A very low calorie ketogenic diet improves weight loss and quality of life in patients with adjustable gastric banding.

Ann. Ital. Chir., 2017 88, 2: 143-148
pii: S0003469X17026550

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BACKGROUND: *Often, in severe obesity, diet and physical activity are not enough to achieve a healthy BMI. Bariatric surgical approach, in particular laparoscopic adjustable gastric banding (LAGB), has encouraging results in terms of weight loss and resolution of obesity-related comorbidities. However, several months after LAGB, some patients are enable to lose weight anymore and don't tolerate a further calibration because of its collateral effects (excessive sense of fullness, heartburn, regurgitation and vomiting).*
AIM: *The aim of this study is to identify the potential role of high protein-low carbohydrate ketogenic diet (KD) in managing weight loss in patients who underwent gastric banding and didn't lose weight anymore.*
METHODS: *50 patients underwent LAGB between January 2010 and December 2013. In twenty patients (GROUP A) we observed a stop in weight loss so we divided this patients into two groups. One group (group A1: 10 patients) continued to follow a LCD low calorie diet and underwent a further calibration; the other group (group A2: 10 patients) started to follow a KD for the next 8 weeks.*
RESULTS: *Both group resumed a significant weight loss, however group A1 patients reported collateral effects due to calibration and a higher Impact of Weight on Quality of Life – Lite (IWQOL-Lite) that correlates with a lower quality of life than patients following KD.*
CONCLUSIONS: *KD can improve the weight loss and quality of life in patients who underwent LAGB and failed at losing more weight allowing a weight loss comparable to that obtained with a further calibration and it is useful to avoid drastic calibrations and their collateral effects.*

KEY WORDS: Laparoscopic adjustable gastric binding, Quality of life, Very low calory ketogenic binding

Introduction

Obesity, defined as a clinical condition characterized by an increased Body Mass Index (BMI), is becoming a global epidemic in both children and adults. WHO estimates that in 2014, more than 1.9 billion were overweight and over 600 million of these subjects were obese [1]. The prevalence of overweight and obesity increased by 28% in adults and 47% in children between 1980 and 2013 [2]. Overweight and obesity are an important public health problem because of their high prevalence in the population and their link with serious health morbidities such as hypertension, Type 2 diabetes, hypercholesterolemia, cardiovascular disease, and some kind of cancers [3]. Although this pandemic condition has a negative impact on healthcare and society, causing higher direct and indirect costs for communities [4] what has be done is not enough. The combination of behavioural therapy with physical exercise and diet is the first and easiest approach for treating obesity but often fails to achieve and especially maintain weight loss [5]. Bariatric surgical approach – whose conditions to access are strict as stated by the

Pervenuto in Redazione Ottobre 2016. Accettato per la pubblicazione Dicembre 2016
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TABLE I - *SICOB requirements to access to bariatric surgery (sicob guidelines, 2008)*

- BMI > of 40 kg/m² without comorbidities;
- 35 < BMI < 40 kg/m² with by surgical intervention (metabolic, cardiopulmonary, serious psychological diseases);
- Failure of non surgical measures in maintaining weight loss for at least 6 months;
- Fit for general anesthesia
- OTHERS: commitment to follow-up; no pre-existing psychiatric illness affecting outcomes.

Italian Society of Obesity and metabolic disease [6] (Table I) - has been related to encouraging results in terms of weight loss and resolution of obesity-related comorbidities including hypertension, type II diabetes mellitus, dyslipidemia, arthritis, obstructive sleep apnea and major cardiovascular diseases (CVD) [7-9].

Among restrictive interventions, laparoscopic adjustable gastric banding (LAGB) is a widely used surgical technique, applicable even to groups at higher risk of complications and peri-operative morbidity and mortality [10]. According to literature, patients obtain moderate weight loss with little anatomical modification and have good quality of life [11]. To reach a significant weight loss and avoid complications it is necessary to create a multidisciplinary team in order to select the right candidates to surgery and set up a tight follow [12-13]. However, we noticed that sometimes several calibration promote a significant weight loss, but often patients may have complications due to calibrations itself (excessive sense of fullness, episodes of regurgitation, nausea and vomiting resulting from the reduced gastric capacity). The aim of the study is to identify the potential role of low calories, high protein-low carbohydrate ketogenic diets (KD) in managing weight loss in patients who underwent LAGB and have failed at losing more weight. KD has been chosen because it have been related to greater weight loss than conventional energy-restricted low-fat diets (LFD) for pathological conditions related to obesity, including cardiovascular diseases [14,15], Type 2 diabetes [16, 17], Polycystic Ovary Syndrome [18,19].

