

# Limited Weight Losses With a Gastric Balloon

F. Matthew Kramer, PhD; Albert J. Stunkard, MD; Theresa A. Spiegel, PhD; Julius J. Deren, MD; Michael G. Velchik, MD; Thomas A. Wadden, PhD; Kathleen A. Marshall

• An evaluation of the Garren-Edwards gastric bubble in the treatment of obesity was done. Several clinical trials have compared the effects of behavior therapy with and without the bubble, but the effects of the bubble alone have not been previously evaluated. Ten obese women averaging 91% overweight received the bubble without adjunctive therapy during a 12-week treatment period. Frequent psychological and laboratory measures as well as weight were obtained during the study to explore the possible mechanisms of the bubble's effect and its side effects. Mean weight change was  $-2.5$  kg, with a range of  $-8.8$  to  $+1.6$  kg. Four patients lost more than  $3.5$  kg, three lost less than  $3.5$  kg, and three gained weight. The Garren-Edwards gastric bubble alone does not appear to provide significant benefit to most obese patients.

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This article evaluates the Garren-Edwards gastric bubble in the treatment of obesity. The bubble is a plastic balloon inserted endoscopically into the stomach and inflated with 220 cc of air. It was approved by the Food and Drug Administration in 1985 but only as an adjunct to behavior therapy for obesity, and in less than a year, 20 000 bubbles had been sold.<sup>1</sup> Reports, so far in abstract form only, describe large weight losses in uncontrolled trials of the bubble in conjunction with diet and behavior therapy.<sup>2-7</sup> Controlled trials, also primarily in abstract form, to assess the effectiveness of behavior therapy with and without the bubble, however, have found that the bubble has little apparent effect.<sup>8-12</sup> There have been no previous efforts to assess the effects of the bubble alone. The result is the curious circumstance that a widely used therapeutic agent, for which there is equivocal evidence of efficacy, has not been tested for its efficacy independent of other intervention. We report herein the results of such a test.

## PATIENTS AND METHODS

Patients included ten obese women who responded to a local newspaper article about the bubble (*The Philadelphia Inquirer*, Dec 8, 1986, p 2-E). The patients had an average pretreatment weight of 111.2 kg, were 91% overweight,<sup>13</sup> and were 36 years old. They were told that the purpose of the study was to examine the effectiveness of the Garren-Edwards gastric bubble without adjunctive therapy. Patients agreed to participate in a four-week baseline period, 12 weeks of treatment with the bubble, and 12 weeks of follow-up.

The bubble was inserted following preliminary endoscopic examination to rule out gastric abnormalities. Patients were given an H<sub>2</sub> blocker (ranitidine [Zantac]) to take as needed for stomach discomfort during the course of the study (150 mg twice a day during the first month following insertion and 150 mg once daily

for the last two months). They were also encouraged to use an over-the-counter antacid as needed.

To evaluate the effects of the bubble alone, patients were not given specific behavioral or dietary advice. They did, however, receive extensive support from study personnel, and they reported positive expectations and high hopes that the bubble would produce significant weight loss.

Each patient with a bubble was matched by percentage overweight (height, weight, and age were also matched as closely as possible) to three women who had participated in a previous behavioral weight control program<sup>14</sup> to compare weight losses by the two methods over a 12-week treatment period. The characteristics of the ten patients receiving the bubble and of the 30 post hoc comparison patients are shown in the Table.

Patients were seen for at least 30 minutes each week during treatment to obtain assessment materials and an interim history. The Eating Inventory<sup>15</sup> was administered at the beginning of the study. This inventory has the following three scales measuring aspects of dieting and eating attitudes: cognitive restraint, disinhibition, and hunger. High cognitive restraint is associated with a high level of conscious control of eating, whereas high disinhibition is associated with a tendency to lose control of intake in the face of disruptive moods or events. High hunger is associated with an increased sensitivity to feelings of hunger. The three following questionnaires were also administered at the beginning of the study and, in addition, every two weeks thereafter: the Beck Depression Inventory, the State-Trait Anxiety Inventory, and the Symptom Checklist 90.<sup>16-18</sup> Patients were asked to record their daily food intake and to rate their stomach discomfort and hunger on 100-mm visual analogue scales before and after each meal throughout the study.

Two types of laboratory measures were obtained to assess potential mechanisms of weight loss associated with the bubble—measurement of eating behavior in the laboratory and of gastric emptying following a test meal. Laboratory test meals were conducted before bubble insertion; at 2, 6, and 10 weeks following insertion; and five and 12 weeks after removal of the bubble. Gastric emptying of a solid meal was assessed before and approximately five weeks after insertion of the bubble and four weeks after its removal. The meal consisted of 300  $\mu$ Ci of technetium Tc 99m sulfur colloid in the form of a 1260-kJ egg sandwich (egg white, 248 g; white bread, 40 g; and butter, 6 g). Images were obtained in the anterior and posterior projections at 15-minute intervals, and the percentage of gastric emptying was calculated with a decay-corrected geometric mean.<sup>19</sup>

## RESULTS

The mean weight change of the patients with bubbles was  $-2.5$  kg, with a range of  $-8.8$  to  $+1.6$  kg. Weight changes of these patients and their matched controls who had undergone behavior therapy are shown in the Figure and Table.

