

# International Federation for the Surgery of Obesity and metabolic disorders

XIII World Congress – Buenos Aires, Argentina – 2008

## HELIOGAST : Anneau gastrique ajustable

### ORAL PRESENTATION

- **O-006 GASTRIC BAND: THE INTERNATIONAL EXPERIENCE WITH THE HELIOGAST SYSTEM**  
*F. BELLINI*
- **O-015 PARS FLACCIDA TO PERIGASTRIC "TWO STEP TECHNIQUE". NOT A RETURN TO THE PAST BUT AN EVOLUTION. THE ITALIAN EXPERIENCE WITH THE HELIOGAST BAND IN 3104 PATIENTS**  
*F. BELLINI*

### POSTER

- **P-014 ADJUSTABLE GASTRIC BANDING, OUR EXPERIENCE ON 200 PACIENTES, 4 YEAR AFTER THE SURGERY**  
*J.A.V. CARIM*
- **P-079 LAPAROSCOPIC AND ENDOSCOPIC SOLUTION IN LAGB COMPLICATIONS**  
*P. PIZZI*

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## **O-006 Gastric Band: The International Experience with the Heliogast\ System**

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**Background :** Laparoscopic Adjustable gastric banding (LAGB) is the bariatric restrictive operation with the most increasing development in the world. Our aim is to gather the experience of numerous international centres by the use of a unique database.

**Methods :** We gathered the retrospective data from Australia, France, Greece, Ireland and Italy in a unique devoted database. The outcomes of more than 6000 procedures are evaluated. We analyse the results according to mortality, comorbidities, laparotomic conversions, intra and postoperative complications, body mass index (BMI) and % excess weight loss (EWL) at different times of follow up.

**Results :** Till November 2007, 6360 patients underwent LAGB (Heliogast\ System) in different countries. Initial mean BMI was 42.2 kg/m<sup>2</sup> with a mean excess weight of 46.7 kg. At 12 months, mean BMI was 34.4 with 47.6% of EWL. At 5 years, mean BMI was 33.4 with 56% of EWL. No intraoperative or postoperative deaths. Long term major complications: slippage: 148 (2.32%), intragastric migration 12 (0.18%), trocar hernias 24 (0.37%), port disconnections 38 (0.59%), band removal 38 (0.60%), failure to lose weight 434 (6.82%).

**Conclusions :** Different international centres seem to have a similar experience with the Heliogast\ gastric band. A preliminary analysis shows a significant efficacy in weight loss with a low rate of complications (less than 1% band removal). Future results should be communicated with the continuous follow up of this patient's group.

## **O-015 Pars Flaccida to Perigastric “Two Step Technique”. Not a Return to the Past but an Evolution. The Italian Experience with the Heliogast\ Band in 3104 Patients**

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**Background :** Bariatric surgery is growing worldwide and LAGB is the bariatric restrictive operation with the faster increasing development in the world. Our aim is to evaluate the advantages of the “pars flaccida to perigastric” twostep technique that most of the Heliogast\ Band applier are using.

**Methods :** Is a retrospective multicentric and non comparative study with a 60 months follow up. The outcomes of 3104 procedures are evaluated. We analyse the results according to mortality, comorbidities, laparotomic conversions, intra and postoperative complications, body mass index (BMI) and % EWL at different times of follow up.

**Results :** From January 2001 to March 2008, 3104 patients (2457 female, 647 male) underwent LAGB (Heliogast\ System). Initial mean BMI was 43.9 for male, 41.9 for female. At 2 years was 32 for male, 30.2 for female with 55% of EWL. At 5 years was 30.6 for male, 30.1 for female with 59% of EWL. No intraoperative or postoperative deaths. Conversion rate: 2(0.068%). Trocar site bleeding: 2 (0.068%)1treated with laparoscopic revision, the other conservatively. Long term major complications: slippage: 79(2.74%), intragastric migration 9 (0.28%), trocar hernias 18 (0,57%), port disconnections 21 (0.67%), failure to lose weight (<25%EWL) 102 (3.2%), band removal for psychological intolerance 20 (0.69%).

**Conclusions :** Pars flaccida to perigastric two-step technique is safe and successful in producing weight loss. At the same time with the two-step approach we have a tight posterior band support, we avoid intimate posterior gastric wall dissection and therefore the posterior slippage.