Patients and Methods

The study was performed on 50 patients (mean age 41.42 ± 7.5 years; 14 males and 36 females; mean initial BMI 44.6 ± 2.6 kg/m^2) consecutively admitted to the Department of Dietetic and Clinical Nutrition of Ospedali Riuniti of Ancona between January 2010 and Dicember 2013 to undergo LAGB for treatment of morbid obesity. Eligibility for surgery was defined according to the 1991 National Institutes of Health Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity [20]. Every patient had followed conservative diet-therapies for morbid obesity unsuccessfully for a period of 5 or more years. A written informed consent was subscribed by all subjects enrolled in the study. Patients have made a first assessment in our department of Dietetics and Clinical Nutrition in Day Hospital (DH) diagnostic regime in order to identify the right candidates. A interdisciplinary team, consisting of doctors (nutritionist, an internist, endocrinologist) and other professionals surgeon, as dietitian, nurse and psychologist, after a careful clinical evaluation decided adequate candidates for the LAGB. The team collaborates with cardiologist, gastroenterologist, pulmonologist, anesthetist regularly trained and updated. Patients underwent the DH study protocol reported in Table II.

The pars flaccida technique was used, using 2 sutures to fix the band to the wall of the stomach. LAP BAND AP® adjustable gastric banding system (Allergan Santa Barbara, CA 93111 USA now became Apollo Endosurgery INC) was used for the entire period of the study; large model has been choosen in order to have a greater range of calibrations. Initially, the band was not calibrated (0 ml). If the weight loss was less than 2

TABLE II - *DH study protocol*

- Clinical History;
- Physical Examination;
- Anthropometric Measures;
- Blood tests: carbohydrate metabolism (ogtt); lipid metabolism (total cholesterol, hdl cholesterol, ldl cholesterol, triglycerides); Protein Metabolism (protein electrophoresis); Haemochrome; Liver, Kidney, Thyroid Function; Hormons And Electrolytes;
- Basal Metabolism Evaluation (calorimetry indirect);
- Body composition (bioimpedentiometry);
- Ergospirometry With Aerobic And Anaerobic Evaluation;
- Electrocardiogram;
- Upper Abdominal Ultrasound;
- Interview with a Personal Trainer;
- Psychological Tests And Interview.

TABLE III - *VLC diet*

LCD (800 Kcal/die)	
Protein	25 %
Lipids	23 %
Carbohydrats	52 %

TABLE IV - *KD*

KD (800 Kcal/die)	
Protein	40 %
Lipids	40 %
Carbohydrats	20 %

kg/month or there was no weight loss for at least 40-50 days, a calibration with 3-3.5 cc of sterile saline was done. The maximum quantity introduced was 11 cc. If there were symptoms of excessive restriction or obstruction (excessive sense of fullness, heartburn, regurgitation and vomiting) fluid was removed. After calibration the patient remained in observation for 4 hours and had a meal. The follow-up was planned every two weeks during the first three months after intervention, then monthly until the end of the first year, bimonthly during the second year. The visit consisted of nutritional status valuation, weight control, check of dietary and physical activity program adherence, psychological counseling. All patients followed a low calorie diet (LCD). The results were evaluated by BMI (Kg/m^2) and EWL% ([(BMI preop – BMI current) / (BMI preop – 25)] x 100). In twenty patients (GROUP A) we observed a stop in weight loss so we divided this patients into two group. One group (Group A1: 10 patients) continued to follow a LCD (Table III) and underwent a further calibration with 3 cc of sterile saline; the other group (Group A2: 10 patients) started to follow a high protein-low carbohydrate ketogenic diet (KD) (Table IV) for the next 8 weeks. Each group was controlled every two weeks to evaluate weight loss, clinical and psychological status. In addition, they were asked to fill in the Impact of Weight on Quality of Life – Lite (IWQOL-Lite) before the a further calibration or the KD beginning and after 8 weeks. It is the shortened version of IWQOL, an obesity-QOL instrument consisting of 31 items and 5 domains about physical function, self-esteem, sexual life, public distress and work; lower scores indicate better QOL [21]

Statistical analysis was performed with Student's "T" test and expressed as mean ± SD. A p value < 0.05 was considered statistically significant.

