OPTIFAST® VLCD™

Pre-operative Weight Loss Protocol

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OPTIFAST® VLCD™ Pre-Operative Protocol

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Introduction

Obesity is a strong risk factor for a variety of disorders, including type II diabetes, insulin resistance, cardiovascular disease and non-alcoholic fatty liver disease. In addition, obesity has been associated with obstructive sleep apnoea and a reduced quality of life. Obesity has also been linked with an increased risk of some surgical and post-surgical complications in patients requiring surgery.[1]

Weight loss in severely obese patients is therefore important to improve health, gain better control of co-morbid disorders, improve quality of life and reduce peri-operative risks in patients requiring surgery.

Bariatric surgery is considered the most effective long-term treatment for severe obesity (where BMI>40), and results in greater overall weight loss than any other form of treatment.[1] Surgical intervention can result in substantial weight loss that is sustained over the long-term when combined with education, ongoing monitoring and patient support. However, features of severe obesity can increase the complexity of the bariatric surgical procedure and may increase the peri-operative risks of surgery.

Pre-operative weight loss is therefore desirable to optimise the safety of surgery in obese patients scheduled for bariatric surgery, in particular by reducing the likelihood of conversion from laparoscopic to an open procedure. Pre-operative weight loss can also improve respiratory mechanics and biochemical factors associated with obesity, reduce the severity of co-morbidities and minimise operating and recovery times. Importantly, weight loss prior to surgery sensitises patients to the potential benefits of complying with post-operative dietary restrictions.

Pre-operative weight loss prior to obesity surgery can be achieved rapidly and safely using a very low energy diet such as the OPTIFAST® VLCD™ program. The OPTIFAST® VLCD™ program can totally replace normal food intake while maintaining sufficient quantities of protein, carbohydrates and essential fatty acids, and includes the recommended daily allowances for vitamins, minerals and trace elements.

A short-term intensive treatment program with the OPTIFAST® VLCD™ program has been shown to produce effective weight loss and improve health outcomes, and is associated with good adherence to treatment.[2] Pre-operative weight loss does not appear to adversely affect immune function or wound healing.[2,3]

This protocol has been developed in consultation with a working party of obesity experts. We would like to thank the following experts for their contribution, feedback and review:

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This protocol is a work in progress and will evolve over time. We would appreciate any feedback or comments you may have on how to improve the protocol and make it more relevant for you and your practice. Resources are currently focused on improving patient outcomes, reducing community costs and encouraging a multidisciplinary approach to chronic weight management.

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Benefits of bariatric surgery for obesity

Surgery is considered the most effective long-term treatment for severe obesity, with good weight management demonstrated 3-8 years after surgery with most procedures.[1] A recent Cochrane review concluded that surgery is more effective than conventional management for weight loss in morbid obesity patients.[4]

Surgery for obesity can result in weight loss of 16-43%, as well as a marked reduction in the incidence and severity of associated co-morbidities. Surgery has been shown to reduce the progression of and mortality from type II diabetes compared to non-surgical treatment of obesity.[1] The majority of patients who undergo bariatric surgery for weight loss experience complete resolution or improvement of concomitant diabetes, hypertension, dyslipidaemia and obstructive sleep apnoea.[5]

Pre- and postoperative patient education and management is more important in bariatric surgery than in other gastrointestinal surgery

Obesity surgery may also be cost-effective in severely obese patients.[1,6,7] Studies have shown that although bariatric surgery is expensive, it is a cost-effective intervention for reducing diabetic medication costs over a 3-5 year period.[8,9]

However, many patients are under the impression that undergoing surgery for obesity will result in inevitable, controlled weight loss. The bariatric surgical procedure is only one part of a comprehensive weight loss program. Greatest success is achieved with surgical patients who are well prepared both physically and mentally for the procedure, and who meticulously comply with a long-term regular monitoring protocol.

Ongoing pre-operative and post-operative follow-up and support is essential for an optimal outcome, and patients need to understand that permanent lifestyle changes are required to optimise the duration and extent of weight loss following surgery.[1] Pre- and post-operative patient education may be more important in bariatric surgery than in other gastrointestinal surgery – it is considered by some as a form of behavioural surgery, where the outcome may be greatly influenced by patient selection and post-operative patient eating behaviour.[10]

Laparoscopic adjustable gastric banding

The frequency of bariatric procedures in Australia has increased markedly in the past decade and continues to rise.[11] Laparoscopic adjustable gastric banding (LAGB) has emerged as the most common weight reduction surgical procedure in Australia and elsewhere, accounting for over 90% of bariatric procedures.

The benefits of the LAGB include:

Adjustability – the most important factor in achieving good weight reduction safely; results in gentle reduction of weight over time, with a less severe rate of weight reduction over two to three years compared to gastric stapling but good maintenance of weight loss in the long-term.[11]

Laparoscopic placement – available in almost all patients who have not had previous gastric surgery, regardless of patient size; can be done as day surgery; enables rapid return to normal daily activities.

Reversibility – can be removed easily, allowing the stomach to return to normal configuration.

Good safety profile – the *Australian Safety Register of New Interventional Procedures – Surgical*, performed a systematic review of LABG versus Roux en Y gastric bypass and vertical banded gastroplasty, and found that the LAGB was associated with much lower mortality than the other two procedures and had an incidence of post-operative complications of less that 2%.[12]

Effective and sustained weight loss – weight loss progresses over 2-3 years and stabilises in the range of 50-60% of excess weight, similar to the degree of weight loss associated with the Roux-en-Y gastric bypass procedure.

Improved health and quality of life – health benefits following LAGB include marked improvement or resolution of type II diabetes, hypertension, dyslipidaemia, reflux oesophagitis, asthma and depression.[10] In addition, LABG improves long-term quality of life.[13]

Allows optimal control of weight change during pregnancy – studies suggest that adjustable gastric banding results in optimal control of weight change during pregnancy and reduces the risk of excessive weight change.[13] However, women should be advised to avoid pregnancy after surgery until their weight has stabilised and any micronutrient deficiencies have been treated.[1]

Risks of surgical intervention

Most surgical procedures are now performed with a low rate of operative mortality and low complication rates.[1] Surgical procedures can result in some loss of absorptive function and even forms of malnutrition, while micronutrient deficiencies are relatively common following bariatric surgery.[14] These require ongoing monitoring and supplementation, often with folate or vitamin B12, to ensure adequate nutritional status is maintained.[15] Some bariatric surgery patients also develop gallstones or other GI problems such as dumping.[1]

Weight changes once surgery has been scheduled: the last supper syndrome

Once accepted for surgery, some patients unfortunately gain weight prior to the date of the bariatric procedure. Patients may increase their caloric intake in the weeks or months preceding surgery because they think it will be their last opportunity to enjoy favourite foods, or because they are anxious about the surgery and post-operative dietary requirements. A US study demonstrated that patients scheduled for bariatric surgery gained an average of 4.4 kg between the date of acceptance for surgery and date of procedure.[16] Creating a drastic extreme between before-and-after eating behaviours can also make complying with the post-operative regimen more challenging.

