

Other FDA Approved Endoscopic Weight Loss Devices

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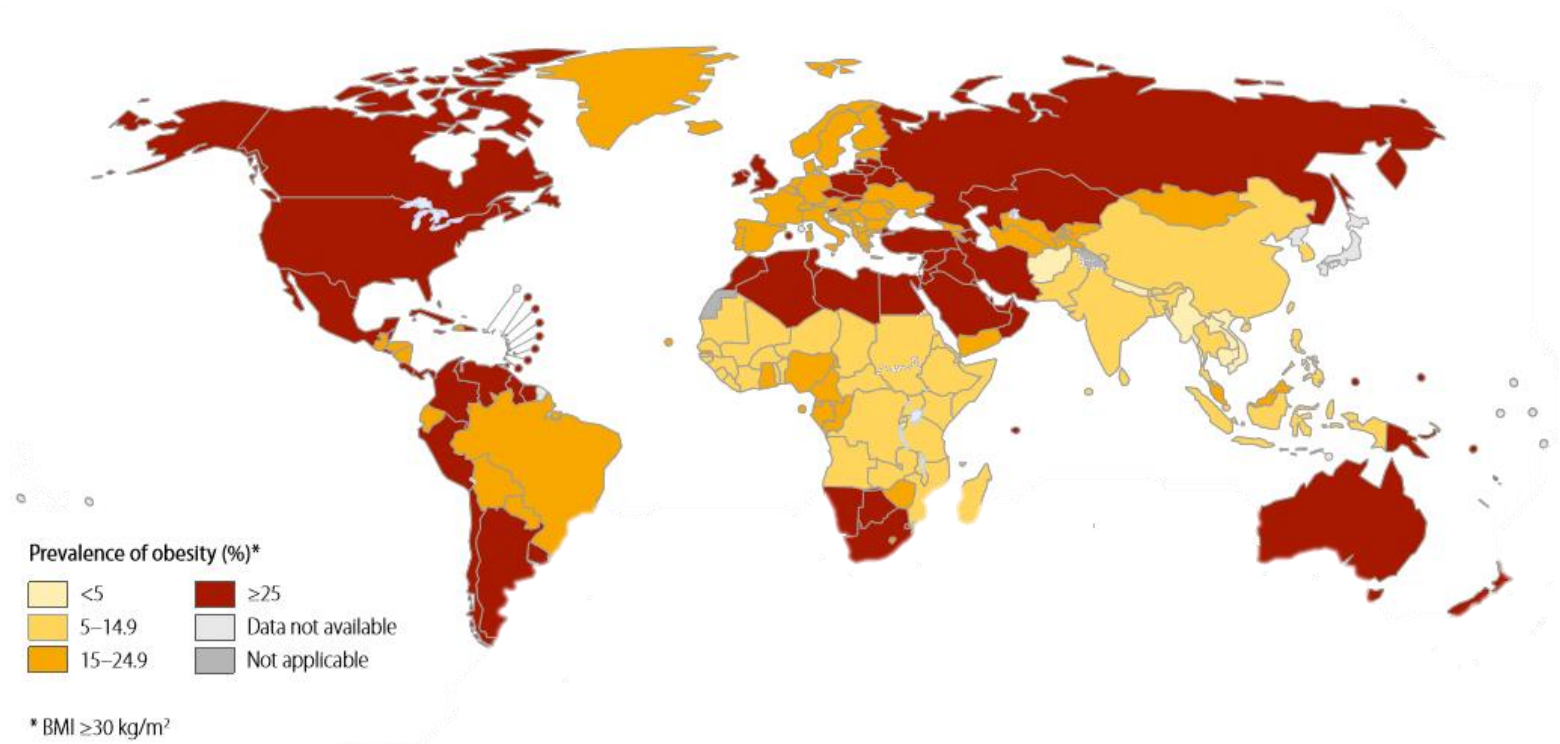
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NYU School of Medicine



A Global Epidemic



Scope of the Problem

- **Demographic:**

- 66% of Americans are overweight or obese
- VHA serves more than 9 million veterans
- 78% are overweight or obese


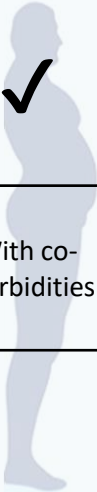




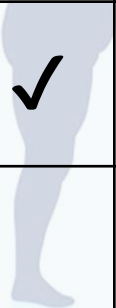


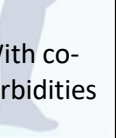

- **Economic:**

- Cost in 1998: \$78.5 billion (6.5% of budget)
- Cost in 2008: \$148 billion (9.1% of budget)
- 37% rise in obesity from 1998 to 2006