Four patients with bubbles lost more than 3.5 kg, three lost less than 3.5 kg, and three gained weight. As can be seen in the Figure, 26 of the 30 patients who had received behavior therapy lost more weight than the patients with bubbles with whom they were matched. Mean weight loss for the patients who had received behavior therapy (8.7 kg) was more than three times greater ( $P < .001$ ) than that of the patients with bubbles (2.5 kg).

Stomach discomfort was reported by most patients. It was assessed in two ways—by the daily home ratings using 100-mm visual analogue scales and by weekly interviews.

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From the Departments of Psychiatry (Drs Kramer, Stunkard, Spiegel, and Wadden and Ms Marshall) and Radiology (Dr Velchik), University of Pennsylvania, and the Gastroenterology Section, Graduate Hospital (Dr Deren), Philadelphia. Dr Kramer is now with the US Army Natick Research, Development, and Engineering Center, Natick, Mass.

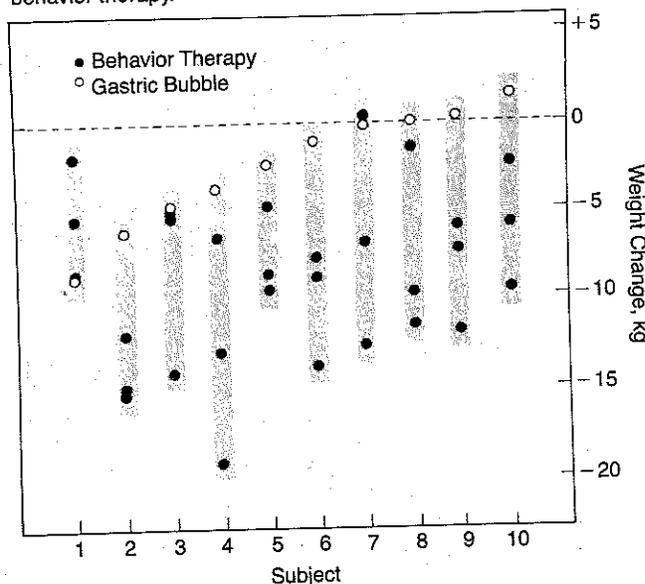
Reprint requests to Behavioral Sciences Division, SATD, US Army Natick Research, Development, and Engineering Center, Natick, MA 01760-5020 (Dr Kramer).

Baseline Characteristics of the Subjects With Bubbles and Matched Patients Who Had Undergone Behavior Therapy\*

Subject Pairs	Weight, kg	Height, m	% Overweight	Age, y	Stomach Discomfort	Endoscopy Results	Weight Loss, kg
1							
Bubble	102.0	1.64	82	50	Severe	...	-8.75
Controls	101.3	1.63	79.2	45.3	...	...	-5.30
2							
Bubble	115.3	1.62	111	32	Moderate	...	-6.25
Controls	115.8	1.61	111.9	34	...	...	-14.14
3							
Bubble	106.4	1.70	74	37	Mild	...	-4.55
Controls	106.3	1.67	79.8	44.7	...	...	-8.26
4							
Bubble	135.5	1.66	136	28	Mild	Erosion	-3.63
Controls	143.6	1.71	133.9	37	...	...	-12.88
5							
Bubble	116.4	1.55	127	33	Moderate	...	-2.39
Controls	123.4	1.66	115.1	46.3	...	...	-7.65
6							
Bubble	111.4	1.73	77	37	Mild	Erythema	-1.14
Controls	110.2	1.65	91.2	41	...	...	-10.27
7							
Bubble	112.3	1.62	101	47	Mild	...	-0.34
Controls	113.0	1.62	102.8	51	...	...	-6.51
8							
Bubble	109.1	1.75	72	29	Moderate	Ulcer	+0.23
Controls	105.2	1.69	75.4	43.7	...	...	-7.60
9							
Bubble	115.9	1.76	76	30	None	...	+0.45
Controls	115.0	1.76	77.9	49.7	...	...	-8.51
10							
Bubble	88.4	1.65	53	37	Mild	...	+1.59
Controls	88.2	1.64	55.4	36	...	...	-6.02
Means							
Bubble	111.3	1.67	90.9	36	...	...	-2.48
Controls	112.2	1.66	92.3	42.9	...	...	-8.71

\*Each patient with a bubble was matched to three patients who had undergone behavior therapy.