## **P-014 Adjustable Gastric Banding, Our Experience on 200 Patients, 4 Year After the Surgery**

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The aim of the work is to show and analyse 200 patients underwent the laparoscopic surgery with adjustable gastric band, and to show the results of BMI evolution and late complications. All 200 patients were operated by the same surgeon and multidisciplinary team, being used two kinds of gastric band, 168 Alergan's Bands and 32 band Heliogastric. In all procedures were used the same surgical technique, with sutures gastro gastro from 3 to 6 points leaving one pouch of 15/20 ml. We had 53 (26.5%) patients that abandoned the treatment during the 4 years, we will consider only the other 147 (73.5%) patients. 17 (8.5%) exchanged the procedure for failure to treatment, being replaced for gastrojejunal Bypass. In 19 (9.5%) occurred band slippage that evolved for replaced the band in 5, in 12 patients the band was removed and another bariatric operation was performed (Gastrojejunal Bypass) and in 2 cases, remove the band. Two patients evolved for gastric necrosis, one was submitted for subtotal gastrectomy, leaving 3 cm of stomach and Bypass gastrojejunal, and the other did subtotal gastrectomy and remove the band. Silicone band migration was observed in 5 (2.5%) patients, that removed the band in 4 cases and in other case, stay with the band migration. The BMI varied from 33 Kg/m<sup>2</sup> to 69.82 Kg/m<sup>2</sup> and measured of 45.48 Kg/m<sup>2</sup>, having at the end of 4 years an BMI who varied from 17.54 Kg/m<sup>2</sup> to 49.52 Kg/m<sup>2</sup> with an average of 31.56 Kg/m<sup>2</sup>, having a percentage of weight loss 65.28 at the end of 4 years. We concluded that LAGB is effective, however in our ambient, after observing a dismissal of 26.5% of the patients with the team, we opt today for a procedure less dependent on our team and more dependent of the surgical procedure, that is bypass gastrojejunal kind Fobi Capella.

## **P-079 Laparoscopic and Endoscopic Solution in LAGB Complications**

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**Background :** We have utilized two different types of gastric banding: • SAGB – Obtech (Swedish) as from June 2000 until July 2001 • HAGA – Heliogast (French) as from July 2001 until February 2008

**Methods :** Our Obesity Centre has it's own personal new database that collects statistics which able's us to view on live time all the data related to: Surgery, the course of Post-Operation, Periodical check-ups and also data of early and late complications.

**Results :** From June 2000 until February 2008 we have operated 1980 patients of LAGB: 75 using SAGB – OBTECH and 1905 using HAGA – Heliogast 1. With SAGB banding we experienced: 2 precocious complications - 1 gastric hernia and 1 bleeding ulcer positioned at the height of the bending. 24 belated complications - 16 intragastric migrations and 8 valve infections. On our patients which were re-operated for removal of banding migrated into the stomach, We performed thorough examinations on the banding - the port - (which all resulted positive against "pseudomonas aeruginosa") and we also undertook histologic examination of the gastric wall near-SAGB (on all there was presence of material compatible with silicone) . 2. With HAG– Heliogast banding we experienced: 0 precocious complications 20 late port (port rotation, infection or disconnection) 2 migration intragastric 38 band slippage

**Conclusions :** The use of the two different types of Adjustable Gastric Banding has emphasized within our Obesity Centre a remarkable difference in respect to incidences and serious complications both for early and late in Favour of Haga-Heliogast Gastric Banding - Against the use of SAGB Banding.



# LAPAROSCOPIC AND ENDOSCOPIC SOLUTION IN LAGB COMPLICATIONS



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## Results

### SAGB Obtech

From Jun 2000 to July 2001 **n° patients 75 (F59/M16)**

#### Early complications: (2pts)

Gastric hernia n° 1 pts  
 Bleeding during the band placement n° 1 pts

#### Late complications: (24pts)

Intra gastric migration n° 16 pts  
 Port infection n° 8 pts

#### SAGS removal procedures: (16pts)

Laparoscopic removal n° 8 pts  
 Endoscopic-laparoassisted removal n° 2 pts  
 Endoscopic removal n° 6 pts

#### Bacterial growth:

Band (with pseudomonas aeruginosa) n° 16 pts  
 Port (no bacterial growth) n° 16 pts

#### Intra gastric migatrions

Histological examination of the gastric wall near the band.  
 In 16 patients (100%) we found the presence of material compatible with silicone.

Operating time : **70 +/- 20min.**

### HAG Helioscope

From July 2001 to Feb 2008 **n° patients 1905 (F1524/M381)**

**Early complications:** n° 0 pts

**Late complications:** n° 60 pts  
 Intra gastric migration n° 2 pts  
 Band slippage n° 38 pts  
 Port rotation, infection or disconnection n° 20 pts

#### Hag Helioscope (late complications): (2pts)

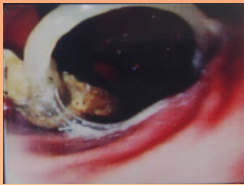
Endoscopic removal n° 2 pts

Histological examination of the gastric wall near the band .  
 We found **NO RESIDUAL of Silicone** in the gastric wall.

