Effect of a commercial hypocaloric diet in weight loss and post surgical morbidities in obese patients with chronic arthropathy, a randomized clinical trial

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Abstract. – INTRODUCTION: The aim of our study was to evaluate in patients with obesity and surgical indication of orthopaedic surgery for chronic osteoarthritis (hip or knee), the impact on weight loss, metabolic control and post surgical co morbidities of a hypocaloric commercial formula (Optisource®) versus conventional nutritional advice before orthopaedic surgery.

MATERIALS AND METHODS: 40 patients were randomized in both branches: diet I with lunch and dinner substituted by two Optisource® (1109.3 kcal/day, 166.4 g of carbohydrates (60%), 63 g of proteins (23%), 21.3 g of lipids 17%) and intervention II with nutritional counselling that decreases 500 cal/day of the previous dietary intake. Previous and after 3 months of the treatment, a nutritional and biochemical study was realized. Postsurgical co-morbities have been recorded.

RESULTS: 20 patients finished in each group. The improvement in weight (-7.56 ± 5.2 kg vs -5.18 ± 5.1 kg; p < 0.05), body mass index (-3.15 ± 2.2 vs -2.1 ± 1.9 kg/m²; p < 0.05), fat mass (-5.5 ± 5.9 kg vs -3.0 ± 2.6 kg; p < 0.05), insulin (-3.6 ± 3.8 mU/L vs -3.0 ± 2.6) and HOMA (-0.5 4 ± 1.2 vs -0.33 ± 1.14; p < 0.05) was higher in group I than in group II. All post surgical recorded parameters such as minutes of orthopaedic surgery, length of stay, vein thrombosis episodes, general infections complications, haemoglobin levels and days till independence of walking were similar in both groups.

CONCLUSIONS: Obese patients with chronic osteoarthritis subsidiary of surgery, lose more weight, fat mass and improve more resistance to insulin treated with a mixed diet with a commercial formula hypocaloric that patients treated only with dietary advice.

Key Words: Arthropathy, Anthropometry, Cardiovascular risk factors, Hypocaloric diet, Obesity.

Introduction

The obesity epidemic is the wide of the century, with a multifactor origin, producing high rates of morbidity and mortality and health costs in Western countries. For example in our country the prevalence of obesity stands at 13%, overweight and over 30%1.

In patients with chronic osteoarthritis, obesity is highly prevalent2. In these patients the surgical replacements of the hip or knee are usually frequent, as a solution to the pain and the inability of walking. Orthopaedic surgery is not risk-free, and there were more frequent blood losses and venous thrombosis in obese patients3-4. Some Authors3 have suggested delaying the surgery to reduce weight and thus the risk of surgical patients, so the protocols aimed at the preoperative weight loss in these patients would be an area of interest.

Physical activity and diet are the two therapeutic manoeuvres that are used to reduce the weight of these patients5. However, joint pain decreases the realization of exercise, being necessary to use hypocaloric diets, with a potential risk of micronutrient intakes deficit. In the literature, there are some studies that have replaced the hypocaloric diet by an oral nutritional supplement. For example, Larsen et al6 evaluated 130 patients with a weight loss program before a total hip arthroplasty. Their protocol reached a weight reduction for 73% of patients with an average loss of 8.6 kg. However, this study not assessed the impact on perioperative co-morbidities or other clinical and metabolic variables. Pekkarinen et al7 evaluated a total of 30 patients with a very low caloric diet (VLCD) for 7-24 weeks in obese patients awaiting for surgery. The average weight loss was 19.6 kg, co-morbidities associat-
ed with surgery or other cardiovascular risk factors were not assessed.

If we take into account the high prevalence of obesity, along with the increasingly used orthopaedic surgery for the treatment of chronic osteoarthritis, as well as the difficulty to perform the exercise of these patients, the use of protocols for weight loss in these patients, is more than justified.

The aim of our study was to evaluate in patients with obesity and surgical indication of orthopaedic surgery for chronic osteoarthritis (hip or knee), the impact on weight loss, metabolic control and post surgical co morbidities of a hypocaloric commercial formula (Optisource®) versus conventional nutritional advice before orthopaedic surgery.

