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Research Article

Interest of the Use of Bariamed 1 (LNC) and Caloric Restriction to Prepare Patients for Bariatric Surgery

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Abstract

Introduction: Hepatic steatosis is an excessive accumulation of fat in the liver. The hepatomegaly caused by steatosis could represent one of the main technical challenges in bariatric surgery. The aim of this prospective study was to analyze by MRI studies the efficiency on hepatic steatosis of the caloric restriction associated with Bariamed 1 treatment (medical nutrition product) in a population of morbid obese patients in the preoperative period.

Methods: Between June 2012-January 2013, 25 patients in the preoperative workup were included in this prospective monocentric study with low-calorie diet (750 kcal for women BMI 35 to 44 and 950 kcal for BMI ≥ 45, 950 kcal for men with a BMI between 35 and 44 and 1050 kcal for those with BMI greater than 45) associated with Bariamed 1. The inclusion criteria were represented by: age 18-70 years, body mass index > 35 kg/m²; suspicion of hepatic steatosis (modified liver functional tests). Each patient received dietary counseling information and inclusion of an abdominal MRI and a biological assessment repeated after 6 weeks of treatment.

Results: 20 women and 5 men with a mean age 41 (range=18-65) were included in our study. The mean BMI was 42.53 kg/m² (range =35-50) and waist circumference 131 cm (range=107-155). The average number of days of treatment was 32 days (range=2-42 days) the evolution of weight loss and waist circumference were 2.8 kg and respectively 4.42 cm. The quantification of hepatic steatosis by MRI study found a significant difference (p=0.000059) with a mean liver density from 26.076 (7.32-45.81) to 22.67 (6.65-41, 53). The analysis of the liver volume revealed a shrinkage by an average of 4.69% (p=0.0047)

Conclusion: The use of Bariamed 1 in addition to a caloric restriction can significantly reduce hepatic steatosis and liver volume. More comparative studies are expected to confirm these results.

Keywords: Hepatic steatosis; Bariatric surgery; Caloric restriction; Magnetic resonance imaging

Introduction

Liver steatosis represents an excessive accumulation of fat in the liver. It is found in aproximatively about 33% of morbidly obese patients with fatty infiltration in more than 50% of hepatocytes [1-3]. The natural history of this disease may be the development of a non-alcoholic Steatotic Hepatitis Syndrome (NASH) in 7.5 to 15% of cases which may then progress to more advanced stages of liver disease such as liver cirrhosis and hepatocellular carcinoma [4-6]. The severity of steatosis seems to play an important role in the development of fibrosis and progression of liver damage [7] Steatohepatitis is now regarded as an important cause of end-stage liver disease and may also be the cause of an unknown number of cases of cryptogenic cirrhosis discovered intraoperatively in 1.4% of morbidly obese patients submitted to bariatric surgery [8]. Unfortunately, once cirrhosis is established, the only treatment available for advanced disease is orthotopic liver transplantation [9]. Encouraging results with some improvement of cirrhosis has been reported in operated patients who have lost weight [10].

Therapy for NASH remains empirical and limited to treating conditions associated with it, such as diabetes mellitus, obesity, and hyperlipidemia, as well as avoidance of hepatotoxic pharmacological agents. Weight loss is considered a treatment for NASH and steatosis, and bariatric surgery is currently considered the only method that provides sustained and substantial weight loss for most severely obese patients.

The purpose of our study was to evaluate the correlation between the measurements of the liver size and consistency on MRI compared to the BMI and waist variation after low energy diet (BARIAMED Phase 1™).

Methods

This was a prospective nonrandomized monocentric study on the preoperative, low energy diet (BARIAMED Phase 1™) used for 6 weeks for 25 selected patients who underwent laparoscopic sleeve gastrectomy between June 2012 and January 2013 in Montpellier University Hospital. The features of NASH syndrome on Magnetic Resonance Imaging (MRI) represent one of the most reliable methods to characterize the different modifications of nonalcoholic fatty liver disease related to morbid obesity. The reversibility of fatty infiltration

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during diet therapy could be monitored by changes in appearance on repeated MRI. The MRI examinations were performed at baseline and after 6 weeks of a low-caloric diet associated to BARIAMED ® Phase 1 (Laboratoires Nutrition et Cardiométabolisme - Bordeaux, France). Nutritional composition includes: 15% carbohydrates, 15% lipids, 70% protein. Composition: whey protein concentrate, isolate and hydrolysate (emulsifier: soya lecithin); milkprotein in calcium caseinate form; aminoacids: L-glutamine, L-leucine, L-arginine, taurine, L-tryptophan; minerals: milkminerals and lactose, magnesium citrate, potassium phosphate, zinc gluconate, chromiumchloride; fructooligosaccharides; maltodextrins; flavours; flaxflour; wheatflour; thickeners: guargum, carrageenans; acidityregulator: citricacid; salt; sweeteners: potassium acesulfame, sucralose; vitamins: D, B6, B9, E; colour: riboflavin; natural rosemary extract.

