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Weight Loss Pharmacotherapy for Obesity and Type 2 Diabetes

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About the expert

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This article provides an overview of the role of pharmacotherapy in the management of obesity and remission of obesity-related type 2 diabetes mellitus (T2DM). Targeting weight primarily can lead to improved glycaemic control if not remission of T2DM. Thus, it is important to treat obesity, particularly in the presence of T2DM. This review is intended as an educational resource for healthcare professionals and has been created with an educational grant from Radiant Health.

Obesity and type 2 diabetes

Obesity is increasingly being regarded as a chronic metabolic disease that requires long-term models of care for what is a life-long condition, frequently beginning in childhood or early adulthood.[1-4]

The metabolic complications of obesity lead to increased morbidity, including T2DM and cardiovascular (CV) disease, and premature mortality.[5-7] Each 5 kg/m^2 or higher increase in body mass index (BMI) is associated with a 30% higher overall mortality rate.[7]

Most individuals with T2DM are either overweight or obese.[4] BMI calculations from weight and height resulting in overweight or obese status are estimations of excess body fat. Excess body fat that is located in the visceral organs such as the pancreas and liver increases the risk for prediabetes and T2DM: obesity in men leads to a 7-fold increased risk for developing T2DM and a 12-fold increase in women.[7]

There is now substantial evidence that modest weight loss through obesity management can prevent or delay the progression from prediabetes to T2DM and is beneficial in the treatment of T2DM.[8] For example, participation in weight loss interventions is associated with a 33% reduction in the risk of progressing from prediabetes to T2DM,[9] and each 1kg of body weight loss is associated with a 16% relative reduction in diabetes risk.[7]

Remission of type 2 diabetes

Because T2DM progresses despite glucose-lowering therapy it is generally considered to be a chronic condition that is treatable but not curable.[10] However, the advent of metabolic (bariatric) surgery some 30 years ago provided the first indication that not only can progression of T2DM be arrested but that remission of T2DM can be achieved. Subsequently, randomised controlled trials established that pharmacotherapy as an adjunct to lifestyle modification can prevent the progression of prediabetes to T2DM in people with obesity.[11-14] Evidence now exists that remission of T2DM is achievable with significant weight loss achieved through low-calorie diets involving meal replacement products.[15,16]

The DiRECT and DIADEM-I randomised trials demonstrated that lifestyle modification-induced weight loss can lead to remission of diabetes in obese people with T2DM managed in primary care settings.[15,17,18] In the DiRECT trial, 46% of patients were in remission at 12 months and 1 year later 70% of those patients remained in remission.[17] Sustained remission was closely linked to the magnitude of sustained weight loss.

Current research suggests that if the magnitude of weight loss is sufficient to induce remission of T2DM it does not matter how the weight loss is achieved as long as it is sustainable.[19]

However, the lifestyle interventions used in the DiRECT and DIADEM-I trials, which comprised total diet replacement and structured lifestyle support, may not be sustainable long term for many people with obesity. In addition, total diet replacement was not tolerated by two-thirds of people who were offered this option in the DiRECT trial.[17] Hence, weight-loss pharmacotherapy has a role to play in facilitating the sustainability of, and adherence to, lifestyle-induced weight loss in people with obesity and T2DM.[5,20,21] In the CAMELLIA-TIMI 61 study, lifestyle modification (intensive behavioural therapy but not total diet replacement) in combination with pharmacotherapy produced statistically-significant weight loss at 1 year versus placebo in people with obesity, which over a follow-up period of 3.3 years was associated with glycaemic improvement in individuals with diabetes and lower rates of incident diabetes in individuals with prediabetes.[13]

Even if remission of T2DM is not achieved after weight loss, it is likely that there will be benefit from improved glucose control and reduced reliance on diabetes medication as well as improved CV outcomes associated with weight reduction.[17,22] In the Look AHEAD trial, obese individuals with T2DM who lost ≥10% of their bodyweight in the first year of the study had a 21% lower risk of serious CV outcomes versus individuals who did not lose weight.[23]

Weight loss interventions

Weight reduction is achievable via three main interventions: i) lifestyle modification; ii) pharmacotherapy; and iii) metabolic surgery. The application of these interventions in primary and secondary care is delineated in the management algorithm (**Figure 1**) developed by the Australian and New Zealand Obesity Society (ANZOS).[24]