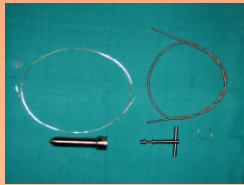
#### Band slippage (late complications): (38pts /1.99%)

Laparoscopic band removal n° 12 pts  
 Laparoscopic band repositioning n° 26 pts

Operating time : **35 +/- 15min.**



Intra gastric migration



Kit endoscopic removal



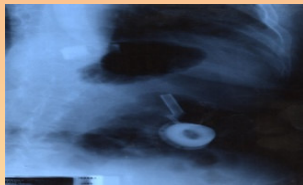
Endoscopic band removal



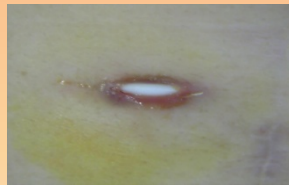
Discontinuity tube-band



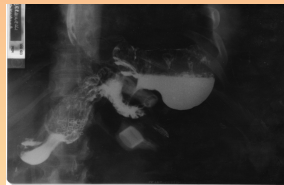
Leaking of the band



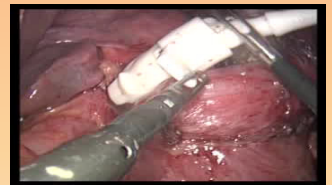
Disconnected port



Skin decubitus of the port



Anterior slippage



Repositioning and closing band

**Conclusions 1:** The intra gastric band migration is related to presence of synthetic material (silicone) in the gastric wall and is strictly related to the band constitution.  
 In our experience changing the band ended in a remarkable reduction of the band migration.

**Conclusions 2:** The use of two different types of LAGB has emphasized, in our Obesity Center, a remarkable reduction of major complications.  
 With the HAGA LAGB the number of major complications is highly decreased.

		XV WORLD CONGRESS OF IFSO Los Angeles, USA			XIV WORLD CONGRESS OF IFSO Paris, France					
		THE GASTRIC BAND: TRICKS AND TIPS TO ACHIEVE SATISFACTORY EWL% AND LOW PERCENTAGE OF COMPLICATIONS - F. BELLINI (2010) XV WORLD CONGRESS OF IFSO - Los Angeles, USA	SIX YEARS EXPERIENCE WITH ADJUSTABLE GASTRIC BAND. ANALYSIS OF 1582 CASES – 41 TONNES WEIGHT LOSS - N. SIKAS (2010) XV WORLD CONGRESS OF IFSO - Los Angeles, USA	GASTRIC BAND: THE PERIGASTRIC "TWO-STEP" TECHNIQUE TO PREVENT POSTERIOR SLIPPAGE. RESULTS AFTER 3492 PATIENTS - F. BELLINI (2010) XV WORLD CONGRESS OF IFSO - Los Angeles, USA	RESULTS FROM A FRENCH PROSPECTIVE MULTICENTRIC STUDY OF HELIOGAST ADJUSTABLE GASTRIC BAND S. MSAKA (2009) XIV WORLD CONGRESS OF IFSO - Paris, France	PRELIMINARY RESULTS WITH THE NEW-HAGA (HELIOGAST SYSTEM) LAGB: STUDY WITH FOUR DIFFERENT SURGICAL TECHNIQUES P. PIZZI (2009) XIV WORLD CONGRESS OF IFSO - Paris, France	TREATMENT OF SEVERE OBESITY WITH ADJUSTABLE GASTRIC BAND. ANALYSIS OF 1350 CASES – 5 YEAR RESULTS N. SIKAS (2009) XIV WORLD CONGRESS OF IFSO - Paris, France	GASTRIC BAND: A MULTICENTRE, INTERNATIONAL EXPERIENCE WITH THE HELIOGAST® SYSTEM - THE FIRST 7,205 PATIENTS F. BELLINI (2009) XIV WORLD CONGRESS OF IFSO - Paris, France	ARE THE COMPLICATIONS OF THE GASTRIC BAND RELATED TO THE SURGEON? THE ITALIAN EXPERIENCE WITH THE HELIOGAST SYSTEM. OUTCOMES AFTER 3492 BANDS F. BELLINI (2009) XIV WORLD CONGRESS OF IFSO - Paris, France	NON-FIXED LAPAROSCOPICALLY PLACED GASTRIC BAND: MY EXPERIENCE WITH THE NEW HELIOGAST HAGA BAND J. P. VOREUX (2009) XIV WORLD CONGRESS OF IFSO - Paris, France
EFFICIENCY	<b>Patients</b>	2834 in 2 centers	1582	3492 in 4 centers	250 in 25 centers	154	1350	7205	3492	30
	<b>Follow up</b>	87% at 5 years	96,6% at 37 months ± 13	5 years	2 years	6 months	5 years	5 years	5 years	6 months
	<b>Mean Age</b>	ND	37 ± 11	ND	ND	Men : 38,7 Women : 40,3	37	42,2	ND	ND
	<b>Initial BMI (kg/m<sup>2</sup>)</b>	Men : 42,6 Women : 41,9	45 ± 7	Men : 43,9 Women : 41,9	43,7	Men : 44,6 Women : 42,1	45	42,6	42,9	44,3 ± 2
	<b>BMI Loss (kg/m<sup>2</sup>)</b>	ND	ND	ND	1 year : 8,3 2 year : 10,1	ND	ND	ND	ND	ND
	<b>Final BMI (kg/m<sup>2</sup>)</b>	ND	ND	Men : 30,6 Women : 30,1	ND	6 months Men : 39,1 Women : 36,6	ND	1 year : 34,7 2 years : 32,2 4 years : 29,7 5 years : 29	1 year : 34,4 5 years : 30,8	ND
	<b>Weight Loss (kg)</b>	ND	ND	ND	ND	ND	ND	ND	ND	ND
	<b>Excess WL (%)</b>	Men : 53,6 Women : 55,1	1 year : 49% 2 years : 60% 3 & 4 years : 65% 5 & 6 years : 68%	54,5	1 year : 46% 2 years : 56%	6 months Men : 27,7 Women : 31,3	1 year : 49% 2 years : 60% 3 years : 65% 4 years : 67%	5 years : 58,6	1 year : 48,6% 5 years : 56%	36,3 ± 9
	<b>Other</b>	6,77% poor weight loss	9,5% rate failure at 2 years (explanted band, lost of follow up...)	7,08% failure to lose weight (<25%EWL)			7% failure to lose weight (<25%EWL)		7% failure to lose weight	
TOLERANCE	<b>Total Band complications (%)</b>	5,5	5,5	5,6	ND	0	4,2	3	4,35	0
	<b>Slippage / dilatation (%)</b>	4,5	4,3	4,5	9,4	0	3	2,7	3,9	0
	<b>Migration erosion (%)</b>	0,5	1	0,5	0	0	1	0,3	0,45	0
	<b>Band Removal (%)</b>	0,5 (psychological intolerance)	ND	0,6 (psychological intolerance)	ND	0	ND	ND	0,6	0
	<b>Band default (%)</b>	ND	0,2% band infection	ND	ND	0	0,2% band infection	ND	ND	0
	<b>Non specific complications (%)</b>	0,91 % trocar hernia 0,07% conversion	0,13% bleeding 0,13% stroma obstruction	0,11% trocar bleeding 0,1% conversion 1,1% trocar hernias	ND	0	0,15% bleeding 0,15% stroma obstruction	ND	1,3% trocar hernia	0
	<b>Complication site (%)</b>	1,3	ND	1,3	ND	0	ND	2,1	1,28	0
	<b>Other</b>		1 death due to massive pulmonary embolism (22days postoperativly)		1 year : 50% HTA resolved and 80% type 2 diabetes to		1 death (0,07%) due to massive pulmonary embolism (22days postoperativly) 4 reoperations			