**Materials and Methods**

A sample of 40 obese patients (BMI > 30) with an indication of orthopaedic surgery for chronic osteoarthritis was enrolled with a non-probability sampling process, starting recruitment in May 2007 and completed follow-up of patients in May 2009. These patients were studied in a Clinical Nutrition Unit, referred by the Department of Traumatology with the diagnosis of chronic osteoarthritis of the knee or hip; all signed an informed consent and the protocol was approved by the Ethics Committee of the Centre. Exclusion criteria were a previous history of ischemic cardiovascular disease or stroke in the previous 36 months, raising the cholesterol > 300 mg/dl, triglycerides > 400 mg/dl, blood pressure > 140/90 mmHg, and the taking of any of the following medications; sulfonylurea, thiazolidinediones, insulin, glucocorticoids, inhibitors of angiotensin converting enzyme, receptor antagonists, angiotensin II.

**Procedure**

All patients had a period of weight stabilization of 2 weeks prior to the completion of the baseline tests. Subsequently patients were randomized (table of numbers) to one of the following treatments: diet I replaced with 2 envelopes of Optisource® each day (lunch and dinner times) (1109.3 kcal/day, 166.4 g of carbohydrates (60%), 63 g protein (23%), 21.3 g of 17% fat) diet and II-based dietary advice to restrict intake by 500 cal/day to the regular intake reported by the patients. The membership of over Optisource® (50 g) is as follows; 210 calories, 15 g protein, 4.5 g fat (1.3 g saturated, 1.6 g monounsaturated, 1.6 g polyunsaturated) and 27, 4 g of carbohydrates). There was no blinding in the study and patients were on the diet 3 months before the surgery.

Weight, blood pressure, basal glucose, C-reactive protein (CRP), insulin, HOMA, total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides blood were measured at baseline and three months after the treatment (the day before the orthopaedic surgery).

**Assays**

Serum total cholesterol and triglyceride concentrations were determined by enzymatic colorimetric assay (Technicon Instruments, Ltd., New York, NY, USA), while HDL cholesterol was determined enzymatically in the supernatant after precipitation of other lipoproteins with dextran sulphate-magnesium. LDL cholesterol was calculated using Friedewald formula⁸.

Plasma glucose levels were determined by using an automated glucose oxidase method (Glucose analyser 2, Beckman Instruments, Fullerton, CA, USA). Insulin was measured by enzymatic colorimetry (Insulin, WAKO Pure-Chemical Industries, Osaka, Japan) and the homeostasis model assessment for insulin sensitivity (HOMA) was calculated using these values⁹.

**Anthropometric Measurements**

Body weight was measured to an accuracy of 0.1 kg and body mass index computed as body weight/(height²). Waist (narrowest diameter between xiphoid process and iliac crest) and hip (widest diameter over greater trochanters) circumferences were measures also to derive waist-to hip ratio (WHR). Tetrapolar body electrical bioimpedance was used to determine body composition¹⁰. An electric current of 0.8 mA and 50 kHz was produced by a calibrated signal generator (Biodynamics Model 310e, Seattle, WA, USA) and applied to the skin using adhesive electrodes placed on right-side limbs. Resistance and reactance were used to calculate total body water, fat and fat-free mass.

Blood pressure was measured twice after a 10 minutes rest with a random zero mercury sphygmomanometer and averaged.

**Dietary Intake and Habits**

The subjects’ nutritional intake was assessed prospectively by analysis of written food records. All subjects enrolled in the study were instructed to record their daily dietary intake for three days, including a weekend day. Handling of the dietary data
was by means of a personal computer equipped with personal software incorporating use of food scales and models to enhance portion size accuracy. Records were reviewed by a dietitian and analysed with a computer-based data evaluation system. National composition food tables were used as references. Regular aerobic physical activity (walking was allowed, no other exercises) was maintained during the period study (120-180 minutes at least 60% of maximal heart frequency).

Post-surgical Complications
Clinical data after orthopaedic surgery as minutes of orthopaedic surgery (minutes), length of stay (days), vein thrombosis episodes (number-percentage), general infections complications (number of pneumonia and tract urinary infections and percentage) and days till independence of walking (days) were recorded. Thromboprophylaxis was based on enoxaparine 4,000 IU s.c. 1 h prior to surgery, continuing postoperatively once daily until day 21. Infection prophylaxis was based on 1.5 g of cefuroxime, administered after induction of anaesthesia.

Statistical Analysis
Sample size was calculated to detect differences over 3 kg in weight loss with 90% power and 5% significance (n=20, in each diet group). The results were expressed as average ± standard deviation. The distribution of variables was analyzed with Kolmogorov-Smirnov test. Quantitative variables with normal distribution were analyzed with a two-tailed, paired Student's-t test. Non-parametric variables were analyzed with the W-Wilcoxon test. Qualitative variables were analyzed with the chi-square test, with Yates correction as necessary, and Fisher’s test. A p-value under 0.05 was considered statistically significant.

