Efficiency of opuntia ficus indica on blood lipids parameters, considered as risk factors for Metabolic Syndrome (Syndrome X)

Monocentric, randomised study, placebo controlled, in parallel double blind format.

Abstract

The clinical study aimed at evaluating the efficiency of opuntia on blood lipid parameters. Sixty-eight females with Metabolic Syndrome (Syndrome X) and a BMI (Body Mass Index) between 25 and 40, participated to this monocentric randomised study, placebo-controlled, in parallel double-blind format.

During 6 weeks, half of the females consumed 1.6g of opuntia per meal and the other half consumed a placebo. The entire group followed a well-balanced diet with a controlled lipid input. The placebo and opuntia were given in the form of capsules.

The efficiency of the tested product was evaluated, on day 14 and on day 42 of the study. Several lipid parameters were measured: changes in LDL cholesterol, HDL cholesterol, serum triglycerides, and at the end of the study, the participants were re-evaluated for metabolic syndrome.

On and after day 14 of the study, opuntia shows a beneficial effect on HDL cholesterol, which is generally associated with a reduced cardiovascular risk. On a receptive population, near than 60% of women who consumed opuntia were diagnosed to be free of Metabolic Syndrome. No adverse effects were observed when taking opuntia.

Results from this clinical trial indicate that opuntia is efficient in applications related to cardiovascular risks prevention, when associated with overweight problems.

I. Context

After several successful in vitro studies made on a well-known gastro-intestinal model, a pre-clinical study was conducted to evaluate opuntia’s capacity to reduce fat absorption.

Beyond the efficacy of opuntia on fat absorption metabolism, we wished to conduct a larger study designed to assess opuntia’s ability to manage 5 risk factors typically associated with Metabolic Syndrome.

Metabolic Syndrome (Syndrome X), is now considered as the sum of non-pathological disorders which constitutes THE factor of cardiovascular risk, and not only blood lipid parameters.

The clinical definition of Metabolic Syndrome is based on five parameters, but the presence of only 3 of them is sufficient to diagnose it. The interest of the study is thus to test opuntia for its ability to regulate those 5 parameters and influence Metabolic Syndrome diagnosis.

These 5 criteria as defined by the International Diabetes Federation (2005) are presented here-after, abdominal obesity being a mandatory criteria of Metabolic Syndrome :

Diagnostic of Metabolic Syndrome	3 out of 5 criteria including abdominal obesity
Fasting glucose	≥1.00 g/l
Abdominal obesity (waist circumference)	≥ 80 cm for women ≥ 94 cm for men
Blood pressure	≥ 130/85 mm Hg
Blood triglycerides	≥ 1.5 g/l
HDL cholesterol	≤ 0.50 g/l for women ≤ 0.40 g/l for men

II. Subjects & Methods

This clinical study1 aiming at evaluating the efficacy of opuntia on blood lipid parameters has been conducted in France on 68 females with a BMI (Body Mass Index) between 25 and 40, and diagnosed with Metabolic Syndrome as defined by the International Diabetes Federation in 2005.

At the time of inclusion, average age of volunteers was 47.3 ±10.1 and they presented the following profiles :

- Average glycemia : 1.06 g/l ± 0.37
- Average LDL-cholesterol : 1.42 g/l ± 0.47
- Average HDL-cholesterol : 0.67 g/l ± 0;2
- Average total cholesterol : 2.29 g/l ± 0.50
- Average triglycerides : 1.11 g/l ± 0.71
- Average waist circumference : 101.41 cm ± 13.37

During six weeks, half of the females consumed 1.6 g de opuntia per meal and the other half consumed placebo. Both placebo and opuntia were given in the form of capsules.
All along the study, volunteers had to follow dietary advice in order to respect a balanced diet (average caloric input of 2000 kcal, lipid input limitation,..) and to have

minimum physical activity (30 min per day). During this study, several blood lipid parameters were controlled (D0, D+14 et D+42), in particular the evolution of LDL cholesterol, HDL cholesterol, triglycerides and metabolic syndrome diagnostic.

