Alimentary tract

Comparison of weight loss with short term dietary and intragastric balloon treatment

D DURRANS AND T V TAYLOR

From the Department of Surgical Gastroenterology, Manchester Royal Infirmary, Manchester

SUMMARY Treatment of 41 morbidly obese patients with a 3·34 mega joule diet has been compared with the same dietary regime together with an intragastric balloon. After eight weeks of closely supervised dietary regime a free floating silicone intragastric balloon with a capacity of 500 ml was inserted and the patient advised to adhere to the same diet for a further eight weeks. Thirty four patients completed the study. Forty eight per cent lost weight during the dietary period compared with 97% during balloon treatment. The mean weight loss with diet alone was 1·9 (3) kg compared with 7·5 (4·1) kg with the balloon ($p < 0·001$). Apart from postinsertion vomiting, which resolved by 72 hours, there were no gastric complications associated with the balloon. This study indicates that, in the short term at least, the intragastric balloon can improve on weight loss achieved by diet alone.

It is a commonly held belief that the British are becoming increasingly obese, a view confirmed by a recent report commissioned by the Department of Health and Social Security which identified 36% of the population to be above normal weight range and 7% to be obese.¹ Evidence from a number of studies^{2,3} indicates that any degree of obesity incurs some risk of premature death, and although more difficult to quantify obesity is undoubtedly associated with a number of medical problems.⁴ As it is unlikely that the medical profession is complacent in its attitude to the problem the prevalence of obesity can only be a reflection that no treatment exists which is appropriate to all grades of obesity.

One prime difficulty with contemporary treatment is that it is impossible to separate efficacy and risk. Surgical procedures while successful in achieving sustained weight loss are associated with significant mortality and morbidity which make their use appropriate only in patients 45 kg or more overweight,^{5,6} these being only 0·2% of the adult population. Conversely, dietary treatment alone, while appropriate to any grade of obesity, is rarely successful even in the short term.⁷ Despite these therapies are probably satisfactory for the extreme ends of the range of obesity. The relative risk of being a few

kilograms overweight makes the use of additional treatments impractical and the demonstrated efficacy of gastroplasty makes it appropriate for the morbidly obese. There remain, however, a large number of moderately obese patients with a mortality risk of 1·5-3·0 times that of the general population for whom no satisfactory treatment exists. This number represents 7% of the population.

In recent years the concept of using an intragastric balloon in such patients has been suggested. The concept that such devices would induce early satiety and thereby reduce caloric intake is attractive, and uncontrolled studies appear to support the hypothesis.⁸⁻¹⁰ Such reports, however, fail to take any account of the potential of placebo effect in such treatment and to date it remains uncertain whether the use of an intragastric balloon has any advantage when compared with supervised dieting undertaken on an outpatient basis.

The aim of this study was to compare early weight loss using dietary treatment with that using diet and balloon therapy in combination.

Methods

PATIENTS

Between January 1985 and June 1986 41 (13 men, 28 women) patients referred for obesity treatment were included in a trial to compare consecutive two month periods of closely supervised reducing diet with and

Address for correspondence: Dr D Durrans, Dept of Surgery, Room 19, Pavillion 10, Withington Hospital, Nell Lane, Manchester M20 8LR.

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without an intragastric balloon. All had a Body Mass Index (BMI) in excess of 30 units; 35 patients being in excess of 40. The mean age was 36.5 years with a range of 18–56 years. The mean duration of obesity history was 18 years with a range of 5–30 years. All patients had previously tried a variety of dietary treatments, this with the aid of their general practitioner in 85% of cases and hospital supervision in 60%. Anorectic drug treatment had been received by 17% and one patient had undergone dental splintage.

An endocrine aetiology for their obesity was excluded by estimation of thyroid hormones, FSH, LH, prolactin and cortisone. In addition serum testosterone concentrations were determined in men. Excluded from the trial were patients less than 18 years of age, those with less than a two year history of obesity, and patients with a history of endocrine disorders, peptic ulceration, intestinal surgery or uninvestigated gastrointestinal symptoms.

Patients were interviewed by the senior hospital dietician and a full dietary history was taken. They were then started on an 800 kcal reducing diet and advised to return for weighing and supportive counselling every two weeks. Before treatment, assessment by a psychiatrist was undertaken to exclude major psychiatric disorders. After two months of dietary treatment patients were admitted for balloon insertion. After an overnight fast the procedure was carried out under light sedation with Diazemuls 5–10 mg intravenously and local anaesthetic throat spray. Upper gastrointestinal endoscopy was done before balloon insertion. A pear shaped silicone balloon (Mill-Rose Technologies, Cleveland, Ohio) was inserted into the stomach by means of an overtube. This was inflated with 500 ml normal saline and then detached from the insufflation tube by traction. Thirty millilitres of hypaque was added to the inflation fluid so position and size of the free floating balloon could be checked radiologically. After balloon insertion patients were observed in hospital until adequate fluid intake had been resumed. On discharge they were instructed to continue with the 800 kcal diet as taken before balloon insertion. Initial follow up was at two weeks after balloon insertion and thereafter at four and eight weeks, patients being seen by surgeon and dietician when their weight was recorded and abdominal radiography carried out.

