



3° WORKSHOP CONGIUNTO SICOb – SID – SIO



CALO DI PESO PRE-OPERATORIO: RUOLO DEL PALLONCINO INTRAGASTRICO

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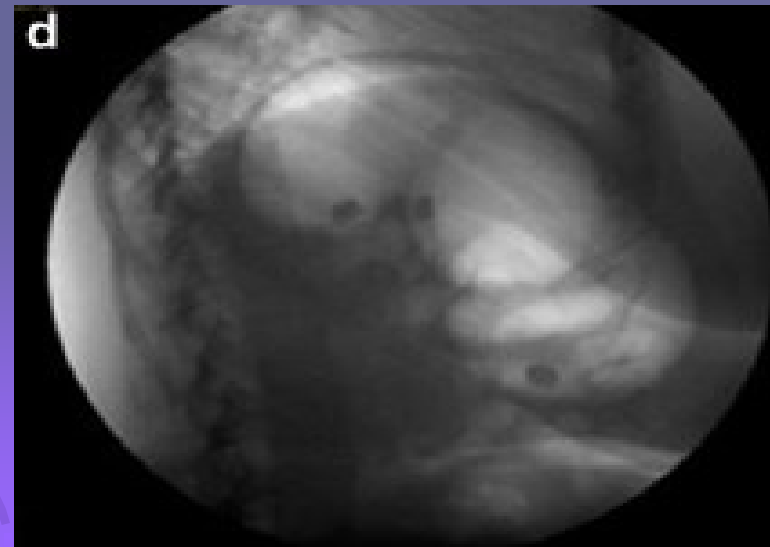
TIPOLOGIE:

1. BioEnterics Intragastric Balloon (BIB)
2. Heliosphere BAG (HSB)



TIPOLOGIE:

3. Pallone OBALON



CONTROINDICAZIONI

- Pregressa chirurgia addominale, soprattutto gastrica;
- Patologia peptica in atto;
- Ernie jatali >4-5 cm;
- Malattia da reflusso gastro-esofageo severa;
- Instabilità psicologica e tossicodipendenza;
- Epatopatie gravi;
- Cardiopatie e pneumopatie non adeguatamente compensate;
- Malattie infiammatorie intestinali croniche.

COMPLICANZE

Table 3 Reported complications of 3,429 patients treated with BIB®

	<i>N</i> ^a	% ^b
Nausea and vomiting after first week	295	8.6
Abdominal pain and other mild digestive disorders ^c	171	5.0
Deflation and displacement of the balloon ^d	87	2.5
Inflammation or lesions in digestive lining ^e	73	2.1
Gastro-esophageal reflux	63	1.8
Dehydration	54	1.6
Deflation without displacement of the balloon ^d	29	0.9
Obstruction in the digestive tract	26	0.8
Diarrhea and/or constipation	23	0.7
Gastric ulcer	12	0.4
Gastric perforation	4	0.1
Mortality related with balloon (gastric perforation)	2	0.1

Imaz I et al., *Obes. Surg.* (2008)
18:841-846

Eventi avversi segnalati più frequentemente

Evento segnalato	Eventi (% soggetti) (n=119)
Nausea	12 (10,1)
Vomito	8 (6,7)
Dolore allo stomaco	6 (5,0)
Reflusso gastroesofageo	4 (3,4)
Crampi allo stomaco	3 (2,5)
Pirosti	3 (2,5)
Altri effetti indesiderati	
Lacerazione esofagea ¹	1 (0,8)
Ulcera identificata endoscopicamente ²	1 (0,8)

RISULTATI

Table 1. Weight losses achieved by intragastric balloon treatment in different patient groups

	Age, years	BMI start	Change, kg	Change, kg/m ²	ECWL, %
Nonmorbidly obese: 5 studies (n = 665)	33.0–37.5	31.0–39.0	9.5–18.6	5.3–5.7	38.1–50.8
Morbidly obese: 5 studies (n = 573)	31.0–43.0	41.0–46.6	13.0–15.0	4.8–5.3	18.7–35.0
Preoperative					
2 studies (n = 58)	38.8–43.3	58.4–60.2	18.1–26.4	6.4–9.4	21.0–26.1
3 studies (n = 2,573, including Genco et al. [37])	38.8–43.3	44.4–60.2		4.9–9.4	21.0–33.9

ECWL = Excess weight loss. Nonmorbidly obese: references [25–29]. Morbidly obese: references [30–34]. Preoperative 2 studies: references [35, 36].

RISULTATI

Table 2 Adverse effects and extraction time according to groups allocation (data were expressed as mean±standard deviation or range)

	BIB	Endobag	P
Early removal	3/30	0	Ns
Partial deflation	1/27	10/30	0.001
Extraction time	10–20 min	30–60 min	0.001

Table 3 Weight loss parameters according to groups allocation (data were expressed as mean±standard deviation), at time of intragastric balloon extraction

	BIB	Endobag	P
Weight	111±21	114±23	Ns
WL	15±8	16±7	Ns
%E/WL	24.4±4.9	24.7±4.2	Ns
BMI	40.8±6.2	41.9±6.5	Ns
BMI loss	5.9±2.4	5.8±2.1	Ns
%EBMIL	23.8±5.0	19.0±4.8	Ns



Il paziente super-obeso ha....

