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New Technique for Endoscopic Removal of Intragastric Balloon Placed for Treatment of Morbid Obesity

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Background: Placement and removal of the intragastric balloon for obesity are performed endoscopically often under general anesthesia. We propose a safer and faster technique for endoscopic removal of the intragastric balloon using standard sedation.

Methods: In 87 obese patients, we performed 3 removal techniques: 1) standard gastroscope and foreign body forceps, 2) standard gastroscope and retrieval snare, 3) double-channel gastroscope and foreign body forceps plus symmetrical "shark model" polypectomy snare. Balloon retrieval time, number of times the grasping devices lost the balloon, amount of antispasmodic drug, symptoms cumulative score and VAS score for discomfort were evaluated.

Results: The technique by double-channel gastroscope and foreign body forceps plus symmetrical polypectomy shark retrieval snare showed a significantly lower balloon retrieval time, number of lost balloons, total number of ampoules used, symptoms cumulative score and VAS score compared to the other two techniques (Dunn's $P<0.05$). Number of lost balloons was positively associated with number of antispasmodic ampoules used, balloon retrieval time and VAS score.

Conclusions: Technique by double-channel gastroscope and foreign body forceps plus symmetrical polypectomy shark retrieval snare, allows balloon removal safely, quickly and easily, avoiding loss of the balloon, with good patient endurance.

Key words: Morbid obesity, endoscopy, intragastric balloon

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Introduction

The use of a gastric space-occuping balloon for achieving weight reduction in obese patients was first reported in 1982.[1,2] Since then, different kinds of free-floating balloons were described for the treatment of morbid obesity,[1-4] but several problems and side-effects persuaded physicians to stop their use. However, the distinctive structural features of new balloons (silicone, liquid-filled, spherical, smooth without traumatic edges) differ from the previous intragastric devices by reducing complications and side-effects, and have created new interest.[5,6]

In the last 6 years, because of the good results in selected patients,[7,8] these new balloons are used by many bariatric centers that perform the placement and removal either with standard sedation or with general anesthesia and oro-tracheal intubation. The use of general anesthesia is often preferred to avoid patient discomfort and for easier handling, especially during retrieval of the deflated balloon.[9,10] However, standard sedation makes the procedure less expensive and time-consuming, but unconfortable for patients even in skilled hands.

Because the removal phase of the gastric balloon could provoke discomfort and could be a trigger for more serious complications, this topic needs further investigation. We hypothesized that a strong secure grasp to remove the balloon, could be the key for improving the success of this procedure, avoiding complications and discomfort.

The purpose of our study was to compare various endoscopic techniques, during standard sedation, for removal of the intragastric balloon.

Patients and Methods

Population

From December 2001 to December 2004, we prospectively studied 87 obese patients undergoing placement of a BioEnterics intragastric balloons (BIB, Inamed/Allergan, USA) for treatment of morbid obesity. Descriptive statistics are shown in Table 1.

Sample Size

In a pilot study from our group,[11] during removal of the intragastric ballon with a double-channel gastroscope and either forceps or polypectomy snare, we found a lower number of lost balloons (35% vs 75%) compared to other tecniques. This was chosen as the primary end-point. With the proposed sample of 25 patients per group, the study would have the power of 80% to yield a statistically significant difference.

Endoscopic Procedure

The treament consisted of balloon placement and removal by upper GI endoscopy (UGE) under standard sedation (diazepam 10 mg/2 ml and hyoscine bromide 20 mg/1 ml ev), via a continous intravenous line.

Removal of balloon consisted of the following steps:

- deflating the balloon, rapidly obtained by a modified endoscopic trocar (Aprime, Waterloo, Belgium);
- injection of hyoscine bromide bolus I.V., to reduce esophageal spasms (due to the extraction of a big foreign body);
- retrieval of the device.