Results
A total of 42 were selected and 40 patients signed informed consent and completed the entire study (7 males and 33 females). The mean age was 65.0 ± 8.5 years with a body mass index (BMI) average 38.6 ± 4.7, the time of dietary management of the group total was 130.2 ± 80.8 days. In four patients a hip replacement were realized and in 36 patients a knee replacement.

All patients had a stable period of two weeks prior to the initiation of treatment (weight change, 0.23 ± 0.1 kg. In the group overall, anthropometric parameters showed the following average values, waist circumference 116.1 ± 16.1 cm, Waist-hip ratio 0.95 ± 0.07 and an average weight of 92.3 ± 11.8 kg. The bioelectrical impedance showed, a lean body mass 48.3 ± 9.6 kg and fat mass 44.9 ± 12.7 kg.

Subsequently patients were randomized (table of numbers) to one of the following treatments: diet I (n=20, Optisource® group, 2 hip replacement and 18 knee replacement) and intervention II (n=20, control group, 2 hip replacement and 18 knee replacement). In Table I, groups I and II shows an improvement in variables such as BMI, weight, body fat, waist circumference decreased significantly in both groups.

Table I shows the differences between intakes reached with both dietary treatments, a significant decrease in kilocalories, proteins, fat and cholesterol intakes was detected in both diets.

In Table III, groups I and II improved triglycerides, total cholesterol and LDL cholesterol. In the group I significantly decreased insulin levels and insulin resistance (HOMA).

In Table IV can be checked as to analyze the differences between the averages modifications (before vs after dietary treatment) between the two treatment groups in the variables after the dietary

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Basal</th>
<th>Optisource® 3 months</th>
<th>Basal</th>
<th>Control 3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²)</td>
<td>38.9 ± 4.6</td>
<td>35.8 ± 4.2*</td>
<td>38.1 ± 4.8</td>
<td>36.0 ± 4.5*</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>94.9 ± 9.4</td>
<td>87.3 ± 10.2*</td>
<td>91.2 ± 13.3</td>
<td>86.9 ± 11.2*</td>
</tr>
<tr>
<td>FFM (kg)</td>
<td>51.5 ± 11.8</td>
<td>50.8 ± 11.5</td>
<td>46.8 ± 3.9</td>
<td>45.6 ± 5.2</td>
</tr>
<tr>
<td>FM (kg)</td>
<td>47.0 ± 15.3</td>
<td>41.4 ± 16.4*</td>
<td>43.5 ± 10.8</td>
<td>39.5 ± 10.1*</td>
</tr>
<tr>
<td>WC (cm)</td>
<td>115.7 ± 8.1</td>
<td>110.2 ± 9.3*</td>
<td>114.4 ± 13</td>
<td>110.2 ± 13.1*</td>
</tr>
<tr>
<td>WHP</td>
<td>0.95 ± 0.07</td>
<td>0.98 ± 0.21</td>
<td>0.94 ± 0.10</td>
<td>0.93 ± 0.10</td>
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</tbody>
</table>

BMI: Body mass index. FFM: fat free mass. FM: fat mass. WC: waist circumference. WHP: Waist to hip ratio. *p < 0.05 in each group. No differences between basal or posttreatment data, between optisource and control groups.
Hypocaloric diet and chronic arthropathy

management, the decrease in weight (-7.56 ± 5.2 kg vs -5.18 ± 5.1 kg; *p < 0.05), body mass index (-3.15 ± 2.2 vs -2.1 ± 1.9 kg/m²; *p < 0.05), fat mass (-5.5 ± 5.9 kg vs -3.0 ± 2.6 kg; *p < 0.05), insulin (-3.6 ± 3.8 mU/L vs -3.0 ± 2.6 kg; *p < 0.05) and HOMA (-0.54 ± 1.2 vs -0.33 ± 1.14; *p < 0.05) were higher in group I than in group II.

Table V shows surgical and postsurgical parameters. All recorded parameters such as minutes of orthopaedic surgery (minutes), length of stay (days), vein thrombosis episodes (number-percentage), general infections complications (number of pneumonia and tract urinary infections and percentage), presurgical and postsurgical haemoglobin (g/dl) and days till independence of walking (days) were similar in both groups.

Discussion

In our work has been shown that both diets are able to produce an improvement in weight, body fat, cholesterol and triglycerides. The commercial formula hypocaloric diet resulted in an additional improvement of insulin and HOMA. However, the better improvement in weight, fat mass and insulin resistance in the commercial formula hypocaloric group did not influence in postsurgical parameters.

