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Supporting healthcare professionals in their war against obesity

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Editor

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The European Commission published a Green paper in December 2005 entitled 'Promoting healthy diets and physical activity: a European dimension for the prevention of overweight, chronic diseases.' The opening statement which describes the state of play at European level, reads as follows: Unhealthy diets and lack of physical activity are the leading causes of avoidable illness and premature death in Europe, and the rising prevalence of obesity across Europe is a major public health concern.¹ The latter statement perfectly describes the situation in our country; a situation which needs to be seriously addressed and tackled on a number of fronts.

This document proceeds to highlight a number of areas for action, one of which is the intervention by health care professionals aimed at improving patients' understanding of the relations between diet, physical activity and health and introducing necessary lifestyle changes. Health care professionals are encouraged to offer advice to patients and their families on the benefits of optimal diets and increased levels of physical activity on routine contacts with patients.

Based on The European Commission's latter recommendation, The Malta College of Pharmacy Practice felt the need to publish a special Journal supplement dedicated to nutrition. The aims of this publication are to (i) highlight nutritional issues, especially the problem of obesity, (ii) support the country's policy in this area (iii) increase the awareness of health care professionals and (iv) provide health care professionals with the necessary practical information on which to base their routine interventions

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related to weight management. The ultimate aim is however, for health care professionals to have a sustained positive impact on society.

Together with two guest editors, who are both pharmacists and nutritionists, a multidisciplinary team was invited to contribute to this supplement. The editorial by Gauden Galea, who has recently been appointed to the top post of Coordinator, Health Promotion within the World Health Organisation, has emphasised the leadership position of the pharmacist in health care and the duty of the pharmacist as health promoter. A leading international Public Health expert, Geof Rayner, provides an excellent overview of the challenge of tackling obesity. The paper provides us with significant food for thought, promoting both governmental action as well as stating that the policy should be 'owned' by the population. While addressing childhood obesity in Malta, Victor Grech also discusses the costs of obesity; an important aspect which requires serious consideration in the debate. Josanne Vassallo gives a comprehensive review of the pathogenesis of obesity, including recent findings and highlights the genetics of obesity.

A very practical paper by Roberta Borg Costanzi provides us with the tools for routine interventions to be performed in overweight individuals. This paper explains how the simple action of measuring waist circumference provides an even better indicator of cardiovascular risk than the more complex calculation of body mass index. Vanessa Bugeja reports findings of an evaluation of a weight reduction programme indicating that the model used was successful in empowering people to change their eating habits and lifestyle. In cases of morbid obesity, diet and lifestyle change may not be sufficiently effective. Eileen Vella presents the pharmacological options currently available to achieve weight loss in the latter situation. The estimated prevalence of diabetes mellitus in Malta is 11.6%, putting us in the top tier of the EU 25.² Hence the importance and relevance of the paper by Mario Caruana which reviews the nutritional recommendations for people with diabetes.

Other nutritional aspects are addressed in this publication and these include the paper by Corinne Bowman regarding the administration of drugs to patients with swallowing difficulties. This paper mainly

highlights the problems associated with patients who need to use an enteral feeding tube and also includes an interesting section on drug-food interactions. Nutritional supplements are widely available and in high demand by the general public. Mario Sammut examines the evidence supporting the use of combined oral glucosamine and chondroitin in osteoarthritis. While the results are encouraging, further study is warranted in this area.

This publication should serve to motivate readers into action. Health care professionals should contribute to our community by taking up the challenge and being proactive in this area. They should lead by example, 'own' the country's policies and intervene at every possible opportunity.

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Malta: an obesogenic island in the Mediterranean

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It would be archeologically correct to state that Malta's history denotes goddesses of fertility with body mass indices that prove obesity was most likely present in the earliest civilizations of early human settlement on these islands.

Vassallo's paper on the pathogenesis of obesity might give some explanation as to why the problem of obesity exists with us till this very date and to such an extent that Malta is amongst the top of the league table both at the European as well as at the global level. This issue of the MCPP journal has ventured into one of the global public health epidemics of this millennium. Obesity reduces the quality of the lives it afflicts and presents a socioeconomic burden for governments.

Currently Malta can be described as having an obesogenic environment that is one which favours the propagation of obesity due to the accent of the food supply and the limited infrastructure for active living. By addressing the key determinants of obesity, the problem will be attacked from its core roots and thereby provide long term favourable results in health outcomes and the corresponding socioeconomic indicators.

The World Health Organization has just convened a major European ministerial conference in Istanbul and the resulting *European Charter on Counteracting Obesity* was signed by the member states. The Charter outlines the action needed to counteract obesity underscoring the urgent need for intersectoral action to reverse the current trend in obesity. The charter provides guidance for future policy through a series of action points.

The European Commission has also taken an active role in the arena of food, nutrition and physical activity through the establishment of a European Platform for Action on Diet, Physical Activity and Health and the subsequent release of a Green paper "Promoting healthy diets and physical activity: a European dimension for the prevention of overweight, obesity and chronic diseases." Both tools have served well in launching a broad consultation

amongst interested parties as well as in developing a comprehensive European nutrition and physical activity strategy.

Through the adoption and implementation of tools provided by WHO and the European Commission, Malta should be able to gradually reverse the trend of obesity both in children and in adults. This will entail the promotion of healthy eating and physical activity as well as the clinical management of the obese. Not doing so would result in a drain of public finances as argued in the paper submitted by Grech. The treatment of obesity and overweight in primary and secondary care needs to be cost effective and models of good practice employed.

We augur that this issue is of interest to all practitioners in public health and also at the individual level it would enhance advocacy for healthy living.

Addressing the nutrition extremes

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Food is essential for health and survival of the human body. This is the main concept behind the subject of nutritional science.

Looking back briefly at the history of Nutrition many would agree that one of the major breakthroughs in Nutrition and the use of Nutrition therapy was the first controlled therapeutic trial conducted by James Lind in 1747 to successfully treat scurvy on twelve patients at sea.

By the mid twentieth century, changes in the concept of Nutrition were introduced and the emphasis was placed on the prevention of nutritional deficiency, especially in post war Britain.

As time moved on, there was a gradual shift from rationing to surplus food in developed countries and this leads us to the current emphasis on dietary guidelines and healthy eating.

In recent years the move from having a sufficient to an excess of food supply in developed countries has meant a change in the nutritional status in these populations - a change from under-nutrition to over-nutrition.

However, in situations of morbid obesity, a healthy balanced diet coupled with increased physical activity may not be enough to achieve desired weight loss. Eileen Vella highlights the next step-pharmacological treatment of obesity and indications for use.

Many diet related conditions we are faced with today are linked to obesity. This has led to the need for more precise methods of nutritional assessment to measure the risk of developing obesity

related conditions such as diabetes and heart disease.

Mario Caruana expertly guides us through the changes which have occurred in the nutrition guidelines for diabetes and explains the role of the multidisciplinary team in diabetes management.

However we must not make the mistake of thinking that the days of malnutrition are over. The World Health Organisation has recently stated that half the children's deaths (53%) in developing countries are linked to poor nutrition. It seems then that we are experiencing two extremes of nutrition with related co-morbidity and mortality. It is up to us as healthcare professionals to find the right tools to diagnose and effectively treat these extremes.

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Seven star pharmacists

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The seven star pharmacist is care-giver, decision-maker, communicator, manager, life-long-learner, teacher and leader.¹ Implicit in these roles is that of health promoter. The pharmacist's continuing relationship with the client, the community-based practice, and multiple entry points for counselling make the pharmacist a leader in health care.

These features also make the pharmacist a potential leader in prevention. None of this is new to the profession. Not many pharmacists may have reflected that, in prevention, the leadership role is two-fold, a formal function (leadership through giving high quality advice) and an informal one (leadership by example).

The issue of obesity in Malta puts this leadership role in the spotlight. The levels of obesity in children², adults³, and the elderly⁴ are making a name for the country as a leader in the prevalence stakes. High

levels of obesity pose a huge threat to personal and national health; resulting in a large present and future preventable burden of disease. A profession that is at the forefront of prevention, needs to question its own behaviour and ask: can a seven star pharmacist afford to be overweight? The challenge I put forward here is thus threefold. First, the pharmacist needs to be informed about the causes of overweight and obesity and acquire the skills to be an effective counselor. Second, the pharmacist needs to critically evaluate the importance

of comprehensive lifestyle change versus possibly more lucrative weight-loss-in-a-box diets. Third, pharmacists need to take a measuring tape to their waist and ask: am I truly walking the talk on the issue of overweight?

Are you unhappy with your girth? Interested in walking the talk? In a simplified Transtheoretical Behaviour Change⁵ model, I propose four stages of weight loss for pharmacists:

- a) **Decide.** In the first phase consider the evidence for your own health. Weight reduction, even if modest, is associated with major improvements in health. In the American and Finnish^{6,7} studies on the prevention of diabetes, approximately 4-5 kg of sustained weight loss was associated with a 58% reduction in the incidence of diabetes. Apart from the personal benefit, think of the satisfaction of a more svelte body image, as well as the responsibility of being a community leader who gives advice that is consistent with their own practice.
- b) **Prepare.** Avoid any temptation to "go on a diet" even if you can get the sachets for free. The sustained improvement will come from small but persistent changes in diet and physical activity. Plan these in advance. Consider making the changes in public, possibly getting family, friends or clients to join. It is easier to remain true to your own resolve if you stand to be embarrassed by your behaviour in front of others.
- c) **Act.** There are many simple actions to reduce the energy intake and increase consumption. Make sure you never miss breakfast. Spread the meals in smaller portions throughout the day. At buffets, use a saucer for your main course. Make sure all plates (at home or eating out) are filled with a variety of colours as this increases fruits and vegetables. Never have a second helping of anything. In the period of weight loss, make sure you add half an hour of vigorous exercise every day. The general advice of walking for half and hour daily is important for everyone in the population but it is only with vigorous exercise that you will lose weight.

d) **Sustain the Weight Loss.** It is remarkable how much weight can be lost with these simple lines of advice. True to my own advice, I lost 20 kg in 2003 following only this advice – you may want to do the same. The more difficult challenge is to keep it off beyond the triumphant feeling on the first months. Keep a visual record of the weight loss and go back to your album for moral support. Consider how quickly you stopped snoring (as the fat off the palate is the first to disappear). Keep giving public advice and refer to yourself as the example – it adds to your worth as a concerned professional and gives you the added impetus to keep it going.

In a country where overweight is taking over, health professionals must feel the need to walk the talk. In the same way as it is today unthinkable for a pharmacist to smoke in front of their clients, so may, one day, it be unthinkable that they appear overweight or obese. Let's look forward to a time when the Maltese pharmacy profession adds another attribute to the list, may all pharmacists be seven star, and slim.

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Tackling obesity: the big challenge

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Keywords: obesity, nutrition, diet, culture, public health

Obesity has risen rapidly in parts of Europe, following the USA. Now classified as a disease by the World Health Organisation, this article argues that the problem has roots in profound societal transitions in the sphere of diet, the physical environment and culture. It was once considered that the countries of the Mediterranean basin had the best diet in Europe and were therefore more protected against diet-related chronic diseases. In fact child obesity is higher in Mediterranean countries, including Malta, than most other European countries and very much higher than the Baltic states, which have always been considered to have a poor diet. It is argued that the consequences for society are profound and that an equally profound policy strategy is called for.

Introduction

Why is obesity a problem? For whom? Where did it come from? These outwardly simple questions can be addressed to a seemingly straightforward topic; after all obesity is the result of energy imbalance: eating too much and doing too little. This article will argue that in fact the causes of obesity are far more complex, being rooted in an immense, if recent, process of societal change. Obesity is now a major problem for Europe, not only for countries highly influenced by the 'Americanised' diet and lifestyle, but for countries once noted for healthy diets, such as the countries of the Mediterranean basin, including Malta, which today has one of the highest rates of child obesity.

It is argued here that in order to understand obesity, we have to comprehend three major societal transitions, those occurring in diet, the physical environment and culture. While there are many

opportunities for health professionals to take action at the individual and community level, the evidence suggests that halting, let alone reversing, obesity will require a society-wide set of measures.

Discussion

Half a century ago, in the years following World War II, millions of Europeans went hungry and obesity as a medical condition appeared little more than a curiosity. These events framed the determination to rebuild agriculture (albeit in different ways) often with large subsidies and create a favourable environment for agri-business.¹⁻³ Even just a decade ago, with most of Europe more than adequately fed and EU farming policy consuming almost half of the EU budget, the average politician might have remarked that obesity was an irrelevance. To find a comparable society suffering from obesity meant travelling to the USA.

Until just two decades ago it might still have been argued that Europe was immune to the rising obesity but today it is obvious – the use of the eyes alone provides the evidence – that Europe is steadily succumbing to rising obesity trends and the factors which many think drive such trends: the 'Americanisation' of diet and society: the rise and rise of car culture and other technical 'advances', including screen based entertainment targeted at children, which marginalise daily physical activity; the over-consumption of food accompanied by its unprecedented, plentiful availability; the culture of clever and constant food advertising; the shift from meal-time eating to permanent 'grazing'; the replacement of water by sugary soft drinks; the rising influence of large commercial concerns framing what is available and what sells; and more.⁴⁻⁷

Copious evidence now exists that both adults and children are affected by rising weight. In Europe much attention has been given to the UK. The UK – with almost two-thirds of the adult population overweight – is now one of the leading countries for population weight gain, although there is still considerable variation in trends across Europe.⁸ Most worryingly, the biggest national weight increases among children have been in countries of the Mediterranean basin, such as Greece and Spain, previously justly celebrated for their Mediterranean diets, high in vegetables, pulses and unrefined carbohydrates, culturally close to the land.⁹ Among these, Malta, the smallest EU country, appears to have perhaps the largest problem. According to data drawn from the 34 (primarily European) participating countries of the 2001–2002 *Health Behaviour in School-Aged Children Study*, the two countries with the highest prevalence of overweight (pre-obese + obese) and obese youth were Malta (25.4% and 7.9%) and the United States (25.1% and 6.8%).¹⁰ In contrast the two countries with the lowest prevalence were the small Baltic states of Lithuania (5.1% and 0.4%) and Latvia (5.9% and 0.5%) – countries of short summers and long winters and not usually known for healthy diets.

Why has this come about? And why are some countries apparently more vulnerable than others? There are some

common elements which might explain the growing trend although there is still considerable variation from country to country in the range of determinants. Given that the culture of the Mediterranean diet no longer appears to provide protection, an explanation must be sought in factors outside this. In comparing Malta with Lithuania, for example, questions might be asked about how far young people have changed their diet, to what degree youngsters in the country engage in active physical activity or the degree to which the way of life encourages everyday activity in contrast with a passive, screen-based culture. Although much of the obesity scientific literature attempts to separate the separate factors a more satisfactory approach might be to consider how factors combine.