		XIII WORLD CONGRESS OF IFSO Buenos Aires, Argentina				12TH WORLD CONGRESS OF IFSO Porto, Portugal			
		GASTRIC BAND: THE INTERNATIONAL EXPERIENCE WITH THE HELIOGAST SYSTEM - F. BELLINI (2008) XIII WORLD CONGRESS OF IFSO - Buenos Aires, Argentina	PARS FLACCIDA TO PERIGASTRIC "TWO STEP TECHNIQUE". NOT A RETURN TO THE PAST BUT AN EVOLUTION. THE ITALIAN EXPERIENCE WITH THE HELIOGAST BAND IN 3104 PATIENTS - F. BELLINI (2008) XIII WORLD CONGRESS OF IFSO - Buenos Aires, Argentina	ADJUSTABLE GASTRIC BANDING, OUR EXPERIENCE ON 200 PACIENTES, 4 YEAR AFTER THE SURGERY - J.A.V. CARIM (2008) XIII WORLD CONGRESS OF IFSO - Buenos Aires, Argentina	LAPAROSCOPIC AND ENDOSCOPIC SOLUTION IN LAGB COMPLICATIONS P. PIZZI (2008) XIII WORLD CONGRESS OF IFSO - Buenos Aires, Argentina	HELIOSCOPIE (HAGA & HAGE) GASTRIC BAND: OUTCOME AND WEIGHT LOSS RESULTS 12 MONTHS POST-OPERATIVELY H. Quach (2007) 12TH WORLD CONGRESS OF IFSO - Porto, Portugal	OUTCOME OF OBESITY-RELATED COMORBIDITIES FOLLOWING LAPAROSCOPIC ADJUSTABLE GASTRIC BANDING: A TWO-YEAR PROSPECTIVE STUDY N. Sikas (2007) 12TH WORLD CONGRESS OF IFSO - Porto, Portugal	HELIOGAST BAND®: MID- TO LONG-TERM RESULTS IN 2,307 PATIENTS F. Bellini (2007) 12TH WORLD CONGRESS OF IFSO - Porto, Portugal	FIRST RESULTS FROM THE FRENCH MULTICENTRIC STUDY ON HELIOGAST® GASTRIC BAND S. Msika (2007) 12TH WORLD CONGRESS OF IFSO - Porto, Portugal
	<b>Patients</b>	6360	3104	200 168 Allergan 32 Heliogast  (147 analyzed)	1980 1905 HAGA Heliogast 75 SAGB Obtech	444	200	2307	250 (121 at 12 months)
	<b>Follow up</b>	5 years	5 years	4 years	ND	1 year	2 years	4 years	1 year
	<b>Mean Age</b>	ND	ND	ND	ND	42	35	41 Women 39,9 Men	36,2 +/- 1,3
<b>EFFICIENCY</b>	<b>Initial BMI (kg/m<sup>2</sup>)</b>	42,2	Men : 43,9 Women : 41,9	45,5	ND	ND	44	42,5 Women 42,8 Men	43,5 +/-0,6
	<b>BMI Loss (kg/m<sup>2</sup>)</b>	ND	ND	ND	ND	11,3	ND	ND	8,62 +/- 0,34
	<b>Final BMI (kg/m<sup>2</sup>)</b>	1 years : 34,4 5 years : 33,4	2 years : Men : 32 Women : 30,2 5 years : Men : 30,6 Women : 30,1	31,6	ND	ND	ND	ND	35,06 +/- 0,5
	<b>Weight Loss (kg)</b>	ND	ND	ND	ND	30	ND	ND	23,51 +/- 1,02
	<b>Excess WL (%)</b>	1 years : 47,6 5 years : 56	2 years : 55 5 years : 59	65,3	ND	60	65	59,2 Women 50,3 Men	47,8 +/- 3,6
	<b>Other</b>	6,8% failure to lose weight	3,2% failure to lose weight	26,5% lost of follow up at 4 years 8,5% failure to lose weight and Bypass procedure					
<b>TOLERANCE</b>	<b>Total Band complications (%)</b>	3,1	3,7	12,9	Heliogast : 2,1 % Obtech : 21,3%	3,4	4	4	ND
	<b>Slippage / dilatation (%)</b>	2,3	2,7	9,5	Heliogast : 2 % Obtech : 0 %	ND	3	2,8	4,8
	<b>Migration erosion (%)</b>	0,2	0,3	3,4	Heliogast : 0,1 % Obtech : 21,3 %	ND	ND	0,3	0
	<b>Band Removal (%)</b>	0,6	0,7 (psychological intolerance)	12,2	Heliogast : nd Obtech : 21,3 %	ND	ND	0,5	1,2
	<b>Band default (%)</b>	0	ND	ND	Obtech : 10,6 % infection	ND	1	0,4	ND
	<b>Non specific complications (%)</b>	0,4 % trocar hernia	0,6% trocar hernia	ND	ND	ND	ND	ND	ND
	<b>Complication site (%)</b>	0,6	0,7	ND	Heliogast : 1 % Obtech : 0 %	3,4	ND	1,6	3,2
	<b>Other</b>		0,07% conversion 0,07% trocar site bleeding						