We used three different systems for balloon retrieval:

1) a standard gastroscope (Olympus GF Q 140, Tokyo, Japan) and a rat-toothed forceps (Pauldrach, Garbsen, Deutchland) inserted in the working channel, used to grasp the balloon;
2) a standard gastroscope (Olympus GF Q 140, Tokyo, Japan) and a retrieval snare (MTW, Postfach, Deutchland) inserted in the working channel, used to grasp the balloon;
3) a double-channel gastroscope (Olympus 2 T 100, Tokyo, Japan) and a rat-toothed forceps (Pauldrach, Garbsen, Deutchland) inserted in the first working channel and a symmetrical shark polypectomy snare (MTW, Postfach, Deutchland) inserted in the second working channel, both used to grasp the balloon. The shark snare contains 4 to 6 spikes to improve the grip on mucosa or the grasp on a foreign body.

At the end of the manoeuvre, after receiving standard instructions, each patient filled-in a standardized questionnaire.

Questionnaire

In our endoscopic unit, we routinely use a standardized questionnaire for evaluating the general discomfort and several symptoms that could be evoked during endoscopies. The questionnaire is administered about 1 hour after the procedure. The following items are scored: diplopia, tachycardia, arrhythmia, hypotension, as presence = 1; absence = 0. When more than one item is scored, the cumulative score is computed for comparisons. Patient discomfort is inde-

Table 1. Overall results calculated in group A, B and C (Median 25th/75th percentiles, Kruskal-Wallis test)

	Group A n= 29	**Group B** n= 27	**Group C** n= 31	***P***
Gender (M/F)	10/19	8/19	10/21	0.93
Age	38 (31.5/43.5)	39 (33.0/45.0)	39 (32.0/36.0)	0.76
Weight (kg)	126.0 (116.5/140.5)	121.0 (110.0/145.0)	121.0 (103.0/146.0)	0.78
BMI (kg/m^2)	43.1 (39.5/51.7)	43.0 (37.2/49.0)	43.6 (39.0/47.3)	0.76
Duration of treatment (months)	5.0 (3.6/5.7)	5.5 (4.2/6.0)	4.8 (3.6/5.4)	0.35
Balloon filling volume (cc)	510 cc	510 cc	510 cc	--
Balloon lost	2.0 (1.0/1.0)	2.0 (1.0/3.0)	0.0 (0.0/0.0)	< 0.001
Balloon retrieval time (min, sec)	4’ 11”(3’ 02”/ 7’ 57”)	4’ 04”(2’ 44”/14’ 28”)	0’ 44”(0’ 33”/ 1’ 02”)	< 0.001
No. of Ampoules	3.0 (2/3.5)	3.0 (2.0/4.0)	1.0 (1.0/1.0)	< 0.001
Symptoms of cumulative score	2.0 (2.0/3.0)	2.0 (1.0/2.0)	1.0 (1.0/2.0)	0.002
VAS score	30.0 (30.0/45.0)	40.0 (30.0/50.0)	30.0 (20.0/30.0)	< 0.001

pendently evaluated on a visual analog scale (VAS). The VAS consisted of a 100-mm long horizontal straight line defined by anchors with verbal labels, with the left end-point (0 mm) indicating no discomfort and the right end-point (100 mm) indicating overwhelming discomfort. We determined the VAS score (1 mm = 1) by measuring the distance from the left end-point to the mark made by the patient.

Experimental Design

To compare the different systems of balloon retrieval, the patients were prospectively randomized with sealed envelopes containing assignment to the following groups of treatment:

- group A (10 males, 19 females, mean age 38.0 ± 7.7 yrs): balloon removed by a standard gastroscope and a rat-toothed forcep;
- group B (8 males, 19 females, mean age 39.0 ± 7.2 yrs): balloon removed by a standard gastroscope and a retrieval snare;
- group C (10 males, 21 females, mean age 39.3 ± 7.9 yrs): balloon removed by a double-channel gastroscope and both a rat-toothed forcep and a symmetrical polypectomy "model shark" snare.