- Aumentata adiposità addominale
- Volume epatico aumentato e aumentata steatosi epatica
- Maggior circonferenza del collo
- Maggior incidenza di complicanze associate all'obesità quali OSAS, diabete, ipertensione arteriosa....

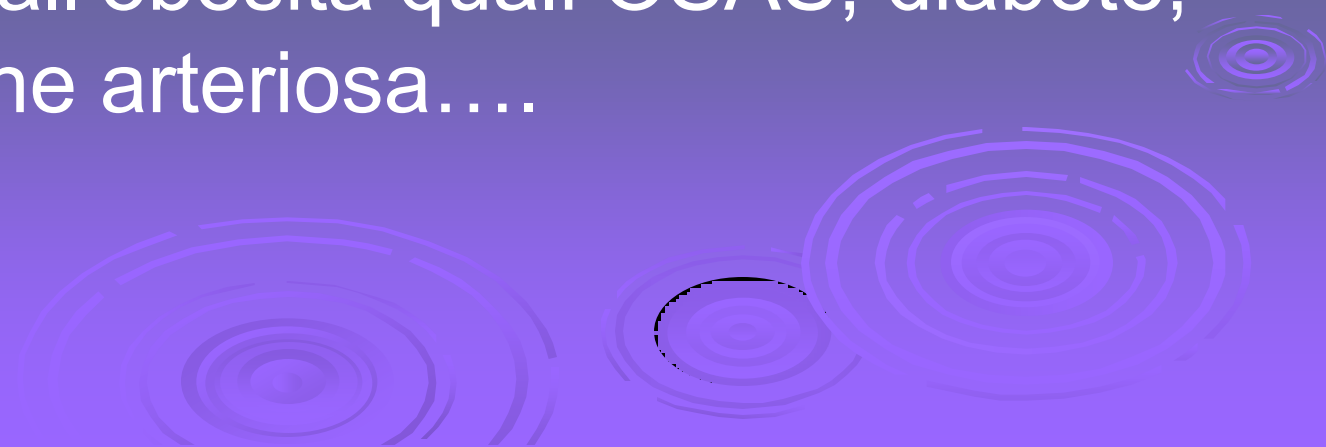


Table VII. Subgroups analyses

Subgroup description	Death ≤ 30 days				Death > 30 days to 2 years			
	t	n/N	%	Meta-analysis, Mean (95% CI)	t	n/N	%	Meta-analysis, Mean (95% CI)
Diabetes	5	8/676	1.2	0.94 (0.00-1.90)	4	28/636	4.4	2.25 (0.00-6.35)*
Hypertension	1	3/461	0.7	0.65 (0.00-1.38)	—	—	—	—
Males	3	7/122	5.7	4.74 (0.00-14.77)*	—	—	—	—
Females	17	2/633	0.3	0.13 (0.00-0.71)	9	0/224	0.0	0.00 (0.00-1.56)
Superobese	28	27/1,808	1.5	1.25 (0.56-1.94)*	6	1/181	0.6	0.81 (0.00-2.42)
Adolescents	5	0/132	0.0	0.00 (0.00-1.94)	—	—	—	—
Elderly	7	2/337	0.6	0.34 (0.00-1.29)	4	0/139	0.0	0.00 (0.00-1.63)

%, percent of patients with mortality; CI, confidence interval; n, number of patients with mortality; N, number of patients in groups reporting mortality; t, number of treatment groups reporting mortality.
 *P < .01 for test of heterogeneity of outcome.

	BIB Pre-Surgical (Case Group)	Lap-Band® Alone (Control Group)
General Data		
Operative time, min	82.5±20.9 (50-120)	102.6±35.1* (45-180)
Hospital stay, days	3.0±0.2 (2-4)	3.3±0.8* (2-6)
Conversion		
Conversion to open	0/43 (0%)	5/43 (11.6%)
Video-assisted	0/43 (0%)	2/43 (4.7%)
Total	0/43 (0%)	7/43* (16.3%)
Intraoperative Complications		
Gastric bleeding	0/43 (0%)	2/43 (4.7%)
Trocar injury	0/43 (0%)	1/43 (2.3%)
Total	0/43 (0%)	3/43 (7.0%)

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Buchwald et al. Surg 2007;142:621

Busetto et al. Obes Surg 2004;14:671

Il calo di peso pre-operatorio riduce i rischi

Un calo del 10% del peso totale pre-operatorio porta a una immediata riduzione del grasso viscerale, riduce il rischio trombo-embolico e cardiovascolare e migliora la meccanica respiratoria. Inoltre...

Table 4. One-Year Followup Data for Patients Based on Preoperative Excess Body Weight Loss Greater Than 5%

Followup data	> 5% EWL	< 5% EWL	p Value
Patients, n	19	25	—
One-year weight, lb (range)	186.6 (125 to 230)	212.7 (164 to 230)	0.009
One-year BMI, kg/m ² (range)	29.8 (21 to 36)	34.8 (22 to 36)	0.003
One-year excess weight loss, % (range)	85.5 (55 to 130)	65.7 (55 to 125)	0.002
One-year BMI change, % (range)	-33.2 (-19 to -58)	-27.8 (-18 to -48)	0.009
One-year comorbidities, n	0.60	0.83	NS

EWL, excess weight loss; NS, nonsignificant.