Although obesity is highly complex, there are some core truths on which thinking can be developed:

- Obesity is now a world-wide phenomenon but it is concentrated in some parts of Europe rather than others, and there is a particularly worrying acceleration of rates among children.¹¹
- Obesity is known to lead to medical problems, long documented although only formally classified by WHO in 1997.¹²
- There are serious and rising social and financial burdens stemming both directly and indirectly from obesity.¹³
- Obesity is linked to – either accelerated or caused by – other societal trends and risks, such as changed food production, motorised transportation and work-home and lifestyle patterns.^{12,14-16}
- Policy-makers have been slow to recognise the seriousness of the issue, which suggests the health community has been slow or ineffective in its advocacy work or that the evidence is not easily translatable into policy or that the tackling of obesity lacks political champions.^{17,18}
- Remedies based upon individual action alone, from diet plans, drugs, surgery or stigma, have limited effectiveness in population terms and often come at high cost.
- There is a powerful temptation in government to limit actions to a choice-based, personalisation approach; in part because this style of intervention is

aligned to the commercial sector's own customer-management and marketing methods but also because a cross-society approach appears so big in conception that it appears too high risk.^{19,20}

- Despite some welcome initiatives,²¹ there are, as yet, no comprehensive structures or set of policy models for *what really to do about obesity*. We are generally still at the 'talking stage' of policy, albeit with some specific initiatives in different parts of Europe, rather than well into implementation.
- Food companies are not adequately changing their behaviour in response to the request to do so by the World Health Organisation under its Global Strategy on Diet, Physical Activity and Health. On the contrary, there is evidence that the big food companies are for the most part unconcerned.¹⁹
- Part of the difficulty in generating effective policy is having a policy package which will deliver a corrective population-wide shift.^{8,22,23}

Among the conceptual models around obesity, the insightfully-termed Nutrition Transition²⁴⁻²⁶ appears the strongest. It has emerged as a central focus of research and policy thinking in the developing world and within the World Health Organization. Despite its strong merits it deserves to be conceptually unbundled. The Nutrition Transition is not one process but, in our opinion, three transitions of:

- Diet;
- Management of, and human interface with, the physical environment; and
- Culture.

These three transitions overlap, combine and amplify each to the other. There is little chance of any obesity policy being effective unless all three domains are tackled. Policy interventions should be judged from the perspective of these transitions, rather than in some isolated or disconnected way which has the potential allure of inoffensiveness or apparently quick results. At its simplest level, anti-obesity strategy will have to tackle diet and physical (in)activity. If the scientific endeavour focuses on unravelling their complex interplay what is often missed out is the role of the third transition, the cultural dimension that bonds diet and physical activity.^{20,27}

The role of health professions

In an ideal world, health considerations would apply to all governmental policy making; in fact, health considerations are usually the least important factors in determining policy. A more likely candidate for determining the shape of obesity policy is cost. For example in the US the Surgeon General notes that obesity is currently costing up to 6% of healthcare budgets, a figure now exceeding \$100 billion.²⁸ In the US obesity is predicted to soon overtake the toll of tobacco.²⁹ In Europe the cost of obesity is now being counted and projections are being formulated.³⁰ Cost considerations do not explain however the appeal to policy-makers of taking a science-based, though in fact medicalised route of individualised treatment, through drugs, therapy, and at the most extreme, bariatric surgery.

Even if government is committed to more radical action, dealing with obesity is difficult for a variety of reasons: the drivers of obesity, as noted, are profoundly wedded to processes of societal change which are now seemingly embedded. Thus, failure to act at an early stage has already produced immense and undesirable consequences since obesity is profoundly difficult to reverse as young people move into adulthood. Hence, as the numbers grow obesity is being socially 'normalised' – even as the trends accelerate and the evidence grows.

As ever in health matters, hope is placed in the accumulation of evidence about 'what works'. However the few intervention trials in prevention of obesity which focus on children or schools (in Crete, Agita Sao Paulo, Singapore, Minnesota)⁸ give little ground for optimism. It has been suggested that strategies like Epoque in France, a 'national to local' model giving an important role to local mayors, or the community development approaches in Australia may in some instances be halting obesity, but there is little indication – although full evaluations have yet to appear – that they are reversing its impact. Although there is a literature of action on different factors such as price, marketing, education, supply,³¹ no mass societal policy intervention has taken a 'full spectrum' approach.³² Most policy overviews suggest that efforts to combat the epidemic have

to be society-wide, extensive and deep.^{8,33} In any terms, refurbishment of health promotion and health development is required, demanding significant alteration of supply chains, product marketing, the constituents of daily existence, indeed whole cultures.

If obesity prevention becomes a genuine policy, engaged with and delivered across government, society and commerce, its accomplishment will require a major paradigm shift, based on principles designed to:³⁴⁻³⁶

- take a whole system rather than partial approach.
- reshape not just the physical and dietary environment but also the social and cultural environments.
- adopt a long-term strategy by asking what an anti-obesogenic environment might look like and then draw out the policy changes needed to deliver it.
- recognise the fundamental nature of the challenge posed and give due political priority to building alliances that could

overcome the obesogenic social forces (as was done for tobacco in a long 50-year process).

- reformulate the roles of government, markets and consumers to shift them away from reinforcing obesity.
- deliver a situation where prevention is the norm, where victim-blaming is unacceptable but responsibility not avoided.
- engage multi-sector, multi-agency action within and beyond the public health professional discourse.

Conclusion

It has been argued that obesity is emerging as a major disease in Europe and that its determinants are rooted in societal change. Gaining weight might not be perceived as just an individualised pathology or even a pathology at all; indeed it could be described as a normal response to an environment which supplies the wrong foods too cheaply and which encourages people to do physically less.

Consequently, while the role of professions in preventing and mitigating the impact of obesity does need consideration, the major response of the health professions must be that of policy advocacy: promoting policy change and promoting social debate on the way forward. The rapid and continuous upward trend in prevalence, it has been argued, demands governmental action. Nevertheless while actions should be led from the higher reaches of government, this policy should also be 'owned' by the population, and particularly young people. In this regard the promotion of a healthy, active society and the building of cultural resistance to obesity requires a long term vision which demands resources, financial and political. Only if obesity is seen as a shared societal problem - 'everyone's business' - and not merely the 'fault' of the people most affected, can an overall response be formulated which acts to break down policy blockages and the refusal to appreciate the nature and the seriousness of the threat.

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Childhood obesity: a critical Maltese health issue

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Overweight and obesity are epidemic and worldwide, at all ages, particularly in Westernised societies. Malta is no exception and indeed, leads this trend. The direct, indirect and long term health risks for the individual and population as a whole are indisputable. Unless tackled, the current Maltese obesity trends will result in an astronomical increase in morbidity and mortality from ischaemic heart disease, stroke and cancers with an estimated crippling additional health budget requirement of at least Lm33.6million per annum. Obesity is arguably the greatest current national health crisis, and a seriously-funded, all-front national campaign must be implemented with urgency in order to assess and address the crisis at all levels including prevention, lifestyle issues and therapy, with outcome monitoring of national interventions and campaigns.

Introduction

Excessive body weight is caused by food intake surplus to energy requirements with the resultant deposition of adipose tissue, and is heavily influenced by a plethora of interconnected factors that include genetic, physiologic, metabolic, social, behavioral, and cultural factors.¹ Genetic factors are

particularly influential with overweight being a 70% inherited trait.²

Overweight is defined as body mass index (BMI) between the upper 85th to 95th percentiles while obesity is defined as BMI greater than the 95th percentile.

Being overweight is not a cosmetic issue and indeed, obesity and overweight

are better viewed as potentially malignant, chronic health conditions since they are independent risk factors for morbidity and mortality. Unfortunately, this condition is manifesting in epidemic proportions, and at ever younger ages with an estimated worldwide overweight childhood (<5 years of age) population of 22 million.³ Up to 250 million people worldwide (7% of the global population) are obese.⁴

Childhood obesity is particularly crucial as obese children down to the age of 5-10 years have been shown to manifest one or more cardiovascular risk factors such as hypertension, hyperlipidaemia, insulin resistance, frank diabetes (almost a fifth of all type 2 diabetes is being diagnosed in the paediatric age group⁵) or the metabolic syndrome.⁶ Specifically, 60% of overweight children have been shown to have one such risk factor and 20% manifest two or more risk factors.⁷

In many ways, obesity is a self-perpetuating condition. It tracks into adulthood in at least a third of cases.⁸ Moreover, overweight and obesity in pregnancy predispose to gestational diabetes which tends to produce neonates that are large for gestational age,⁹ and high birth weight is itself a predictor of overweight and obesity in adult life, thereby completing the circle.

The association of obesity with cancer is high and should not be eclipsed by cardiovascular complications. In the United States, it has been estimated that overweight and obesity account for up to 20% of all cancer deaths in women and 14% in men. Such cancers include those of the uterus, kidney, esophagus, gallbladder, colon and rectum, breast (in postmenopausal women), liver, pancreas, prostate, cervix, ovary, and stomach (in men), non-Hodgkin lymphoma and multiple myeloma. Obesity compounds cancer by independently increasing cancer mortality.¹⁰

Overweight and obesity statistics are increasing worldwide, in all age groups, and particularly in the lower socioeconomic groups,¹¹ where other cardiovascular risk factors, such as smoking, are likelier to be present.¹²



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Childhood obesity is caused by two main factors:

1. Poor diet: fast foods are quicker to prepare and cheaper to buy.
2. Lack of exercise: at least 30 minutes of moderate physical activity on most days of the week is the recommended minimum. However, nearly a quarter of children and nearly half of adults get no free-time physical activity at all.

Surprisingly, childhood obesity is also skyrocketing in developing countries, with 8% of Northern African children being overweight. Similarly, in South America, 5% of pre-schoolchildren are overweight while the percentage of undernourished children (< 3rd percentile of weight for age) has dropped to under 2%.¹³

Malta unfortunately leads trends in childhood obesity in that a recent systematic review comparing estimates of the prevalence of overweight and obesity in school-aged youth from 34 countries participating in the 2001-2002 Health Behaviour in School-Aged Children Study showed that Malta topped the list with the highest prevalence of overweight (pre-obese + obese) and obese youth at 25.4% and 7.9% respectively, followed by the United States at 25.1% and 6.8% respectively.¹⁴

Non-cardiovascular and non-malignant co-morbidities associated with childhood obesity include:

1. Sleep apnoea with poor attention at school.
2. Orthopaedic problems including tibia vara, slipped femoral capital epiphysis, genu valgum, flat kneecap pressure/pain, flat foot, spondylolisthesis, scoliosis and osteoarthritis.
3. Skin problems particularly fungal skin infections and acanthosis nigricans.
4. Hepatic steatosis, gastro-oesophageal reflux, fatty liver (precursor to cirrhosis) are common gastrointestinal manifestations.
5. 'Benign' intracranial hypertension (pseudotumor cerebri) may independently cause blindness.
6. Psychological and behavioral problems including low self-esteem, depression, anxiety and bullying.

Practice Points

1. Obesity and overweight are potentially malignant, chronic health conditions.
2. Obese children become obese adults – 'puppy fat' is a myth.
3. Obese individuals who lose weight tend to relapse.
4. Prevention (particularly in childhood) is therefore the cheapest and most effective strategy. Proper diet and exercise are vital.
5. We must document Maltese childhood BMIs in order to gauge the severity of the local problem and monitor outcomes of national intervention and campaigns.

The cost of obesity can actually be quantified. For example, the direct costs represent approximately 7% of the total US health care expenditure. Preventable morbidity and mortality related to obesity is predicted to exceed those associated with cigarette smoking.¹⁵ For the EU, the direct and indirect annual costs of obesity account for €33 billion.¹⁶ Annual deaths attributable to overweight and obesity totaled 7.7% (1 in 13) of all deaths: 70% were cardiovascular deaths (195 000) and 20% were cancer deaths.¹⁷ A simple calculation shows us that when we completely catch up with the US (i.e. in the very near future), the cost to Maltese taxpayer will be Lm33.6 million per annum (Maltese population 400214, US population 298444215).

On a more positive note, the lifetime health and economic benefits of a sustained 10% reduction in body weight for men and women aged 35 to 64 with any degree of obesity have been calculated and are staggering: for example, a reduction in the expected lifetime incidence of coronary heart disease by 12 - down to 38 cases per 1000.¹⁸ However, an increased risk of cardiovascular disease remains in obese adolescents who lose their excess weight during the adult period.¹⁹

This paper has attempted to illustrate that it is crucial to tackle obesity in childhood. However, it is impossible to attempt to approach the subject without up-to-date information on national childhood BMI as this baseline information will not only tell us the magnitude of the problem, but will also allow us to gauge the effectiveness of any interventions that we may decide to carry out.

There are three levels of prevention for obesity:¹¹

Primordial prevention maintains normal BMI throughout childhood and adolescence

Primary prevention is directed toward preventing overweight children from becoming obese. Secondary prevention is directed at the treatment of obese children in order to reduce co-morbidities and to reverse overweight and obesity.

All must participate. Clinicians should screen all children presenting at routine visits by calculating and graphing BMI with appropriate dietary history and counseling. Parents should be made aware that they are their children's role models and that they themselves must therefore exemplify desired eating habits. Reinforcement is critical as 90% of obese children who lost weight eventually returned to their original weight percentile, further underscoring the importance of prevention.² However, primary care clinicians will only undertake obesity prevention and treatment with adequate resources and reimbursement.²⁰

Conclusion

Paediatric cardiology practice with the Maltese Health Division encompasses all paediatric cardiac patients in Malta, with the bulk being comprised of congenital heart disease. These individuals comprise a large followup cohort since the vast majority survive, and result in approximately 20 surgical operations a year and 40 cardiac catheter interventions. And yet, this is as nothing when compared with our obesity epidemic which will immensely deepen national healthcare bills. A baseline anthropometric study is mandatory, now. Prevention of obesity is of paramount importance, particularly in childhood. An interdisciplinary public health campaign at all levels is crucial, stressing the importance

of proper eating and lifestyle habits. Help should also be offered for obese individuals to lose weight and to treat co-morbidities. Only sincere political commitment will produce an impact on this disease.

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¹ Law M. *BMJ* 2000; 320: 861-864.
² Katan MB et al. *Mayo Clin Proc* 2003; 78: 965-978.
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Pathogenesis of obesity

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The escalating prevalence of obesity worldwide is an ever increasing source of concern to disease surveillance units, health monitoring agencies and healthcare providers globally. Resource allocation in healthcare has had to be tailored to the management of this global epidemic. However the key to success in tackling this problem lies in prevention and this in itself mandates a thorough understanding of the physiology of weight control and the pathogenesis of obesity. The development of obesity is undoubtedly multifactorial with the major underlying causes being inappropriate diet and lifestyle. Genetic factors have been shown to modulate the phenotypic expression of obesity. Medications such as steroids and endocrine disorders such as hypothyroidism can also lead to disturbances in the normal physiology of weight control in a small percentage of instances. However in the vast majority of weight problems and obesity, the aetiology is a mismatch between food intake and energy expenditure.

The physiological basis of obesity

A complex feedback control system consisting of a central processing unit which receives afferent signals and generates appropriate efferent stimuli in response controls food intake, satiety and subsequently weight.

Age and gender differences in food intake have been identified with an increase in adolescence, peaking in the second decade after which it declines.¹ Men tend to eat more than women in keeping with their higher fat free mass.² An age-related decrease in food intake is associated with a slow decline in energy

expenditure and in middle age the latter is faster than the former. Concomitantly the decline in sex steroid levels occurring in the perimenopause results in an increase in visceral fat and an increased risk of the development of the metabolic syndrome (Figure 1). The latter is a constellation of manifestations originally described by Gerald Reaven in 1993 comprising obesity, insulin resistance and increased atherosclerotic risk with diabetes, hypertension and hyperlipidaemia.³

The regulatory control system

The feedback system regulating body weight and appetite is the target of ongoing intense research with appreciation of the complexity of this system increasing as new modulators and players are identified.