Surgical complexities of obesity

Excess visceral adiposity and hepatomegaly associated with steatosis increases the technical difficulty of laparoscopic surgery because these features obstruct the surgical field

While the weight loss that results from bariatric surgery is similar with laparoscopic compared to open procedures, fewer serious complications occur with laparoscopic surgery.[4,17] In comparison to open surgical procedures for obesity, laparoscopic bariatric surgery is associated with:[4,17]

- Reduced blood loss;
- Reduced proportion of patients requiring intensive care unit stay;
- Reduced length of hospital stay;
- Reduced risk of incisional hernia;
- Reduced days to return to activities of daily living; and
- Reduced days to return to work.

However, excess visceral adiposity and hepatomegaly associated with steatosis increases the technical difficulty of laparoscopic surgery because these features obstruct the surgical field.[18,19] The presence of an enlarged liver and excessive intra-abdominal fat reduces operating space and exposure, and may hide important anatomical markers. Access to the upper stomach and gastroesophageal junction becomes more difficult, increasing the complexity and risks of surgery. The presence of hepatomegaly also makes retraction during surgery more difficult.

Reducing abdominal fat and liver size prior to laparoscopic surgery is highly desirable in order to minimise risks and difficulty of surgery

Australian researchers have shown that hepatomegaly or excessive visceral fat are the most common reasons for conversion from laparoscopic to open surgical procedures.[20] Excessive visceral fat stores and hepatomegaly are more often seen in people with central obesity (waist circumference ≥88cm in women and ≥102cm in men), the super-obese (BMI>50), or those with metabolic abnormalities.[21-24]

Reducing abdominal fat and liver size prior to laparoscopic surgery is therefore highly desirable in order to minimise risks and difficulty of surgery.

Additional complexities in the super-obese

People who are super-obese pose additional risks to the bariatric surgery team. There are more intraoperative complications in the super-obese compared to those who are morbidly obese[25] and the extreme central and upper body obesity in these patients can make endotracheal intubation and mechanical ventilation very difficult.[26,27] The laparoscopic operative field is often very hard to visualise in the super-obese patient, and the creation of the pneumoperitoneum can be difficult to achieve.[28] There is also a higher rate of conversion to open surgery in this patient population.

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Benefits of pre-surgical weight loss

Some of the surgical complexities of obesity surgery may be overcome with weight reduction prior to surgery. However, it is essential that clinicians and patients realise that the initial weight loss program is seen as the commencement of a life long management plan incorporating surgery, behavioural change, dietary modification, and increased exercise and movement. In addition, pre-operative weight loss is not undertaken to delay surgery, nor is it a substitute for surgery.

The key benefits of pre-surgical weight loss include:

Reduced visceral fat levels and liver size. Weight loss prior to bariatric surgery can effectively reduce visceral fat levels and liver size, leading to greater access for the surgeon and less chance of conversion to an open procedure.[28-34] Reductions in visceral adipose tissue and hepatomegaly have been demonstrated following weight loss.[25, 35, 36] There is also a preferential loss of visceral fat during the early stages of weight loss.[30]

Improved exposure and view of anatomical markers. When anatomical markers are more visible, damage to nearby vessels and structures is less likely and the positioning and fixation of the laparoscopic adjustable band is likely to be more accurate and less time consuming.

Reduced pre-existing metabolic abnormalities. Weight loss has a strongly beneficial effect on the co-morbidities of obesity, including hypertension, hyperlipidemia, insulin resistance, hyperglycaemia, sleep apnoea.[37-39] The positive effects on these parameters are usually related to the degree of weight loss achieved, although even a modest weight loss of 5-10% of starting weight can result in significant health benefits.[1] Weight loss also favourably afters clotting factors and may reduce the risk of post surgery deep venous thrombosis.[40-42]

Patients more sensitive to post-operative requirements. Weight loss prior to surgery can sensitise patients to the potential benefits of complying with the dietary restrictions that will be required post-operatively.[43] Successful pre-operative weight loss may also increase patients' confidence that they can deal with post-operative requirements. A study examining weight loss with a very low energy diet in the pre-bariatric surgery setting found that patients began to make lifestyle changes before their surgery that potentially helped them to adjust to the post-operative requirements.[2]

Improved peri-operative outcomes. Weight loss prior to surgery can have a significant positive impact peri-operatively. It can improve respiratory mechanics, and reduce the metabolic, pro-inflammatory and pro-fibrotic elements of the metabolic syndrome commonly seen in severely obese patients. Improvement in these parameters may reduce the risk of complications in the post-operative phase.[37-42]

Reduced operating time, reduced post-operative risks. A greater ease of performance can minimise operating time and recovery time, thus reducing the risk of venous thrombosis, pulmonary embolism, atelectasis and analgesic requirements. A less risky surgical procedure also maximises chances of a good outcome for the patient.

Reduced hospital costs. Minimising conversion to an open procedure will also minimise the hospital costs and result in a shorter length of hospital stay compared to patients who have to undergo an open procedure.

Improvement of physical function and mobility in the postoperative phase. Reducing weight prior to surgery helps patients to improve mobility in preparation for post-operative physical activity requirements.

Benefits amplified in super obese patients

The benefits of pre-surgical weight loss are even greater in patients who are superobese.[28] A study examined the impact of pre-surgical weight loss in super-obese patients by comparing treatment with an intragastric balloon followed by LABG versus LABG alone.[28] The study found that there was a reduced risk of conversion to an open procedure and a lower risk of intraoperative complications in patients treated with pre-surgical weight loss compared to those who underwent LABG alone. Operative time and hospital stay were also significantly shorter in those who underwent sequential treatment with pre-operative weight loss followed by LABG.

Benefits of pre-surgical weight loss

For the surgeon

- Reduces visceral fat levels and liver size leading to greater access for surgeon and less chance of conversion to an open procedure
- Improves exposure and view of anatomical markers, making damage to nearby vessels and structures less likely
- Enables greater accuracy of laparoscopic adjustable band positioning and fixation

For the patient

- Minimises operating times and recovery times, thus reducing the risk of venous thrombosis, pulmonary embolism, atelectasis and analgesic requirements
- Improves respiratory mechanics and biochemical factors associated with obesity
- Reduces severity of co-morbidities including sleep apnoea and cardiovascular disorders
- Maximises improvements in physical function and mobility in the postoperative phase
- Sensitises patients to potential benefits of complying with post-operative dietary restrictions

Pre-operative weight reduction

Treatment with the OPTIFAST® VLCD™ program before bariatric surgery has been shown to result in significant weight loss and good compliance to the dietary regimen

Long-term weight reduction with very low energy diets alone is generally not recommended, unless closely supervised by a physician. However, the use of very low energy diets for short-term weight reduction has been shown to significantly and safely reduce weight, with concomitant improvement in obesity-related conditions.[44]

Treatment with very low energy diets before bariatric surgery has also been shown to result in significant weight loss and good compliance to the dietary regimen.[2] In a study of a 7-24 week pre-surgery very low energy diet program supported by individual therapy sessions, mean weight loss prior to surgery was 15% of initial weight, or 19.6 kg (mean pre-treatment weight 125 kg), with a low drop-out rate of 7%.[2] Importantly, these improvements were seen in patients who had failed previous weight control programs. In addition, treatment with short-term very low energy diets has been shown to reduce the severity of many co-morbid conditions such as diabetes, hypertension, dyslipidaemia and sleep apnoea. Serious complications with short term very low energy diets are uncommon.[44]