Mayo Clinic Data of 30,000 employees:



Obesity Treatment Guide

Intervention	BMI Category (kg/m)					Effectiveness	Complications
	25-26.9	27-29.9	30-34.9	35-39.9	≥40		
Diet, Exercise, Behavior Tx	✓ 	✓ 	✓ 	✓ 	✓ 	↓	↓
Pharmacotherapy		With co-morbidities 	✓ 	✓ 	✓ 		
Surgery				With co-morbidities 	✓ 		

The bottom line...

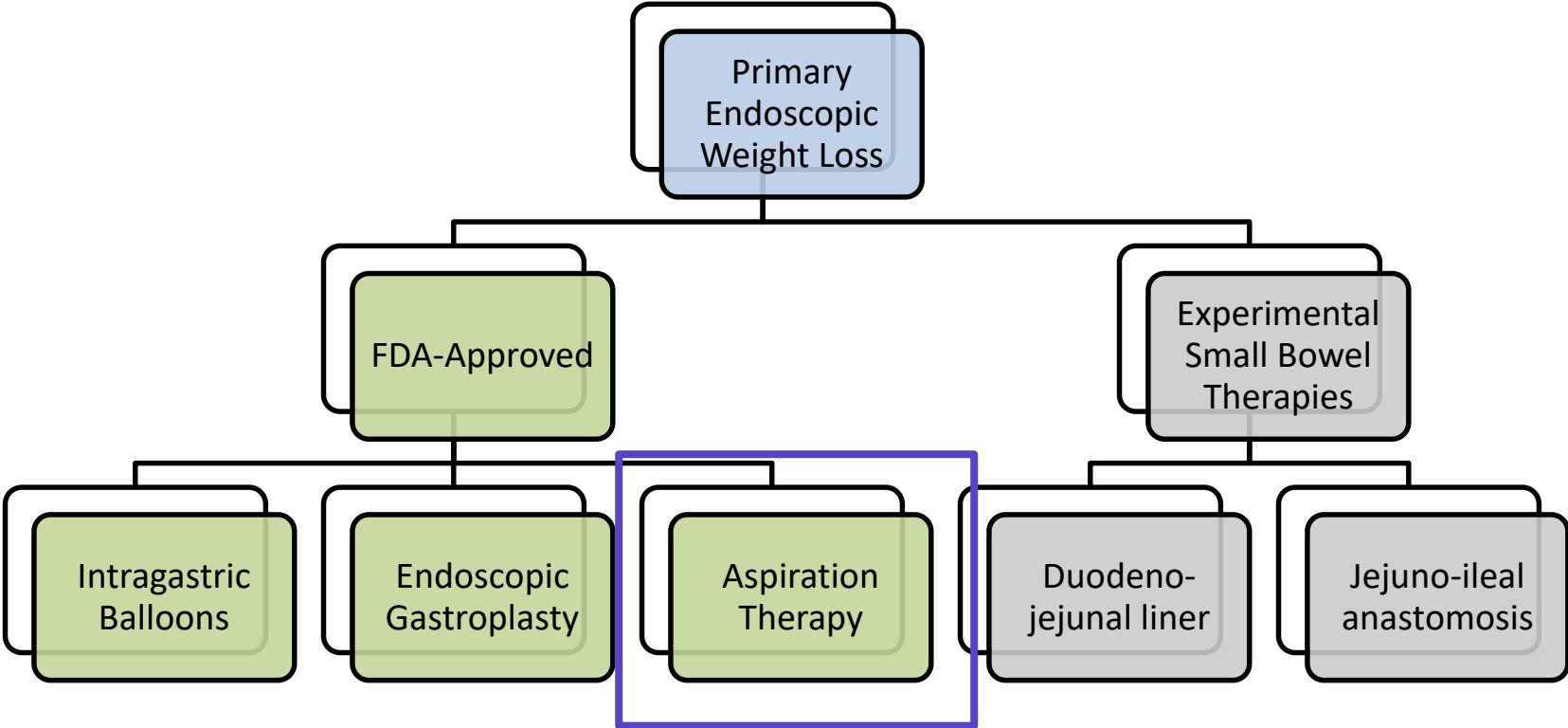
- Lifestyle/medications hard to maintain, low efficacy
- Surgery alone cannot contain the obesity epidemic

New Therapeutic options that are more effective than medications and less invasive than surgery are needed

What is Bariatric Endoscopy?