Previously in the literature have been described differences in the response, both in the anthropometric and metabolic variables, secondary to diets with different distribution of macronutrients. However, there have been conflicting data with regard to these anthropometric variables, being used very heterogeneous design, dominated by short-term studies and replacing all the oral intake for dietary supplements. This strategy requires a closer monitoring of the patient (hospital admission) and limits their use for extended periods of time and even an outpatient basis.

In our study, one difference is detected by improvement in insulin resistance, the explanation for this is in fact the largest decrease in fat

<table>
<thead>
<tr>
<th>Table II. Basal and post dietary intervention dietary parameters (average ± standard deviation).</th>
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<tbody>
<tr>
<td>Parameters</td>
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<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Energy (kcal/day)</td>
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<tr>
<td>CH (g/day)</td>
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<tr>
<td>Fiber (g/day)</td>
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<td>Proteins (g/day)</td>
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<td>Fat (g/day)</td>
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<td>SF (g/day)</td>
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<tr>
<td>PSF (g/day)</td>
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<tr>
<td>MSF (g/day)</td>
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<tr>
<td>Cholesterol (mg/day)</td>
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</table>

CH: carbohydrate. SF: saturated fat. PSF: poly-unsaturated fat. MSF: mono unsaturated fat. *p < 0.05 in each group.

<table>
<thead>
<tr>
<th>Table III. Basal and post dietary intervention biochemical parameters (average± standard deviation).</th>
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<tr>
<td>Parameters</td>
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<td>---------------------</td>
</tr>
<tr>
<td>Glucose (mg/dl)</td>
</tr>
<tr>
<td>Total chol. (mg/dl)</td>
</tr>
<tr>
<td>Chol-LDL (mg/dl)</td>
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<tr>
<td>Chol-HDL (mg/dl)</td>
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<tr>
<td>TG (mg/dl)</td>
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<tr>
<td>Insulin (mU/L)</td>
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<tr>
<td>HOMA</td>
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<tr>
<td>SBP (mmHg)</td>
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<tr>
<td>DBP (mmHg)</td>
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</table>

Chol: Cholesterol. TG: Triglycerides. SBP: systolic blood pressure. DBP: diastolic blood pressure. *p < 0.05 in each group.
mass and weight with supplemented diet. This result has already been described in protocols using weight loss supplements like our work\textsuperscript{15}. More controversial is the role of the change in the distribution of macronutrients in the diet on insulin resistance. We could relate the improvement in the insulin resistance to the change in the intakes of type of fat or protein. This protein intake relationship with the resistance to insulin has been described by other previous studies\textsuperscript{16-17}. However, protein intake changed in the control group, too.

Another outcome of our work is the improvement of the lipid profile with weight loss, confirming the results in the literature\textsuperscript{18}. One of the hypotheses that are being proposed to explain this improvement is the change in body composition after weight loss. Low-calorie diets cause a loss of visceral fat, an important way of improving the lipid profile and the different components of metabolic syndrome\textsuperscript{19}.

The use of dietary supplements for weight loss with hypocaloric and very low hypocaloric diets has been very widely in the literature\textsuperscript{20-26}, demonstrating their safety with the new formulations\textsuperscript{27} and being recommended in clinical guidelines used in our country\textsuperscript{28}. However, their signs should be evaluated with specific protocols for certain situations, such as pre-surgical patient. A work done recently in our country with a nutritional supplement replacing one of the main meals in a group of obese patients, reached some results very similar to ours\textsuperscript{29}, with a weight loss, cholesterol and triglycerides decreases similar of our group. There were no differences in weight loss or insulin resistance between the two treatments. However, the

\begin{table}
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\begin{tabular}{|l|l|l|l|}
\hline
\textbf{Parameters} & \textbf{Difference of averages} & \textbf{CI 95\%} & \textbf{\(p\)} \\
\hline
BMI & -1.04 & (-2.44 -0.35)* & 0.040 \\
Weight (kg) & -2.37 & (-5.89 -1.14)* & 0.045 \\
FFM (kg) & -3.27 & (-3.99 0.63) & 0.121 \\
FM (kg) & -2.5 & (-5.65 -0.63)* & 0.028 \\
WC (cm) & -4.7 & (-7.35 15.68) & 0.578 \\
WHR & -0.00006 & (-0.065 0.15) & 0.362 \\
Glucose (mg/dl) & -0.72 & (-0.34 1.89) & 0.734 \\
Total coL. (mg/dl) & -20.14 & (-52.78 12.51) & 0.638 \\
Chol-LDL (mg/dl) & -7.4 & (-44.29 29.38) & 0.549 \\
Chol-HDL (mg/dl) & -4.15 & (-10.66 2.35) & 0.539 \\
TG (mg/dl) & -8.4 & (-32.24 15.39) & 0.681 \\
Insulin (mUI/L) & -0.42 & (-4.47 3.62) & 0.681 \\
HOMA & -0.17 & (-1.01 -0.09)* & 0.029 \\
SBP (mmHg) & 0.96 & (-9.21 11.14) & 0.359 \\
DBP (mmHg) & 2.86 & (-2.99 8.71) & 0.456 \\
\hline
\end{tabular}
\caption{Differences between optisource group and control group of averages modifications after dietary treatments with confidence interval 95\%.}
\end{table}