Summary table of collected data

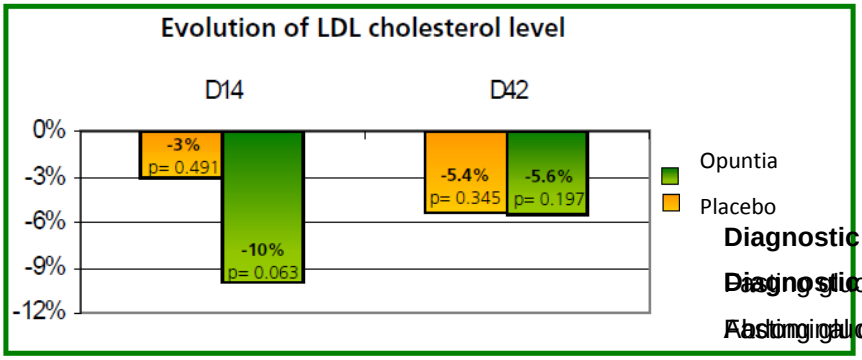
Collected data / measured parameters	D -28	D0	D +14	End of study D +42
Preparation of the patient	§			
Demographic data	§			
Patient codification		§		
Measurement of anthropometric parameters				
Dietary consultation		§		
Hygienical-dietary advice	§	§	§	§
Biological sampling : Evaluation of lipid disorders *(total cholesterol, triglycerides, HDL-cholesterol, glycemia)*	§	§	§	§

Parameters evolutions have been evaluated according to a variance analysis, to allow the comparison of averages and study if the differences observed per group are statistically significant. The intra-group evolutions have been evaluated by a « Student » test. The first level of risk α is set up at 5%, the test is thus significant when $p < 0.05$. We then speak about significant trend when p is comprised between 0.05 and 0.10.

III. Results

No adverse effects were observed when taking opuntia. The ingested dose of opuntia did not imply any particular discomfort during the test : no gastric disorder nor bloated feelings were reported.

On day 14 of the study, opuntia tripled the benefits of a well-balanced diet alone. Opuntia allows to decrease LDL cholesterol level by 10%, compared to only 3% (placebo group), for the females who were not under additional hypolipemiant treatment.



Diagnostic of Metabolic Syndrome

Diagnostic of Metabolic Syndrome

Fasting glucose

Abdominal obesity (waist circumference)

Blood pressure

Blood triglycerides

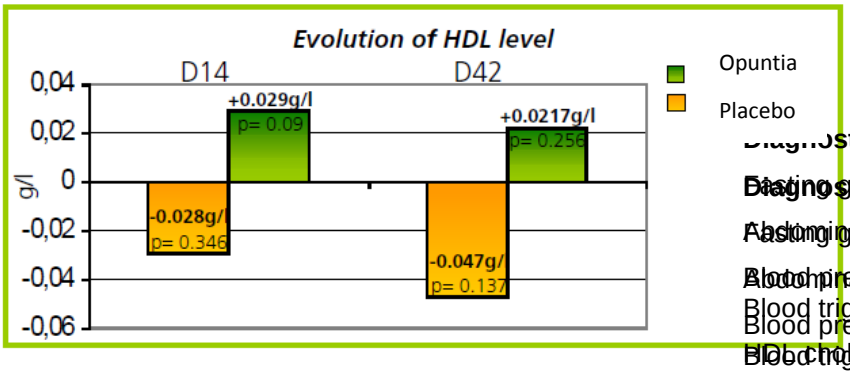
HDL cholesterol

	Evolution from D0 to D14		Statistical analysis of the evolution between D0 and D14
Opuntia group	- 0.1382 g/l	-10%	p = 0.063
Placebo group	- 0.0495 g/l	- 3%	p = 0.491

Although results at day 14 are encouraging, we still have to figure out why the LDL levels go back to normal on the longer term (D 42).