Results

The follow-up rate was 100%. At the follow-up of the first month after surgery there was a significant weight loss, with BMI 41.89 ±2.72 and 14.1 ± 3,2 EWL % (p<0.001). A further weight loss has been recorded also at the follow-up of the 3rd month after surgery, with BMI 38,9 ± 2,79 and 29.61 ± 6.09 EWL % (p<0.001). Until the 6th-month follow-up, all patients reached a significant weight loss, with BMI 36,44 ± 2,57 (p<0.001) and 42 ± 7.07 EWL % (p<0.001). The average calibration of the bandage at the end of this period was 6 cc (min 4 max 8 cc).

At the follow-up of the 12th month after surgery we noticed a group (GROUP A) of patients that didn't lose weight anymore (5 males/15 females; mean 9th month BMI 36.37 ± 2.7; 42,85 EWL % ± 7,82) (Table V; Figs. 1-3). We divided this patients into two group, group A1 underwent a further average calibration (8cc)

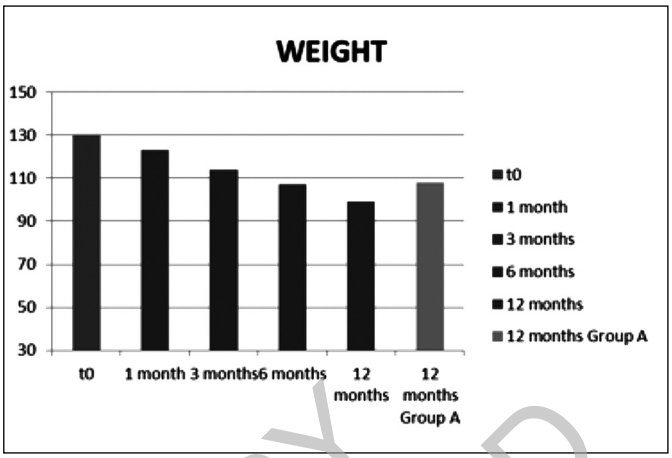

Fig. 1: weight change after LAGB.

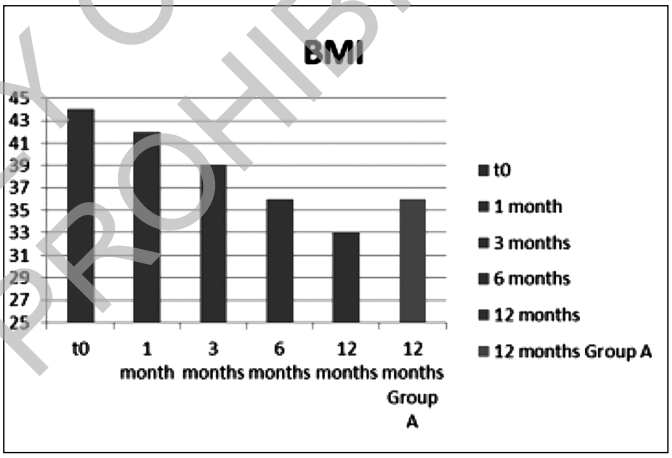

Fig. 2: BMI change after LAGB.

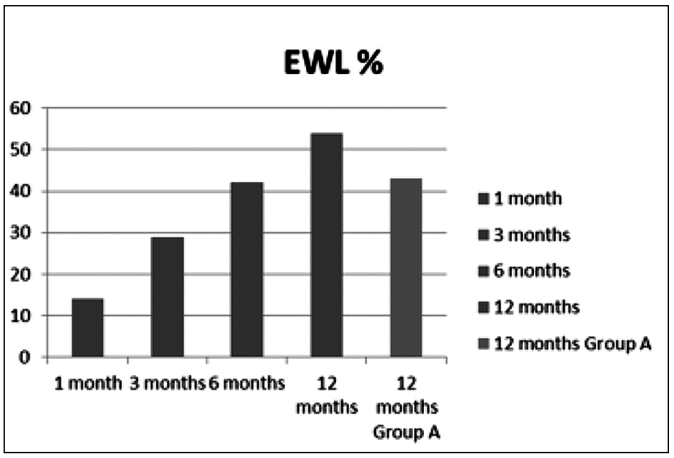

Fig. 3: EWL% change after LAGB.

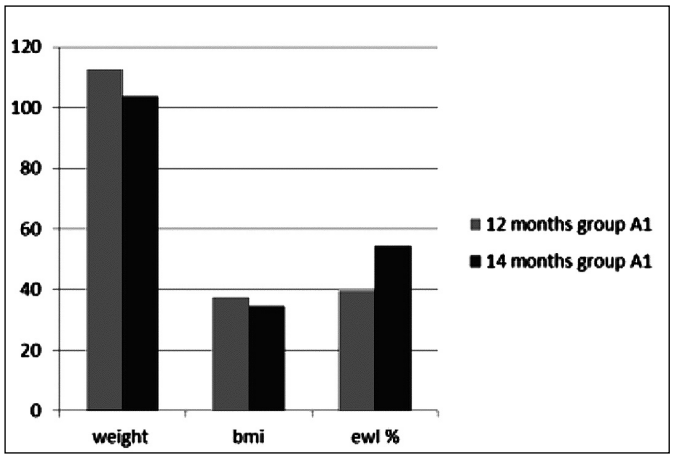

Fig. 4: Change in weight, BMI, EWL% after calibration.