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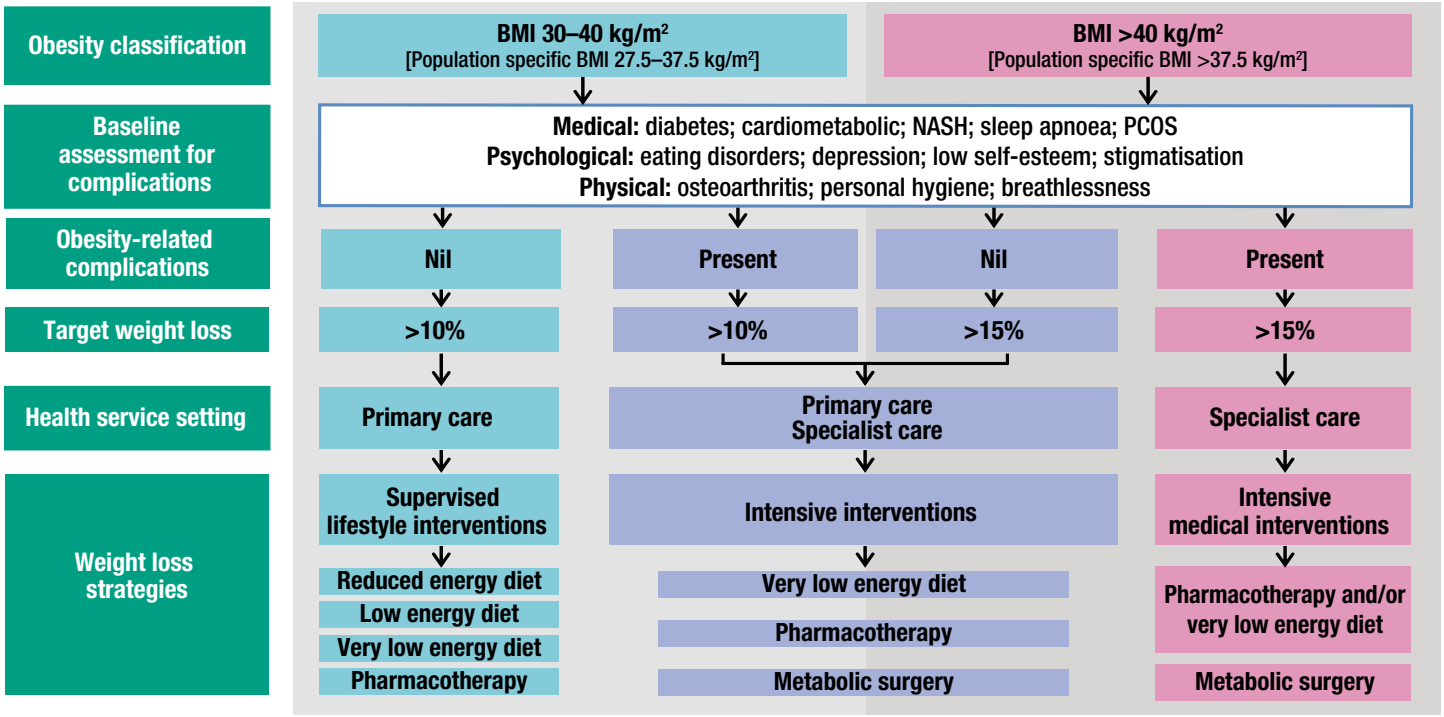

Figure 1. ANZOS obesity management algorithm.[24]
NSASH = non-alcoholic steatohepatitis; PCOS = polycystic ovary syndrome.

In terms of managing obese patients with T2DM, patient motivation to achieve weight loss should be assessed and weight loss goals and intervention strategies discussed and jointly agreed by the patient and physician (**Table 1**).[8]

In obese patients with T2DM, modest and sustained weight loss has been shown to improve glycaemic control and to reduce the need for glucose-lowering medications.[8] Health benefits from reducing comorbidities begin once an overweight person loses 5–10% of their initial body weight.[6]

	BMI category (kg/m²)				
	25–26.9	27–29.9	30–34.9	35–39.9	≥40
Lifestyle modification	†	†	†	†	†
Pharmacotherapy		†	†	†	†
Metabolic surgery			†	†	†

Table 1. Weight-loss interventions (by BMI category thresholds) for overweight and obese patients with T2DM.[8] † = treatment may be indicated for select motivated patients.