Effetti anatomici del calo di peso -1

(dopo 6 mesi di trattamento con palloncino intragastrico)

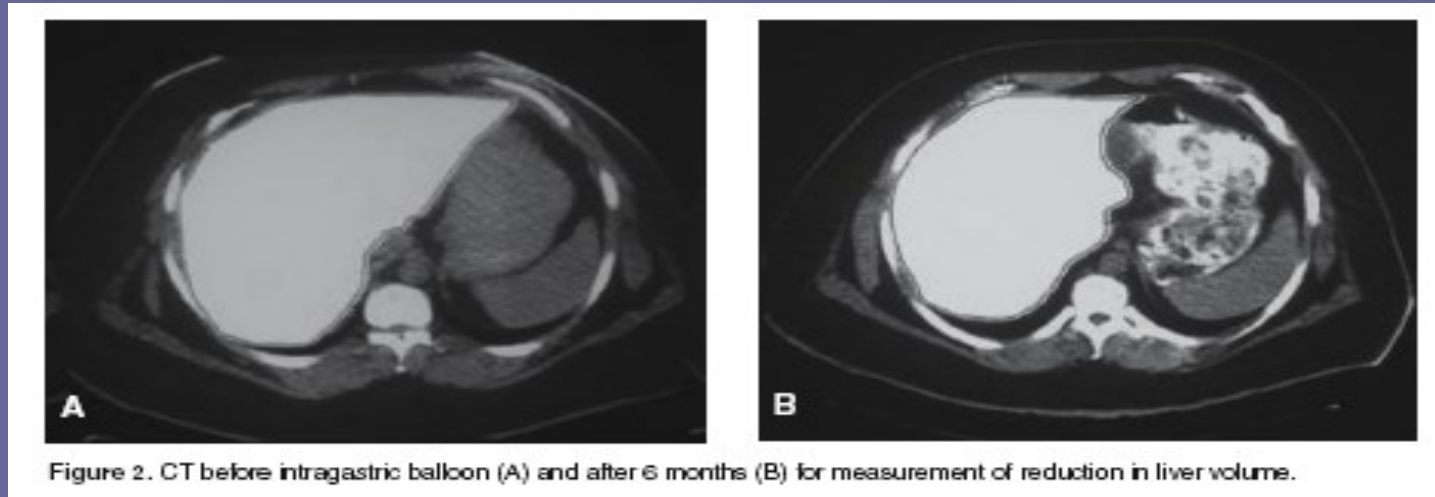
Table 1—Clinical Characteristics of 17 Morbidly Obese Patients Before and After Treatment With the Intragastric Balloon*

Characteristics	Before	After
Anthropometry		
Body weight, kg	168.1 ± 27.9	143.9 ± 29.4†
BMI, kg/m ²	55.8 ± 9.9	48.6 ± 11.2†
Waist circumference, cm	156.4 ± 17.6	136.8 ± 18.4†
Sagittal abdominal diameter, cm	37.8 ± 3.0	32.3 ± 4.0†
Neck circumference, cm	51.1 ± 3.7	47.9 ± 4.4†

Busetto et al. Chest 2005;128:618

Effetti anatomici del calo di peso – 2

(dopo 6 mesi di trattamento con palloncino intragastrico)

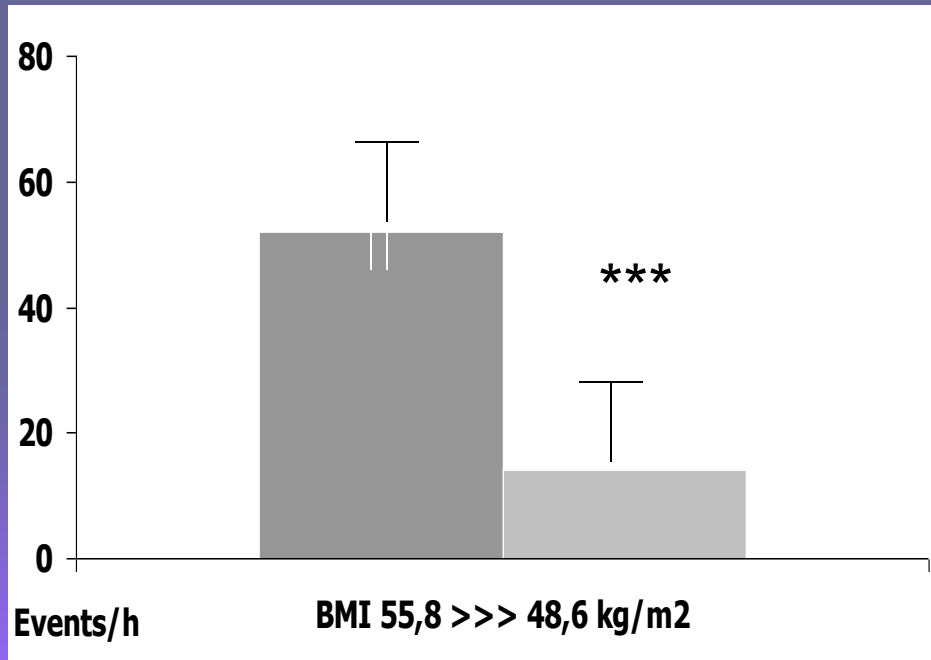


- Measurement of liver volume in 29 patients before and after BIB.
- Mean %EWL: $22.1 \pm 7.4\%$.
- Mean liver volume reduction: $31.8 \pm 18.1\%$