11TH WORLD CONGRESS OF IFSO Sydney, Australia								
	HELIOGAST® BAND: OUR EXPERIENCE AFTER 1,756 POSITIONINGS. F. Bellini (2006) 11TH WORLD CONGRESS OF IFSO - Sydney, Australia	SYSTEMATIC FOLLOW-UP RESULTS IN SUPERIOR WEIGHT LOSS FOLLOWING LAPAROSCOPIC ADJUSTABLE GASTRIC BANDING N. Sikas (2006) 11TH WORLD CONGRESS OF IFSO - Sydney, Australia	OUTCOMES AFTER LAPAROSCOPIC ADJUSTABLE GASTRIC BAND, USING SAGB OBTECH® AND HELIOGAST BAND® F. Bellini (2006) 11TH WORLD CONGRESS OF IFSO - Sydney, Australia	LAPAROSCOPIC ADJUSTABLE GASTRIC BANDING : LONG-TERM FOLLOW-UP IN A LARGE SERIES C. Karaindros (2006) 11TH WORLD CONGRESS OF IFSO - Sydney, Australia	"PERIGASTRIC"VERSUS "PARS FLACCIDA" LAPAROSCOPIC TECHNIQUE: A COMPARATIVE STUDY USING A NEW ADJUSTABLE GASTRIC BAND (HELIOGAST®) AS TREATMENT OF MORBID OBESITY G. SILECCHIA (2006) 11TH WORLD CONGRESS OF IFSO - Sydney, Australia	SAFETY AND EFFECTIVENESS OF LAPAROSCOPIC ADJUSTABLE GASTRIC BANDING IN OBESE PATIENTS WITH "LOW" BODY MASS INDEX. N. SIKAS (2006) 11TH WORLD CONGRESS OF IFSO - Sydney, Australia	HELIOSCOPIE (HAGA) GASTRIC BAND : WEIGHT LOSS RESULTS AND EXPERIENCE AT ONE YEAR H. Quach (2006) 11TH WORLD CONGRESS OF IFSO - Sydney, Australia	ERMS EVALUATION DE L'EFFICACITE ET DE LA SECURITE D'UN ANNEAU GASTRIQUE AJUSTABLE. Y. Claret Le journal de ceolochirurgie, 2005 ; 55, 68-73
<b>Patients</b>	1756	200 Group A : "free" follow up Group B : regular follow up	75 SAGB Obtech 758 HELIOGAST	2948	100 Group 1 : 50 Perigastric technique Group 2 : 50 Pars Flaccida technique	41	264	497
<b>Follow up</b>	3 years	1 year	ND	4 years	1 year	18 months	3 months	18 months
<b>Mean Age</b>	Men : 39 Women : 41	ND	ND	43,4	G 1 : 43,4 G 2 : 43	39	41	38,4 +/- 11,4
<b>Initial BMI (kg/m<sup>2</sup>)</b>	Men : 43,8 Women : 41,6	ND	ND	43,2	G 1 : 43,3 G 2 : 42,5	32,5 +/- 1,6	43kg/m <sup>2</sup>	42,88 +/- 3,7
<b>BMI Loss (kg/m<sup>2</sup>)</b>	ND	ND	ND	13,8	ND	ND	11,5	-9,86
<b>Final BMI (kg/m<sup>2</sup>)</b>	ND	ND	ND	ND	ND	ND	ND	6 months : 37 12 months : 34,4 18 months : 33
<b>Weight Loss (kg)</b>	ND	ND	ND	ND	ND	ND	ND	ND
<b>Excess WL (%)</b>	Men : 53 Women : 55	6 months: Group A : 29,2 Group B : 50 1 year: Group A : 36,4 Group B : 68	ND	56	nd	1 year : 77 +/- 23 1,5 years : 878 +/- 11	61	55,75
<b>Other</b>	1,53% failure to lose weight			Weight loss insuffisant in 12.5%				
<b>Total Band complications (%)</b>	3	ND	ND	1,6	G 1 : 4 G 2 : 2	2,4	3,7	10,5
<b>Slippage / dilatation (%)</b>	2,80%	ND	1,33 1,27	0,7	G 1 : 4 G 2 : 0	ND	ND	6,1
<b>Migration erosion (%)</b>	0,2	ND	30,7 0,13	0,2	G 1 : 0 G 2 : 2	ND	ND	0
<b>Band Removal (%)</b>	0,62	ND	ND	ND	G 1 : 0 G 2 : 2	ND	ND	0
<b>Band default (%)</b>	0,17% leak	ND	ND	0,2 leak 0,7	ND	2,4% leak	ND	4,4
<b>Non specific complications (%)</b>	0,4% trocar hernia	ND	1,3 ND	0,54% gastric perforation 0,3% bleeding	ND	ND	4,2	ND
<b>Complication site (%)</b>	1,88	ND	10,7 1,9	ND	ND	ND	2,6	0,8
<b>Other</b>	0,06% conversion							