Afferent signals

Gastric distension via activation of vagal afferents is a signal for satiety, with gastric contractions signalling for hunger. Nutrients, neural impulses and hormones themselves act as afferent signals in the regulation of energy intake and expenditure (Figure 2). Nutrient absorption eg that of glucose⁴ initiates a sensation of satiety whereas a fall in glucose promotes hunger. This effect is itself mediated by different neurotransmitters, hormones and peptides

Leptin⁵ is a peptide produced by adipocytes which has been closely correlated with fat mass, with secretion increasing as fat deposition increases. It acts to reduce food intake and is believed to increase sympathetic nervous system activity.⁶ This peptide has found use in a small number of individuals who have been shown to be deficient in the leptin gene.

Another important peptide is Growth Hormone (GH) relin which is secreted by the stomach and duodenum and has been shown to stimulate GH secretion. It is an endogenous ligand for the GH receptor. GH relin increases food intake and its secretion is in turn suppressed by food intake.⁷⁻⁹ Serum concentrations increase in anticipation of a meal. Its secretion has been shown to increase after diet- and exercise-induced weight loss and is believed to be one of the reasons why lifestyle modification does not lead to permanent weight loss.

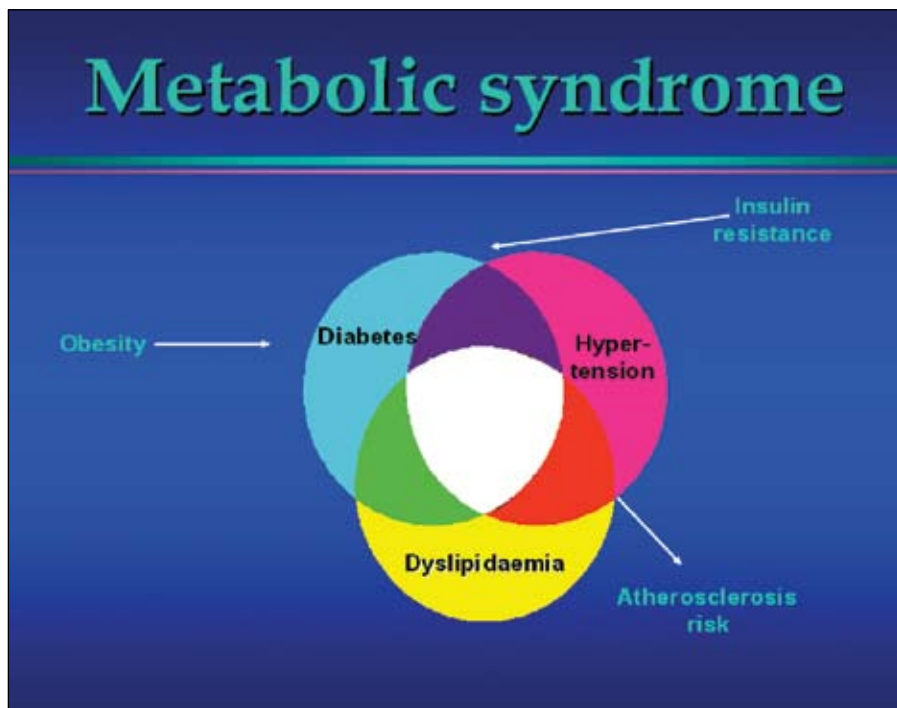


Figure 1: Features of the metabolic syndrome

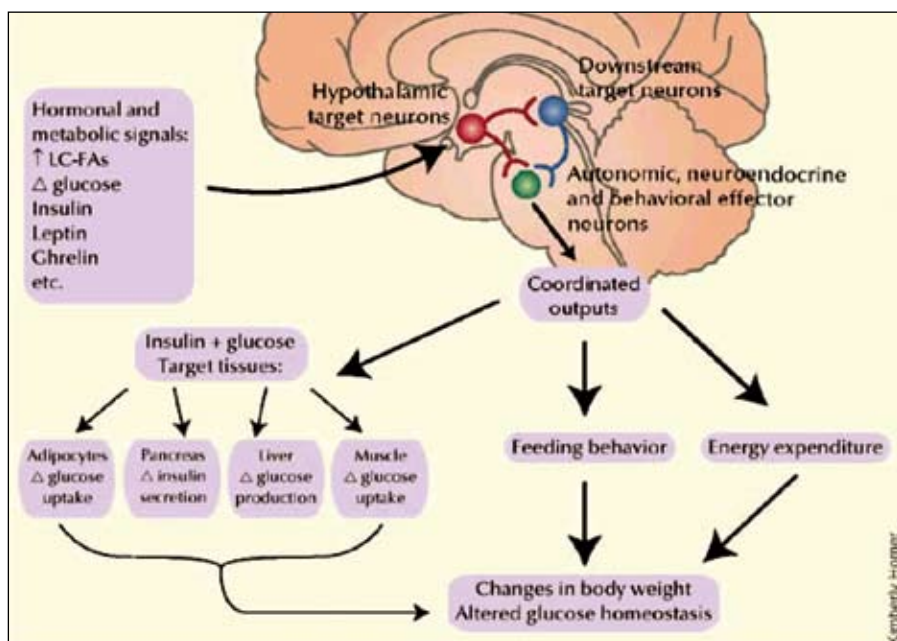


Figure 2: Overview of the integrated regulatory pathway

Table 1: Monoamines and peptides that affect feeding	
Stimulatory	Inhibitory
GH releasing hormone	Leptin
Neuropeptide Y	Cholecystikinin
Melanin-concentrating hormone	Enterostatin
Opioids	Serotonin
Norepinephrine	CRH/urocortin
	Alpha melanocyte stimulating hormone
	Glucagon-like peptide 1

Other peptides that have been shown to reduce food intake are cholecystikinin (CCK),¹⁰ enterostatin¹¹ and polypeptide Y 3-36.¹² The list of peptides is ever on the increase but the precise interaction between them and their relevance in humans awaits the outcome of further research (Table 1).

Central processing unit

Afferent impulses proceed centrally to the hindbrain and the hypothalamus for integration and processing. A number of specific anatomical sites have been implicated as a result of *in vivo* studies generally involving destruction of the said area and observation of outcomes.¹³ The nucleus of the tractus solitarius in the hindbrain is the site where vagal and other neural input are integrated.

The arcuate nucleus at the base of the hypothalamus receives signals from leptin and in turn increases both production and secretion of neuropeptide Y (NPY) and Agouti-related peptide (AgRP) thereby increasing food intake. On the other hand, cocaine-amphetamine-related transcript (CART) and pro-opiomelanocortin (POMC) decrease food intake.

The paraventricular nucleus of the hypothalamus is itself stimulated by peptides from arcuate nucleus and relays signals further. Destruction of the ventromedial hypothalamus has been shown to lead to increased food intake and subsequently obesity in animals treated experimentally. The lateral hypothalamic nucleus in turn exerts opposite effects such as decreased feeding and lowering body weight. Furthermore specific areas of the amygdale can affect feeding partially through the ventromedial hypothalamus.

Efferent mediators

The peripheral nervous system has a definite role in stimulating thermogenic tissues via activation of beta 3 adrenergic receptors resulting in a reduction in food intake.¹⁴ The sympathetic nervous system plays a tonic role in maintaining energy expenditure. Amongst the hormones that interact at the efferent end of the regulatory system, glucocorticoids are believed to play an important permissive role¹⁵ these effects possibly mediated via the sympathetic nervous system. For

example, it has been noted that leptin deficiency does not result in obesity in the absence of glucocorticoids.

Factors affecting energy expenditure

Seventy percent of daily energy expenditure in man is utilised in maintaining basal metabolic processes whereas ten percent is utilised in the thermic response to food. An inter-individual variation has been noticed in humans which is believed to be multifactorial:

- a) A strong relationship between total daily expenditure or resting energy expenditure and fat free mass is present. Therefore it is believed that differences in fat free mass account for approximately 80% of variance.¹⁶
- b) The sedentary lifestyle prevalent in the Western world definitely contributes significantly to the ever increasing prevalence of obesity.^{17,18}
- c) Activity and exercise including spontaneous physical activity such as fidgeting can account for one to eight hundred kcal energy expenditure per day.^{16, 19}

Genetics of obesity

Obesity can be either monogenic or polygenic in inheritance. Five single gene defects have been identified:

- a) **Agouti gene:** The protein binds to melanocortin-4 receptor in the hypothalamus thereby modulating food intake. Concentrations have been found to be higher in obese than non-obese men and correlate well with basal metabolic index (BMI).²⁰ A related gene which has been identified is the mahogany gene.²¹
- b) **Leptin gene:** Leptin is produced in fat cells, the gut, and the placenta and signals the brain about the amount of stored fat.^{22,23} Deficient mice have hyperphagia, insulin resistance and

Practice Points

1. Obesity has reached epidemic proportions worldwide
2. The pathogenesis of obesity is multifactorial with genetic and environmental/lifestyle mediators playing a role
3. A complex regulatory system exists comprised of a central processing unit which analyses and responds to afferent input and sends out efferent messages
4. A number of genetic mutations predisposing to obesity have been identified in animals and humans
5. The major cause of obesity is energy intake/output mismatch

infertility. In humans leptin may act on the arcuate nucleus to decrease NPY production (which usually stimulates food intake). Obesity due to leptin deficiency has been reported in two families, affected subjects responding well to leptin therapy.^{24,25} In contrast the majority of obese subjects have a high level of circulating leptin level suggesting a level of leptin resistance.²⁶

- c) **Leptin receptor gene:** Leptin receptor deficiency secondary to mutations in the leptin receptor gene has been reported in humans.²⁷
- d) **Melanocortin-4²⁸ and melanocortin-3 receptor gene defects²⁹:** Transgenic mice with mutations in these genes exhibit hyperphagia and severe obesity. Observations in these mice suggest that receptors for MSH normally inhibit food intake and fat accumulation.
- e) **Serotonin** subtype receptor elimination in transgenic mice results in similar manifestations.³⁰

Genetic factors

The heritability of weight, metabolic rate, thermic responses to food and spontaneous physical activity has been studied in families which included twins or adoptees. Twins separated at birth maintained the same characteristics regarding weight control despite different environmental backgrounds. Similarly studies in adopted children showed that regulation of weight and body composition

was similar to that of biological parents and differed from that of the adoptive parents.^{31,32}

A number of genetic syndromes featuring obesity have also been described in the literature and are associated with chromosomal aberrations as in the Prader Willi Labhart syndrome.³³

Studies to identify genetic abnormalities in common obesity have so far proved unsuccessful, not an common situation in polygenic disorders.³⁴ A number of candidate genes have been analysed such as the beta3 receptor gene,³⁵ peroxisome proliferators-activated-receptor (PPAR) gamma³⁶, and melanocortin-4 (MCR-4) receptor.^{37,38}

Conclusion

Obesity is a multifactorial and complex disorder that has significant implications for affected subjects and the healthcare services that have to deal with the consequences of this disorder. For example, a recently identified genetic polymorphism³⁹ in 10% of 4 study populations in the United States (rs7566605 on chromosome 2q14.1) can be expected to have a significant impact on health and healthcare despite being associated with only a low relative risk. Further research into the physiology and pathophysiology of obesity should hopefully enable the development of preventive and therapeutic strategies to curb the obesity epidemic.

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Weight management: an evidence-based approach

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Keywords: weight management, body mass index, waist circumference, risk factors

The management of obesity includes an individualized assessment of the need for weight loss and the determination of appropriate weight goals. Treatment includes dietary, exercise, and behavioural interventions, with emphasis on a particular treatment modality being dependent on individual circumstances. In general, dietary recommendations include a moderate caloric restriction and modifications in meal pattern and selection of foods. Once a health care professional has identified the need for weight loss by assessing body mass index, waist circumference, and risk factors, he/she can translate nutrition and health information into dietary choices for the overweight individual. This paper discusses a strategy for the evaluation and treatment of overweight patients using a practical treatment algorithm.

Treatment of obesity and overweight

Obesity is a disease in its own right, and overweight and obese patients should be assessed and treated using evidence-based methodology. After acquiring the

necessary skills, health care professionals can guide patients on how to achieve their goal and maintain it long term. Some practical steps are outlined in Table 1 and discussed in detail later. Treatment of the overweight and obese patient is a 2-step process: 1) Assessment and 2) Management.

Assessment and classification of overweight and obesity

Two practical tools for assessing a patient's need for weight loss are body mass index and waist circumference.

Body mass index (BMI) can be calculated as follows:

$$\text{BMI} = \frac{\text{weight (kg)}}{\text{height squared (m}^2\text{)}}$$

Normograms and charts are also available to help calculate the BMI. Body mass index provides a more reliable measure of total body fat than simple body weight.¹ It accounts for differences in body composition by defining the level of adiposity according to the relationship of weight to height, thus eliminating dependence on frame size.²

The recommended classification for BMI, adopted by the Expert Panel on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults (National Heart, Lung and Blood Institute, USA) is shown in Table 2.

Waist circumference is a practical way of evaluating abdominal fat before and during weight loss. Fat located in the abdomen is associated with greater morbidity than fat in the gluteal-femoral region.³ In fact, a high waist circumference is associated with an increased risk for type II diabetes, hypertension, and CVD in patients with a BMI between 25 – 34.9 kgm⁻².^{4,5} Waist circumference is a better indicator of relative risk than BMI⁶. It is measured by placing a measuring tape around the abdomen at the level of the ileac crest. The measurement is made at the end of expiration. Men are at increased risk if their waist circumference exceeds 102cm. For women, the figure is 88cm. Changes in waist circumference are useful predictors of changes in CVD risk factors.⁷

The next step is assessing co-existing risk factors. Detecting cardiovascular disease or end-organ damage presents the greatest urgency. Risk factors include cigarette smoking, hypertension, high LDL, low HDL, impaired fasting glucose, family history of premature CHD and age (>45 for men, >55 for women). Patients are considered to be at high absolute risk for obesity-related disorders if they have 3 or

Table 1: Practical steps in treating overweight and obesity

1. Height and weight are measured and BMI estimated
2. Waist circumference is measured
3. Co-morbidities are assessed
4. Decision on treatment is taken
5. Level of motivation is evaluated
6. Appropriate amount of calories is prescribed
7. Achievable exercise goals are recommended
8. Dietary information is given
9. Food and activity diary is reviewed
10. Patients progress is charted

more of the risk factors just mentioned. In these cases, more attention must be paid to cholesterol lowering therapy and blood pressure management.^{8,9} Patients with a BMI ≥ 30 or high risk waist measurements and 2 risk factors should be encouraged to lose weight.

Management of overweight and obesity

Attention must be given to dietary changes, exercise therapy and behavioural modification. The first goal is a reduction in body weight of 5-10% which already results in decreased morbidity.¹⁰ Many patients have unrealistic targets and will need to be advised about their feasibility.^{11,12} Once the first goal is reached, many experts advise maintaining this weight for a few months before setting a new target. A 10% reduction in weight should usually be achieved within 6 months.

Dietary changes

A calorie deficit of between 500-1000 calories/day is advised and this should give a weight loss of 0.5-1kg/week. After the patient has maintained his/her new weight for a few months, diet and physical activity goals are revised, creating a new energy deficit which will lead to further weight loss.¹³ In practice, a low calorie diet (LCD) containing 1200kcal/day can be prescribed for most women, and a 1500kcal/day is recommended for men. A higher intake can be prescribed for the more obese patient and then slowly adjusted.

Very low calorie diets are not recommended for routine weight loss therapy as they need special monitoring.¹⁴ Steady weight loss over a longer period favours the reduction of fat stores, limits

the loss of vital protein tissues, and avoids the sharp decline in resting metabolic rate that accompanies rapid weight reduction. Also, clinical trials have shown LCDs are just as effective as VLCDs in producing weight loss after 1 year.¹⁵ Dieting is more likely to be successful when a patient's preferences are taken into consideration. A tailor made diet should, however, satisfy all the recommended dietary allowances.