The slight decrease of the LDL cholesterol level observed on the placebo group shows that volunteers have well followed the dietary advice given. Nevertheless, the association of opuntia to a well-balanced diet brings additional effect and allows optimizing the beneficial effects of this particular diet on LDL cholesterol level.

Opuntia has a beneficial effect on « good » cholesterol level (HDL cholesterol), which is closely associated with a reduced cardiovascular risk. This result has been observed on all the volunteers, whether they followed additional hypolipemiant treatment or not.



Diagnostic of Metabolic Syndrome

Fasting glucose
Abdominal obesity (waist circumference)
Blood pressure
Blood triglycerides
HDL cholesterol

Diagnostic of Metabolic Syndrome

Fasting glucose
Abdominal obesity (waist circumference)
Blood pressure
Blood triglycerides
HDL cholesterol

The beneficial effect of opuntia on HDL cholesterol level is observed from day 14 and continues until a stabilization on day 42.

	Evolution of HDL from D0 to D14		Statistical analysis of the evolution between D0 et D14
Opuntia group	0.0294 g/l	+ 4.3%	p = 0.090
Placebo group	- 0.0288 g/l	- 4.4%	p = 0.346

	Evolution of HDL from D0 to D42		Statistical analysis of the evolution between J0 et J42
Opuntia group	0.0217 g/l	+ 3.2%	p = 0.256
Placebo group	- 0.0470 g/l	- 7.2%	p = 0.137

The analysis of the results clearly shows an upward significant trend for the HDL cholesterol (D14) for the opuntia group, and a downward trend for the HDL cholesterol for the placebo group.

This analysis is confirmed by the inter-group statistic analysis which highlights a significant difference between the 2 groups evolutions (p = 0.092 to D14, p = 0.058 to D42).

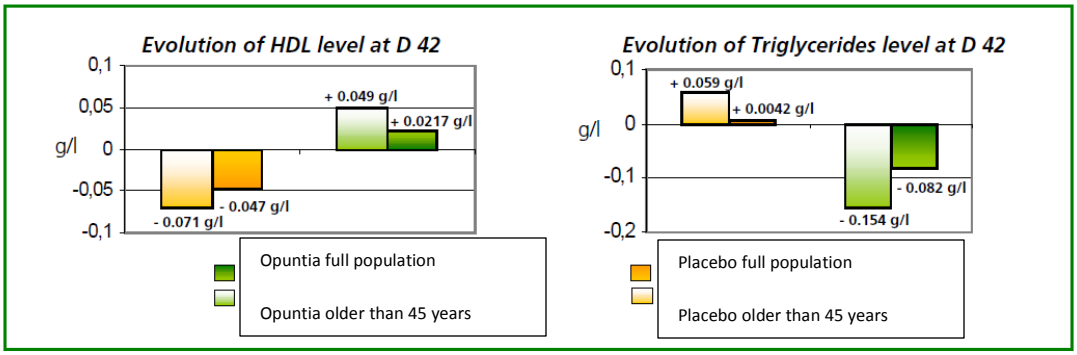
Focus on 45+ years old women

The use of opuntia increased the level of good HDL cholesterol and decreased the level of harmful triglycerides. The opuntia group of this specific subdivision (45 years and older) benefited from a favorable evolution of their HDL level (significant difference between the 2 groups evolution: p = 0.029). This effect has been reinforced by a positive evolution of triglycerides according to a p close to the significant trend.

In this specific group, exceptional positive effects of opuntia were observed:

- The level of good HDL cholesterol (+ 0.049 g/l) p= 0.029 Significant
- The level of harmful triglycerides. (- 0.154 g/l) p= 0.103 Significant trend

Age > 45	Evolution from D0 to D42	Statistical analysis of the difference between the the 2 groups evolutions
Placebo	+ 0.059	**p = 0.103**
Opuntia	**- 0.154**	