# International Federation for the Surgery of Obesity and metabolic disorders

**XIII World Congress – Buenos Aires, Argentina –  
2008**

## **HELIOSPHERE : Ballon intragastrique**

### **POSTER**

- ***P155. AIR-FILLED INTRAGASTRIC BALOON: A PRE-SURGICAL DEVICE TO REDUCE BMI AND MORTALITY BEFORE GASTRIC BYPASS.***  
*A. GIOVANELLI*

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## **P155. AIR-FILLED INTRAGASTRIC BALLOON: A PRE-SURGICAL DEVICE TO REDUCE BMI AND MORTALITY BEFORE GASTRIC BYPASS.**

A Giovanelli

*Background:* literature data shows gastric bypass mortality rate is > 2% for > 50 BMI but less than 1% for < 50 BMI. Air-filled intragastric balloon have been proposed to induce body weight loss in obese subjects with a > 50 BMI.

*Methods:* we report about a selected group of 882 patients from Italy, Spain, France and Dominican Republic till February 2007. F:M 4,2:1. mean age 37,7 (range 15-67). Two indications: unique treatment in BMI<35 (50,3%) and preoperative placement in morbid obesity with BMI>35 (33,2%) and superobesity BMI>50 (16,5%). In particular 20 patients with BMI > 50 underwent a gastric bypass after BAG procedure. The other ones treated with adjustable gastric band without mortality or postoperative problems or are waiting for other bariatric steps. Balloon insertion was successful in all cases and placed in 87% in sedation. 97,2% removed six months later in sedation or general anaesthesia without evidence of problems.