Patients are made familiar with:

- caloric value of various foods
- food composition
- reading food labels
- purchasing healthier foods
- low-fat cooking
- avoiding high calorie foods
- reducing portions
- ensuring adequate water intake
- limiting alcohol

These should become life-long habits and will help weight maintenance. Patients are given copies of low-fat/low-calorie menus and a food exchange system is explained to them. This allows them to make their own choices from a variety of foods having similar calorie counts and nutritional values. This flexibility usually leads to better adherence. A sample reduced calorie menu for a typical 1200kcal diet is given in Table 3.

Exercise therapy

Increasing physical activity is an essential component of weight loss therapy.¹⁶ However, it does not result in a much greater weight loss than diet alone over a period of 6 months.¹⁷ In fact, it is most useful in the prevention of weight regain.^{18,19} After being assessed by a doctor, patients should be encouraged to select

activities they enjoy and which fit in with their lifestyle. A daily walk, for example, is something most people can manage. Initially, they can start by walking for 10 minutes, three times a week and gradually build up to 30-45 minutes on most days of the week.^{18,19} Other changes, like taking the stairs, and parking far from a destination, should be encouraged. A patient can keep track of his progress and increase motivation by keeping an activity diary.

Behavioural modification

Behavioural motivation relies on identifying barriers to adherence with dietary and exercise changes. Behaviour is analysed to identify events which are associated with inappropriate eating behaviour.²⁰ Having identified the problem, the practitioner can take steps to modify the situation. For example, if an individual finds that he or she overeats when angry; steps are taken to help the patient deal with anger in a more constructive way. This part of treatment is just as crucial as dietary and exercise changes.

The principle components of treatment are:

- self-monitoring
- problem-solving
- stimulus control
- slowing of eating and cognitive restructuring²⁰

Self-monitoring is best done by keeping a food and exercise diary, which not only records time and place of food intake, but also accompanying thoughts and feelings. This helps identify the physical and emotional settings in which eating occurs. It provides feedback on progress and puts responsibility for change on the patient. The diary is assessed every week and can give valuable clues as to the reason why lapses occur and how they can be

Table 2: Classifications for BMI

	BMI
Underweight	<18.5 kg/m ²
Normal weight	18.5-24.9 kg/m ²
Overweight	25-29.9 kg/m ²
Obesity (Class 1)	30-34.9 kg/m ²
Obesity (Class 2)	35-39.9 kg/m ²
Extreme Obesity (Class 3)	≥ 40 kg/m ²

prevented. This is dependent on the honesty of the patient concerned. It is a useful record of food consumed and compliance with exercise and gives the practitioner a window into the patient's life.

Problem-solving is a process whereby the problem is identified, solutions are found, and new behaviours are implemented.

Stimulus control involves modification of the social and environmental cues which encourage undesired eating. Strategies such as avoiding combining eating with reading or watching T.V. are helpful.

Cognitive restructuring teaches patients to identify, challenge, and change negative feelings. Many people are very self-critical after a minor lapse and this can lead to abandonment of the diet. Motivation is of paramount importance at this time.

Follow-up visits are opportunities for monitoring progress and giving more information. The practitioner should have a non-judgemental approach and keep a positive outlook even when goals have not been met. By reassessing the circumstances of unmet goals, new effective strategies can be tried. If, however, a target has been

reached, the patient can enter the phase of weight maintenance and long-term monitoring.

Weight maintenance

Maintaining the new weight is now a major challenge. In the past, clinicians focused entirely on weight loss and did not give much importance to weight maintenance. It was assumed that reaching target weight meant the end of weight therapy. However, as many as 80% of patients would gain the weight back. Now, however, it is acknowledged that dietary

Table 3: Sample Reduced Calorie Menu – 1200kcal

Breakfast	Calories	Fat (g)	% Fat	Exchange for:
• Whole wheat bread, 1 medium slice	70	1.2	15	(1 bread/starch)
• Jam, regular, 2 tsp	30	0	0	(half fruit)
• Cereal, shredded wheat, half cup	104	1.0	4	(1 bread/starch)
• Milk, 1%, 1 cup	102	3.0	23	(1 milk)
• Orange juice, three quarters cup	78	0	0	(1 and a half fruit)
• Coffee, regular, 1 cup	5	0	0	(free)
Breakfast Total	389	5.2	10	
Lunch	Calories	Fat (g)	% Fat	Exchange for:
• Chicken sandwich:				
Whole wheat bread, 2 medium slices	139	2.4	15	(2 bread/starch)
Chicken, unseasoned, 2 oz	60	1.5	23	(2 lean protein)
Lettuce, several leaves	1	0	0	
Tomato, 3 medium slices	10	0	0	(1 vegetable)
Mayonnaise, low calorie, 1tsp	15	1.7	96	(one third fat)
• Apple, 1 medium	80	0	0	(1 fruit)
• Water, 1 cup	0	0	0	(free)
Lunch Total	305	5.6	16	
Dinner	Calories	Fat (g)	% Fat	Exchange for:
• Salmon, 2 ounces edible	103	5	44	(2 lean protein)
• Vegetable oil, 1 and a half tsp	60	7	100	(1 and a half fat)
• Baked potato, three quarters medium	100	0	0	(1 bread/starch)
• Margarine, 1 tsp	34	4	100	(1 fat)
• Green beans, seasoned, half cup	25	0	0	(1 vegetable) (half fat)
• Carrots, seasoned	35	0	0	(1 vegetable)
• White dinner roll, 1 small	70	2	28	(1 bread/starch)
• Water, 2 cups	0	0	0	(free)
Dinner Total	427	18	35	
Snack	Calories	Fat (g)	% Fat	Exchange for:
• Popcorn, 2 and a half cups	69	0	0	(1 bread/starch)
• Margarine, three quarters tsp	30	3	100	(three quarters fat)
Total	1220	34	22	

Adapted from: *The practical guide: Identification, evaluation and treatment of overweight and obesity in adults.*
US department of Health and Human Services, Public Health Service, NIH, NHLBI, Publication No: 00-4084

therapy, physical activity and behavioural modification must continue indefinitely. Long-term monitoring and encouragement are crucial for success in keeping the weight off.

Conclusion

Excess body weight is the sixth most important risk factor contributing to the overall burden of disease worldwide. This means that it is of paramount importance to treat these patients. The role of the clinician or nutritionist is to open the door to a healthier lifestyle that encompasses not only changes in dietary and exercise regimens but also the added benefits of improved parameters such as serum cholesterol and blood glucose. Weight control should be considered as an ongoing journey and not a final destination.

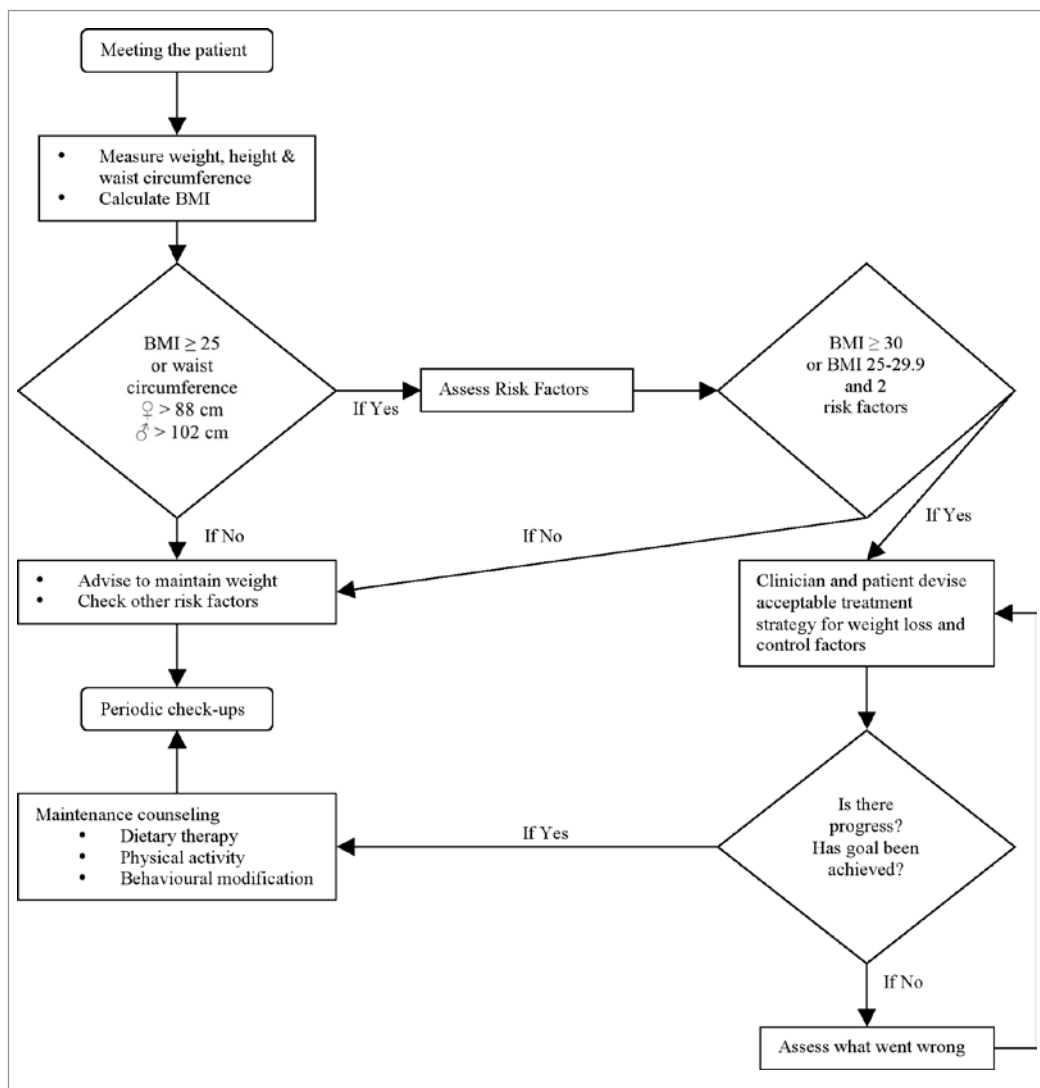


Figure 1: Treatment Algorithm

Adapted from: The practical guide: Identification, evaluation and treatment of overweight and obesity in adults. US department of Health and Human Services, NIH, NHLBI, Publication No: 00-4084

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The weight reduction service organised by the Health Promotion Department, Malta

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The very first participants of the weight reduction programme organised by the Health Promotion Department did so in 1995. This was a key breakthrough in services provided free by the national health service whereby a key risk factor to the most prevalent non-communicable diseases (NCD's) is tackled directly by motivating patients to lose excess weight over a period of eight weeks.

The programme proved successful and popular from the start. The pilot group had been run in conjunction with Naxxar Local council and subsequent groups were then held in the various health centers around Malta and Gozo. The programme has attracted persons who are either self-referred or advised to do so by their family doctor or any other health professional.

The philosophy of the programme

The programme is one of its kind due to its design which utilizes the cognitive behaviour model established by Prochaska and DiClemente in 1984 and clearly explained in the following paper by Magro.

Throughout the eight weeks patients are taken through the programme and at each stage the individual progress is reported to enable the facilitator to monitor outcomes and advice accordingly.

The design of the programme

The programme encourages changes in lifestyle by focusing on the role of healthy balanced meals, regular exercise and coping with day-to-day stressors that in many instances lead to binges on high calorie foods. Participants are weighed individually over eight weekly instances and an individual calorie reduced diet is explained to them with key goals for realistic weight loss. Participants are in their greater majority placed on one of two diets depending on gender and the extent of their obesity, namely 1,200 Kcal or 1,500 Kcal respectively for females and males.

Throughout the course, skills necessary to maintain a healthy weight are taught. The programme is run in groups of 20 people maximum and through group work patients are encouraged by the facilitator to motivate each other and give the necessary psychological support.

One does note that this programme is ideal for those persons willing to discuss their weight, health and lifestyle with other persons however it is discouraged in the morbidly obese (ie BMI>40) or persons who have a medical history that does not allow participation in such a programme eg.eating disorders. Furthermore persons younger than 25 are not allowed to attend.

Each group is assigned a health care professional who has been specifically trained to facilitate the programme and to assist these persons in losing an appropriate amount of weight to improve their health.

What results are to be expected?

It is estimated that each person who follows the diet and exercises for at least 30 minutes three times weekly, an average weight loss of 3.5kg throughout the eight weeks is to be expected. However this is also dependent on the starting weight of the person and the adherence to the diet in the absence of any metabolic or endocrinologic problem.

Who can apply and how?

Prospective participants can either call the Health Promotion Department on 23 26 6000 and ask for this service or alternatively download an application from the www.sahha.gov.mt website. All particulars are to be filled and the application will be acknowledged on receipt. Applicants will be informed of the next session starting within their locality.

What do participants say?

Evaluation sheets filled by the participants in the last session of the programme are filled with positive comments.

Many comment that they wish the programme to continue for more weeks and others find that the motivation acquired throughout the programme is also helping all the family to eat well and adopt a healthier lifestyle. The majority comment that their knowledge on food and health has improved greatly following the programme. In general the programme is in popular demand by the general public and some show the desire of repeating the programme to sustain their weight loss.

Knowledge, attitude and behaviour change in participants attending an eight-week weight reduction programme

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Keywords: weight reduction, behaviour change

The importance of continuous evaluation and improvement of weight reduction programmes has been clearly established in the literature. This study aimed to evaluate the knowledge, attitude and behaviour change in participants attending an eight-week weight reduction programme. Data was obtained from pre- and post-intervention self-administered questionnaires. The findings indicated that the participants' weight loss was statistically significant and that knowledge on healthy eating and healthy lifestyle improved in the post-intervention period. Attitudes and behaviours changed positively. Whilst the weight reduction programme is effective in empowering people to change their eating habits and lifestyle, there are key aspects where it can be changed to improve its achievements.

Introduction

Obesity is a condition in which body fat stores are enlarged to an extent which is detrimental to health and is generally defined by a Body Mass Index (BMI) of over 30 kilograms per metre squared (kg/m²).¹ Obesity is characterized by the gradual accumulation of excess body weight due to a positive energy balance resulting from excess caloric intake or decreased energy expenditure.² Globally there are over one

billion overweight adults, three hundred million of whom are obese.³ Various studies, including the First National Health Interview Survey of 2002, have shown that obesity is high and prevalent in Malta.^{4,5}

The rising obesity epidemic is a result of recent dramatic changes in society and in communities' behavioural patterns. Abundance, good taste and display of food entice people to over eat.² Watching television and listening to a story stimulate

a greater intake of low-nutrient, energy-dense, sweet foods besides decreasing physical activity.^{6,7} Overeating may be induced by boredom, stress, anxiety and frustration.^{2,6} Familial eating patterns and attitudes towards obesity also determine the chances of becoming obese.² The increased consumption of foods high in sugar and saturated fats, combined with reduced physical activity, has led to high rates of obesity.³

Management of obesity

Interventions to prevent obesity and its complications - non-communicable diseases, health problems, psychosocial disadvantages^{2,3} - should address obesity in an integrated manner, inclusive of the causative behavioural, cultural, social and genetic factors.^{8,9} Weight management programmes have moved from the traditional advice on eating and exercise to actively helping patients achieve and maintain an ideal weight through dietary behaviour change.¹⁰ The promotion of healthy behaviours to encourage, motivate and enable individuals to lose weight by eating healthily and doing regular physical activity is also emphasized by the World Health Organization (WHO).³

Knowledge, attitude and behaviour

The provision of knowledge does not necessarily lead to healthy lifestyles. The adoption of health-enhancing behaviour is often limited by physical, social, economic and cultural factors.¹¹ However, education with consultation and creation of motivation can lead to weight reduction and improved health status.^{12,13}

"Dieting" is perceived by most people as a short-term hardship. A weight reduction programme is successful and long-lasting, only if a permanent change in attitudes and behaviours occurs. Unless food habits change and exercise is continuous, the perpetual cycle of weight loss followed by weight gain is inevitable.^{2,14} The Prochaska and DiClemente model of behaviour change (Figure 1^{6,16}) implies that people change their behaviour through a gradual dynamic process.¹⁵ Thus, in weight control it is realistic to promote the action and maintenance stages.

