.6	-9.2 ±5.3	-11.4
BMI (kg/m ²)	28.2 ±4.5	24.8 ±3.0	-3.3 ±2.1	-11.4
Fat mass (kg)	27.6 ±7.4	20.0 ±4.9	-7.5±6.2	-25.8
Lean mass (kg)	50.9±10.0	49.3 ±9.9	-1.6±3.2	-3.1
Systolic blood pressure (mmHg)	128±15.8	117.6 ±12.1	-10.5±14.1	-7.4
Diastolic BP (mmHg)	80.2±10.8	70.0 ±6.1	-10.3±9.7	-11.7
T. Cholesterol (mmol/l)	5.7±1.0	5.1 ±0.7	-0.6±0.6	-9.4
HDL (mmol/l)	1.5±0.5	1.5 ±0.4	0±0.1	0.7
LDL (mmol/l)	3.6±0.9	3.3±0.8	-0.3±0.5	-7.9
TC/HDL	4.2±2.4	3.6±1.8	-0.5±0.8	-9.4
Triglycerides (mmol/l)	1.2±1.0	1.0 ±0.3	-0.2±0.8	-7.5
Blood glucose (mmol/l)	5.8±2.8	5.1 ±0.4	-0.7±2.7	-4.8
Insulinaemia (µU/ml)	10.5±6.9	7.0 ±4.6	-3.5±3.1	-30.1
HOMA-IR	3.2±3.8	1.6 ±1.1	-1.6±3.2	-35
CRPus (mg/l)	2.3±3.1	1.4 ±1.6	-0.9±2.1	-17.8
Fibrinogen (g/l)	3.6±0.8	3.2 ±0.6	-0.5±0.5	-11.5
Creatinine (mg/l)	7.8±1.8	7.6 ±1.2	-0.2±1.2	
Urea (g/l)	0.4±0.1	0.4 ±0.4	0±0.4	