*Results:* Good weight loss: mean BMI reduced from 55,4 (range 50-76) to 49,7 (range 45,7-49,9) in 56% of the superobese with a mean BMI loss of 4,26 kg/m<sup>2</sup>. Good tolerance of the device with a lower early-removal. In particular, no death after laparoscopic gastric bypass are reported in our experience.

*Conclusions:* Intragastric balloon is safe and an effective first-step in super-obesity treatment. Risk of failure of laparoscopic approach, peroperative complications and mortality are reduced in the second step surgical procedures.

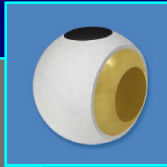


# AIR-FILLED INTRAGASTRIC BALLOON: A PRESURGICAL DEVICE TO REDUCE BMI AND MORTALITY BEFORE GASTRIC BYPASS



**Multicentric European experience: France – Italy –Spain**

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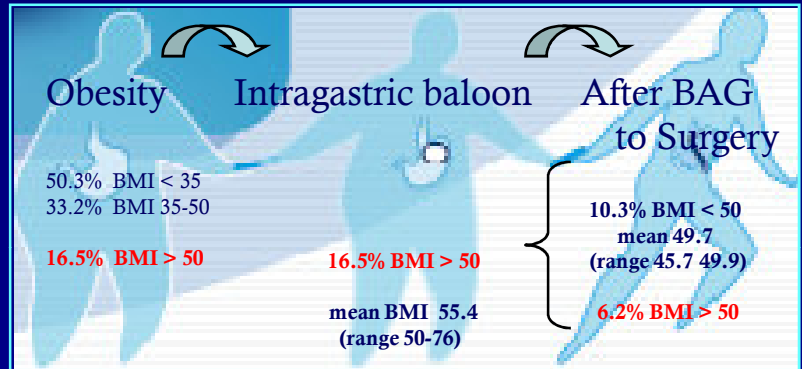
Literature data shows gastric bypass mortality rate is > 2% for > 50 BMI but less than 1% for < 50 BMI.

Air-filled intragastric balloons have been proposed to induce body weight loss in obese subjects with a > 50 BMI.

**782 patients**

till February 2007 are analyzed in a similar clinical and demographic features group from France, Italy and Spain

Among these, 602 were removed and the analysis concerns the data on extraction



**Good weight loss**

in most of the patients with mean BMI loss of 3.12 kg/m<sup>2</sup> after BAG procedure

Spanish series followed a drastic diet (from 900 to 2,000 kcal/day - Median : 1,000kcal/day), with a very good efficiency :  
more than 26kg lost in 6 months

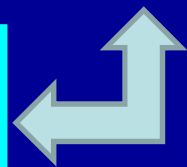
## RESULTS

**Good weight loss in particular in super obesity**

Mean BMI reduced from 55.4 to 49.7 in 56% of the super obese with a mean BMI loss of 4.26 kg/m<sup>2</sup>. Good tolerance of the device with a low early-removal and low occurrence of complications.

13.3% of super obese treated with BAG before surgery underwent a VLS gastric bypass without mortality .

86.7% underwent a VLS adjustable gastric band or other gastrorestrictive procedures without surgical problems or mortality.



## CONCLUSIONS

Air-filled intragastric balloon is safe and an effective first-step in super obesity treatment. Risk of failure of laparoscopic approach, preoperative complications and mortality are reduced in the second step surgical procedures.