Weight change over 12 weeks of treatment for individual patients with bubbles and three matched patients who had undergone behavior therapy.



The daily home ratings revealed a small average increase in stomach discomfort following bubble insertion from 2.9 to 14.3 mm. Increase in discomfort ratings was greatest in the two patients who lost the most weight, and discomfort was correlated with weight loss ( $r = .72, P < .03$ ).

Results of the more detailed inquiry possible in the weekly interviews were consistent with the visual analogue ratings and revealed that nine of the ten patients experienced discomfort that ranged from severe and persistent in one patient to mild and transient in five patients (Table). There was little relationship between discomfort and endoscopic evidence of disease. As shown in the Table, disease was limited to a small gastric erosion in the proximal stomach, with minor friability in the antrum in patient 4, mild erythema in the proximal portion in patient 6, and a small, benign-appearing ulcer in patient 8. Endoscopy at bubble removal showed no other disease and revealed that all ten bubbles were still inflated.

At the start of the study, the patients scored within normal limits on the psychological measures, and they did not show any systematic changes over the course of treatment.

Two of the three subscales on the Eating Inventory showed a relationship with outcome and with parameters of eating behavior. The cognitive restraint and the "disin-

hibition" scales each correctly classified nine of the ten patients as losing more or less than 4.5 kg. Thus, patients who reported a high level of cognitive restraint at baseline lost larger amounts of weight, while patients who reported a tendency toward disinhibition lost smaller amounts. Higher scores on the cognitive restraint scale were significantly related to decreased meal length in the laboratory following bubble insertion ( $r = .76$ ,  $P < .03$ ) and tended to be related to decreased meal length at home ( $r = .62$ ,  $P = .1$ ). Higher scores on the disinhibition scale were significantly related to increased laboratory meal length both before and after bubble insertion ( $r = .74$  and  $.76$ ,  $P < .05$ ) and less decrease in laboratory meal length as a result of the insertion ( $r = -.66$ ,  $P < .08$ ).

Neither of the two measures of eating behavior—laboratory meals and reports of food intake at home—contributed to an understanding of the results, nor did the measurement of gastric emptying. Bubble insertion was followed by a decrease in all measures of food intake—laboratory meals decreased by 36% ( $P < .01$ , from an average of 2566 kJ during baseline to an average of 1634 kJ with the bubble); reported daily intake decreased by 25% ( $P < .01$ , from 7316 to 5435 kJ); meal duration in the laboratory decreased by 19% ( $P < .05$ , from 24 to 19.6 minutes); and reported meal duration at home decreased by 18% ( $P < .05$ , from 41.2 to 33.7 minutes). There was, however, little relationship between measures of food intake and weight loss.

Similarly, although bubble insertion was followed by a decrease in gastric emptying at 22.8% ( $P < .05$ , from 53.3% to 42.7% at 60 minutes), there was no relationship between changes in gastric emptying and weight loss.

At three months after bubble removal, average weight change decreased from  $-2.5$  kg at the end of treatment to  $-1.6$  kg. Similarly, stomach discomfort, laboratory meal size, and gastric emptying returned toward baseline levels.

#### COMMENT

The Garren-Edwards gastric bubble alone did not seem to provide significant benefits to obese patients in the absence of behavioral and dietary intervention. This result is perhaps not surprising. It is true that large weight losses were reported from early studies of the bubble, but

only when it was used in conjunction with other therapies. The largest such losses, reported by Garren and associates,<sup>2</sup> averaged 19.5 kg at six months and 34.8 kg at ten months in 144 patients. Losses in other uncontrolled trials were 6.5 kg and 10 kg at three months in two studies<sup>3,4</sup> and 10.5, 15, and 19.5 kg at four months in three others.<sup>5-7</sup>

Controlled trials have reported smaller weight losses ranging from 5 to 14 kg.<sup>8-12</sup> The use of adjunctive behavioral and dietary intervention in each case makes it difficult to ascribe an effect to the bubble. Only one of the five reports indicated that weight losses from behavior therapy were increased by the bubble as compared with sham insertion.<sup>10</sup>

The distinctive feature of the current study is that it is the first in which the effects of the bubble were assessed without adjunctive therapies. The small weight losses are consistent with the finding from controlled trials that the bubble conferred minimal benefit over that achieved with behavior therapy.

The relationship of the Eating Inventory scores to weight loss is similar to that in previous studies in which cognitive restraint was positively<sup>20,21</sup> and disinhibition negatively<sup>21</sup> related to weight loss. It is difficult to understand the lack of relationship between weight loss and the laboratory tests and measures of food intake. The small size of the sample, limited range of weight losses, and differences in energy requirements may have contributed to the failure to find such relationships.

Currently, there is little evidence that the Garren-Edwards gastric bubble is responsible for clinically significant weight losses.

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