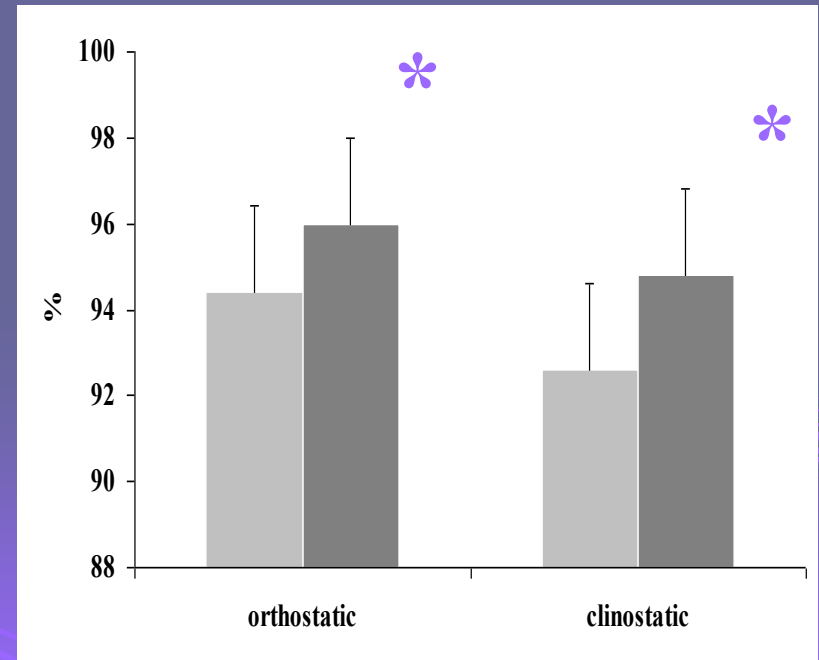
Effetti clinici del calo di peso: OSAS-1

(dopo 6 mesi di trattamento con palloncino intragastrico)

Apnea/Hypopnea Index



Oxygen saturation



Effetti clinici del calo di peso: OSAS-2

(dopo 6 mesi di trattamento con palloncino intragastrico)

Table 2 Effects of intragastric balloon on weight, body mass index, and lung function parameters over a 6-month period

	Baseline	After 6 months	<i>p</i> value ^a
Weight (kg)	111 (95.5–119.8)	93.8 (80.2–108.7)	0.0001
BMI (kg/m ²)	39.1 (35.7–44.2)	34.5 (30.2–40)	0.0001
FVC (L)	3.21 (2.86–3.83)	3.38 (3.06–4.02)	0.0001
FEV ₁ (L)	2.75 (2.35–3.14)	2.88 (2.57–3.26)	0.0001
FEV ₁ /FVC (%)	85 (82.5–88.8)	81 (79–84)	0.0001
MIP (cm H ₂ O)	68 (51.3–114.5)	68.5 (38.8–116.0)	0.21
MEP (cm H ₂ O)	85.5 (70.5–102.8)	74.5 (65–121)	0.91
TLC (L)	4.42 (3.83–4.87)	4.68 (4.17–5.60)	0.0001
FRC (L)	1.56 (1.36–1.83)	2.08 (1.69–2.42)	0.0001
RV (L)	1.13 (0.95–1.34)	1.30 (1.07–1.57)	0.0005
RV/TLC (%)	25.5 (22–29.8)	27 (24–32)	0.015
ERV (L)	0.39 (0.25–0.67)	0.74 (0.51–1.03)	0.0001
DLeo (ml/min/mmHg)	22.8 (19.7–25.5)	22.7 (19.5–26.2)	0.36

BMI body mass index, *FVC* forced vital capacity, *FEV₁* forced expiratory volume in one second, *MIP* maximal inspiratory pressure, *MEP* maximal expiratory pressure, *TLC* total lung capacity, *FRC* functional residual capacity, *RV* residual volume, *ERV* expiratory reserve volume, *DLeo* carbon monoxide lung diffusion capacity

^aWilcoxon signed-rank test

Effetti clinici del calo di peso

(dopo 6 mesi di trattamento con palloncino intragastrico)

CO-MORBIDITY	RESOLUTION	IMPROVEMENT†	NO CHANGE
Hypertension	228/509 (44.8%)	249/509 (48.9%)	32/509 (6.3%)
Diabetes	160/488 (32.8%)	264/488 (54.4%)	64/488 (13.1%)
Respiratory disorders	205/247 (83.0%)	42/247 (17.0%)*	–
Osteoarthropathy	111/271 (40.9%)§	125/271 (46.1%)	35/271 (12.9%)
Dyslipidemia	49/318 (15.4)#	116/318 (36.5)°	153/318 (48.1%)
Others	126/176 (71.6%)	15/176 (8.5%)	35/176 (19.8%)

† = lower drug dosage or shift to other therapy.

* = sleep apnea disappeared, but remain tachypneic after physical activity.