These envelopes were shuffled to produce a random sequence and were dispensed to patients in sequence as they qualified for the study. The investigators were not able to anticipate the next assignment.

All the patients were treated by the same skilled endoscopist. For each group, we evaluated:

- number of times the grasping devices lost the balloon in the esophagus and stomach during retrieval, as the primary end-point;
- balloon retrieval time, after deflation, expressed in minutes;
- amount of antispasmodic drugs used to retrieve the balloon, expressed as total number of ampoules (hyoscine bromide 20 mg/1 ml ev) used;
- symptoms cumulative score, calculated by questionnaire;
- VAS score for discomfort.

Statistical Analysis

All data are presented as median and 25th and 75th percentiles (25th/75th), unless otherwise indicated. The groups were compared regarding: number of times the grasping devices lost the balloon during retrieval; the balloon retrieval time; number of antispasmodic drug ampoules used; symptoms cumulative score and VAS score. Statistical comparisons were performed by Kruskall-Wallis one-way ANOVA and followed by Dunn's test for multiple comparisons. Ordinal logistic regression was used to estimate relationships between an ordinal dependent variable (number of lost balloons) and a set of independent variables (balloon retrieval time, number of antispasmodic drug ampoules used, symptoms cumulative score and VAS score). Wald and confidence intervals were calculated.

Significance was expressed at $P<0.05$ level. The SPSS software package for Windows (release 12.0.1; SPSS Inc., Chicago, IL, USA) and GraphPad Prism for Windows (release 3.00 GraphPad Software, San Diego, CA, USA) were used for statistical analysis.

Ethics of the Treatment

A full and informed consent was obtained from all patients, and the work was performed in accordance with the human and ethical principles of research set for the Helsinki guidelines. The study protocol was approved by Ethics Committee of Naples University "Federico II" School of Medicine.

Results

At the end of treatment, removal of the balloon was successful by upper GI endoscopy with standard sedation in all patients. Age and gender distribution was similar among the three groups (ANOVA, $P=0.8$, χ^2 $P=0.9$).

Table 1 shows the overall results for groups A, B and C. Group C was significantly different, compared to groups A and B, in number of lost balloons, balloon retrieval time, total number of ampoules used, symptoms cumulative score and VAS score (Dunn's $P<0.05$), while no difference was found between group A and B.

The number of lost balloons was positively associated with balloon retrieval time, number of antispasmodic ampoules used and VAS score (Table 2).

Discussion

Surgical treatment of morbid obesity has gained popularity globally due to the unsatisfactory results of medical therapy, despite a wide variety of conservative treatments (pharmacologic, dietetic, behavioral). The endoscopic intragastric balloon was proposed, for the following indications:

- for temporary weight loss therapy in patients who are at least 40% above their ideal weight (as defined by the Metroplitan Life 1983 Weight and Height Tables) and who have failed to achieve weight loss with other weight control programs;[5]
- a treatment bridge to planned bariatric surgery.[12,13]

Prolonged follow-up has shown that after the BIB, the weight lost is very often regained after removal.[6,7,14,15] The bridge-to-surgery is very useful in poor-risk morbidly (BMI >40) and super-obese (BMI >50) patients, to reduce anesthesiological, surgical and postoperative complications.[6,12-15] The anesthesiological risk may be more critical in surgical management in obese patients[16-18] so that weight loss is important before surgery.

Most studies on the BIB have not addressed the technical points for a safer and easier removal. The most common advice is to perform removal under general anesthesia to avoid patient discomfort and complications during the retrieval phase.[9,10] Nevertheless, in our opinion, it is a self-contradiction to reduce anesthesiological risk by a general anesthetic. Thus, we targeted our efforts to standardize a technique to remove the balloon quickly, safely and without discomfort, under standard sedation, without using further antispasmodic drugs.