Importance of primary care

The major role that primary care can play in the management of people with obesity, including those with T2DM or other obesity-related comorbidities, is highlighted in the ANZOS obesity management algorithm (**Figure 1**).[24] Primary care providers can raise the issue of weight loss if a person is likely to benefit from a reduction in body weight and encourage them to adopt healthy lifestyles and offer appropriate medical interventions and support, including the initial prescribing of weight-loss medication.[5] One analysis suggests that people advised to lose weight by a primary care health professional are almost 4-fold more likely to attempt to do so than those who do not receive such advice.[25]

In a pragmatic obesity trial, the responses of primary care providers to pre- and post-intervention surveys indicated that they tended to undervalue pharmacotherapy.[26] However, exposure to education and greater experience of pharmacotherapy resulted in a higher level of comfort and effectiveness in the use of weight-loss medications.

Lifestyle modification

The health benefits of a low-calorie diet, increased physical activity, and behavioural change extend beyond weight loss; as such, lifestyle modification is the foundation for improved health outcomes in the management of obesity (**Figure 1**).[5,21]

Lifestyle modification is effective for glycaemic control as well as weight loss.[27,28]. In a landmark study undertaken by the Diabetes Prevention Programme Research Group, one case of T2DM was prevented for every seven at-risk people (elevated fasting glucose and mean BMI of 34 kg/m²) treated for 3 years with a lifestyle modification programme (low-calorie, low-fat diet and exercise.[29]

Because weight loss requires a life-long commitment by patients to maintain lifestyle modification, long-term patient monitoring and support in primary care is recommended.[5] Nonetheless, many people struggle over time to maintain optimal glycaemic control and/or bodyweight with lifestyle alone).[27,30]

Adaptive neurohormonal mechanisms that function to maintain fat mass and the obesogenic environment in which people live have the net effect of promoting weight regain and undermining adherence to weight maintenance.[31-33]

The inability of many people to achieve and sustain lifestyle-induced weight loss emphasises the need for a multimodal approach to care in patients with obesity and T2DM.[24,34]

Pharmacotherapy

Weight-loss pharmacotherapy for the management of obesity should be considered an adjunct to lifestyle modification (**Figure 1**), just as it is for managing hypertension, diabetes, and CV disease, not as a replacement.[21] Moreover, if the rationale for using lifestyle modification to promote weight loss in patients with T2DM is to reduce HbA1c levels, it is reasonable to consider the use of drugs that have a primary effect on body weight rather than glycaemic control in patients with T2DM.[35]

The rationale for prescribing weight-loss medication is to help patients adhere to low-calorie diets and to reinforce lifestyle changes.[8] Familiarity with the available medications allows practitioners to balance the potential benefits of successful weight loss against the potential risks of the medication for each patient.

Use of weight-loss medication can facilitate initial weight loss and prevent weight regain in longer-term management of obesity.[5,24] Weight-loss pharmacotherapy can also offset weight gain associated with diabetes medications that have a propensity to cause weight gain, such as the sulfonylureas.[36,37]

In a real-world study that compared the short-term effectiveness of weight-loss medications adjunctive to lifestyle modification, patients lost a mean 3.5% body weight from baseline after 12 weeks.[38] As would be expected, the degree of weight loss was less than that seen in randomised clinical trials. However, the weight loss was still clinically meaningful. Of the four medications assessed, patients who received phentermine and phentermine/topiramate lost the highest percentage of body weight.