WITHDRAWALS

Seven patients were withdrawn from the trial. Two patients failed to attend for dietary counselling before balloon insertion and were withdrawn on the grounds of non-compliance. One suffered a myocardial infarction during the initial dietary treatment. Four patients, two of whom had Pickwickian

syndrome, were unable to tolerate balloon insertion, respiration becoming impaired on passage of the balloon insertion tube.

STATISTICAL ANALYSIS

The number of patients losing weight with each treatment was compared using the χ^2 test. Comparison of individual weight loss before and after balloon insertion was made using Wilcoxon's matched pair signed rank sum test and correlation analysis performed between pre and post balloon insertion weight change using the Spearman rank correlation coefficient.

Results

Thirty four patients conformed to the study protocol and all had inflated balloons at the eighth week of treatment. Weight changes during the two periods of treatment are shown in the Figure. Ninety seven per cent of patients lost weight with balloon treatment compared with 48% on dietary treatment alone ($\chi^2 = 17.0$ $p < 0.0001$). Only one patient with an intragastric balloon in place failed to lose weight. The mean weight loss during dietary treatment alone was 1.9 kg (range +3–11 kg, SD 3). In contrast the mean loss after balloon insertion was 7.5 kg (range 0–18 kg, SD 4.1). This difference is significant at the 1% level ($p < 0.01$ two tailed test). Thus the average weight loss with diet was 0.2 kg per week compared with 0.94 kg per week after balloon insertion. Correlation analysis showed a significant association between dietary and balloon weight losses ($r = 0.48$ $p < 0.01$).

Figure Comparison of dietary and balloon weight change after eight weeks treatment.

No patient developed any gastric side effects from balloon insertion apart from vomiting which occurred in all patients after insertion for an average duration of 18 hours. In no case did this persist for over 72 hours. No patient presented with gastrointestinal bleeding as a consequence of balloon placement and endoscopy at the end of the study was normal. A feeling of early satiety was reported by all patients but was apparently of variable degree.

Discussion

The concept of using an intragastric balloon for the control of obesity is attractive in its simplicity. A large number of such devices have already been used in the United States, but satisfactory controlled trials comparing results with placebo or other obesity treatments are lacking. The only controlled study yet published, examining a single design of 200 ml in only 10 patients, failed to show any benefit by use of a balloon.¹¹ This study, however, using a larger volume balloon, has shown a distinct advantage, albeit over short periods of treatment.

The rarity of controlled trials in obesity treatments is probably a reflection of some of the difficulties in the management of these patients and also a recognition of the heterogeneity of aetiology. The present study has been an attempt to use the patient as his or her own control. It is impossible with this type of treatment to conduct anything but an open trial and an element of bias in results is difficult to exclude, most particularly in relation to placebo response. While the observed weight losses would indicate that the balloon improves dietary compliance it is impossible to distinguish whether this results from improved satiety or a more powerful placebo response to balloon treatment over that with diet alone. Although it may remain impossible to resolve this controversy in human studies, our own experiments in a canine animal model have shown balloon insertion to result in a mean reduction of daily caloric intake by 54% without any evidence of aversive behaviour, presumably the result of induced satiety.¹²

The periods of study in this trial are relatively short. The study was designed in this way so that it could be more carefully monitored from the point of view of recording weight change, dietary compliance and balloon complications. Such a study fails, however, to establish that use of such a device is a realistic approach to the treatment of obesity, particularly with respect to the duration over which treatment is effective, and whether relevant amounts of weight loss can be achieved. On follow up the patients in this study achieved a mean weight loss of 15.6 kg (range 3–54.6 kg) over a mean duration of 23.5 weeks (range 12–36 weeks), only 16% of patients losing sufficient

weight to bring them within 50% of their ideal weight.¹² While such results are not impressive it is to be emphasised that the patients studied were shown to be incapable of losing weight by dietary means alone.

One particular problem experienced during follow up has been that of balloon deflation, replacement being necessary on average every 13 weeks. Until performance in this respect can be improved it remains uncertain whether the above results fairly reflect what might be achieved with a reliable device. Balloon deflation has also been the cause of the only major side effect we have experienced using the technique, four of 52 balloon insertions culminating in small bowel obstruction, one patient requiring laparotomy. Spontaneous deflation has been a problem with most balloon designs so far described, and for the present it seems advisable that elective replacement should be undertaken every three months. No gastric side effects have been experienced with the device used in this study, and histological studies in a canine animal model have shown no specific abnormalities to result from the presence of the balloon in the stomach over a period of 20 weeks.¹²

Recently, a number of reports from the United States have led to doubts about the efficacy and safety of intragastric balloons, particularly with regard to the incidence of gastric ulceration. The majority of these reports relate to the 'Garren Gastric Bubble'¹³ and we feel that the results may be a reflection of the design of this particular device rather than a failure of the concept itself. We believe the concept deserves further scientific evaluation, there being a danger that a useful technique is rejected on the basis of results obtained with a device that may well be of inadequate volume and poor design. Although experience with other designs is limited, to date none have been associated with gastric ulceration and it seems possible that this might be a complication specifically related to the Garren design.

In conclusion the use of a 500 ml intragastric balloon in combination with an 800 kcal diet improved weight loss when compared with diet alone over an eight week period of treatment.

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