The problem of a quick balloon removal has been recently considered by other authors.[19] The noteworthy point seems to be the relationship between the small size of endoscopic grasping devices and balloon size, weight and slipperiness, especially in the presence of strong esophagogastric spasms during balloon retrieval. Moreover, the withdrawal may be hindered by the high pressure zone in the esophagus, particularly at the cricopharyngeal level. A number of specific devices have been developed to facilitate balloon removal, but difficulties can still be encountered.

Our technique (Figure 1) proposes a double-grasp by a rat-toothed forcep, inserted in the first working channel, and a symmetrical polypectomy snare "model shark", inserted in the second working channel of a double-channel gastroscope. By working with two parallel devices on the same axis with the gastroscope, traction force is distributed over two points, avoiding loss of the grasp; moreover, the use of a toothed snare makes the grasp stronger and prevents slippage of the balloon.

This study demonstrated that the retrieval technique by the double-channel scope (group C) is more effective than the other two techniques by the single-channel scope for all five of the variables considered: number of lost balloons, balloon retrieval time, number of antispasmodic ampoules, cumulative symp-

Table 2. Multiple regression analysis with number of lost balloons as dependent variable, and balloon retrieval time, number of antispastic drug ampoules used during procedure, symptoms cumulative score, VAS score for discomfort, age, gender and groups, as independent variables

	Unstandardized coefficients		Standardized coefficients	*t*	*P*	95% CI	
	B	SE	Beta			Lower limit	Upper limit
(Constant)	-.904	.524		-1.727	.088	-1.946	.138
Balloon retrieval time (minutes)	.001	.000	222	2.507	014	.000	.001
Number of antispastic drug ampoules used	.357	.123	.291	2.903	.005	.112	.602
Symptoms cumulative score	.170	.095	.120	1.782	.079	-.020	.359
VAS score	.029	.008	.285	3.681	.000	.014	.045
Age	.011	.009	.051	1.190	.237	-.007	.029
Gender (M = 1 F=2)	.116	.146	.034	.792	.431	-.175	.406
A = 1, b = 2, c = 3	-.340	.102	-.179	-3.329	.001	-.544	-.137

Dependent variable: number of lost balloons. B = linear regression coefficient; SE = standard error; Beta = standardized coefficient Beta; Constant = coefficient "a" of linear regression (intercept) – SPSS software.

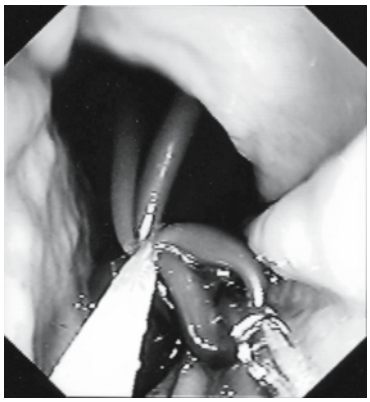

Figure 1. Balloon deflated and double-grasp by a rat-toothed forcep and a symmetrical polypectomy snare model shark, both inserted in the two working channels of a double-channel gastroscope. Working with two parallel devices on the same axis with the gastroscope, traction force is distributed over two points, avoiding loss of the grasp; moreover, the use of a toothed snare makes the grasp stronger and prevents the slippage of the balloon.

toms score and VAS discomfort score.

The number of lost balloons was positively associated with the number of antispasmodic ampoules used, balloon retrieval time and VAS score. The number of times the grasping device lost the balloon in the stomach or esophagus determined the duration and discomfort of the procedure; i.e. when the gastroscope had to go up and down to re-grasp the balloon one or more times, this resulted in significant trans-parietal stimulation and reactive cardial and esophageal spasm, requiring more antispasmodic drug, and increased discomfort.

In conclusion, by this technique, the endoscopist can retrieve the balloon safely, quickly and easily by steady traction distributed over two points on the same axis by the gastroscope, avoiding loss of the balloon with a very good endurance by the patients.

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