Short-term very low energy diets can help to initiate weight loss in obese patients, and thereby help them comply with the requirements of long-term weight management post-surgery.[43] Pre-operative weight loss does not appear to adversely affect immune function or wound healing.[2] In a study of very low energy diets prior to surgery, the numbers of circulating leukocytes, neutrophils, basophils, monocytes, CD3, and natural killer cells did not change significantly, although there was a significant reduction in immunoglobulin serum concentration.[2]

Pre-operative weight reduction may be considered in any candidates for obesity surgery

Suitable candidates for pre-operative weight loss

Indications for bariatric surgery are evolving as safety is increasing and more long-term data demonstrate its effectiveness.[9,10,45] Overall, pre-operative weight reduction may be considered in any candidates for obesity surgery, but is best suited to well motivated patients who have acceptable operative risks and strongly desire substantial weight loss. In particular, consider a pre-surgical weight loss program for surgical patients who are at higher surgical risk, including:

- Super-obese patients with a BMI>50.
- Patients with a BMI>40 and central obesity or android distribution of body fat. This would include all men, and women with central obesity, polycystic ovary syndrome, diabetes or the metabolic syndrome.
- Any patient with a BMI>35 and high-risk co-morbid medical conditions such as severe diabetes mellitus, obesity-related cardiomyopathy or Pickwickian syndrome. Other possible indications for patients with BMIs between 35 and 40 include obesity-induced physical problems that are interfering with lifestyle (e.g. musculoskeletal or neurologic disorders, problems with body size that preclude or interfere with employment or ambulation).
- Patients with severe obstructive sleep apnoea.
- Patients with end-stage obesity syndrome. Some candidates for surgical treatment of severe obesity have such impaired health that they must be hospitalised
  pre-operatively and undergo treatment to improve their operative risk.

Previous successful or unsuccessful attempts at using very low energy diets as a weight loss method should not be seen as a reason to avoid short-term use in the pre-operative setting.

All patients who have been accepted for bariatric surgery and a pre-operative OPTIFAST® VLCD™ program should be evaluated by a multidisciplinary team with medical, surgical and nutritional expertise

Recommended pre-surgery OPTIFAST® VLCD™ protocol

The type and duration of the OPTIFAST® VLCD™ program used must be considered in the context of scheduling surgery, with the aim of ensuring maximal weight loss prior to surgery, reducing surgical risk factors and motivating the patient. The ideal duration of the OPTIFAST® VLCD™ program and degree of weight loss is unknown, although an Australian study is currently underway to address these issues. The following recommendations are those of the expert advisory panel.

Pre-treatment evaluation

All patients who have been accepted for bariatric surgery and a pre-operative OPTIFAST® VLCD™ program should be evaluated by a multidisciplinary team with medical, surgical and nutritional expertise.[1] During this evaluation, it is important to listen carefully to patient expectations and to provide patients with a realistic assessment of probable outcomes.

Patients should have a clear understanding of basic nutrition, and nutritional counselling and support by a dietitian is recommended. In addition, patients should understand the risks and benefits of the OPTIFAST® VLCD™ pre-operative program, the surgical procedure and post-operative dietary and lifestyle requirements. They also need to fully understand the required substantial changes to their long-term future eating habits, and that lifelong medical surveillance will be essential after surgery.[1]

Role of multidisciplinary team

Surgeon – selection of patients for pre-operative weight loss; gather information about previous surgeries, past or existing GI problems.

Dietitian – perform nutritional evaluation, ascertain eating habits, provide information about the OPTIFAST® VLCD™ program, implement and monitor the pre-operative OPTIFAST® VLCD™ program, provide comprehensive information about post-operative eating program.

Medical practitioner – identification of co-morbid conditions, sleep apnoea, ongoing medical monitoring.

Pre-operative weight loss program: OPTIFAST® VLCD™ intensive phase protocol

The OPTIFAST® VLCD™ program is a formula that has been scientifically formulated to assist medically at-risk patients to rapidly lose weight and reduce their obesity-related health risks. The OPTIFAST® VLCD™ program can totally replace normal food intake while maintaining sufficient quantities of protein, carbohydrates and essential fatty acids. The OPTIFAST® VLCD™ program includes the recommended daily intake (RDI) for adult males and females for vitamins, minerals and trace elements.

	Per sachet (40g)#	Per 3 sachets (120g)	Per 100g
Protein (g)	17.3	51.9	43.3
Carbohydrate (g) **Total** **Sugars**	 15.0 9.2	 45.0 27.6	 37.6 23.0
Fat (g)	2.3	6.9	5.8
Energy **(kJ)** **(Cal)**	 635 152	 1905 456	 1590 381

Based on Milkshake Formulation

Amino Acid Profile	Alanine, Arginine, Asparagine + aspartic acid, Cysteine, Glutamine + glutamic acid, Glycine, Histidine, Isoleucine, Leucine, Lysine, Methionine, Phenylalanine, Proline, Serine, Threonine, Tryptophan, Tyrosine, Valine
Carbohydrate Profile	Sucrose, Lactose, Maltotriose, Oligosaccharide Maltodextrin
Fatty Acid Profile	Lauric acid, Myristic acid, Palmitic acid, Stearic acid, Oleic acid, Linoleic acid, a-Linolenic acid, Arachidonic acid, Eicosapentaenoic acid (EPA), Docosahexaenoic acid (DHA), other fatty acids
Gluten	**FREE***

*The OPTIFAST® VLCD™ milkshakes and dessert are gluten free.
The OPTIFAST® VLCD™ bars and soups contain gluten.

In order to lose weight pre-operatively, the OPTIFAST® VLCD™ 12-week intensive phase protocol is recommended

In order to lose weight pre-operatively, the OPTIFAST® VLCD™ 12-week intensive phase protocol is recommended. This involves total replacement of normal daily food intake with the OPTIFAST® VLCD™ program according to the daily dosage outlined below:

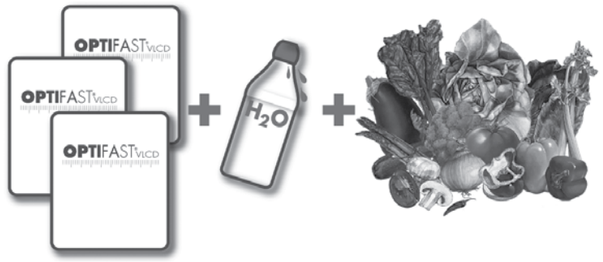
Intensive phase daily dosage and administration

- Milkshakes alone: 3 sachets / day; **or**
- Soup alone: 3 sachets / day; **or**
- Dessert alone: 3 sachets / day; **or**
- Bars alone: 3 bars / day; **or**
- Combination: 3 of any product / day
- Additional allowances: 2 cups low starch vegetables (see table on page 19)

Please note: If protein requirements are more than 70g/day you may consider using 5 sachets.

Mix each sachet with 200mL cold or warm water to provide the essential nutrients required by the body as you lose weight. Stir, blend or shake well. Bars are ready to eat and no preparation is required. Supplement this with at least 2 litres of calorie free liquids (e.g. water, diet soda, mineral water, tea, etc.). A maximum of 2 cups of low starch vegetables (see “Additional Allowances”) is also allowed each day, as outlined on page 19.