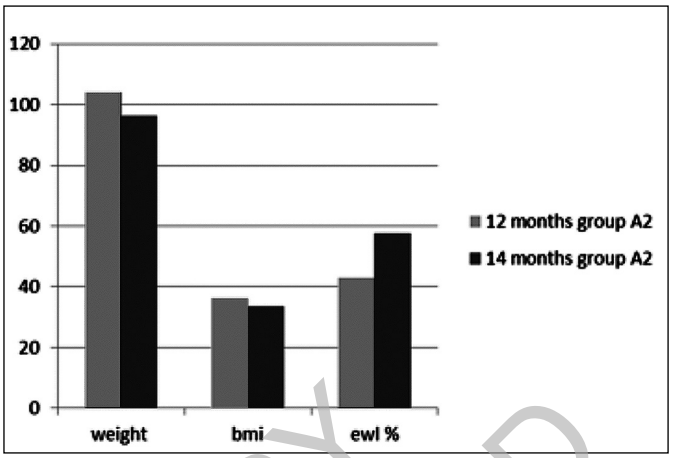

Fig. 5: Change in weight, BMI, EWL% after KD.

TABLE V - *Weight loss*

	Weight	BMI	EWL%
T0	130 ± 15,81	44,6 ± 2,65	
1 MONTH	123.04 ± 15,56	41,89 ± 2,72	14,10 ± 3,21
3 MONTHS	114,38 ± 15,.98	38,9 ± 2,8	29,62 ± 6,09
6 Months	107.22 ± 15.25	36,45 ± 2,57	42,09 ± 7,07
12 Months	99.4 ± 13.82 GROUP A	33,8 ± 2,35 GROUP A	54,89 ± 7,57 GROUP A
	108.65±15.76	36,95±2,84	41,22±7,64

TABLE VI - *GROUP-A follow-up*

	Weight		BMI		EWL %	
	A1	A2	A1	A2	A1	A2
12 Months	112,7 ± 18,98	104,6 ±11,27	37,52 ± 3	36,37 ± 2,7	39,6 ± 7,5	42,84 ± 7,8
14 Months	103,1 ± 19,09	96,3 ± 10,25	34,49 ± 2,98	33,49 ± 2,49	54,52 ± 9,32	57,51 ± 8,03

TABLE VII - *Complications due to calibration in group A1*

	N. Patients	% Patient
excessive sense of fullness	3	30
heartburn	2	20
regurgitation	2	20
vomiting	1	10
TOT	8	80

TABLE VIII - *IWQOL-LITE*

	A1	A2
Pre-intervention	61,4±25,3	56,7±28,9
Post-intervention	51,9±18,1	38,9±19

and group A2 followed KD for 8 weeks (Table VI). Both group resumed a significant weight loss (Table VI; Figs. 4, 5). However group A1 patients reported collateral effects due to calibration: excessive sense of fullness, heartburn, regurgitation and vomiting occurred in 80% of them (Table VII), requiring more medical medications (proton pump inhibitors, antiemetics, aluminum hydroxide) and visits. They also reported a higher IWQOL-Lite score that correlates with a lower QoL than patients following KD (Table VIII).

Discussion

The LAGB is the only intervention that allows a weight loss and a caloric intake that can be modulated and adapted to individual patient need [22]. To achieve a good