Weight management guidelines are consistent in advocating weight-loss medication as an adjunct to lifestyle modification for patients who fail to respond to lifestyle changes after 6 months, have a BMI ≥30 kg/m^2, or have a BMI >27 kg/m^2 with T2DM or other weight-associated comorbidities.[5,6,24]

Weight-loss medications

Three weight-loss medicines are approved (but not subsidised) as adjunctive treatment for weight loss (**Table 2**).[39-41]

Phentermine:

Phentermine is a sympathomimetic amine stimulant that acts on the CNS and suppresses appetite,[40] including greater reduction in cravings for fats and sweets compared with placebo.[42]

Greater effects on appetite suppression are achieved with lower-dose phentermine when it is combined with low-dose topiramate; however, this is an off-label use of topiramate in NZ.[5] In three phase III trials (EQUIP, CONQUER, and SEQUEL), treatment with phentermine in combination with topiramate produced statistically significant weight loss compared with placebo (5–10.5% at 1 year).[43]

Phentermine should not be used in patients with a history of CV disease due to its effects on the CV system.[5] Other contraindications include anxiety disorders, hyperthyroidism, history of drug or alcohol abuse or dependence, and pregnancy.

Liraglutide:

Liraglutide is a glucagon-like peptide-1 (GLP-1) agonist developed to treat T2DM as it controls hyperglycaemia without causing hypoglycaemia.[37] Its additional weight-loss effect, mediated by increasing satiety and reducing food intake, led to liraglutide (at the higher 3mg dose) being approved as a weight-loss medication.[37,41] Weight loss and glycaemic improvements with adjunctive liraglutide have been demonstrated in the SCALE trials.[44-48]

Liraglutide is administered by subcutaneous injection.[41] The most common adverse events associated with liraglutide are gastrointestinal disorders.[21,41] Liraglutide is contraindicated in severe renal or hepatic insufficiency, pregnancy, past history of pancreatitis, and past history of major depression or psychiatric disorder.

Orlistat:

Orlistat is a potent and selective inhibitor of pancreatic lipase that reduces the intestinal breakdown and absorption of dietary fat.[39]

Faecal fat loss and related gastrointestinal symptoms with orlistat are common,[39] and the main reason for discontinuation of orlistat.[21] Orlistat is contraindicated in patients with chronic malabsorption syndrome, cholestasis, and pregnancy.[39] Due to its mechanism of action, absorption of fat-soluble vitamins may be reduced and patients should be advised to supplement with multivitamins to ensure adequate nutrition.

	Dosage and administration	Weight loss vs placebo (% or kg)	Adverse events	Cost
Phentermine	15 or 30 mg once daily orally	3.6–4.5 kg at 6 months	Dry mouth, insomnia, agitation, constipation, tachycardia	$100 per month
Liraglutide	0.6–3.0 mg once daily by subcutaneous injection	5.4% at 1 year	Nausea, vomiting, diarrhoea, constipation Rare: cholecystitis, pancreatitis	$500 per month
Orlistat	120 mg three-times daily orally	2.9–3.4% at 1 year	Steatorrhea, oily spotting, flatulence with discharge, faecal incontinence, fat-soluble vitamin malabsorption	$150 per month

Table 2. Summary of the weight-loss medications that are approved for the management of obesity in NZ.[21,37,39-41]

Treatment duration

Patients should be monitored monthly for the first three or four months of pharmacotherapy and its efficacy and tolerability evaluated at the end of three or four months.[5,8,21] The emergence of a safety or clinically-significant tolerability issue requires immediate discontinuation of pharmacotherapy.

A weight-loss medication that is well tolerated and effective should be continued, in the same way that antihypertensive and antidiabetic medications are continued after blood pressure or glycaemic targets have been achieved.[21] Given that obesity is a chronic disease that requires prolonged treatment, pharmacotherapy has an important role to play in long-term weight control.

Pharmacotherapy should be continued in patients who have achieved clinical benefit, e.g., ≥5% weight loss.[5,6] If clinical improvement is determined to be insufficient after 3–4 months with one weight-loss medication, increasing the medication dose (if applicable) or use of an alternative medication should be considered.[8,49]

Despite the efficacy of weight-loss pharmacotherapy being well established there is, in general, a reluctance to start weight-loss medications and a propensity to stop them.[21] One of the reasons may be concern about long-term adverse effects, especially safety issues related to CV and mental health. However, to date, no safety signals have emerged to suggest that any of the currently approved medications are not suitable for use in the long-term management of weight, especially if pharmacotherapy is individualised and appropriately monitored.