Three or four OPTIFAST® VLCD™ sachets mixed with 200mL of fluid per day or 3 OPTIFAST® VLCD™ bars, every day for 12 weeks, provides the necessary essential nutrients required by the body to lose fat stores. Medically supervised OPTIFAST® VLCD™ treatments have been shown to achieve rapid weight loss, with an average of 1.0-2.5 kg per week.



Three OPTIFAST® VLCD™ sachets, each mixed with 200mL water, or 3 bars, taken every day for 12 weeks provides essential nutrients required by the body to lose fat stores.

Time using the OPTIFAST® VLCD™ program	Average weight loss achieved
4 weeks	7-10 kg
12 weeks	20 kg
Average weight loss per week	
Males	1.5-2.5 kg
Females	1.0-2.0 kg

Vitamin content of OPTIFAST® VLCD™ milkshake formulation and recommended daily intake (RDI) for men and women.

MACRONUTRIENTS	OPTIFAST® VLCD™ Milkshake		Recommended Dietary Intake (RDI)[52]		
	Per sachet (40g)	Per 3 sachets (120g)#	Men 19-70 yrs	Women# 19-70 yrs	Safe Upper Limit (UL)
Protein (g)	**17.3**	**51.9**	64*	46	NP
Carbohydrate (g)	**15.0**	**45.0**	No AI, RDI or UL Set		
Dietary Fats:					
- Linoleic acid (omega 6) (g)	**1.15†**	**3.45†**	13[AI]	8[AI]	NP
- a-linolenic acid (omega 3) (g)	**0.17†**	**0.51†**	1.3[AI]	0.8[AI]	NP
- DHA/EPA/DPA (mg)	**75†**	**225†**	160[AI]	90[AI]	3,000
Dietary Fibre (g)	**3.6†**	**10.8†**	30	25	NP

*Consumption of 4 sachets/day of OPTIFAST® VLCD™ is required to meet the protein RDI requirements for men.
† Data relates to OPTIFAST® VLCD™ Strawberry and Coffee Milkshakes per sachet (54g) and per 3 sachets (162g).

VITAMINS	OPTIFAST® VLCD™ Milkshake		Recommended Dietary Intake (RDI)[52]		
	Per sachet (40g)	Per 3 sachets (120g)#	Men 19-70 yrs	Women# 19-70 yrs	Safe Upper Limit (UL)
Retinyl Acetate (Vitamin A) (µg)	**330**	**990**	900	700	3,000
Thiamin (Vitamin B1) (mg)	**0.53**	**1.6**	1.2	1.1	NP
Riboflavin (Vitamin B2) (mg)	**0.66**	**2.0**	1.3	1.1	NP
Nicotinic acid (Niacin Equivs) (mg)	**6**	**18**	16	14	35
Pantothenic Acid (Vitamin B5) (mg)	**2.67**	**8**	6[AI]	4[AI]	NP
Pyridoxine (Vitamin B6) (mg)	**0.66**	**2**	1.3-1.7	1.3-1.5	50
Cyano-cobalamin (Vitamin B12) (µg)	**1**	**3**	2.4	2.4	NP
Folic Acid (µg)	**133**	**400**	400	400#	1000
Ascorbic Acid (Vitamin C) (mg)	**25**	**75**	45	45	NP
Cholecalciferol (Vitamin D3) (µg)	**1.6**	**4.8**	5-10[AI]	5-10[AI]	80
dl-alpha Tocopherol (Vitamin E) (mg)	**4.4**	**13.2**	10[AI]	7[AI]	300
Biotin (Vitamin H) (µg)	**67**	**200**	30[AI]	25[AI]	NP
Phytomenadione (Vitamin K1) (µg)	**33**	**100**	70[AI]	60[AI]	NP

#The table does not include levels required for pregnant or lactating women as OPTIFAST® VLCD™ is contraindicated in these areas.

RDI: Recommended Dietary Intake – The average daily dietary intake that is sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in a particular life stage and gender group.

UL: Safe Upper Limit

NP: Not Possible to establish a Safe Upper Limit

AI: Adequate Intake – Used when RDI cannot be determined is based on observed or experimentally determined approximations or estimates of nutrient intake by a group or groups of apparently healthy people that are assumed to be adequate.

Mineral content of OPTIFAST® VLCD™ milkshake formulation and recommended daily intake (RDI) for men and women.

MINERALS	OPTIFAST VLCD Milkshake		Recommended Dietary Intake (RDI)[52]		
	Per sachet (40g)	Per 3 sachets (120g)#	Men 19-70 yrs	Women# 19-70 yrs	Safe Upper Limit (UL)
Calcium Total (mg)	**300**	**900**	1000	1000-1300	2500
Chromium (µg)	**33**	**100**	35[AI]	25[AI]	NP
Copper (mg)	**0.83**	**2.5**	1.7[AI]	1.2[AI]	10
Iodine (µg)	**50**	**150**	150	150#	1100
Iron (mg)	**5**	**15**	8	8-18#	45
Magnesium (mg)	**116**	**348**	400-420	310-320#	350
Manganese (mg)	**1**	**3**	5.5[AI]	5[AI]	NP
Molybdenum (µg)	**67**	**200**	45	45	2000
Potassium Total (mg)	**668**	**2004**	3800[AI]	2800[AI]	NP
Selenium (µg)	**17**	**51**	70	60**	400
Sodium Total (mg)	**332**	**996**	460-920[AI]	460-920[AI]	2,300
Zinc (mg)	**5**	**15**	14	8	40

#The table does not include levels required for pregnant or lactating women as OPTIFAST® VLCD™ is contraindicated in these areas.

** 4 sachets/bars of OPTIFAST® VLCD™ per day would increase the selenium intake to meet the RDI.

RDI: Recommended Dietary Intake – The average daily dietary intake that is sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in a particular life stage and gender group.

UL: Safe Upper Limit

NP: Not Possible to establish a Safe Upper Limit

AI: Adequate Intake – Used when RDI cannot be determined is based on observed or experimentally determined approximations or estimates of nutrient intake by a group or groups of apparently healthy people that are assumed to be adequate.

Additional foods allowed on the OPTIFAST® VLCD™ program

ALLOWED				AVOID
FRUIT*	One of – 200g strawberries, 1 lychee, 1 apricot, 100g cooked rhubarb, 1 slice of pineapple, 2 passionfruits, 100g grapes, 1 lime, 1 apple, 50g cherries, 1 mango, 1 medium orange, 1 peach, 1 small pear, 120g pear in natural juice, 120g plums, 5 prunes.			All other fruit
LOW STARCH AND GREEN VEGETABLES**	alfalfa sprouts asparagus beans bok choy broccoli brussel sprouts celery cabbage capsicum carrots	cauliflower cucumber eggplant garlic lettuce leeks mung beans mushrooms onions	radish shallots silver beet snow peas spinach squash tomato watercress zucchini	corn green peas legumes lentils potato pumpkin sweet potato
SOUPS	stock cubes bonox (in moderation)	vegetable soups (using allowed vegetables)	miso soup	All others
SAUCES AND CONDIMENTS	lemon juice vinegar worcestershire sauce	soy sauce (in moderation) chilli	mustard tomato paste	
SPICES AND HERBS	all spice basil celery flakes chilli chives cinnamon cloves coriander cumin curry powder	dill fennel garlic ginger lite salt mint mustard seed nutmeg	oregano paprika parsley pepper rosemary sage thyme tumeric taragon	
MISCELLANEOUS	artificial sweetners	Unsweetened lollies/gum	Diet Jelly Essence – banana, mint, strawberry	
CALORIE FREE FLUIDS (at least 2 litres extra per day)	water tea diet soft drink	diet cordial mineral water		fruit juice alcohol

*Fruit is permitted during the Transition, Maintenance and Stabilisation Phases of the program.