§ = patients without radiological evidence of arthritic modification.

= patients with hypertriglyceridemia.

° = the improvement was prevalently linked to normalization of tryglicerides while cholesterolemia has been less influenced by the weight loss after 6 months.

Effetti del calo di peso sul rischio pre-operatorio

1. RISCHIO ANESTESIOLOGICO

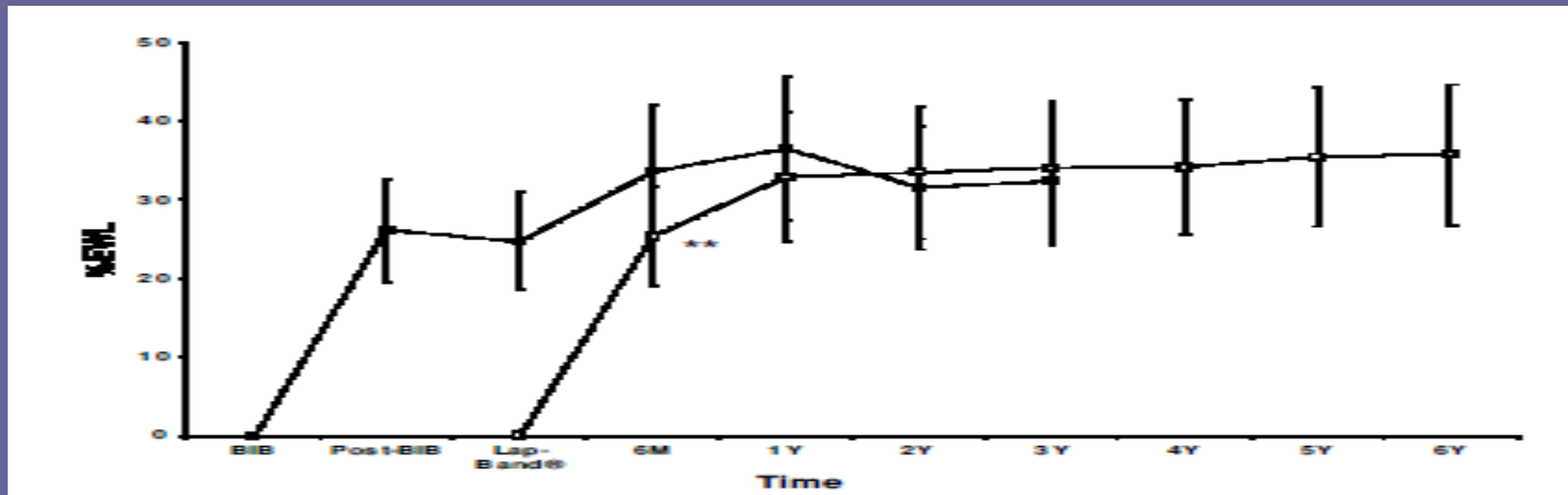
- Vie aeree superiori più larghe → Intubazione
- Circonferenza del collo ridotta → Intubazione
- Ventilazione migliorata → Ventilazione meccanica
- OSA migliorata → Recupero Post-op

2. RISCHIO CHIRURGICO

- TA viscerale ridotto → Campo operatorio
- Fegato ridotto → Campo operatorio



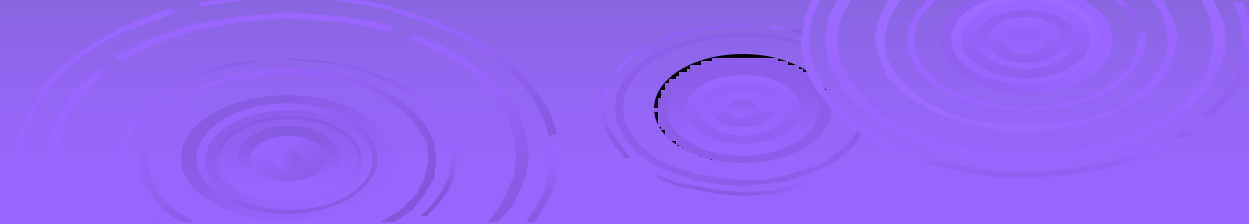
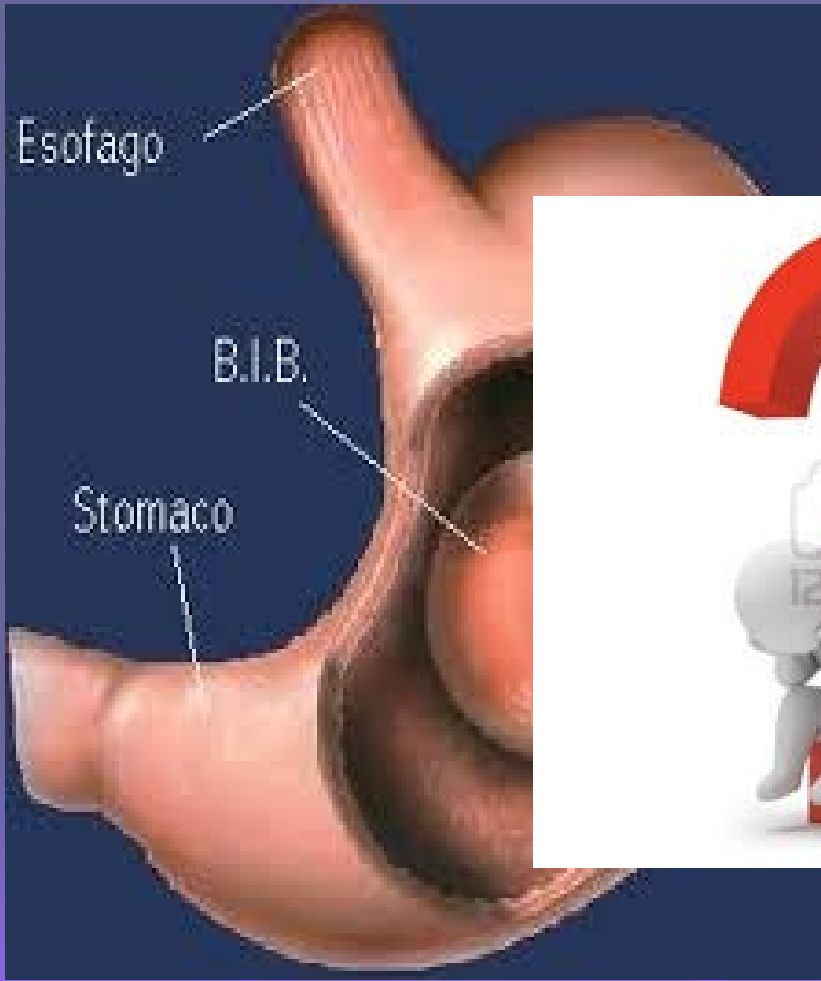
Effetti del palloncino intragastrico sul calo di peso post-operatorio