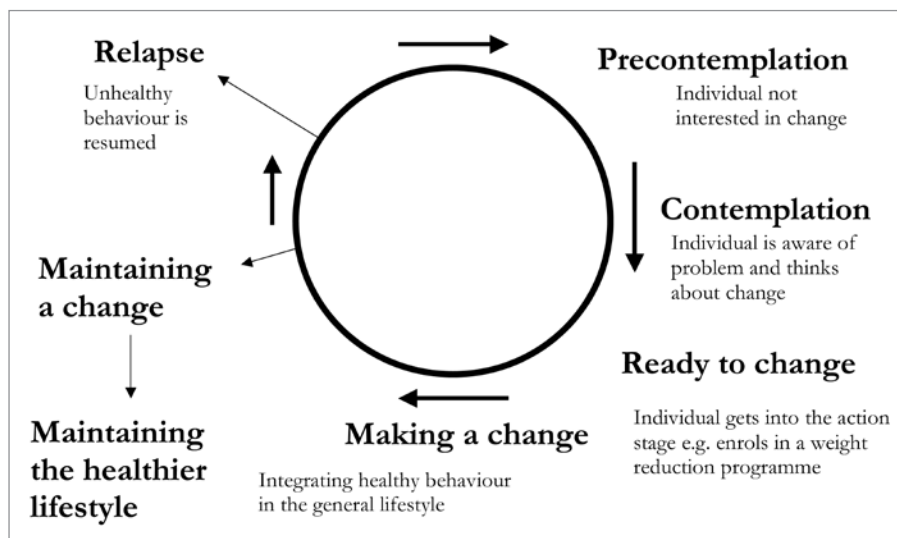


Figure 1: The stages of change model

Aims and objectives

Evaluation research is essential to find out how well a programme, treatment, practice or policy is working.¹⁷ There is often a need to pose questions such as “How are we doing?”, “Are we accomplishing goals?” or “Is there a more effective way to do things?” This study aimed to evaluate how an eight-week weight reduction programme benefits overweight (BMI >25) and obese participants. It explored the motivations and expectations of participants, and the slimming strategies adopted. It assessed eating behaviour and the effects of knowledge on behaviour change, and tried to understand how the programme improves health and eating behaviour.

Methodology

The eight-week weight reduction programme organised by the Division of Health within the Ministry of Health, the Elderly and Community Care, focuses on the concept of a healthy diet and the role of physical activity, while also addressing body image, control, coping mechanisms, self-confidence and relapse.

The programme is known as “Weight Reduction Programme: Lose Weight, Stay Healthy!”. Each of the 8 interactive 2 hour sessions includes the weighing of the participant, and words of encouragement, motivation and empowerment, as well as the distribution of handouts on nutritional information. Different specific themes are

covered every week:

1. Orientation and introduction
2. Eating sensibly – The concept of a ‘Healthy Diet’
3. The role of physical activity in achieving and maintaining weight loss
4. Understanding obesity and its effects on health
5. Body image
6. Coping mechanisms, self-confidence and relapse
7. Past failures in achieving weight loss
8. Group experience

The targeted programmes for the study were facilitated by the same qualified and registered nutritionist in spring of 2005 in 2 health centres and included 2 afternoon courses in each centre; 2 courses started at 4pm and 2 at 6pm. One nutritionist was involved in the study so that the findings would not be generalised, and the limited time available for the study – part of the 2 year course work for a post-qualification diploma - did not allow for more health centres or programmes to be included. The number of expected participants was 43. Inclusion criteria were attendance of the first and last sessions and attendance of at least 6 sessions.

A tool containing 24 structured-response and open-ended questions was designed, piloted and implemented in line with the approval given by the Ethics Committee.^{18,19}

The questions were divided in 13 different categories:

1. Demographics
2. Physical measurements
3. Motivations and expectations
4. Health, body image and lifestyle
5. History of slimming diets
6. Weight and diet status
7. Hobbies and exercise
8. Daily diet
9. Healthy eating
10. Healthy cooking
11. Barriers to a healthy diet
12. Behaviour during meals
13. Self-confidence and coping mechanisms

The nutritionist gave the designed questionnaire and a letter requesting voluntary participation, to the participants during the introductory session for the pre-intervention data collection. Those who wished to participate signed an informed consent form. A code number was given to each participant to ensure anonymity. The post-intervention data was collected after the last session. A stamped self-addressed envelope was given to the participants, and the nutritionist phoned them once to remind them to answer the questionnaire and post it.

Demographic data was collected. The questionnaire included Likert scales which aimed to assess the attitudes and beliefs of the participants. Multiple choice questions were used to assess the diet and lifestyle status as well as the knowledge and behaviour of the study group. A few open-ended questions explored the participants’ diet history, motivations, and expectations.

The data analysis was carried out manually. Closed questions were analysed quantitatively. The percentage number of participants was identified for each parameter. Open-ended questions were processed using content analysis.^{17,20} Due to the lack of reproducibility of the Likert scale, the results were analysed with respect to response patterns rather than total scores.²⁰ The Paired sample t-test was used to analyse weight data, using SPSS 10.0.

Analysis of demographic and open-ended questions, was carried out for all the participants who eventually attended the programme. However, analysis of questions

which provided data on the change that occurred from pre- to post-intervention, was carried out only for those who qualified for all the inclusion criteria of the study.

Results

Seven of the targeted 43 participants did not turn up, 5 were drop outs (drop out rate of 0.14), 2 did not attend the minimum of 6 sessions and 3 did not return the post-intervention questionnaire. Thus, only 26 fulfilled the selection criteria for participation in the pre- and post-intervention study.

Participants were males (11%) and females (89%) with an age ranging from 24 to 65 years. Fifty-eight percent were housewives while 28% worked. Only 14% of the attendees had an education level lower than secondary; 53% had a secondary education level, 25% post-secondary and 8% tertiary.

Main motivations for attending the programme were excess weight (53%) and wanting to improve health and feel better (47%). The most popular strategies adopted in trying to lose weight were calorie-counting, reducing fats and attending beauty salons. Seeking health professional advice was amongst the least common strategies. Participants expected guidance and advice (36%), knowledge on healthy eating and a healthy lifestyle (31%), and support (31%) from the programme.

The weight status of the 26 participants changed from pre- to post-intervention (Figure 2). Average weight was reduced from 91.7kg to 85.3kg ($p < 0.05$). Before the programme the BMI ranged from 25.33kg/m² to 51.63kg/m² while after the programme it ranged from 24kg/m² to 46.68kg/m². The change from an initial mean BMI of 37kg/m² to a final mean BMI of 34kg/m² was also significant ($p < 0.05$).

Embarrassment about weight and body looks decreased. Participants achieved a positive attitude with respect to weight, body looks, clothes, going out and performing other activities. Findings also showed a significant increase in physical activity from 27% to 81% with participants walking, running, swimming, cycling or doing aerobics. Following the programme 35% of the participants exercised more than 3 times weekly and 39% exercised daily,

while exercising time was 30 to 60 minutes (50%) or more (31%).

The initial statement "I eat what I want when I want to eat it" (65%) changed to "somewhat less" or "a little less food"

than they would like to eat (73%). Daily eating frequency increased to more than 3 times daily (77%) while tendency to take second helpings decreased from 58% to 12%. The consumption of unhealthy snacks

Table 1: Participants' attitude to cues for eating pre- and post-intervention (n=26)

<i>Cues for eating</i>	<i>Percentage number of participants</i>	
	<i>Pre-intervention</i>	<i>Post-intervention</i>
Hunger	54	69
Time to eat	65	81
Boredom	58	39
Anger	50	31
Stress	58	50
Delicious taste	73	50
Other people eating	35	12
Food is going to be wasted	46	19

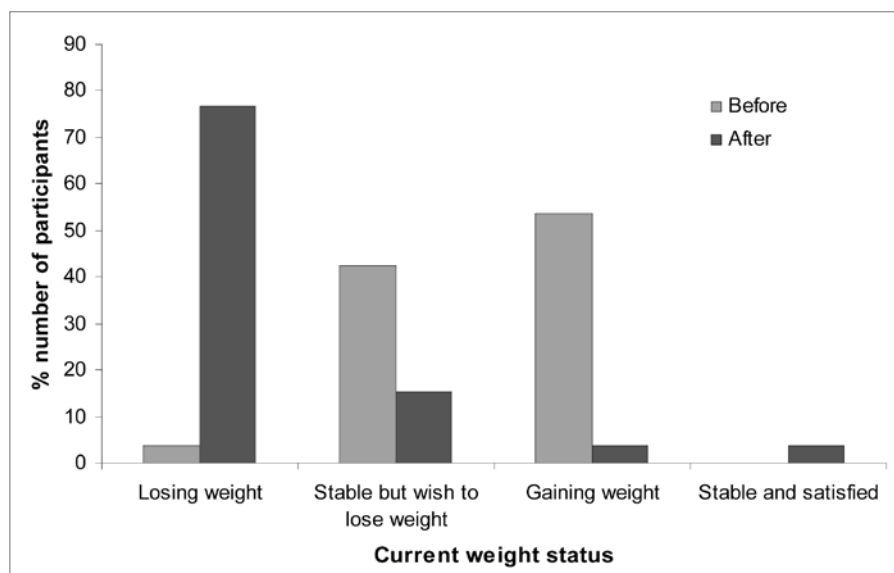


Figure 2: Description of the current weight status pre- and post-intervention (n=26)

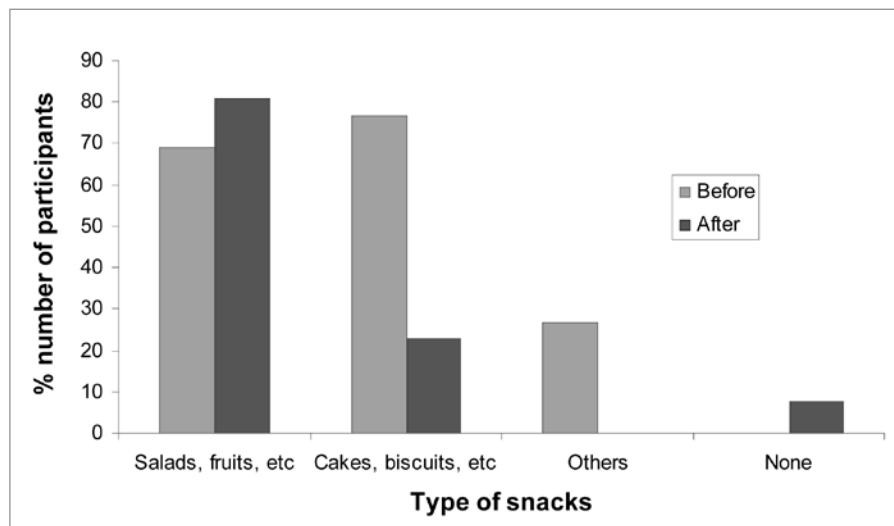


Figure 3: Participants' description of snacks taken pre- and post-intervention (n=26)

decreased (Figure 3) thus increasing the probability of weight loss¹⁴. An increase in awareness of healthier alternatives to full fat milk, yoghurt and cheese, as well as a decrease in fat intake was observed. There was a positive attitude to the consumption of vegetables before (73%) and after the programme (81%). The latter increased the popularity for micro-waving and decreased frying practices. Frying was classified as the worst cooking method pre- (85%) and post-intervention (96%).

An increase in the participants' control of cues which previously led to excessive eating was observed (Table 1). Distracting stimuli like the television or other activities during mealtimes were only slightly decreased. Participants learnt to eat slowly and chew longer, both factors ideal to increase enjoyment of food and aid digestion.¹⁰

Participants managed to achieve a certain level of self-confidence and control over their diet and lifestyle (70%). However, only 42% of the subjects were confident of keeping their weight stable. The need for knowledge on healthy eating and keeping a healthy lifestyle remained (73%), and only 30% stated that they did not need any more help.

Discussion

Demographics indicate that people attending a weight reduction programme are generally obese adults of a female gender with a mean BMI of 37kg/m²; having attended a secondary level of education and who are mainly housewives. Studies have actually shown that there are more females than males who are overweight or obese in Malta.^{4,5} No local studies or statistics were traced which could explore links between social class, occupation and BMI across the population.

Weight loss was successfully achieved by the weight reduction programme, but the latter goes beyond the modification of physical measurements. Health concerns and illness provide a catalyst for dietary change.²¹ People have little motivation to change their diets even when they intend to do so. But they do expect a lot from a weight reduction programme. Knowledge of these expectations should be acted upon to reduce dropout rates and participant

Practice Points

- In weight control, the action and maintenance stages of the Stages of Change Model (Figure 1) should be promoted and supported.
- A weight reduction programme is successful and long-lasting only if attitudes and behaviours change permanently.
- Weight loss and maintenance are determined by positive changes in eating habits e.g. small meals evenly spaced throughout the day.
- The general advice to achieve and maintain a healthy lifestyle is 30 minutes of brisk walking 5 days weekly.
- Long-term support for motivation and maintenance of healthy behaviours is needed by those seeking permanent weight control.

dissatisfaction. Dropouts should be offered alternatives to group therapy according to their expectations e.g. literature, videos, one-to-one sessions etc. The strategy adopted by the nutritionist includes counting food portions. Since, calorie-counting was found to be quite popular, and possibly motivating, among the participants, it might be helpful to take into consideration calorie-counting for those willing to count calories.

The knowledge and empowerment given to attendees caused an overall decrease in the usual consumption of food. Traditionally patients are advised to have small meals evenly spaced out throughout the day.¹ The importance of breakfast, lunch and dinner was conveyed well. Eating behaviours also changed. Weight loss and maintenance are determined by such positive changes in eating habits.^{10,14} Participants were quite knowledgeable on healthy cooking methods and highly aware of the risks to health from frying practices. Distractions during meals can decrease the enjoyment of the food and cause over-eating.⁷ The programme would benefit by addressing more the importance of identifying and eliminating such distractions.

The general advice for obese individuals is 30 minutes of brisk walking 5 days weekly.¹ Similarly to other behaviour modification programmes for weight management, physical activity levels increased drastically.¹⁰ However, the inclusion of gymnasium training in the programme might be even more supportive towards behaviour change.

The issue of body image is successfully addressed. More significant

changes in feelings may be achieved by a psychologist contributing to the programme applying behaviour and mental processes involving cognition, emotion and motivation.⁶ An increase in flexible control of eating behaviour is necessary to ensure maintenance success. Behaviour modification programmes give subjects confidence that they can maintain dietary changes for life.¹⁰ However, attendees were not empowered enough to independently take care of their weight status and health by the end of the programme. Eight weeks might not be long enough to empower participants to take full control of themselves. Ongoing support is sought by participants who seek to share and refresh elements of the programme, obtain additional guidance about weight management and sustain their motivation.¹⁵

Limitations

The main limitations of the study had to do with the size of the study and the restricted time. Also, in such studies, underreporting is very common and is more likely among heavy rather than normal-weight individuals, females than males, and people with a low level of education.⁶ Such underreporting may have affected the results obtained. However, despite these limitations, the study achieved an insight into the knowledge and behaviour of obese people and how these are changed by the weight reduction programme.