	FROM OVERWEIGHT TO SUPER-OBESITY: THE EFFICACY OF AIR FILLED BALLOON A. Giovannelli (2009) 14TH WORLD CONGRESS OF IFSO, Paris, France	GASTRIC BALLOON EFFICIENCY ON WEIGHT LOSS (WL) WITH A MULTIDISCIPLINARY MEDICAL FOLLOWS UP V Costil (2009) 14TH WORLD CONGRESS OF IFSO, Paris, France	CARIBBEAN PROSPECTIVE MULTIDISCIPLINARY STUDY OF MANAGEMENT OF OBESITY WITH THE AIR-FILLED INTRAGASTRIC BALLOON R Romney (2009) 14TH WORLD CONGRESS OF IFSO, Paris, France	AIR FILLED BALLOON - BRAZILIAN MULTICENTRIC STUDY M Falcao (2009) 14TH WORLD CONGRESS OF IFSO, Paris, France	AIR-FILLED INTRAGASTRIC BALLOON: A PRE-SURGICAL DEVICE TO REDUCE BMI AND MORTALITY BEFORE GASTRIC BYPASS A. Giovannelli (2008) 13TH WORLD CONGRESS OF IFSO, Buenos Aires, Argentina	AIR FILLED INTRAGASTRIC BALLON (BAG) ITALIAN MULTICENTRIC RESULTS A. Giovannelli (2007) 12TH WORLD CONGRESS OF IFSO, PORTO, Portugal	AIR FILLED INTRAGASTRIC BALLON (BAG) ITALIAN MULTICENTRIC RESULTS A. Giovannelli (2006) 11TH WORLD CONGRESS OF IFSO, SYDNEY, AUSTRALIA	HELIOSPHERE INTRAGASTRIC AIR BALLOON: OUR INITIAL EXPERIENCE IN THE DOMINICAN REPUBLIC DK Ramirez (2006) 11TH WORLD CONGRESS OF IFSO, SYDNEY, AUSTRALIA	INTRAGASTRIC BALLOON FOR OBESITY: COMPARATIVE STUDY WITH 420 PATIENTS: NEW GENERATION AIRFILLED VS LIQUID-FILLED. C Hermida (2006) 11TH WORLD CONGRESS OF IFSO, SYDNEY, AUSTRALIA	TOLERANCE AND EFFICACY OF AN AIR-FILLED BALLOON IN NON-MORBIDLY OBESE PATIENTS: RESULTS OF A PROSPECTIVE MULTICENTER STUDY F. Mion Obesity Surgery, 2007; 17, 764-769	PRIMARY EXPERIENCE WITH AIR FILLED INTRAGASTRIC BALLOON CONFRONTED TO LIQUID INTRAGASTRIC BALLOON LITERATURE DATA H. Claudes (2005) 13TH UNITED EUROPEAN GASTROENTEROLOGY WEEK, COPENHAGEN, DENMARK
Patients	583 167 with BMI < 35 353 with 35 ≥ BMI > 49 63 with BMI ≥ 50	137	75	236	882	350	195	64	420 192 Heliosphere 228 BIB	32	32
Follow-up	6 months	6 months	6 months	6 months	6 months	6 months	6 months	8 months	6 months	6 months	6 months
Removal	6 months	6 months	6 months	6 months	6 months	6 months	6 months	8 months	6 months	4 months	6 months
Average age	ND	ND	37 ± 2	ND	38 (15-67)	38 (15 - 67)	38 ± 10	36	37 (18 - 56)	47 (24 - 60)	35 (18 - 57)

EFFICIENCY	Initial BMI (kg/m <sup>2</sup> )	ND	33.9	39.4 ± 1.48	34.8 (34-52)	ND	43.5 (29 - 76)	41.1 (29 - 72)	38.9	37.7 +/- 4.5	36.8 (30 - 44)	35 (30.1 - 40)
	BMI Loss (kg/m <sup>2</sup> )	ND ND 5.88	4.1	5.4 ± 0.7	ND	ND	ND	ND	ND	ND	5 (2 - 9)	3.3 (1.1 - 7.7)
	Final BMI (kg/m <sup>2</sup> )	ND	ND	ND	ND	ND	39.6 (25 - 72)	36.6 ± 3.8	32.4	ND	34.6 (25.8 - 50.8)	31.8 (24.6 - 38.1)
	Weight Loss (kg)	12.2 ± 1.1 19.8 ± 1.2 15.9 ± 2.6	10.5 ± 1.5	15.18 ± 1.9	ND	ND	ND	ND	17.2	H: 24.7 +/- 10.9 B :24.3 +/- 9.9	13.1 (6 - 27)	9 (3 - 20)
	EWL (%)	62 51.3 ND	54.7 ± 1.0	42.5 ± 5.4	42 (15-72)	ND	33 (2.2 - 96)	ND	51	ND	31 (0 - 86.7)	38.6 (10.7 - 114)

TOLERANCE	Vomiting & Nausea (%)	ND	> with BIB than with Héliosphère (p<0.05)	ND	35.1	ND	Vomiting : 4.3 Nausea : 23	Vomiting : 4.3 Nausea : 16	Most related Adverse events : nausea, vomiting and abdominal pains Mean time : 2.7 days	H : 12 B : 40	84 Mean time : 3.1 days (1 to 8)	10
	Epigastric Pains (%)	ND	> with BIB than with Héliosphère (NS)	7	25	ND	4.3	4.3		H : 8 B : 46	31	80 Epigastric pains (1st week)
	Early removal (%)	<3	ND	0	0.42	ND	ND	ND	ND	H : 0.7 B : 8.1	ND	ND
	Migration (%)	ND	ND	1 removal > 6 months	0	ND	0.6	0	0	ND	0	No migration No gastrique perforation
	Deflation (%)	ND	ND	6.7 removal > 6 months	0.85	ND	ND	ND	0	ND	0	1 spontaneous deflation (4th month) without migration