Busetto et al. *Obes Surg* 2004;14:671

- 140 pz che avevano inizialmente rifiutato la chirurgia bariatrica ma erano concordi al posizionamento di IGB 32% ha accettato nei 18 mesi di FU successivi a proseguire per l'iter chirurgico

Melissa J et al. *Obes Surg* 2006;16: 897-902



Liver steatosis (LS) evaluated through chemical-shift magnetic resonance imaging liver enzymes in morbid obesity; effect of weight loss obtained with intragastric balloon gastric banding

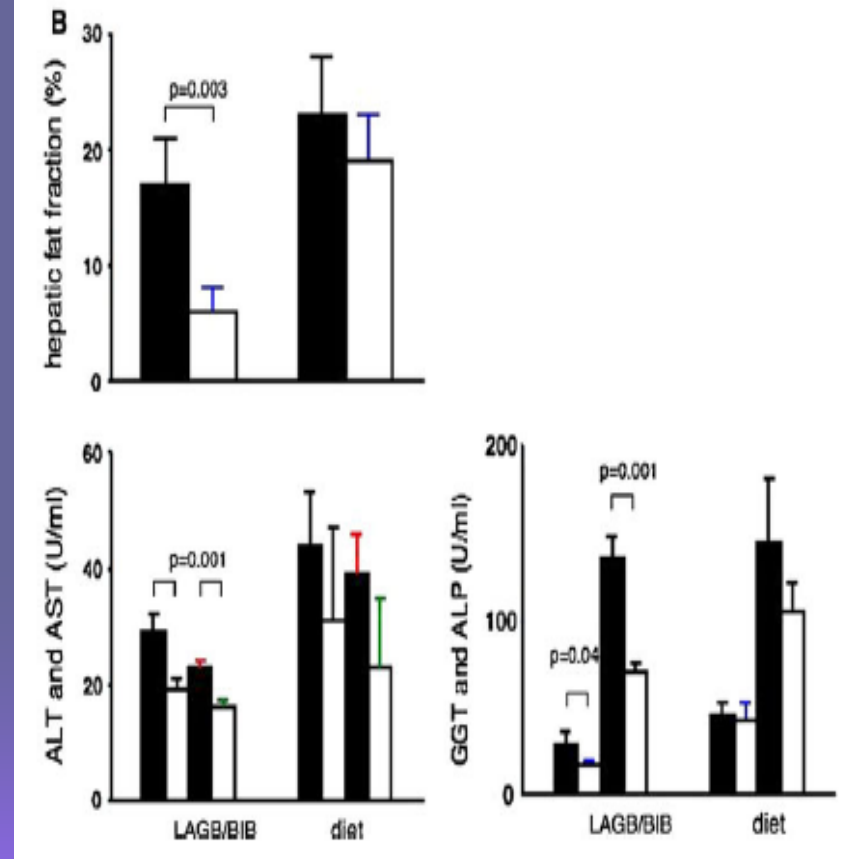
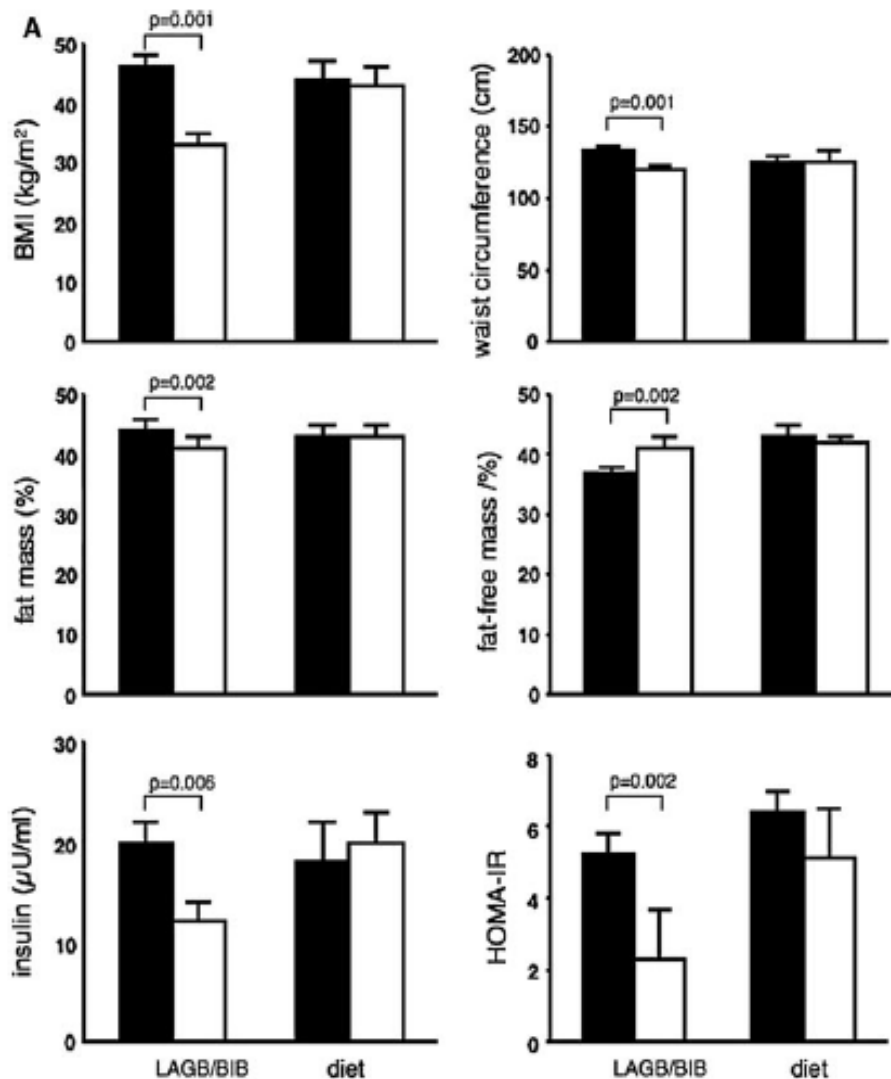
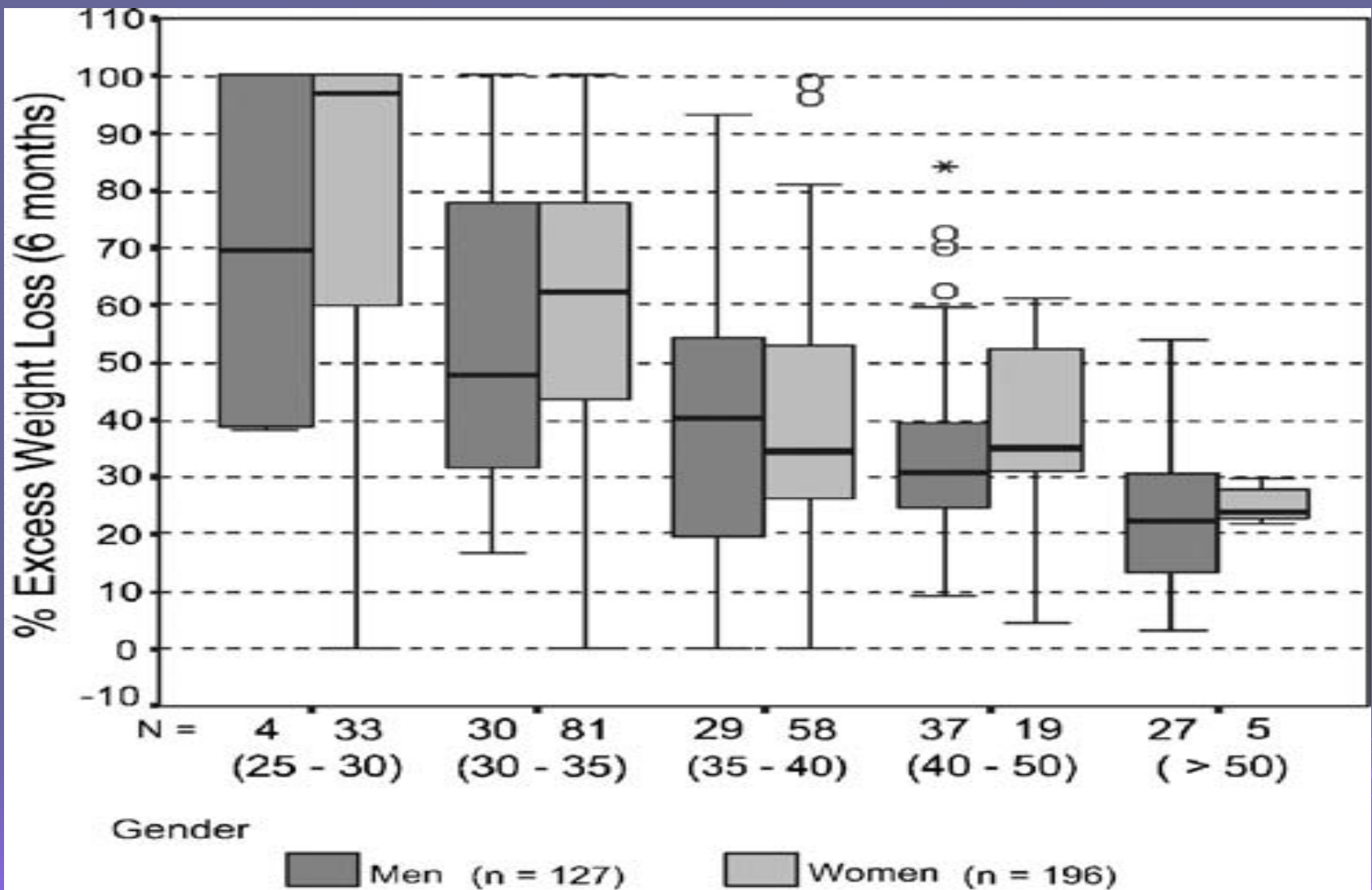