** 1 teaspoon of vegetable oil is permitted with daily serve of vegetables.

Improved health outcomes with the OPTIFAST® VLCD™ intensive phase management

Studies have demonstrated that rapid weight loss with the OPTIFAST® VLCD™ program is associated with significant improvements in health-related outcomes. The following beneficial changes have been shown following short-term therapy with the OPTIFAST® VLCD™ program:

- Decrease in serum insulin levels, serum leptin and TNF-alpha[46]
- Improved glycemic control, with reduction in integrated insulin and C peptide secretion[36]
- Reduction in apoprotein A1, apoprotein B, total cholesterol, LDL-cholesterol and triglyceride concentrations[47]
- Improvement in obstructive sleep apnoea syndrome[48]
- Reduction in blood pressure in hypertensive patients[49]
- Improvement in control of type II diabetes[50]
- Reduction in visceral fat[51]

Implementation, monitoring and support

During the OPTIFAST® VLCD™ intensive phase program, weekly monitoring and support from a health professional is essential. Weekly meetings should involve setting and reviewing realistic weight loss goals, development of strategies for dealing with difficult situations, review of recipes and consultation with other health professionals as needed (e.g. psychologist, group counsellor, exercise physiologist, dietitian).

Initial consultation

Prior to commencing the OPTIFAST® VLCD™ intensive phase, a 10 minute interview should be conducted to establish appropriate goals and expectations. During this consultation, the following should be established:

- Understanding of the OPTIFAST® VLCD™ program;
- Understanding of the role of the OPTIFAST® VLCD™ program prior to bariatric surgery;
- Short- and medium-term goals;
- Appropriate care plan;
- Prescription for physical activity; and
- Signed commitment form.

Weight can be recorded in the OPTIFAST® VLCD™ clinical weight loss diary.

Nutrition

Any OPTIFAST® VLCD™ products 3-4 times per day plus 2 cups low starch green vegetables are the only permitted sources of nutrition in this phase. Total caloric intake is <800 kcal per day.

Medical guidelines and visits

Weekly visits with a health professional are essential during this phase. After the initial 10 minute interview, weekly meetings should carry on for the 12-week program. Each of these visits may only take 3-5 minutes. GP and/or physician care during the program is necessary to:

- Monitor safety;
- Monitor and adjust ongoing medications;
- Enhance patient adherence to the program; and
- Provide support and encouragement.

At each visit, the clinician should assess:

- Status of all obesity-related conditions;
- Medications and dosages;
- Excessive weight loss for very obese patients;
- Signs of electrolyte imbalance;
- Side effects to therapy;
- Patient adherence to the OPTIFAST® VLCD™ program; and
- Patient motivation.

Medication changes

Patients taking medications for co-morbid conditions such as type I and II diabetes, hypertension, dyslipidaemia, as well as patients on lithium, anticoagulant or anticonvulsant therapy, should be closely monitored while on the OPTIFAST® VLCD™ program. In the initial weeks of the program, blood glucose, blood pressure and serum cholesterol may significantly decrease and a change to medication dosages may be required.

Behavioural support

Behavioural support is a crucial phase of the program. Support is ideally provided from several sources, e.g. dietitian, pharmacist, diabetes educator, exercise physiologist, GP, practice nurse. Ongoing positive support and encouragement is essential, and will also help to motivate the patient for the changes that are required following bariatric surgery.

Physical activity

Setting physical activity goals is extremely important both during the OPTIFAST® VLCD™ intensive program and in preparation for post-operative management.

Low-intensity, prolonged aerobic exercise results in metabolic benefits and is generally suitable for obese patients. Consultation with an appropriate health professional, e.g. exercise physiologist, can help in developing an appropriate, tailored program to suit each patient's abilities and interests. Specialist consultation is recommended if there are any concerns about safety or a patient's ability to exercise.

Next goal: preparation for surgery

Once the OPTIFAST® VLCD™ intensive program is underway, patients will need to prepare for their bariatric surgery. Patients should be well informed and motivated, with acceptable operative risks.[1] Careful patient selection is critical, and surgery should only proceed after careful evaluation by multidisciplinary team members to assess medical, nutritional, psychological and surgical status. Patients need to know that surgery is only one part of a comprehensive weight management program that involves lifelong dietary and behavioural changes and ongoing monitoring.

Post-operative nutrition

A person's nutritional needs change dramatically following bariatric surgery. Over several weeks and months post-surgery, food intake progresses from clear to opaque liquids, followed by pureed foods, a soft food diet and eventually consumption of regular foods that are extremely well chewed.

A danger during this time is low or inadequate protein intake. Procedures that provide significant malabsorption of macronutrients, such as bilio-pancreatic diversion, may also lead to serious protein malnutrition. It is therefore recommended that after surgery, patients eat foods and supplements that are high in protein and are fortified with key nutrients. The OPTIFAST® VLCD™ program is an appropriate supplement to meet the nutritional needs of bariatric surgery patients, and can be used both prior to and after surgery. All formulas have adequate protein to preserve lean body mass during weight loss, promote healing after surgery and improve immunity. Carbohydrate levels have been optimised to normalise and maintain blood sugar levels.

Initial assessment	High Risk	Low Risk
Medical history	✓	✓
Commitment and consent	✓	✓
Blood tests: Complete blood count with differential and platelet count, blood chemistry, liver function tests, chol, TG, fasting BGL	✓	✓
Urinalysis: Microalbuminuria, ketones, pH, etc.	✓	✓
Electrocardiogram (ECG) with computed QTc interval	✓	✓
Weight, waist circumference	✓	✓
Physical examination conducted heart, lung, abdomen, extremities	✓	✓
Intensive phase (12 weeks)		
Full chemistry	Every 4 weeks	Every 4 weeks
Electrolytes	Every 2-4 weeks	Wks 1,12
ECG	Every 22kg lost/week 12	Every 22kg lost/week 12
Medical Visits/GP/Dietitian monitoring: Weight, pulse, BP, waist, improvement in health factors	Each week for 4 weeks, then every 2 weeks	Each week for 2 weeks, then every 4 weeks
Pharmacy visit	Each week	Each week
Counselling	Each week	Each week

Case study: OPTIFAST® VLCD™ PROGRAM for pre-surgical weight loss

Presentation

Mr DL is a 63-year-old morbidly obese man (BMI 44) with a 15-year history of type II diabetes, hypertension and dyslipidaemia. He was referred to a bariatric surgery clinic by his GP for advice on laparoscopic adjustable gastric banding (LAGB) in June 2004. He was assessed by a surgeon and was accepted into the LAGB program.