weight loss, careful selection of candidates and close follow-up over time are needed. For this reason, we have established a multidisciplinary team made up of clinical nutritionists, dieticians and psychologists who follow the patient throughout the process. In this way, you can change the life style of patients, increasing physical activity, improving the quality of ingesta and obtaining a significant weight loss. However, as it emerged from the literature and from our experience, about 9-12 months after surgery several patients considerably slow down the weight loss particularly those who didn't follow the programmed follow-up in a good way. The stop in the weight loss may be due to several reasons. We noticed that, over time, patients become bored by the diet and the collateral effects of calibrations. So, they no longer follow the received nutritional advice about the duration of the meal (at least 20-30 minutes) and slow chewing, often because these practices are incompatible with the rhythms of life. So patients start to prefer high-calorie liquid foods that don't cause troubles even with tightened calibrations so they stop to lose weight. So far the resumption of weight loss was achieved by calibrating the bandage again, however, this additional calibration may cause collateral effects to the patients (excessive sense of fullness, episodes of regurgitation, nausea and vomiting). These complications may further worsen the patient's life quality. To prevent this, we have undertaken an experimental clinical study in which we compared the weight loss, complications and quality of life in two groups of patients who had a stop in weight loss. Group A1 underwent a further calibration and Group A2 followed a ketogenic diet for 8 weeks. KD has been chosen since many studies have demonstrated that it is safe and well-tollerated, it leads not only to a rapid weight loss that will be maintained over time [23], but also improves glycemic control, haemoglobin A1c, insulin resistance [24], lipid markers and cardiovascular risk parameters [25]. Moreover, evidence supports that a high proportion of calories from protein increases weight loss because proteins induce satiety increasing secretion of gastrointestinal satiating hormones and diet-induced thermogenesis [26]. Further, there is evidence that meals rich in proteins reduce gastric emptying time because of a greater stimulatory effect on gastrointestinal hormones such as cholecystokinin and glucagon-like peptide-1, probably through increased secretion of cholecystokinin and glucagon-like peptide 1 [27]. Some studies have also showed that KD may have positive effects on mood in overweight subjects [28]. Moreover, even if during the first 4-5 days of a ketogenic diet patients may sometimes complain of lethargy, this effect passes rapidly and subjects subsequently report an improved mood [29]. After 8 weeks of KD we obtained a significant weight loss, more than the one obtained with a further calibration, without complications due to the calibration itself. Moreover, subjects who followed KD reported a lower IWQOL-Lite score that correlates with a better mood and QoL than patients that have undergone a further calibration.

In conclusion, KD can improve the weight loss and quality of life in patients with LAGB. This approach has a positive effect to reduce weight in resistant patients, particularly in those who didn't follow the tight programmed follow-up and were unable to change their style of life. In fact, this method, allowing a weight loss comparable to that obtained with a further calibration, is useful to avoid drastic calibrations necessary in resistant cases and their collateral effects, improving patient's quality of life. In the study, we exploited the effect of protein meals on gastric emptying in patients with a significantly reduced gastric reservoir because of LAGB. In this way, we obtained the most satiating effect of meals and a reduced caloric intake, so we gained a significant weight loss maintaining a good QoL for patients. However, the amount of the subjects analyzed is low so further studies will be necessary to confirm our argumentations.

Riassunto

Background: Spesso, nella grave obesità, la dieta e l'attività fisica non sono sufficienti per raggiungere un BMI adeguato. La chirurgia bariatrica, in particolare il bendaggio gastrico regolabile (LAGB), ha risultati incoraggianti in termini di perdita di peso e miglioramento delle comorbidità correlate all'obesità. Tuttavia, diversi mesi dopo LAGB, alcuni pazienti non riescono più a perdere peso e non tollerano un ulteriore calibrazione a causa dei suoi effetti collaterali (eccessivo senso di pienezza, pirosi gastrica, rigurgito e vomito).

Obiettivo: L'obiettivo di questo studio è quello di identificare il ruolo potenziale di una dieta chetogenica (KD) nella gestione del calo ponderale nei pazienti sottoposti a bendaggio gastrico che non riescono più a perdere peso.

Metodi: 50 pazienti sono stati sottoposti LAGB tra gennaio 2010 e dicembre 2013. In venti pazienti (gruppo A) abbiamo osservato un arresto del calo ponderale; abbiamo diviso questi pazienti in due gruppi: un gruppo (Gruppo A1: 10 pazienti) ha continuato a seguire una dieta LCD ed ha subito un ulteriore calibrazione; l'altro gruppo (gruppo A2: 10 pazienti) ha iniziato a seguire una dieta KD per le successive 8 settimane.

Risultati: Entrambi i gruppi hanno ripreso un significativo calo ponderale, tuttavia i pazienti del gruppo hanno riportato effetti collaterali dovuti alla calibrazione A1 e una variazione di (IWQOL-Lite) che correla con una qualità di vita inferiore rispetto ai pazienti sottoposti a KD.

Conclusioni: KD può migliorare la perdita di peso mantenendo una buona qualità della vita. Nei pazienti sottoposti a bendaggio gastrico in cui si oserva un arresto del calo ponderale, permettendo una perdita di peso para-

gonabile a quella ottenuta con un ulteriore calibrazione in caso di arresto del calo ponderale evitando drastiche calibrazioni e i conseguenti effetti collaterali.

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