A simple approach to the assessment of liver fat is the so-called In-Phase/Opposed-Phase (IN/OP) technique. IN/OP technique was performed using a breath-hold 2-dimensional spoiled double-echo gradient echo sequence. MR imaging were performed during the same examination by using a 3.0-T unit (Magnetom Skyra, Siemens Medical Solutions, and Erlangen, Germany) with a 70 cm Bore using peak gradient amplitude of 45 mT/m and a time to peak of 200 µ sec. All patients were in supine position, and to allow correct positioning, localizing sequences in the coronal, and transverse planes were performed during a breath hold. An axial IN/OP sequence was performed through the liver, it was T1-weighted two-dimensional double-echo spoiled gradient-echo sequence with the following parameters: Repetition Time (TR) msec/TE msec, 196/ 3.69 [OP], 4.92 [IP]); flip angle, 20°; section thickness, 6 mm; intersection gap, 1 mm; matrix, 256 × 192; number of sections, 20; and acquisition time, 17 seconds. The full volume of the liver was imaged by using three separate breath holds. MR imaging results were interpreted by a radiologist (B.G., with 15 years of experience with liver imaging) who was blinded to the type of treatment the patient had received. The reader did not know either if the examination had been carried out before or after the treatment. A Region of Interest of 1 cm 2 was drawn in a non vascular area of the right liver. The Signal Intensity (SI) in the ROI was recorded for IP and OP. The fat liver fraction was calculated using dedicated software (Myrian, Intrasense, Montpellier, France).

The inclusion criteria were represented by patients with indication for bariatric surgery (BMI > 35 with comorbidities or BMI > 40) with suspected hepatic steatosis (abnormal liver functional tests and positive fibrotest). The exclusion criteria included: lactose intolerance, inflammatory bowel disease (Crohn's disease or ulcerative colitis).

After the baseline MRI investigation, all subjects were treated with BARIAMED Phase 1™ during 6 weeks. The treatment was initiated by a specialist in internal medicine and supervised by a dietician. Two sachets of powder BARIAMED Phase 1™ were provided per day, with breakfast and snacking (at 5 pm) associated to a caloric restriction of:

- 750 kcal for women BMI 35 to 44 and 950 kcal for BMI ≥ 45;

- 950 kcal for men for those with a BMI between 35 and 44 and 1050 kcal for those at or above 45. The Phase 1 BARIAMED product contains 185 kcal.

The weight, BMI, waist, CRP and LFTs levels were assessed initially and after 6 weeks. The objective of this study was to assess the correlation between the measurements of the liver size and consistency on MRI compared to the BMI and waist variation. All patients then underwent uneventful laparoscopic sleeve gastrectomy by the same technique.

Statistical analysis was performed using the SSPS statistical package, version 11.5 (SSPS, Inc Chicago, IL). Fisher's exact test was used to investigate relationships between categorical variables. For all comparative analysis, a two – sided P value of < 0.05 was considered significant.

Results

20 women and 5 men with a mean age 41 (range=18-65) were included in our study. The mean BMI was 42.53 kg/m^2 (range=35-50) and waist circumference 131 cm (range=107-155). The average number of days of treatment was 32 days (2-42) the treatment compliance was an average of 60 sachets for a period of 6 weeks (4-84). The variations in weight loss and waist circumference were respectively -2.8 kg (-6.1 kg, 4), -4.42 cm (-19cm; 4.8). The quantification of hepatic steatosis on MRI analysis found a significant difference (p = 0.000059) with an average density liver from 26.076 (7.32 to 45.81) to 22.67 (6.65 to 41.53). A significant difference was found equally on the analysis of liver volume (p=0.0047), the MRI revealing a liver shrinkage with an average of 4.69% (-20% to + 9 %).

Table 1 shows the body weight in kg, BMI, liver volume, and % of liver steatosis measured at baseline and after 6 weeks of low caloric diet with BARIAMED Phase 1™.

There was no difference between men and women when comparing change in liver size (although there were few men). Although none of the patients, who did not lose weight preoperatively on the 6 weeks BARIAMED Phase 1™ diet, had a liver that prevented performing the laparoscopic sleeve gastrectomies, all of these livers had obvious visible infiltration and abnormal liver function tests.