Due to marked central adiposity, he was advised to undergo 12 weeks of OPTIFAST® VLCD™ treatment intervention prior to surgery. Following assessment by a clinic GP and counselling by a dietitian, Mr DL commenced the intensive phase protocol of the OPTIFAST® VLCD™ program. He met the inclusion criteria for an ongoing study examining changes in liver size and visceral fat mass during the OPTIFAST® VLCD™ program, and consented to participate.

Past medical history

History of glaucoma, microalbuminuria, urinary incontinence; had bilateral knee reconstructions 2 years ago.

Medication

Diabex, Novomix, Lipitor, Lopid, Hydopa, Felodur ER and Micardis. Insulin was commenced one month prior to surgical assessment.

Social history

Married, retired teacher. Multiple attempts have been made to lose weight since diabetes was diagnosed. Previously tried a number of commercial weight loss programs, dietitian, hypnotherapy, exercise and diet pills, none of which lead to permanent weight reduction. Previous smoker (2 packs per day, ceased 20 years ago). Moderate drinker: consumes 2 standard drinks per day on average.

Feels unable to participate in regular physical exercise and notices a reduced physical capacity; reports low energy levels and the need for a daily nap. Mr DL also reports increasing feelings of embarrassment about his shape and weight, and fears for his future health and life expectancy.

Biochemistry

Blood tests were taken at baseline, week 6 and week 12 (see table 1).

Anthropometry

Weight peaked at 155 kg 2 years ago, following knee surgery. Overall, Mr DL's weight had been increasing for the past 20 years. At the time of surgical assessment, Mr DL weighed 147.8 kg with a body mass index (BMI) of 44.1kg/m^2. Pre-surgical weight was 92% above his ideal body weight for height (Table 2).

Liver size measurements

As part of the study protocol, a CT scan of the liver, along with a single abdominal slice at the level of the third lumbar vertebrae, was carried out at baseline and at the end of the OPTIFAST® VLCD™ program. These measurements were used to assess total loss of liver volume and peritoneal fat mass during the OPTIFAST® VLCD™ treatment phase. In addition, MRI measurement of liver volume took place at week 2, week 4, week 8 and week 12 in order to characterise the pattern of liver size reduction over the study period (Table 3).

OPTIFAST® VLCD™ program

Prior to commencement of the OPTIFAST® VLCD™ program, a full medical review was carried out by the clinic GP and a dietitian counselled the patient about the requirements of the OPTIFAST® VLCD™ program. The patient was monitored and reviewed fortnightly by the GP and dietitian throughout the process, and was also monitored by his endocrinologist.

Page 15 outlines the intensive phase eating program that Mr DL followed for 12 weeks.

Program outcomes

Mr DL successfully completed the 12-week intensive phase of the OPTIFAST® VLCD™ program prior to bariatric surgery. He had no notable side effects during the program.

Comorbidities: Following modification of his insulin regimen, Mr DL's glucose levels were maintained within the normal range throughout the duration of the program. Other biochemical parameters are listed in Table 1. All other measures of diabetic control improved, and lipid levels and LFTs remained within the normal range. At week 8 of the study, in consultation with a GP, Mr DL was able to cease his blood pressure and lipid lowering medication.

Table 1: Biochemical indices throughout the 12-week OPTIFAST® VLCD™ program

Week	F Glucose	Hb a1c	Plasma Insulin	C pep	T	TG	LDL-	HDL-	ALP	AST	ALT	GGT
0	14.1	9.4	17	0.93	3.4	2.5	1.1	1.2	60	21	29	26
6	8.2	7.8	9	0.56	2.4	1	1	0.96	50	20	28	12
12	5.3	7	9	0.39	2.4	1	0.8	1.1	52	17	18	12

Weight and Anthropometry: Mr DL lost 21.1 kg during the 12-week treatment phase, which reduced his BMI to 37.8kg/m^2. He also lost 15cm off his waist and 3cm off his neck circumference (Table 2).

Table 2: Anthropometric measurements throughout the 12-week OPTIFAST® VLCD™ program

Week	Weight	Waist	Neck	Blood Pressure
0	147.8kg	142cm	50cm	190/80
6	130kg	131cm	48cm	160/70
12	126.7kg	127cm	47cm	140/60
Loss	**21.1kg**	**15cm**	**3cm**	

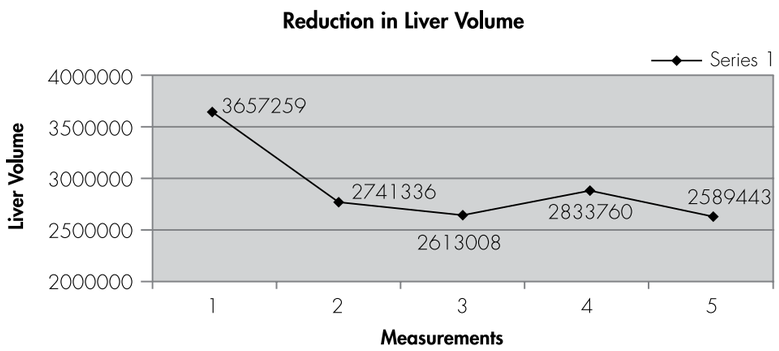
Liver size and visceral fat mass: Monitoring of liver volume and peritoneal fat mass over the course of the study revealed a marked 29% reduction in liver volume. By the conclusion of the 12-week treatment phase, there was also a significant 53.5% reduction in visceral fat mass (Table 3).

Table 3: Liver volume measurements throughout the 12-week OPTIFAST® VLCD™ program

Week	Liver Volume	Visceral Fat Mass
0	3657259 mm^3	76478 mm^2
2	2741336 mm^3	Not measured
4	2613008 mm^3	Not measured
8	2833760 mm^3	Not measured
12	2589443 mm^3	35567 mm^2
Loss	**1067816 mm^3 or 29.2%**	**40911 mm^2 or 53.5%**

Significant liver volume reduction was evident by week 2 (25% reduction), with the remaining 4% reduction occurring by the end of the 12-week protocol (Figure 1).

Figure 1: Pattern of liver volume reduction throughout the 12-week OPTIFAST® VLCD™ program.



Additional outcomes: During the OPTIFAST® VLCD™ program, Mr DL's energy levels increased and with encouragement he was able to commence light, regular exercise during the course of the diet. He was also encouraged to continue regular physical activity in the post-operative period.

As part of the study protocol, Mr DL also completed the SF-36® Health Survey, a multipurpose 36-item questionnaire that has been well validated in measuring self-reported quality of life. His responses indicated a significant improvement by the end of the 12-week OPTIFAST® VLCD™ program.

Mr DL went on to have LAGB surgery. He recovered well and was slowly graded back onto solid foods over the ensuing weeks. At review 5 weeks post surgery his weight had reduced by 3 kg, with a further 5 kg weight reduction in the following month. He has continued to participate in regular exercise and his blood glucose remains well controlled.

Product Information

Description

To assist with compliance, the OPTIFAST® VLCD™ product range comes in a variety of products including Milkshakes, Dessert, Soup and Bars.