Conclusion

This study showed how an eight-week weight reduction programme benefits overweight and obese participants, in terms of weight loss ($p < 0.05$) as well as

knowledge, attitudes and behaviour change. The empowerment of the attendees enabled them to change their behaviours and attitudes and thus improve their health and lifestyle. Key aspects which may need to be

addressed more within the programme in order to improve further its achievements, were identified. Eight weeks may not be long enough to ensure a permanent behaviour change.

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Options in the pharmacological management of morbid obesity

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Obesity is one of the most common medical problems worldwide and a risk factor for illnesses such as hypertension, diabetes, degenerative arthritis and myocardial infarction. It is a cause of significant morbidity and mortality and generates great social and financial costs.¹ WHO's latest projections indicate that globally in 2005, approximately 1.6 billion adults were overweight and that at least 400 million adults were obese.² Weight loss medications may be appropriate for use in selected patients who meet the definition of obesity or who are overweight with comorbid conditions. Medications are formulated to reduce energy intake, increase energy output or decrease the absorption of nutrients. Drugs cannot replace diet, exercise and lifestyle modification, which remain the cornerstones of obesity treatment.¹

Overweight and obesity are serious medical problems that affect over 55% of the adult population worldwide and

both require appropriate and effective management by suitably trained members of a multidisciplinary team.³ In Malta, 35% of

children aged between 7 and 11 years are overweight.⁴

The National Institute for Clinical Excellence (NICE) considers people to have morbid obesity if:

- they have a Body Mass Index (BMI) of 40 kg/m² or more or
- they have a BMI of between 35 kg/m² and 40 kg/m² and other significant disease (for example, diabetes, high blood pressure) that may be improved if they lose weight.⁵

The recognition of the health consequences of overweight and obesity, the benefits of modest weight loss and the frequent failure of lifestyle interventions for both weight loss and weight loss maintenance, has led to the search for effective pharmaceutical anti-obesity treatments.³

The initial treatment of obesity should focus on a diet and exercise program that has been individualized to the patient's lifestyle and physical needs. Behavioural therapy should be implemented as an adjunct to this program.⁶

Anti-obesity drug therapy is often useful as an adjunct for patients who cannot achieve sufficient weight loss through lifestyle and behavioural modification.³ A useful medication for obesity treatment must:

- be effective for body weight reduction and result in overweight-dependent conditions improvement;
- have long-term efficacy and safety;
- be related to tolerable or transitory side effects;
- not be addictive;
- have a known mechanism of action;
- be reasonably affordable.⁷

Anti-obesity drugs are classified on the basis of their mechanism of action – appetite suppression, altered nutrient absorption, or increased energy expenditure.⁶

Appetite suppression

Sibutramine is a norepinephrine and serotonin reuptake inhibitor which does not stimulate secretion of serotonin. The drug produces weight loss by two

mechanisms: sibutramine's central action on neurotransmitters results in early satiety with reported 20% reduction in food intake. Secondly, sympathetically mediated thermogenesis maintains original Basal Metabolic Rate which usually falls as weight is lost.⁷ Two studies have looked at the incidence of valvular heart disease and essentially did not report any difference between patients on sibutramine or placebo. Sibutramine 10 or 15 mg provided significantly greater weight loss than dietary advice alone in a 1-year study of 485 patients with a BMI of 27 to 40kg/m².⁶

The National Institute of Clinical Excellence reported in 2001 that randomised controlled trials found that sibutramine produced a dose-related weight loss when given in the range 5 – 30mg/day, with an optimal dose of 10 – 15 mg/day. Mean weight loss was greater with sibutramine than with placebo, on average by about 3 kg at 8 weeks, between 4 and 9 kg at 24 weeks and between 4 and 5 kg at 1 year. People who had lost weight on sibutramine

were more likely to maintain the loss when sibutramine use was extended than were those who were randomised to diet and exercise alone. Retrospective subgroup analysis found no statistically significant differences between men and women, or between ethnic groups in the effects of sibutramine treatment.⁹

Adverse effects attributed to sibutramine include headache, insomnia, constipation and dry mouth. Increases in blood pressure and pulse rate may also occur. Patients with cardiac conditions should be given this drug with caution. The manufacturer advises against giving sibutramine to patients with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke.¹⁰

Altered nutrient absorption

Orlistat reduces the systemic absorption of dietary fat by potently and irreversibly inhibiting gastric and pancreatic lipases. These enzymes catalyse hydrolytic removal of triglycerides fatty acids and produce free

fatty acids and monoglycerides.⁶ Orlistat binds irreversibly to lipase active sites through covalent binding.⁸ By blocking these enzymes, triglycerides in dietary fat cannot be metabolized into absorbable free fatty acids and monoglycerols, and thus are excreted in the faeces.⁶ Studies have shown weight loss of 8.5% at one year compared with 5.4 % for placebo.¹ A study looking specifically at the effect of orlistat on obese adults with coronary heart disease risk factors (type 2 diabetes, hypercholesterolaemia or hypertension) found that more orlistat-treated patients than placebo recipients maintained a weight loss of > or equal to 5%. However, for a weight loss of > or equal to 10% there was no statistical difference between the placebo and treated groups.¹¹ The view that orlistat may be beneficial in patients with comorbid conditions related to obesity, such as diabetes and hyperlipidaemia is supported in several recent reviews. One review noted that in some long-term studies, orlistat-treated patients had

Table 1: Comparison of drugs licensed for the treatment of obesity ^{10,14,15}

	Orlistat	Sibutramine	Rimonabant
Presentation	120mg hard capsules	10mg and 5mg hard capsules	20mg film-coated tablets
Clinical Indications	Treatment of obese patients with a body mass index (BMI) greater or equal to 30 kg/m ² , or overweight patients (BMI ≥ 28 kg/m ²) with associated risk factors, in conjunction with a mildly hypocaloric diet.	As an adjunct to diet and exercise for the treatment of obese patients (BMI ≥ 30 kg/m ²), or overweight patients (BMI > 27 kg/m ²) with associated risk factor(s), such as type 2 diabetes or dyslipidaemia.	
Adult Dose	One 120 mg capsule taken with water immediately before, during or up to one hour after each main meal. If a meal is missed or contains no fat, the dose of orlistat should be omitted.	One capsule of 10 mg swallowed whole, once daily, in the morning, with liquid. The capsule can be taken with or without food. In those patients with an inadequate response to 10mg (defined as less than 2 kg weight loss after four weeks treatment), the dose may be increased to one capsule of 15mg once daily, provided that the 10mg dose was well tolerated.	One 20 mg tablet daily to be taken in the morning before breakfast.
Interactions	Ciclosporin Acarbose Fat soluble vitamins Oral anticoagulants Amiodarone	CYP3A4 inhibitors e.g. ketoconazole, itraconazole, ritonavir, telithromycin, clarithromycin, erythromycin and ciclosporin. CYP3A4 inducers e.g. rifampicin, phenytoin, Phenobarbital, carbamazepine and dexamethasone. Drugs which raise serotonin levels in the brain Simultaneous use of two SSRIs or an SSRI with certain antimigraine drugs or with certain opioids	

FAST ACTIVE PAIN RELIEF



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diclofenac potassium
WORKS WHERE IT HURTS

- Pain relief within 15 to 30 minutes¹
- Therapeutic effect in 93.7% of patients²
- Good / excellent tolerability perceived by 92.2% of patients²

(1). Data on file. Novartis Pharma AG, Basel, Switzerland. (2). Anonymous. Post-marketing surveillance of Cataflam in daily general practice - observation in 10,377 patients. Folha Med (Br) 1986; 92: 53-63

Presentation: Diclofenac potassium: coated tablets of 25 mg and 50 mg. **Indications:** Short-term treatment in the following acute conditions: post-traumatic and postoperative pain and inflammation, dysmenorrhoea, migraine attacks, painful syndromes of the vertebral column and non-articular rheumatism as an adjuvant in severe infections of the ear, nose, or throat. **Dosage:** Adults: 50-150 mg/day in divided doses (dysmenorrhoea and migraine attacks: up to 200 mg/day). **Contraindications:** Gastric or intestinal ulcer, known hypersensitivity to diclofenac or other non-steroidal anti-inflammatory drugs. Known hypersensitivity to excipients. **Precautions/warnings:** Symptoms/history of gastrointestinal disease, asthma, impaired hepatic, cardiac, or renal function. NSAIDs may mask infections or temporarily inhibit platelet aggregation. Pregnancy and lactation. Porphyria. Caution in the elderly. Extracellular volume depletion. Central nervous disturbances can influence the ability to drive and use machines. If in exceptional cases prolonged treatment proves necessary, periodic monitoring of liver function and blood counts is recommended. **Interactions:** Combination with lithium, digoxin, methotrexate, cyclosporin, diuretics, anticoagulants, oral antidiabetics, quinolones, other NSAIDs. **Adverse reactions:** Occasional: gastrointestinal disorders; headache; dizziness; vertigo; rashes; elevation of serum transaminases. Rare: gastric or intestinal ulcer; gastrointestinal bleeding; abnormalities of renal function; hepatitis; hypersensitivity reactions. In isolated cases: pancreatitis; diaphragm-like intestinal strictures; aseptic meningitis; pneumonitis; erythema multiforme; Stevens-Johnson syndrome; Lyell's syndrome; erythroderma; purpura; blood dyscrasias; cardiovascular disturbances; disturbances of sensation or vision. **Note:** Before prescribing consult full prescribing information.

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moderate decreases in diastolic blood pressure, insulin levels while fasting, and total cholesterol and LDL cholesterol, with a small cholesterol-lowering effect that was independent of weight loss.¹¹

Side effects of orlistat include steatorrhea, flatus, faecal incontinence and oily spotting. These effects are more dramatic with the consumption of fatty foods and may contribute to weight loss by discouraging dietary indiscretion. In two randomized controlled studies, gastrointestinal side effects were considered mild to moderate and improved in the second year of treatment.¹

Increased energy expenditure

Agents that increase energy expenditure are scarce. The search for a thermogenic medication that has a tolerable side effect profile has yielded few drugs, and none is recommended for weight loss treatment.¹ Ephedrine and the xanthines, such as caffeine and theophylline, increase metabolic rate. Studies have demonstrated their efficacy as short-term weight loss medications, but the risk of cardiac complications from hypertension, increased heart rate, increased myocardial oxygen consumption and increased cardiac output limit their clinical use.¹

Other drugs

Rimonabant

Rimonabant was the first selective cannabinoid-1 receptor blocker to enter clinical trials. In genetic and diet-induced obesity, rimonabant, reduces overactivation of the central and peripheral endocannabinoid system and prevents weight gain and associated metabolic disorders.¹² The results of a randomized, double-blind, placebo-controlled 2-year multicenter study suggest that 20mg per day of rimonabant is effective in reducing body weight and waist circumference, while also favourably affecting several cardiometabolic risk factors.¹² Most of these effects were dose-dependent. The RIO-North America trial concluded that compared with patients who received placebo, patients who received 20mg of

Practice Points¹⁶

- The aims of treatment for overweight and obesity should be modest weight loss maintained for the long term, with treatment methods and goals being decided for each individual after careful assessment of the degree of overweight and any associated co-morbid conditions.
- The first-line strategy is a combination of supervised diet, exercise and behaviour modification.
- Anti-obesity drugs may be used in adult patients at medical risk from obesity (BMI 30 or greater), or overweight patients with established co-morbidities (BMI 27) if the drug license permits.
- Not all obese patients respond to drug therapy. An anti-obesity drug should therefore be prescribed for no longer than 12 weeks in the first instance and weight loss should then be measured. The drug treatment should be stopped in those obese patients who have not achieved a 5% weight reduction after 12 weeks of treatment. If a 5% weight loss is attained then the drug may be continued beyond this initial period, provided body weight is continually monitored and weight is not regained.
- The duration of treatment with an anti-obesity drug must never exceed the time period recommended by the product license of the drug.
- Prescribers of anti-obesity drugs must be aware of their possible adverse actions. When assessing the suitability of a patient for drug treatment, it is important to consider the risk/benefit ratio, remembering that drug therapy is not without risk.
- All obese patients receiving drug therapy should be given regular review.

rimonabant had favourable changes in levels of HDL cholesterol, triglycerides, and fasting insulin that appeared to be approximately twice that expected from the achieved weight loss alone, suggesting a direct pharmacological effect of rimonabant on glucose and lipid metabolism beyond the weight loss achieved.¹³

In placebo-controlled studies, the discontinuation rate due to adverse reactions was 15.7 % for patients receiving rimonabant and the most common adverse reactions resulting in discontinuation were: nausea, mood alteration with depressive symptoms, depressive disorders, anxiety and dizziness.¹⁴

Over the counter (OTC) products

A number of OTC products are advertised as treatments for weight loss. Patients and physicians should be aware that such products are packaged in uncertain dosages and are usually of uncertain potency and purity. This in turn can lead to unpredictable therapeutic and adverse effects. Thus, the treatment of choice for patients with a low risk of

obesity is not OTC products but dietary intervention accompanied by exercise and behavioural modification.

Treatment considerations

Most antiobesity medications produced 5% to 10% weight loss in clinical trials, which is likely to be of significant medical benefit even if the patient has not reached his or her desirable body weight. Obesity is a chronic disease, as evidenced by the high likelihood of weight regain, and consequently a long-term approach to treatment is needed.⁶

Clinicians must learn to recognize treatment failure and alter the drug therapy regimen. Patients who do not lose at least 4lbs during the first 4 to 8 weeks of therapy should be considered non-responders to that medication. In this situation, the medication should be stopped and another anti-obesity drug should be considered. Table 1 gives a comparison of drugs licensed for the treatment of obesity. Once a patient has lost a significant amount of weight, it becomes important to sustain the weight loss.⁶

Conclusion

Obesity is recognized as an epidemic condition that affects populations worldwide. Therefore, the need to improve the quality and efficacy of therapeutics has emerged. The core to current obesity management is based on specific behavioural therapies aiming to

change eating habits and raise energy expenditure, nutritional counseling to lower the intake of calories, particularly fat as well as increased daily physical activities.

Pharmacological management is seen as an additional tool to this basic therapy in those patients where dietary

and lifestyle modifications have proved unsuccessful. The thoughtful use of medications for the management of obesity can be valuable for many patients, however, no medication alone will solve the problem of obesity and no medication should be used as a substitute for the development of healthier adults.

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Nutritional recommendations for people with diabetes

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Keywords: diabetes, nutrition, blood glucose, carbohydrates

Nutrition management is considered to be a cornerstone of therapy for patients with diabetes mellitus (DM). The prevalence of DM is increasing around the world at such a dramatic rate to be characterized as an epidemic.¹ Many factors have been postulated to contribute to the DM epidemic. This paper discusses nutritional recommendation related to the management of DM.

Introduction

The field of nutrition therapy in diabetes has undergone a series of transformations during the years – from starvation treatment in 1915 to current evidence-based recommendations. Over the years, generations of medical professionals have alternated between recommending high-carbohydrate and low-carbohydrate foods to people with diabetes. Most of the diets for diabetes were rigid and monotonous, making them barely edible as well as nutritionally deficient. Prior to 1994, all nutrition recommendations for diabetes attempted to define an ‘ideal’ nutrition prescription that would apply to

nearly everyone with the condition. Current nutritional recommendations from diabetes and nutritional associations around the world continue to identify ideal percentages of carbohydrate, protein, and fat. However, this approach needs to involve individualization if diet is to be effective in controlling blood sugar levels.