There is also a role for pharmacotherapy as an adjunct to metabolic surgery when additional weight loss is required or to prevent weight regain after weight loss surgery.[50]

Combination with metabolic surgery

As with pharmacotherapy, metabolic surgery is used as an adjunct to lifestyle modification in weight management (**Figure 1**).[5,6,24] Publicly-funded metabolic surgery is an option for select patients with weight <160kg and BMI <55 kg/m^2 or individuals with a BMI >35 kg/m^2 in the presence of comorbidities, who are motivated to maintain lifelong dietary and other lifestyle changes.[5]

Weight loss with metabolic surgery is associated with improvements in T2DM,[5] including remission of T2DM.[16,22] In the STAMPEDE trial, 5-year outcome data showed that metabolic surgery was more effective than medical management for patients with obesity and T2DM.[51] However, the weight loss and glycaemic benefits of metabolic surgery may attentuate with time, with some people observing relapse of T2DM after an initial period of remission.[34,52]

With novel classes of weight-loss medication now available, and emerging evidence of benefit when given post-bariatric surgery, adjunctive use of pharmacotherapy to manage weight regain following surgery should be considered.[53]

Conclusions

Weight loss maintenance is difficult with lifestyle modification alone and may require adjunctive therapies. There is good evidence for the efficacy and tolerability of approved weight-loss pharmacotherapies in individuals with T2DM.

Given the link between obesity and T2DM, a weight-centric therapeutic approach including use of anti-obesity pharmacotherapies and weight-reducing anti-diabetes therapies is both intuitive and rational to improve glycaemic and other metabolic outcomes in patients with obesity and T2DM.

Weight Loss Pharmacotherapy for Obesity and Type 2 Diabetes

EXPERT'S CONCLUDING COMMENTS

Obesity is a prevalent condition and is a risk factor for many complications that need to be screened for and managed in primary care. It is important to monitor weight and discuss how to lose weight as part of clinical care. Discussing medication options after lifestyle strategies is an important part of obesity management.

Weight-loss medications may be an effective option for those who do not have contraindications and can afford these. Adults, including those who have headaches, may benefit from topiramate in combination with low-dose phentermine because this combination has been shown to produce superior weight loss when compared with either agent alone. However, it is important to ensure women of childbearing age are taking reliable contraception, given both medications are contraindicated in pregnancy.

Liraglutide requires subcutaneous injection, and may be prescribed to those with pre-existing CV disease. Liraglutide 1.8mg daily is approved for the treatment of T2DM, while the higher dose of 3mg daily is approved for the treatment of obesity. There is a greater weight loss benefit at the 3mg dose than the 1.8mg dose, which is independent of its side effects of nausea.

It is important to monitor side-effects and response to drug therapy, observing the stopping rule if your patient does not lose ≥5% of weight after 12 weeks on the full dose of the medication. Since early weight loss response is predictive of subsequent effectiveness, it is best to stop any medications among non-responders at the 12-week mark.

Since obesity is a chronic condition, most people will need to take weight-loss medications long term in the context of lifestyle management of food activity and behaviour.

Phentermine or liraglutide can be used in combination with a low-energy diet and among those patients who regain weight following bariatric surgery.

TAKE HOME MESSAGES

- Obesity is a chronic metabolic disease with T2DM being a common comorbidity.
- Primary care engagement positively influences patient attempts to change and sustain weight-related behaviours.
- Preventing progression to T2DM and inducing remission of T2DM are viable treatment goals in obese individuals.
- Lifestyle modification is the foundation of obesity and T2DM management but is not always effective in providing lasting weight loss success.
- As with other chronic diseases, interventions beyond lifestyle modification are needed to achieve and sustain beneficial outcomes in patients with obesity.
- Given the link between obesity and T2DM, use of weight-loss pharmacotherapy is rational to improve glycaemic and other metabolic outcomes in obese patients with T2DM.
- Weight loss medications registered in NZ as an adjunct to lifestyle modification are:
  - Phentermine, which acts to suppress appetite.
  - Liraglutide, which acts to increase satiety.
  - Orlistat, which reduces intestinal absorption of dietary fat.
- Pharmacotherapy augments lifestyle modification and has a useful role to play in the long-term management of obesity.
- Metabolic surgery as an adjunct to lifestyle modification is an effective weight loss intervention in select individuals but its beneficial effects may diminish with time.
- Adjunctive pharmacotherapy may help to sustain the weight loss and glycaemic benefits of metabolic surgery.

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