Discussions

Laparoscopic bariatric surgery can become more difficult in the obese patient, and particularly in the morbidly obese male with enlarged liver. The fatty infiltration and cirrhotic changes often associated with morbid obesity add further operative problems, in that the enlarged heavy liver may cause increased difficulty for laparoscopic surgeons, not only in achieving a safe view, but also with the risk of severe bleeding from retraction trauma. The fibrofatty liver can bleed easily with the required traction, or even fracture. Technical difficulties due to an enlarged liver are one of the most common reasons for conversion to an open procedure [11]. Eriksson et al. showed that abnormal liver function tests in morbidly obese

Table 1: Body weight, BMI, liver volume, and % of liver steatosis measured at baseline and after 6 weeks of low caloric diet with BARIAMED Phase 1™.

	Baseline	After 6 weeks	P - value
Body weight (kg)	119.25 +/- 14.1	116.42 +/- 13.7	0.000011
BMI (kg/m^2)	42.52 +/- 4.28	41.51 +/- 4.2	0.000011
Liver volume	2464.56 +/- 421.22	2336.92 +/- 390.1	0.0047
% of Liver steatosis	26.07 +/- 10.64	22.67 +/- 9.54	0.000059

patients improve or even return to normal after significant weight loss, it seemed possible that preoperative weight loss might induce fat loss from the liver, and thus by reducing the liver size, improve the surgical view and reduce the risk of complications due to a bleeding traumatized liver [12].

In our experience after the 6 weeks of diet therapy, the mean liver volume was significantly reduced with 4.69 %, with an important reduction of liver density from 26.07 % to 22.67 %. Two sequential MRI examinations, performed before and after diet therapy, may be useful for evaluating obese patients with elevated serum transaminase activity. This will increase the surgeon confidence that the hepatomegaly associated with steatohepatitis will be improved. Since instituting this regime, no significantly enlarged or fibrotic livers have been encountered in such patients. Lewis et al. reported for six weeks of very low caloric diet a 15 % reduction in liver size as measured by Magnetic Resonance Imaging (MRI), while Colles et al. showed for a very low caloric diet for 12 weeks a 19 % reduction, as determined by Computed Tomography (CT) [13,14]. The reliability of the ultrasound in evaluating the size and consistency of the left lobe of the liver was analyzed by Jaser et al. [15]. They have included in the study 100 patients scheduled for bariatric surgery. All the patients underwent preoperative abdominal ultrasound to evaluate the size and consistency of the left lobe of the liver. Their results showed that the ultrasound has a sensitivity of 35 % in evaluating the size and 80 % for the consistency of the left lobe, which allow to concluding that abdominal ultrasound has limited prognostic value for surgical complications and complexity of surgery.

Preoperative weight loss programs of different kinds have been used to facilitate bariatric surgery. In the literature, decreases in operative time [16-18] and blood loss have been reported [19]. Shorter postoperative hospital stay after bariatric surgery [20] as well as less postoperative complications [21] has also been claimed in association with preoperative weight loss; Furthermore, preoperative weight loss has also been reported to increase postoperative weight loss in a meta-analysis by Livhits et al. [18]; however, others have found no such correlation [22-24].

Recently, Martins I. reported the interest in magnesium therapy that may prevent mitochondrial apoptosis that afflicts many of the global chronic diseases, including NASH syndrome [25]. Diets high in fat/carbohydrate are connected to magnesium deficiency and these diets promote the absorption of bacterial lipopolysaccharides that interfere with magnesium/Sirt1 regulation of hepatic membrane cholesterol homeostasis with relevance to toxic Aβ formation. Lifestyles that involve stress, exercise and unhealthy diets lead to abnormal magnesium therapy with inactivation of Sirt1 with early cell senescence. The same protective factor of the gene Sirt 1 with p53 dysregulation linked to the defective adipose tissue-liver crosstalk was reported in different papers [26,27]. Nutritional diets that promote Sirt 1 binding to chromatin and prevent its disassociation by various drugs and unhealthy diets will prevent adipose tissue transformation and activation of immune responses that involve macrophages, NK cells and lymphocytes that are linked to NASH and other organ diseases in various communities.

Conclusions

In our experience, using Bariamed 1 in association with a restriction caloric diet can significantly decrease the steatosis and the liver volume. This finding can diminish the postoperative complications and consequently the hospital stay. We are highly recommending this preoperative protocol, but more comparative prospective randomized trials are expected to confirm these results.

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