Actions

Rationale. The use of modified fasting is well established as a safe and effective method of rapid weight loss provided that medical supervision is maintained. Weight loss rates are comparable to those achieved by total fasting, but the disadvantages of severe ketosis and loss of lean body mass are minimised. Adequate nutritional status is also maintained. Individuals have undertaken modified fasting regimens for many months but are advised to seek the advice of a doctor or healthcare professional to review progress. Progress should be reviewed at least twice monthly if the duration of modified fasting exceeds three months.

Indications

Total food replacement for the obese. OPTIFAST® VLCD™ treatment is intended for use as part of the management of the moderately to severely overweight, even when there is associated secondary pathology e.g. non-insulin-dependent diabetes, hypertension, osteoarthritis, hypothyroidism corrected by replacement therapy, gynaecological disorders, hyperlipidaemia or where obesity is an impediment to surgery.

Contraindications

Acute cerebrovascular or cardiovascular disease, renal disease, hepatic disease, juvenile onset diabetes, porphyria or overt psychosis.

Use in pregnancy. Contraindicated.

Use in lactation. Contraindicated.

Use in children. Use of very low energy diets is not recommended in persons below 18 years.

Use in elderly. Use of very low energy diets is not recommended in persons above 65 years of age.

Precautions

Individuals with recent myocardial infarction should be referred to a cardiologist to determine suitability for modified fasting.

Individuals receiving medication for diabetes, hypertension, hyperlipidaemia or those on lithium therapy may require a reduction in dose or withdrawal of treatment whilst undergoing modified fasting. Such individuals should be monitored carefully in the first weeks of an OPTIFAST® VLCD™ program.

Individuals with a history of hepatic or renal disease should also be monitored carefully. Individuals on lithium therapy require more frequent monitoring of blood lithium levels. Alcohol should not be consumed when using the OPTIFAST® VLCD™ program.

Monitoring

At the commencement of the program, individuals should be checked for normal renal and hepatic function and thereafter regular checks for weight, blood pressure and urinalysis.

Adverse Reactions

Initial transient effects have been observed: sensitivity to cold, dry skin, temporary rash, temporary hair loss, postural hypotension, fatigue, diarrhoea, constipation, muscle cramps, halitosis, irritability, menstrual disturbances. These are generally insufficient in magnitude or duration to warrant cessation of the program. In some rare cases, numbness and the appearance of previously unsuspected gallstones have been reported.

Rapid weight loss occasionally leads to higher serum uric acid levels and might precipitate an acute attack of gout in a predisposed individual. This may be ameliorated by ensuring adequate fluid intake and including one teaspoon of oil with 2 cups of additional vegetables.

Although the OPTIFAST® VLCD™ program contains adequate electrolytes for the needs of most individuals, some individuals may become hyponatraemic or hypokalaemic, especially if they are receiving diuretic therapy. In such circumstances, electrolyte supplements may be required.

Dosage and Administration

Preparation. See pack for directions.

Administration. The OPTIFAST® VLCD™ program should replace all food. Each sachet/bar to be taken at meal times.

Supplement this program with at least 2 litres of energy free liquids (e.g. water, diet soda, mineral water or tea). Up to two cups per day of green vegetables (or low starch vegetables), prepared with a teaspoon of oil, is also recommended. A program of regular light exercise enhances wellbeing and, therefore, likelihood of success.

Overdosage

Symptoms of overdosage would become apparent after prolonged ingestion of at least 22 sachets/bars per day. Such symptoms would be due to an intake of over 10,000 µg per day of vitamin A (from over 22 sachets/bars per day) or over 600 µg of selenium (from over 35 sachets/bars per day). A yellow colouration of the skin may result due to the excessive intakes of the carotenes derived from the vitamin A, but disappear when the carotenoid intake is reduced. Signs of selenium toxicity may include loss of hair and nails. Potential toxicity may also result when persistent ingestion of large amounts of vitamin D (cholecalciferol) exceed the recommended allowance by severalfold, and may result in hypercalcaemia and consequent calcification of soft tissues.

Presentation

OPTIFAST® VLCD™ Milkshakes
Chocolate and Vanilla: 46g x 21 sachets
Strawberry Flavour and Coffee: 54g x 8 sachets

OPTIFAST® VLCD™ Chocolate Dessert:
46g x 8 sachets

OPTIFAST® VLCD™ Soups
Chicken Flavour: 46g x 8 sachets
Mixed Vegetable: 54g x 8 sachets

OPTIFAST® VLCD™ Bars
Chocolate: 70g x 6 bars
Berry Crunch Flavour and Cappuccino Flavour: 60g x 6 bars

Poisons Schedule Unscheduled.

Further information is available on request:

Australia:
Nestlé Healthcare Nutrition,
1 Homebush Bay Drive, Rhodes NSW 2138, Australia
Telephone: **1800 671 628** (toll free)

New Zealand:
Nestlé Healthcare Nutrition
1 Broadway, Newmarket, Auckland, New Zealand
Telephone: **0800 607 662** (toll free)

References

1. NHMRC. Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults. 2003, National Health and Medical Research Council: Canberra.
2. Pekkarinen T, Mustajoki P. Use of very low-calorie diet in preoperative weight loss: efficacy and safety. Obes Res 1997; 5: 595-602.
3. Martin LF, Tan TL, Holmes PA, et al. Can morbidly obese patients safely lose weight preoperatively? Am J Surg. 1995; 169: 245-53.
4. Colquitt J, Clegg A, Sidhu M, et al. Surgery for morbid obesity. Cochrane Database Syst Rev 2003; 2: CD003641.
5. Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. JAMA 2004; 292: 1724-37.
6. Liberman M, Look D, Auger S, et al. Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients. Ann Surg 2004; 240: 416-23; discussion 423-4.
7. Clegg A, Colquitt J, Sidhu M, et al. Clinical and cost effectiveness of surgery for morbid obesity: a systematic review and economic evaluation. Int J Obes Relat Metab Disord 2003; 27: 1167-77.
8. Narbro K, Agren G, Naslund I, et al. Decreased medication for diabetes and cardiovascular disease after weight loss. Int J Obes 2000; 24 (Suppl. 1): S42.
9. Christou NV, Sampalis JS, Liberman M, et al. Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients. Ann Surg 2004; 240: 416-423.
10. Kral JG. Selection of patients for anti-obesity surgery. Int J Obes Relat Metab Disord 2001 May; 25 Suppl 1: S107-12.
11. O'Brien PE, Dixon JB, Brown W. Obesity is a surgical disease: overview of obesity and bariatric surgery Anz J Surg 2004; 74: 200-204.
12. Chapman A, Kiroff G, Game P, et al. Laparoscopic adjustable gastric banding in the treatment of obesity: a systematic literature review. Surgery 2004; 135: 326-51.
13. Dixon JB, Dixon ME, O'Brien PE. Pregnancy after lap-band surgery: management of the band to achieve healthy weight outcomes. Obes Surg 2001; 11: 59-65.
14. Rhode B, MacLean L. Vitamin and mineral supplementation after gastric bypass. In: Deitel M (Ed) Update: Surgery for the Morbidly Obese Patient. Toronto: FD-Communications: 2000: 161-70.
15. Dixon J, Dixon M, O'Brien P. Elevated homocysteine levels with weight loss after Lap-Band surgery: Higher folate and vitamin B12 levels required to maintain homocysteine level. Int J Obes Relat Metab Disord 2001:219-27.