Composition of the diet

The existing nutritional recommendations of the European Association for the Study of Diabetes (EASD) and American Diabetes Association (ADA) on dietary composition^{2,3,4,5} are summarized, with minor changes, in Tables

1 and 2. Important differences from the previous UK recommendations^{6,7} are:

- greater flexibility in the proportions of energy derived from carbohydrate and from monounsaturated fat [MUFA] (Table 1). MUFA (Table 3) are promoted as the main source of dietary fat because of their lower susceptibility to lipid peroxidation and consequent lower atherogenic potential.⁸ Moreover, provided that energy intake is controlled, the use of monounsaturated fat instead of carbohydrate as a replacement for saturated fat causes an increase as opposed to a decrease in HDL cholesterol¹⁰, which is of particular benefit in type 2 diabetes;
- further liberalization in the consumption of sucrose from the previous 25g per day up to 10% of total daily energy, provided that this is eaten in the context of a healthy diet and distributed throughout the day.
- more active promotion of carbohydrate foods with a low glycaemic index (GI);⁹
- greater emphasis on the benefits of regular exercise.

The traditional rule for people with diabetes was to avoid sugar, and although reflecting a commonly accepted idea, the advice had little or no research to substantiate the claim. This belief was based on the assumption that sucrose and other sugars were more rapidly digested and absorbed than starch-containing food and would therefore aggravate hyperglycaemia. More than 20 years ago, investigators challenged this traditional theory. They found that the responses were not related to the popular theory of sugar versus starch; the total amount of carbohydrate was found to be just as important as the source of the carbohydrate.² The above recommendations emphasize the concept that it is the total amount of carbohydrate which matters most to blood glucose control. In practical terms, one day's supper could be a plate of pasta (complex carbohydrate) while the next day's supper could be syrup and milk (simple carbohydrate) – the choice is unlikely to affect the overall insulin needs and glucose control since it is TOTAL carbohydrate intake, rather than simple sugars which needs to be targeted. Nevertheless, careful use of simple sugars is important for everyone, with or without diabetes.

Table 1: The composition of the diet⁷

Component	Comment
Protein	Not >1 g per kg body weight
Total fat	<35% of energy intake
<i>Saturated + trans-unsaturated fat</i>	<10% of energy intake
<i>n-6 Polyunsaturated fat</i>	<10% of energy intake
<i>n-3 Polyunsaturated fat</i>	Eat fish, especially oily fish, once or twice weekly Fish oil supplements: not recommended
<i>cis-Monounsaturated fat</i>	10–20% (60–70% of energy intake)
Total carbohydrate	45–60%
<i>Sucrose</i>	Up to 10% of daily energy, provided it is eaten in the context of a healthy diet. Those who are overweight or who have hypertriglyceridaemia should consider using non-nutritive sweeteners where appropriate
Fibre	No quantitative recommendation Soluble fibre: has beneficial effects on glycaemic and lipid metabolism Insoluble fibre: no direct effects on glycaemic and lipid metabolism but its high satiety content may benefit those trying to lose weight and it is advantageous to gastrointestinal health
Vitamins and anti-oxidants	Encourage foods naturally rich in vitamins and anti-oxidants. With the exception of some patients e.g. malnourishment, cancer etc. there is no evidence for the use of supplements and some evidence that some are harmful
Salt	approx 6 g sodium chloride per day

Table 2: Food choices⁷

Choice	Comment
Nutritive sweeteners	
<i>Fructose</i>	No proven advantage over sucrose fructose in fruits, etc.
<i>Sugar alcohols</i>	Lower cariogenic effect but no other advantages over sucrose May cause diarrhoea
Non-nutritive (intense)	Useful in beverages Potentially useful in the overweight Safe if 'acceptable daily intake' not exceeded – heavy users should use a variety of different products
Diabetic foods	Unnecessary, expensive May cause diarrhoea Not recommended
Plant stanols and sterols	approx 2g/day can reduce LDL cholesterol by 10–15%
Fat replacers and substitutes	May facilitate weight loss Long-term studies needed
Herbal preparations	No convincing evidence of benefit

Concept of diet and lifestyle

Dietary and lifestyle education is essential to delay the onset, or even prevent diabetes in those at risk of type 2 diabetes and for the effective management of the condition in those with type 1 and type 2 diabetes. The aim is to provide those living with diabetes with the information required to make appropriate choices on the type and quantity of the food which they eat. The goals of dietary advice are as shown in Table 4. The advice must take account of the individual's personal and cultural preferences, beliefs and lifestyle, and must respect the individual's wishes and willingness to change. It must be adapted to the specific needs of the individual which may change with time and circumstance; for example, age, pregnancy, hospital admission, nephropathy, inter current illness such as coeliac or cystic fibrosis. The interaction between food intake, physical activity levels and diabetes medication and the relationship between exercise, energy balance and body weight are an integral part of nutritional counselling. Nevertheless, the practicality of these recommendations should not be underestimated for clinical effectiveness to be accomplished.

Translating theory into practice

There have been major changes in nutrition recommendations over the past decade for persons with type 1 and type 2 DM. The most recent set of nutritional recommendations for DM advocate flexibility in the distribution of caloric intake between monounsaturated fats and carbohydrates. The relative allocation of intake between carbohydrate and monounsaturated fats is not specifically delineated but instead it is recommended that this be individualized on the basis of eating preferences and other considerations. Several of these areas of revision have direct implications for the role of dietary sugars in the nutritional management of DM. Among these is the consideration that MUFAs can lower plasma triglycerides relative to isocaloric consumption of carbohydrates.¹⁰ Current recommendations are that intake of sugars can be appropriate for those with DM, provided the consumption of sugars is taken into account on the basis of calorie consumption. Although the nutritional

merits of low-GI compared with higher-GI carbohydrates continue to be examined and debated, numerous variables can alter the GI, even for a given source of carbohydrate, and this consideration limits the practicality of implementing patient education on this topic. Moreover, whether the GI is a meaningful determinant of metabolic control in DM continues to be challenged on the basis of the collective data of prior clinical trials.

A common issue occurring in clinic is the uncertainty newly diagnosed diabetic clients have regarding the food they should eat. A report by Diabetes UK on the needs of the newly diagnosed found that people with diabetes, particularly the recently diagnosed are confused about what to eat and they find diet, one of the most challenging aspects of diabetes self-care.¹¹ It takes considerable skill to apply the nutritional recommendations for diabetes management in a way which is practical. Many health professionals still suggest a

'diabetic diet' and strict removal of certain food which is perceived as solely affecting DM. For most patients, the actual goal will be to make specific dietary changes towards the ideal. These changes will vary according to individual nutritional and clinical priorities, habitual diet and lifestyle and prevalence of risk factors. The focus should always be on changing an individual's current eating habits (food choice and the timing of its consumption) in an acceptable and hence achievable way and make provision for ongoing support according to individual needs as part of integrated diabetes care.

Conclusion

Achieving good metabolic control of postprandial hyperglycemia remains one of the most challenging aspects of attaining good overall glycaemic control. It is essential that all team members understand nutrition issues and guide the patient's efforts by reinforcing basic and important

messages, referring patients with diabetes for dietetic consultation, promoting the importance of lifestyle changes, and providing support for the nutrition intervention process. Nutrition remains essential for effective diabetes management and successful medical nutrition therapy involves an ongoing process of problem solving, adjustment, and readjustment. Patients must learn how to anticipate and deal with the wide variety of daily decisions they must make regarding food choices and physical activity. Healthy food choices and regular physical activity also improve overall health, an added benefit for people living with a chronic disease such as diabetes.

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Table 3: Sources of fatty acids

<i>cis-Monounsaturated</i>	<i>trans-Unsaturated</i>	<i>polyunsaturated</i>
Olive oil	Hydrogenated vegetable oils (hard margarine)	<i>n-6</i> Corn, sunflower, safflower, soya bean oils and seeds Fat spreads derived from these oils
Some rapeseed oils	Manufactured foods containing hydrogenated vegetable oils (e.g. pies, pastry, biscuits, cakes)	<i>n-3</i> Oily fish and marine oils
Fat spreads derived from olive oil		

Table 4: Goals of dietary advice

- To delay onset/reduce risk of developing diabetes in high risk groups such as women with a history of gestational diabetes
- To maintain or improve nutritional health by facilitating the adoption of healthy food choices
- To achieve and maintain optimal metabolic and physiological outcomes, including reduction of risk for microvascular disease by achieving near normal glycaemia without undue risk of hypoglycaemia; reduction of risk for macrovascular disease, including management of bodyweight, dyslipidaemia and hypertension
- To optimize outcomes where diabetic complications already exist, e.g. in diabetic nephropathy
- To maintain or improve health where any concomitant disorder such as coeliac disease or cystic fibrosis

Administration of drugs to patients with swallowing difficulties

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Patients who are unable to swallow due to a debilitating condition become dependant on an enteral feeding tube both for nutritional needs and for administration of medicines. In general medicines are unlicensed for use in enteral tubes, due to the specialist area and due to the limiting licence conditions.¹ Information regarding this mode of administration is very scarce and also associated with increased risk of tube obstruction, increased toxicity and reduced efficacy due to an inadequate administration method.² It must be kept in mind that any instructions regarding the administration and cautions of an oral dosage formulation also apply when one considers administering the medicine down an enteral feeding tube. Possibly the enteral feeding tube must be used as the last option for administering medicines.

Introduction

This article aims to highlight a few issues which one encounters when advising about how best to administer a medicine to

a patient who cannot swallow or who has an enteral feeding tube.

The British Association for Parenteral and Enteral Nutrition (BAPEN) established

a multi professional working group in early 2002 led by the British Pharmaceutical Nutrition Group (BPNG) to develop information resources on this subject. In 2003 BAPEN launched Guidance on administering drugs via enteral feeding tubes which brings together a concise compilation of information regarding techniques in this mode of administration in a concise way.¹

Unfortunately, crushing tablets is mistakenly taken for granted by some healthcare professionals without considering that the properties of the medication may be affected. As a result of this practice, the treatment may not be effective and may actually cause toxicity and in extreme cases fatality has occurred – eg. A fatality occurred from administration of labetalol and crushed extended-release nifedipine because the sustained release property of nifedipine was broken down and therefore affected its bioavailability.³

Alternative routes

When patients are on multi drug regimens and then are suddenly switched to an enteral route, the treatment needs to be revised and the necessity of each medication evaluated for temporary discontinuation or changed to an alternative route such as an injection. Consideration could also be made to change a medicine to a different drug which has the same pharmacological effects but would be available in an alternative route to oral.

When changing formulations, dose equivalencies need to be taken into account eg. phenytoin, digoxin and fusidic acid. 1g of sodium fusidate is approximately equivalent to 0.98g of fusidic acid, therefore doses of fusidic acid suspension appear relatively higher.⁴ Carbamazepine suppositories need to be adjusted to be equivalent to the oral dose. Therefore dosage or frequency adjustments may be necessary when changing administration routes especially from one agent to another.² Avoid changing the brand of the product used since formulations of the same drug may vary between manufacturers.⁵

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Dysphagia and Malnutrition:

The first ready-to-eat food for a new nutritional Intervention



Issues with liquid formulations

Liquids, soluble or dispersible tablets are the preferred formulation for administration via feeding tubes however not all liquids are suitable for use in enteral tubes.^{4,6} They may be too viscous for administration *via* this route and may also be associated with 'bezoars' which consist of indigestible concretions which may form in the stomach of patients with impaired gastric emptying. Some liquids are not recommended for enteral tube administration because they are absorbed or bound to the plastic tubing eg. diazepam liquid and phenytoin liquid.⁶

The excipients in liquids also need to be considered for their side effects when given enterally. Many sweeteners cause or worsen diarrhea, however sorbitol most commonly causes GI problems.² Cumulative sorbitol doses of 7.5 to 30g may cause adverse effects, with symptoms being particularly severe above 20g.⁶ The content of sorbitol varies depending on the manufacturer and the concentration of the preparation. Care must be taken as to the volumes used and the fact that a patient may be taking multiple liquids which may lead to large concentrations of sorbitol and therefore increase the possibility of associated side effects.

Osmolality of liquids is also associated with GI adverse effects such as diarrhoea. Many liquids have an osmolality higher than 1000mOsm/kg which is much higher than the osmolality of GI secretions (100-400mOsm/kg). However the osmolality data of many liquids is not readily available. These adverse effects may be avoided by

diluting the liquid although this procedure cannot be generally recommended due to the manufacturer warning against its dilution and due to lack of stability information.

Although not all elixirs and suspensions are recommended for administration via an enteral feeding tube (some may cause clogging), they are generally preferable to syrups since the latter have an acidic pH and 'clump' when in contact with enteral feeds.

Issues with oral solid dosage forms

When an alternative route is not possible and liquid preparations are not available, solid oral dosage forms including tablets and capsules is usually considered. However one must be aware that generally an unlicensed use of the medicine is occurring and that the responsibility lies with the prescriber, dispenser and/or person responsible for providing or administering the drug.⁷ Crushed tablets are the most frequent cause of obstruction of feeding tubes which results in increased morbidity and trauma to the patient besides the cost of replacing the tube.⁸ This may require surgical intervention.⁶

Tables 1 and 2 below give examples of preparations that should not be crushed. However the properties of the drug must be also considered, such as light sensitivity or water sensitivity which would be a major contributory factor in the degradation of the drug during the crushing process. Medications may be offensive-tasting and may cause irritation of the oral mucosa

or gastric lining if crushed and therefore consideration has to be given to the site of entry ie. directly into the buccal cavity or *via* a nasogastric tube.

The same principles are true when considering splitting tablets. As a general rule tablets which are not scored, should not be split, let alone crushed. If a tablet is scored, then it is usually considered by the manufacturer to be suitable for division, although this may still be a problem if the tablet does not break evenly into equal sizes.⁹ The halved tablet is then exposed and therefore stability cannot be guaranteed.

The same reasoning holds for opening capsules where the powder may be light-sensitive eg. nifedipine or irritant eg. doxycycline hydrate. Some capsules contain enteric-coated granules which should not be crushed eg. omeprazole, however controversial methods exist of how such granules may be administered via an enteral feeding tube.