Table I*Comparing studies of weight loss with a low calorie diet*

	<i>Year</i>	<i>Type of study</i>	<i>N</i>	<i>WL</i>	<i>WL > 5%</i>	<i>WL > 10%</i>
Alvarado et al.	2005	retrospective	90	7.25% (0-23%)	70%	18%
Alger-Mayer et al.	2008	retrospective	150	9.5% (3.7-29.7%)	75%	43%

Table II*Comparing studies of weight loss with a very low calorie diet*

	<i>Year</i>	<i>Type of study</i>	<i>N</i>	<i>Follow-up</i>	<i>WL</i>	<i>WL > 5%</i>	<i>WL > 10%</i>
Fris et al.	2004	prospectively	40	2 weeks	4.1% (3.5-4.7%)	50%	1%
Lewis et al.	2006	prospectively	18	6 weeks	15.1% (9.6-21.1%)	100%	100%
Colles et al.	2006	prospectively	32	12 weeks	10.6% (0.7-19%)	100%	100%

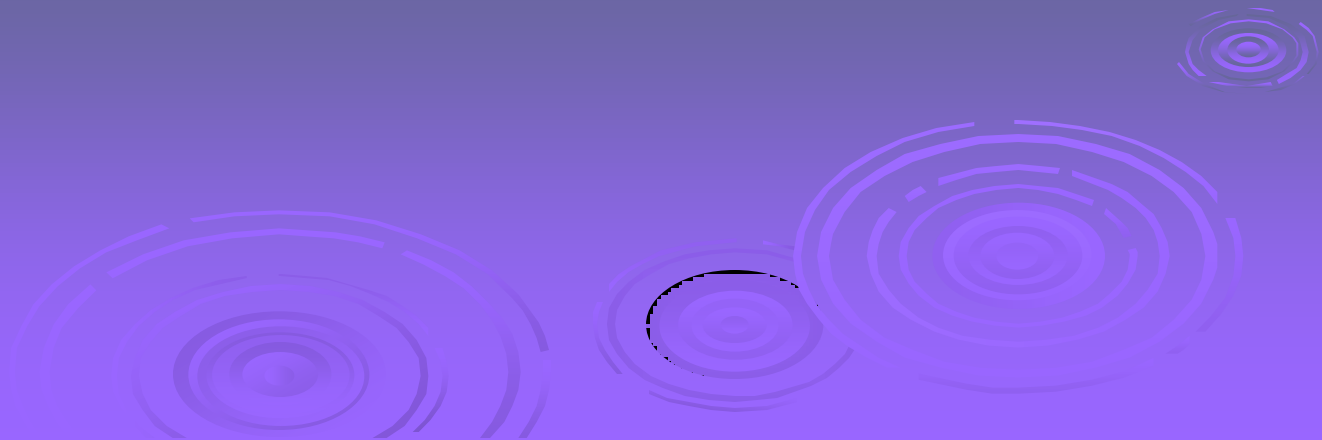


TAKE HOME MESSAGES

- E' fondamentale avere un'ottimo controllo delle comorbidity associate all'obesità prima di un intervento di chirurgia bariatrica
- Nei pazienti con obesità grave un calo ponderale pre-operatorio riduce l'obesità viscerale, migliora la dinamica respiratoria e migliora il controllo delle comorbidity
- La restrizione gastrica temporanea mediante pallone intragastrico è relativamente sicura e consente un calo ponderale superiore a quanto ottenibile con la terapia dietetica convenzionale.

TAKE HOME MESSAGE

Ogni paziente è un soggetto
unico e come tale deve
essere trattato



GRAZIE PER L'ATTENZIONE

Prof. R. Vettor

Dott. L. Busetto

Dott. R. Fabris

Dott. R. Serra

Dott.ssa C. Dal Prà

Dott. A. Scarda

Dott.ssa G. Milan

Dott. M. Foletto

Dott. L. Prevedello

Dott.ssa E. Bison

Dott.ssa M. Sanna

Dott.ssa V. Zanato

Dott.ssa E. Zabeo

Dott.ssa V. Bettini