16. de Witt Hamer PC, Tuinebreijer WE. Preoperative weight gain in bariatric surgery. Obes Surg 1998 Jun; 8(3): 300-1.

17. Nguyen NT, Wolfe BM. Laparoscopic versus open gastric bypass. Semin Laparosc Surg 2002; 9(2): 86-93.

18. Belachew M. Legrand MJ, Vincent V. History of Lap-Band: from dream to reality. Obes Surg. 2001: 297-302.

19. Schwartz ML, Drew RL, Chazin-Caldie M. Laparoscopic Roux-en-Y gastric bypass: preoperative determinants of prolonged operative times, conversion to open gastric bypasses, and postoperative complications. Obes Surg 2003; 13: 734-8.

20. O'Brien PE, Dixon JB, Brown W, et al. The laparoscopic adjustable gastric band (Lap-Band): a prospective study of medium-term effects on weight, health and quality of life. Obes Surg 2002: 652-60.

21. Pouliot M, Despres JP, Lemieux S, et al. Waist circumference and abdominal sagittal diameter: best simple anthropometric indexes of abdominal visceral adipose tissue accumulation and related cardiovascular risk in men and women. Am J Cardiol 1994: 460-8.

22. Luyckx FH, Lefebvre PJ, Scheen AJ. Non-alcoholic steatohepatitis: association with obesity and insulin resistance, and influence of weight loss. Diabetes Metab 2000: 98-106.

23. Timar O, Sestier F, Levy E. Metabolic syndrome X: a review. Can J Cardiol 2000: 779-89.

24. Busetto L. Visceral obesity and the metabolic syndrome: effects of weight loss. Nutr Metab Cardiovasc Dis 2001: 195-204.

25. Bloomston M, Zervos EE, Camps MA, et al. Outcome following bariatric surgery in super versus morbidly obese patients: does weight matter? Obes Surg 1997; 7: 414-9.

26. Benumof JL. Obstructive sleep apnoea in the adult obese patients: implications for airway management. Clin Anesth 2001; 13: 144-56.

27. Ogunnaike BO, Jones SB, Jones DB, et al. Anaesthetic considerations for bariatric surgery. Anesth Analg 2002; 95: 1793-805.

28. Busetto L, Segato G, De Luca M, et al. Preoperative weight loss by intragastric balloon in super obese patients treated with laparoscopic gastric banding: a case control study. Obes Surg 2004; 14: 671-76.

29. Marks SJ, Moore NR, Ryley NG, et al. Measurement of liver fat by MRI and its reduction by dexfenfluramine in NIDDM. Int J Obes Relat Metab Disord 1997; 21: 274-9.

30. Marks SJ, Chin S, Strauss BJ. The metabolic effects of preferential reduction of visceral adipose tissue in abdominally obese men. Int J Obes Relat Metab Disord 1998; 22: 893-8.

31. Fris RJ. Preoperative low energy diet diminishes liver size. Obes Surg 2004; 14: 1165-70.

32. Tiikkainen M, Bergholm R, Vehkavaara S, et al. Effects of identical weight loss on body composition and features of insulin resistance in obese women with high and low liver fat content. Diabetes 2003; 52: 701-7.

33. Laaksonen DE, Kainulainen S, Rissanen A, et al. Relationships between changes in abdominal fat distribution and insulin sensitivity during a very low calorie diet in abdominally obese men and women. Nutr Metab Cardiovasc Dis 2003; 13: 349-56.

34. Li Y, Bujo H, Takahashi K, Shibasaki M, et al. Visceral fat: higher responsiveness of fat mass and gene expression to calorie restriction than subcutaneous fat. Exp Biol Med (Maywood) 2003; 228: 1118-23.

35. Busetto L, Tregnaghi A, Bussolotto M, et al. Visceral fat loss evaluated by total body magnetic resonance imaging in obese women operated with laparoscopic adjustable silicone gastric banding. Int J Obes Relat Metab Disord 2000: 60-9.

36. Numata K, Tanaka K, Saito M, et al. Very low calorie diet-induced weight loss reverses exaggerated insulin secretion in response to glucose, arginine and glucagon in obesity. Int J Obes Relat Metab Disord 1993; 17: 103-8.

37. Dixon JB, O'Brien PE. Lipid profile in the severely obese: changes with weight loss after lap-band surgery. Obes Res 2002a; 10: 903-10.

38. Dixon JB, O'Brien PE. Changes in comorbidities and improvements in quality of life after LAP-BAND placement. Am. J Surg 2002b; 184: S51-4.

39. Luyckx FH, et al. Liver abnormalities in severely obese subjects: effect of drastic weight loss after gastroplasty. Int J Obes Relat Metab Disord 1998: 222-6.

40. Hankey CR, Lean ME, Lowe GD, et al. Effects of moderate weight loss on anginal symptoms and indices of coagulation and fibrinolysis in overweight patients with angina pectoris. Eur J Clin Nutr 2002; 56: 1039-45.

41. Marckmann P, Toubro S, Astrup A. Sustained improvement in blood lipids, coagulation, and fibrinolysis after major weight loss in obese subjects. Eur J Clin Nutr 1998; 52: 329-33.

42. Folsom AR, Qamhieh HT, Wing RR, et al. Impact of weight loss on plasminogen activator inhibitor (PAI-1), factor VII, and other hemostatic factors in moderately overweight adults. Arterioscler Thromb 1993; 13: 162-9.39.

43. Monnier L, Colette C, Percheron C, et al. Very low calorie diets: is there a place for them in the management of the obese diabetic? Diabetes Metab 2000; 26 (Suppl 3): 46-51.

44. National Institutes of Health. Very low calorie diets. National task force on the prevention and treatment of obesity. JAMA 1993; 270: 967-74.

45. Flum DR, Dellinger EP. Impact of gastric bypass operation on survival: A population-based analysis. J Am Coll Surg 2004;199: 543-51.

46. Xenachis C, Samojlik E, Raghuwanshi MP, et al. Leptin, insulin and TNF-alpha in weight loss. J Endocrinol Invest 2001; 24: 865-70.

47. Gossan VV, Gunaga KP, Carella MJ, et al. Apolipoproteins in obesity: effect of weight loss. J Med 1997; 28: 251-64.

48. Herrendorf G, Hajak G, Rodenbeck A, et al. Ambulatory, comprehensive behaviour therapy-oriented weight reduction program (OPTIFAST® VLCD™ program). An alternative therapy in obstructive sleep apnea. Nervenarzt 1996; 67: 695-700.

49. Valenta LJ, Elias AN. Modified fasting in treatment of obesity. Effects on serum lipids, electrolytes, liver enzymes, and blood pressure. Postgrad Med 1986; 79: 263-67.

50. Kirschner MA, Schneider G, Ertel, et al. An eight-year experience with a very low calorie formula diet for control of major obesity. Int J Obes 1988; 12: 69-80.

51. Miyashita Y, Koide N, Ohtsuka M, et al. Beneficial effect of low carbohydrate in low calorie diets on visceral fat reduction in type 2 diabetic patients with obesity. Diabetes Res Clin Pract 2004; 65: 235-41.

52. NHMRC. Recommended Dietary Intakes for use in Australia. 1998, National Health & Medical Research Council, Canberra.

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