Drug-feed interactions

Besides problems associated with the formulation of the drug, other problems include the correct timing of drug administration in relation to feeding times and the importance of flushing the feeding tube before and after each drug administration in order to prevent drug-nutrition incompatibilities.⁸ Generally, if the absorption of a medicine is affected by food, the same will happen with enteral feeds. Avoiding drug interactions is largely dependent on whether the feed is being administered in an intermittent

Table 1: Formulations that should not be crushed or opened ^{2,7,9,10,11,12}

Unscored tablets
Unusually thick or oddly shaped tablets
Film and sugar coated tablets
Enteric or protective coated tablets
Sustained release preparations
Sustained release granules eg. omeprazole
Microencapsulated products
Buccal or sublingual preparations
Chewable tablets
Bitter tasting

Table 2: Classes of drugs that should not be crushed or opened ^{2,7,9,10,11,12}

Antibiotics
Drugs with teratogenic, carcinogenic or cytotoxic properties such as antineoplastics
Teratogenic or Carcinogenic drugs
Nitrates
Steroids
Pancreatic enzymes
Hormone preparations
Prostaglandin analogues
Irritant drugs; also corrosive to oral mucosa and GI tract.
Staining oral mucosa and teeth
Drugs causing allergic reactions

Cross contamination is also possible from the crushing device

or continuous regimen and how often medicines need to be administered.⁶ A classical example of a problematic drug for administration via an enteral feeding tube is phenytoin. Phenytoin absorption may be impaired both due to interaction with the enteral feed and due to binding to the feeding tube. An adequate approach needs to be planned out depending on the frequency of the dose which needs to be timed in between feeds. Usually a 2 hour feed-free period is required before and after phenytoin liquid administration. Appropriate monitoring is important to check the blood levels of phenytoin and especially when any changes are being made both with the drug and the feed. Such interactions need to be noticed and followed up. If doses were adjusted due to lack of therapeutic response, toxicity may ensue when feeds are discontinued (or changed to oral or parenteral), particularly in drugs with a narrow therapeutic index⁶ such as phenytoin. Adding medicines to the enteral feed is never recommended due to possibility of microbial contamination and lack of information on interactions and stability.⁶

Besides interactions related with feeds, interactions are also possible with tap water although this has been rarely reported. Drugs such as ciprofloxacin and doxazocin,

Practice Points for administering medicines via an enteral feeding tube

- Try to use an alternative route to the oral route.
- If no alternative exists, use dispersible tablets or liquid (caution with syrups)
- If a tablet or capsule has to be used, consider the properties of the formulation
- Time the medicines administration in between feeds to avoid drug-feed interaction
- Correct flushing techniques are important to avoid blockage of tube

may chelate with the ions in tap water used to administer the drug. In these cases deionized water should be used.⁶

Other issues related to feeding tubes

The type, size and placement of tube is an important factor which may influence the administration of the drug eg. fine bores are unsuitable for thick liquids. The site of placement of the tube should be noted before administering a drug to avoid a situation where the placement may extend beyond the main site of absorption of the drug. Drugs that may be affected by this include cephalixin, ketoconazole; and also drugs that have a narrow therapeutic window eg. digoxin, warfarin, theophylline, carbamazepine, sodium valproate, phenytoin, and other anticonvulsants.^{6,7,13} It is necessary to monitor the patient for signs of reduction in efficacy of these medicines.

Blockage of the tube occurs when the precautions mentioned above are not taken into consideration. It is important to take precautions as well as assessing the possibility that a particular drug may cause obstructions such as bulk forming medicines (laxatives) as well as sucralfate. The drugs must be administered separately. A correct administration technique is required with adequate flushing between drugs to avoid blockage which must be recorded especially in cases of fluid restriction.

Conclusion

Administering drugs through this route requires trained and experienced healthcare professionals due to the highly specialized area. Each drug must be analysed as to the best possible way to be administered without tampering with its properties. If the oral dosage form is being used differently than the manufacturer intended it, then the responsibility lies with the prescriber and must be aware that this is an unlicensed use.

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Are chondroitin and glucosamine in combination effective in the treatment of osteoarthritic pain?

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Keywords: chondroitin, glucosamine, treatment, osteoarthritis, pain

Non-steroidal anti-inflammatory drugs today are contraindicated for osteoarthritic pain in elderly patients with cardiovascular disease due to adverse effects. An internet review of the evidence regarding the use in osteoarthritis of oral chondroitin and glucosamine in combination produced three relevant randomised controlled trials with valid results. After critical appraisal for reliability and applicability, chondroitin-glucosamine was found to significantly reduce pain in moderate knee osteoarthritis, while significantly improving disability in mild to moderate cases. If the results are generalisable to osteoarthritis of all joints, combined chondroitin-glucosamine in purified therapeutic doses should help care for osteoarthritis patients safely and at moderate expense.

Introduction

Osteoarthritis (OA), the commonest form of arthritis, is the medical condition associated with the highest risk of disabling

immobility over the age of 65 years when the knee joint is involved.¹ Beyond disability, OA also affects quality of life, with consequences on emotional well-

being and body image, relationships, social activities and socio-economic status.²

Of non-surgical treatments for OA, non-steroidal anti-inflammatory drugs (NSAIDs) are effective in reducing pain (as is paracetamol) and inflammation³. However, besides their well-documented adverse effects on the gastrointestinal tract,⁴ some NSAIDs have been said to worsen OA through accelerating cartilage degeneration or analgesia-associated joint overuse.⁵ Recently NSAIDs have also been associated with increased risk of myocardial infarction.³ In fact, the latest NSAIDs of the selective COX-2 inhibitor group are now contraindicated in vascular disease,⁴ which of course is predominant in the elderly.

Therefore, as NSAIDs can no longer be used for OA in elderly patients with cardiovascular disease, and if paracetamol is found to be ineffective, in such cases there certainly would be a place for another form of oral treatment. Chondroitin and glucosamine are such alternative therapies for osteoarthritis made popular with the general public as a result of media publicity.^{1,6,7}

Glucosamine stimulates the production of glycosaminoglycan, a constituent of joint cartilage, while the degradation of glycosaminoglycan is inhibited by chondroitin, thus leading to the hypothesis of a synergistic effect when these are used in combination.^{7,8} Glucosamine and chondroitin thus may be effective in slowing the degenerative process of OA as disease-modifying osteoarthritis drugs, and could have an important effect in postponing the need for joint replacement in severe OA.⁷

A review of the evidence was thus performed regarding the use of oral forms of chondroitin and glucosamine in combination as an alternative treatment for osteoarthritis, which would effectively tackle the pain without causing the adverse effects associated with traditional analgesics.

Methodology

The review was carried out through an internet search of secondary and primary sources, followed by a critical evaluation of the results. Primary sources consist of original research studies, of which Randomised Controlled Trials (RCTs) are

Table 1: Details of the four evaluated randomised double-blind controlled trials

<i>Author/s ± Name</i>	<i>Subjects</i>	<i>Inclusion criteria</i>	<i>Method</i>
Leffler <i>et al.</i> ⁵	34 US Navy males in their 40s	Chronic pain for at least 3 months due to radiographic mild to moderate degenerative joint disease of the knee and/or lower back	One group treated with capsules of glucosamine 1500mg/day, chondroitin 1200mg/day and manganese 228mg/day, with the other given placebo capsules, for 8 weeks. Patients then crossed over to the alternative regimen for an additional 8 weeks, with the study thus lasting 16 weeks in all*
Das & Hammad ⁷	93 patients (aged 45 to 75 years, of both sexes), from a single orthopaedic practice in the USA	Radiographic evidence of mild to severe osteoarthritis (OA) of the knee and symptoms for more than 6 months	Intervention group was prescribed capsules of glucosamine 2000mg/day, chondroitin 1600mg/day and manganese 304mg/day, with the other group receiving placebo capsules, for 6 months
Rai <i>et al.</i> ¹⁶	100 out-patients (ages 50 years plus) from an orthopaedic department in north India	Clinical and radiological OA of the knee	Chondroitin and glucosamine (at unspecified doses) to intervention group and placebo capsules to control group, for 1 year
Clegg <i>et al.</i> 'Glucosamine/ chondroitin Arthritis Intervention Trail' (GAIT) ⁶	1583 patients (from both sexes, 40-70 years old) in 16 US centres	Over 6 months' symptoms of radiographic OA knee	5 groups received one of the following treatments for 24 weeks: glucosamine 1500mg/day, chondroitin 1200mg/day, glucosamine 1500mg/day plus chondroitin 1200mg/day, celecoxib 200mg/day, or placebo

*The trial attempted to minimise post-treatment crossover effects through washout periods before data collection (5 weeks for dairy data and 7 weeks for examination data)

regarded as the gold standard. Secondary sources comprise reviews or meta-analyses of primary studies (normally RCTs).

Secondary source search and evaluation

The Cochrane Database of Systematic Reviews (<http://www.cochrane.org/>) was searched for the combined terms "osteoarthritis", "chondroitin" and "glucosamine" in all fields. Only two reviews (by Singh *et al.*⁹ and Towheed *et al.*¹⁰) looked at the use of chondroitin and glucosamine for the treatment of osteoarthritis. However, as the therapies were assessed on an individual basis (chondroitin and glucosamine respectively) and not in combination, they were unsuitable for consideration by this study.

Subsequently the Database of Abstracts of Reviews of Effects (DARE) (<http://nhscrd.york.ac.uk/>) was searched for these same combined terms in all fields, and produced two hits, namely McAlindon *et al.*¹¹ and Richy *et al.*¹² As these two meta-analyses appraised studies of separate (not combined) use of chondroitin and glucosamine, they too could not be

considered for this review. The next section will thus focus on the primary search for relevant evidence.

Primary source search and evaluation

A search was performed of Medline through PubMed (<http://www.pubmed.gov/>) for the Medical Subject Headings (MeSH) terms "Osteoarthritis/therapy"[MeSH] AND "Chondroitin/therapeutic use"[MeSH] AND "Glucosamine/therapeutic use"[MeSH] using the following limits: '10 Years, only items with abstracts, English, Randomized Controlled Trial, Humans'. This search resulted in six randomised controlled trials.^{5-8,13,14} Two other pertinent RCTs^{15,16} were identified through a search of the Cochrane Central Register of Controlled Trials (CENTRAL) 2006 Issue 1 (<http://www.cochrane.org/>) using the combined terms "osteoarthritis", "chondroitin" and "glucosamine" in an 'all field' search.

Of these eight relevant RCTs, four were eliminated immediately as three did not consider the effect of combined glucosamine and chondroitin as oral therapy^{13,15} for radiologically confirmed

osteoarthritis,⁸ while the fourth just looked for a possible side effect on glycosylated haemoglobin levels.¹⁴ The remaining four trials which were suitable for evaluation are described in Table 1. These four RCTs were then critically appraised for the validity, reliability and applicability of their results.

Critical appraisal of validity of results

The validity of the results of the RCTs was critically appraised using questions developed by Rosenberg & Donald¹⁷ shown in Table 2. Of the four trials, that by Rai *et al.*¹⁶ did not account properly for all patients who entered the trial and attribute them at its conclusion. Moreover, it was the only one of the four studies which did not specify the doses of chondroitin and glucosamine administered. As such, this study was eliminated from further consideration.

Critical appraisal of reliability and applicability of results

This critical appraisal of the reliability and applicability of the three remaining trials is based on the check-list of questions

Table 2: Critical appraisal of result validity of the relevant RCTs based on questions developed by Rosenberg & Donald¹⁷

Are the results valid?	Leffler <i>et al.</i> ⁵	Das & Hammad ⁷	Rai <i>et al.</i> ¹⁶	Clegg <i>et al.</i> ⁶
1. Was the assignment of patients to treatments randomised?	Yes	Yes	Yes	Yes
2. Were all patients who entered the trial properly accounted for and attributed at its conclusion?	Yes	Yes	No	Yes
3. Was follow-up complete?	Yes	Yes	Yes	Yes
4. Were patients analysed in the groups to which they were randomised?	Yes	Yes	Yes	Yes
5. Were patients, health workers and study personnel blinded to treatment?	Yes	Yes	Yes	Yes
6. Were the groups similar at the start of the trial?	Yes	Yes	Yes	Yes
7. Aside from the experimental intervention, were the groups treated equally?"	Yes	Yes	Yes	Yes

(Rosenberg & Donald)¹⁷ shown in Table 3. All three RCTs were performed for a minimum of 8 weeks and a maximum of 6 months, giving enough time for the medication to have an effect, and included at least two recommended outcome measures¹⁸ (see Table 4 for details).

The Leffler *et al.*⁵ study of mild to moderate OA showed a statistically significant improvement in visual analogue scale for pain ($p=0.02$) for knee and back data in subjects in the intervention group. This was attributed mainly to the knee data which, when examined individually, showed a mean reduction in the visual analogue score for pain of -26.6% during clinic visits (95% CI -53.0% to -0.20%; $p=0.048$) and -28.6% in a diary kept by subjects (95% CI -52.7% to -4.50%; $p=0.02$).

In the Das & Hammad trial⁷, there was a statistically significant drop in the Lequesne disability index in subjects with mild to moderate OA (N=72) treated with chondroitin/glucosamine compared to the placebo group, from 10.2 (± 0.4) at baseline, to 7.2 (± 0.6 ; $p=0.003$) at 4 months, and 7.4 (± 0.6 ; $p=0.04$) at 6 months.

In the GAIT large multi-centre study, Clegg *et al.*⁶ found that, in subjects with moderate to severe OA (N=352), chondroitin and glucosamine in combination were significantly more effective than placebo (24.9 % points higher in the WOMAC pain score, $p=0.002$). For mild to severe OA, combined chondroitin-glucosamine also showed a higher rate of response compared to placebo than either of its individual components, but this improvement did not reach significance (when taken as $p<0.05$).

Table 3: Critical appraisal of the reliability and applicability of the relevant RCTs (Rosenberg & Donald)¹⁷

Are the results reliable?

- How precise was the treatment effect?
- How large was the treatment effect?

Are the results applicable?

- Can the results be applied to my patient care?
- Will the results help me care for my patients?
- Were all clinically important outcomes considered?
- Are the likely benefits worth the potential harms and costs?

Table 4: Outcome measures recommended for osteoarthritis trials by the Osteoarthritis Research Society¹⁸ and their use by the three appraised trials

Outcome measure	Used by
Global pain score for index joint (visual analogue or Likert scale)	Clegg <i>et al.</i> ⁶ Das & Hammad ⁷ Leffler <i>et al.</i> ⁵
Pain on walking for index joint (visual analogue or Likert scale)	None
Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index Pain Subscale (visual analogue or Likert scale)	Clegg <i>et al.</i> ⁶ Das & Hammad ⁷
Lequesne index (questionnaire-based disability score)	Das & Hammad ⁷ Leffler <i>et al.</i> ⁵
Pain in index joint during activities other than walking (visual analogue or Likert scale)	None

Discussion

When the results of the three RCTs are taken together, chondroitin and glucosamine in combination were found to:

- significantly reduce pain in mild to moderate OA measured by the global pain

visual analogue scale⁵, and in moderate to severe OA measured by the WOMAC Scale;⁶

- significantly improve disability in mild to moderate OA as measured by the Lequesne Index.⁷

As patients in the community have similar characteristics to the subjects within the three trials (males and females aged over forty, with painful mild, moderate or severe osteoarthritis of the knee), the results can be applied to such patient care. However the quality and standardisation of commercially-available food supplements such as chondroitin and glucosamine are questionable, and thus effects in practice may not be equivalent to RCTs' results based upon purified and assayed preparations.^{6,7,19,20}

Nevertheless, if the results are taken to be generalisable to OA of all joints, and if the chondroitin-glucosamine combination used in practice is pure and potent, the results should help care for patients in practice as long as the optimal therapeutic

doses are used. This would involve doses ranging from glucosamine 1500mg/day and chondroitin 1200mg/day^{5,6} to glucosamine 2000mg/day and chondroitin 1600mg/day.⁷

As signs and symptoms of side effects were rare and mild, and were similar between the intervention and placebo groups, the benefit-risk ratio seems favourable. However, one needs to consider the adverse effects of long term use, such as on diabetes control¹⁴, and also any effects resulting from drug interactions. Regarding financial aspects, chondroitin and glucosamine each cost up to \$25 each month.¹⁹ Studies need to be carried out to establish if this expense may be considered as an investment in view of a possible reduction of any expensive management options necessitated by complications of osteoarthritis.

Conclusion

There are good indications that combined oral preparations of chondroitin and glucosamine may be effective and quite useful in the treatment of osteoarthritis due to their safety and moderate expense, as long as their purity and potency are ensured. In order to facilitate any possible recommendations for their use in clinical practice, long-term and larger studies are needed to elaborate more definite results and investigate their preventive use as disease-modifying osteoarthritis drugs.

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