\begin{table}
\centering
\begin{tabular}{|l|l|l|}
\hline
\textbf{Parameters} & \textbf{Optisource\textsuperscript{®}} & \textbf{Control} \\
\hline
Minutes of orthopaedic surgery (minutes) & 86.5 ± 21.8 & 91.8 ± 41.7 \\
Length of stay (days) & 8.1 ± 2.7 & 8.9 ± 6.7 \\
Vein thrombosis episodes (number – %) & 1 (5\%) & 1 (5\%) \\
General infections complications (number – %) & 0 (0\%) & 0 (0\%) \\
Days till independence of walking (days) & 6.1 ± 2.9 & 5.6 ± 4.5 \\
Mortality (number – %) & 0 (0\%) & 0 (0\%) \\
Presurgical Haemoglobin (g/dl) & 12.8 ± 4.1 & 12.6 ± 3.9 \\
Postsurgical Haemoglobin (g/dl) & 12.6 ± 4.3 & 12.2 ± 4.9 \\
\hline
\end{tabular}
\caption{Surgical and postsurgical parameters.}
\end{table}
latter was not measured. These differences with our work may be due to a shorter duration of dietary intervention (4 weeks), there is no control on the intake of patients and the use of a supplement different to that used in our design.

The use of protocols for weight loss in obese patients with chronic osteoarthritis and a subsidiary of orthopaedic surgery, should be evaluated as these patients gain weight after surgery\(^{30}\) and on the other hand surgery on an obese patient presents more morbidity partner. Recently, Christensen et al\(^{31}\) have demonstrated that a weight reduction of 10% improved function by 28% in patients with knee osteoarthritis with a randomized clinical trial using a low-energy diet. These results have been confirmed in other studies with knee osteoarthritis\(^{32}\) and hip osteoarthritis\(^{33}\). The type of weight loss is essential, for example decreasing body fat, as our data, is more important than body weight loss or decreasing other indices of obesity in producing relief of knee osteoarthritis\(^{34}\). Some orthopaedic surgical techniques are contraindicated in patients with obesity, due to the higher rate of complications and rehabilitation time\(^{35}\). These techniques, such as ankle arthroplasty, would lower morbidity that more invasive techniques, but are contraindicated in obese patients due to technical problems. It is, therefore, important to losing weight for these patients to be able to offer different surgical options.

Severely obese patients have greater surgical blood transfusion requirements, lengthier surgery times\(^{36}\), surgical complications, require more staff assistance with postoperative transfers from supine to sit\(^{37}\) and long of hospital stance\(^{38}\). Nevertheless, Optisource\(^{39}\) group with a higher weight loss and metabolic improvement than control group did not show an improvement in postsurgical co morbidities. Despite these positive results of our work, we are aware of the potential problems of our design as a high Type II error because of the small sample size as well as secondary issues to the lack of a blind design, with possible biases not detected and corrected. Secondly, the weight loss was a small amount; perhaps a more severe weight loss had shown improvements in post-surgical co morbidities. However, our study is the first randomized, controlled clinical trial to study the effect of different dietary interventions in weight loss and postsurgical co morbidities in patients with chronic osteoarthritis. From a clinical perspective, these results suggest that physicians can prescribe diet for their obese patients with osteoarthritis, with an important metabolic effect and an unclear effect on postsurgical co morbidities.

Conclusions

Obese patients with chronic osteoarthritis subsidiary of surgery lose more weight, fat mass and improve more resistance to insulin treated with a mixed diet with a commercial hypocaloric formula that patients treated only with dietary advice. The effect on postsurgical co morbidities was equal with both protocols. The evaluation of these protocols for pre-surgical weight loss, as well as the impact on morbidity and mortality of these patients is an area of clinical interest.

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