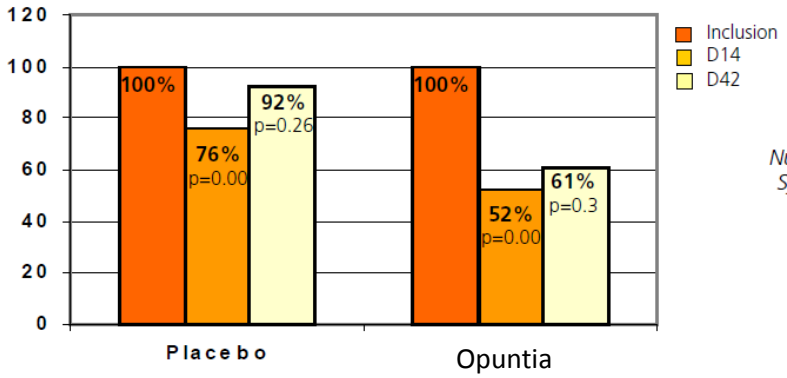


Evolution of HDL and triglycerides level : comparison of the full population and the specific group of 45+ years old women

Opuntia and Metabolic Syndrome.

On the 68 women of the study, although the evolution is not statistically different between the 2 groups, the number of volunteers with Metabolic Syndrome decreases in both groups during the first 14 days.

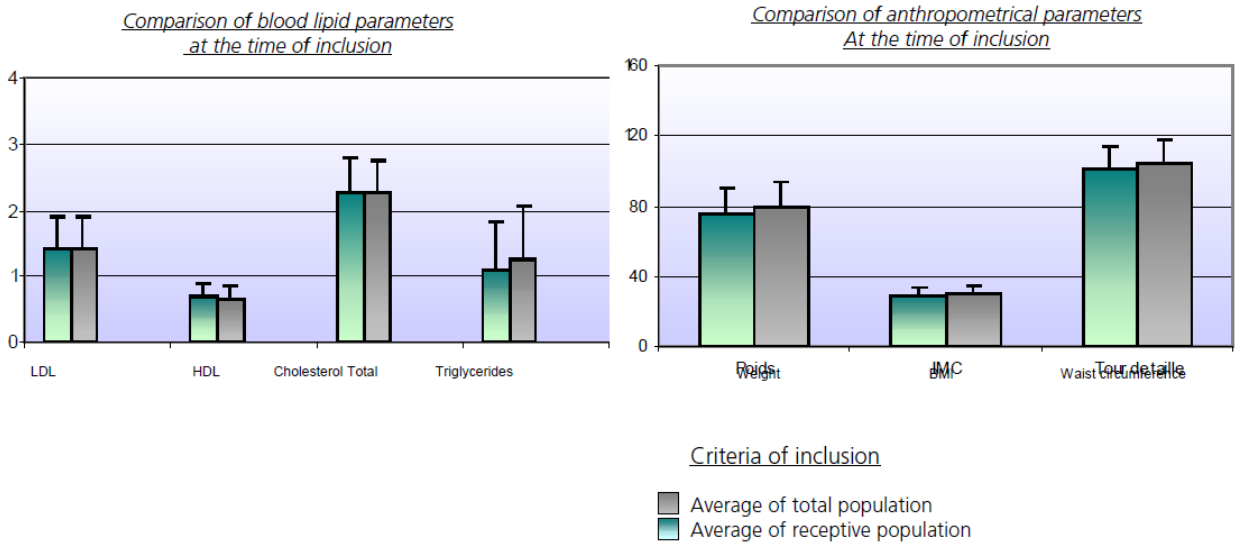
After 42 days of treatment, 39% of the volunteers from the opuntia group were diagnosed to be free from Metabolic Syndrome, in comparison with only 8% for the placebo group.



