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Inside

For want of a placebo

...the strongest evidence for therapeutic interventions is provided by systematic review of randomized, double-blind, placebo-controlled trials involving a homogeneous patient population and medical condition. In contrast, patient testimonials, case reports, and even expert opinion have little value as proof because of the placebo effect, the biases inherent in observation and reporting of cases, difficulties in ascertaining who is an expert, and more.

Wikipedia

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The Wikipedia quote above is one of countless examples that show the almost universal acceptance of this principle. There are, however, serious implications when the criteria for 'evidence' are defined in a manner that excludes other forms of valid evidence. A cliché catchphrase can become a cloak of invisibility. The idea of evidence based medicine would seem to be fairly uncontroversial, and indeed guides the actions of the UK healthcare community. After all, if there is no proof of efficacy, there is no justification for the use of a given treatment.

The classic randomised, double blind, placebo controlled trial is undoubtedly a powerful tool in the development of therapeutic treatments and procedures in the world of healthcare. The placebo effect is a well-known and unquestioned factor in the assessment of any potential treatment, and it is therefore logical to defer to any study that works to eliminate this effect. For this reason, all respected medical journals, most of the healthcare community, and certainly the government regulators require studies to meet these criteria before a treatment will even be considered.

Unfortunately, there are drawbacks. The most immediate difficulty with the classic notion of evidence based research is that some situations do not lend themselves well (or at all) to placebo controlled, double blind studies. In such cases, valuable information may be filtered out by the qualifiers set during literature searches and that information will never be seen by the very community that stands to benefit.

As a case in point, one of the more serious current healthcare problems is the rapid proliferation of type 2 diabetes. Current estimated

costs to the NHS for treatment of this problem are a staggering £1 million per hour. However, a weight loss approach is available that costs the NHS nothing, can usually normalise blood sugars within a few days (even in long standing diabetes) and in most cases actually put type 2 diabetes into remission. This important clinical knowledge is virtually unknown because in this instance, it is impossible to design a placebo controlled study. Even thorough research of existing literature will be futile, since the information will usually be filtered out and not available for consideration.

Type 2 diabetes is usually a consequence of excess weight and it has been recognised for decades that weight loss will improve the clinical condition. In recent years, bariatric surgeons have become bolder with their own assertions and many now claim to 'cure' diabetes or at least put the disease into remission. It is certainly true that the weight loss associated with bariatric surgery can indeed put diabetes into remission, but the secondary claim – that surgery is the only means of accomplishing this – cannot be supported. If however, evidence of alternative means of substantial weight loss are filtered out and never even considered, bariatric surgery (by default) becomes the method of choice.

Shifting the balance of evidence

While case studies are often considered to be a lesser level of evidence, the balance of believable evidence must shift, especially when the number of cases being audited becomes virtually the entire treatment population. For the past 25 years GPs and pharmacists have been treating overweight and obese patients with very low calorie diets and monitoring their progress weekly over the course of their treatment. Those medical details and weekly progress reports have all been recorded, and a number of audits from individual GP practices and a 25 practice meta-audit have been published. As it is impossible to provide a placebo control for a VLCD, these results have been largely unrecognised.

As the population of GP practices and pharmacies managing weight with VLCD has expanded and computer records become more available, it has become theoretically possible to audit the entire population. An audit from a group of pharmacies in the Republic of Ireland has provided data for over 9,000 Lipotrim patients. A single pharmacy in Prestwich, Manchester has provided audit data for over 1,100 dieting patients. Since these patients are seen weekly and their progress recorded by the health professionals, the information should be viewed as highly credible. The weight losses are having the same effect on type 2 diabetes as that reported for surgery. Patients, therefore, are not permitted to start the diet unless the GP has stopped diabetic medication. Blood sugars will normalise within a few days, and with a few weeks weight loss it is unlikely that any further diabetic medication will be required as long as they maintain some of the weight loss.

The key to the safety and efficacy of weight loss with VLCDs is the knowledgeable screening and continued monitoring by well trained health professionals. The extension of the medical programme as a pharmacy service has proven invaluable since pharmacy offers many advantages over GP treatment for a substantial number of reasons, not the least of which are accessibility and the availability for continued support long after the weight is lost.

The benefits of weight loss

NICE guidelines acknowledge extended use of VLCDs when properly monitored by healthcare professionals. There is certainly plenty of justification for helping overweight patients: weight loss can lower blood pressure, normalise blood lipids, practically eliminate type 2 diabetes, reduce the severity of asthma, bring relief to arthritics, increase fertility, relieve sleep apnoea, provide an opportunity for patients to be considered for elective surgery, decrease the need for antidepressants, make exercise more possible – thus improving cardiovascular health and vastly improve the quality of life for patients.

There is now a 30 year history of safe and effective worldwide usage of total food replacements based upon the concept of low fat nutrient-complete enteral feeds (VLCDs as they came to be known). An enormous volume of scientific and medical literature has been thoroughly evaluated by expert committees and they have been recognised as safe and, in cases such as type 2 diabetes, more effective than standard weight loss methods. An expanding network of health professionals in UK and Irish pharmacies are now offering a range of treatments for weight problems. They have the training, the respect of the public, the contact hours and the desire to offer weight management as an expanded professional service. NICE recommends that specialists be used; these trained and experienced pharmacists and GPs are achieving considerable success and their success should not remain invisible for want of a suitable placebo.

"The current burden of morbid obesity in the UK is approximately 720,000 patients who meet NICE criteria for eligibility for surgery. Last year, only 4,000 operations for morbid obesity were performed in the public and private sector combined."[1]

Even if the number of patients being treated by surgery was doubled, the impact on the problem would still be small. Doubling the costs of the surgery and aftercare would raise the percentage from a paltry 0.5 per cent to a marginally less paltry 1.1 per cent. This is still far short of the treatment needs of the seriously overweight population. Most surveys now estimate that 60 per cent of the UK population is overweight and about 30 per cent already obese. Assuming a total population of 60 million in the UK, the number of people with a weight problem calculates to 36 million overweight and 18 million obese. In the audit from the Irish pharmacies mentioned earlier, 7,259 people lost more than 5 per cent of their prediet weight. 2,969 lost more than 10 per cent. In the Prestwich pharmacy, 94 per cent lost more than 5 per cent of their prediet weight, 47 per cent lost more than 10 per cent and. 21 per cent of the patients lost more than 20 per cent.

Obviously, something more readily available than just surgery is needed, not only for treatment but also to prevent the progression from overweight to obesity to the massive obesity that passes the threshold for surgical intervention. Such methods are already available and would be more widely recognised if the usual search limits for evidence based treatments were modified to accept other perfectly valid forms of evidence.

Reference

1. The Provision of Bariatric Surgery in the United Kingdom – Past, Present and Future Considerations: The Road to Excellence. Department of Bariatric Surgery, Imperial College Healthcare, Charing Cross Hospital, London, September, 2009.