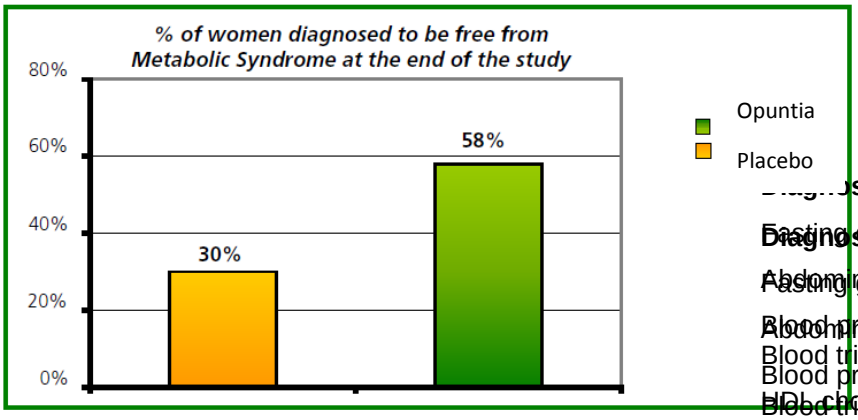
Numbers of volunteers with Metabolic Syndrome per group and per period, on the whole tested population.

With a more in-depth analysis, for a better understanding and interpretation, **remarkable results have been highlighted on a receptive population.** This population corresponds to the persons who obtained a beneficial effect during the treatment whatever the improved parameter. 40 volunteers distributed into the 2 groups: Opuntia (18) and Placebo (22)

The criteria of inclusion of this receptive population were compared to the total population in order to ensured that no drift were at the origin of the exceptional results presented here-after. No significant difference was highlighted, neither related to blood lipid parameters, nor to anthropometrical parameters.



Within this receptive population, near than 60% of women who consumed opuntia were diagnosed to be free from Metabolic Syndrome, as shown on the graph here-after.



Diagnostic of Metabolic Syndrome

Fasting glucose

Abdominal obesity (waist circumference)

Blood pressure

Blood triglycerides

HDL cholesterol

These results imply that the women who consumed opuntia among the responding population could improve 1 to 3 of the criteria linked to Metabolic Syndrome initially reported.

Evolution of volunteers for each criteria of Metabolic Syndrome

Criteria of Syndrome X	Placebo (33 persons)		Opuntia (35 persons)	
	Day 0	Day 42	Day 0	Day 42
HDL cholesterol < 0,5 g/l	13	16	8	7
Triglycerides > 1,5 g/l	9	9	6	4
Fasting Glucose > 1 g/l	17	22	15	15
Waist circumference > 80cm	33	33	35	33
Blood pressure > 130/85 mm Hg	18	4	18	8

IV. Analysis of the results

These results are complementary to the studies already conducted on the physiological effects associated to the consumption of opuntia ficus indica cactus powder, and seem even more interesting.

Opuntia & LDL

According to the results of the Coronary Primary Prevention Trial2, a decrease of 1% of the LDL cholesterol would be associated to a reduction of 2% of clinical events.
The beneficial effects of opuntia observed on the reduction of LDL cholesterol level could then imply a reduction of nearly 20% of clinical events risks.

Opuntia & HDL

HDL cholesterol ensures the evacuation of excess « bad » cholesterol accumulated in blood vessels, towards the liver. HDL cholesterol plays thus an essential role as it is responsible for freeing arteries from fat. Very often, hypocholesterolemiant formulations or diets allow to reduce both and indifferently LDL and HDL cholesterol. But if it is indeed better to reduce LDL cholesterol level, HDL cholesterol level, on the contrary, should increase, in order to efficiently reduce the risk of atheroma growth.

The Coronary Primary Prevention Trial has highlighted that an increase of 0.01 g/l of HDL cholesterol corresponded to a reduction of cardiovascular risk of 5.5%.
In the case of the clinical study, the increase in HDL cholesterol level after 42 days consuming opuntia was of 0.0217 g/l, which would correspond to a reduction of more than 11% of cardiovascular risks.

The consumption of 1.6 g of opuntia per meal allows re-balancing of blood lipids levels, reducing thus cardiovascular risks.

Opuntia & Metabolic Syndrome

Although we know that at least one of the five parameters inducing Metabolic Syndrome was improved, the study does not show which specific ones. The results obtained on both HDL cholesterol and triglycerides suggest that these 2 factors may play a key role.