- Treat **complications after weight loss surgery**
 - Revision of failed bypass
 - Treatment of complications: fistulas, leaks
- Endoscopic **weight loss methods**
 - Early intervention
 - Bridge to decrease surgery risk
 - Metabolic

Bariatric Endoscopic Methods: Primary Therapies



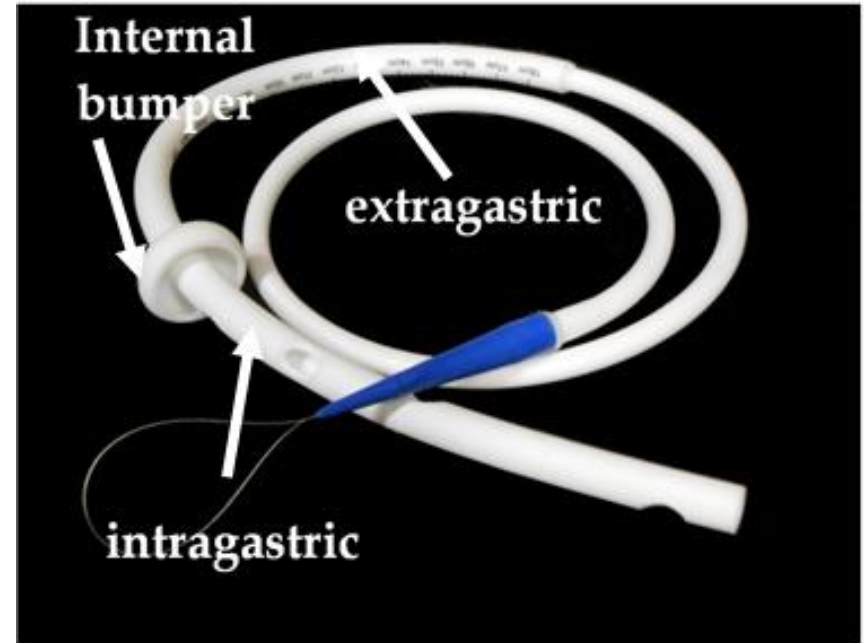
Aspiration Therapy

- Approved for age 22-65
- Indicated for BMI of 35 to 55 kg/m²
- Approved for long-term use
- Requires a nutritionist follow-up

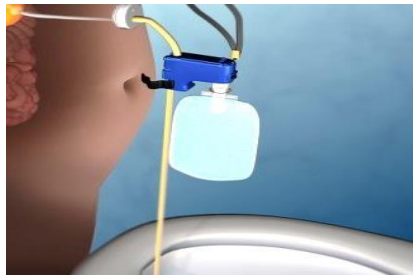
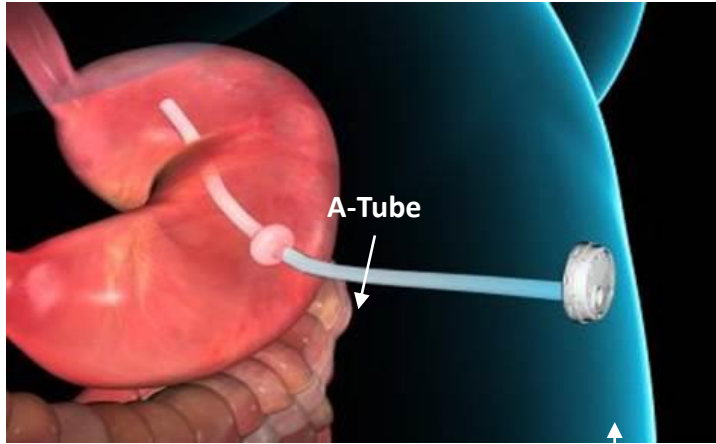


Concept

- Percutaneous Endoscopic Gastrostomy (PEG) tubes
 - Used for feeding in patients unable to eat
 - Used for removal of gastric fluid in patients with intestinal obstruction
- AspireAssist® System
 - Concept developed by Drs. Sam Klein, Moshe Shike, and Steve Solomon
 - Used for Aspiration Therapy (AT): removal of a portion of gastric contents after a meal for weight loss
- AspireAssist used by over 1000 patients in US & Europe
 - Maximum duration of use to date: 6 years



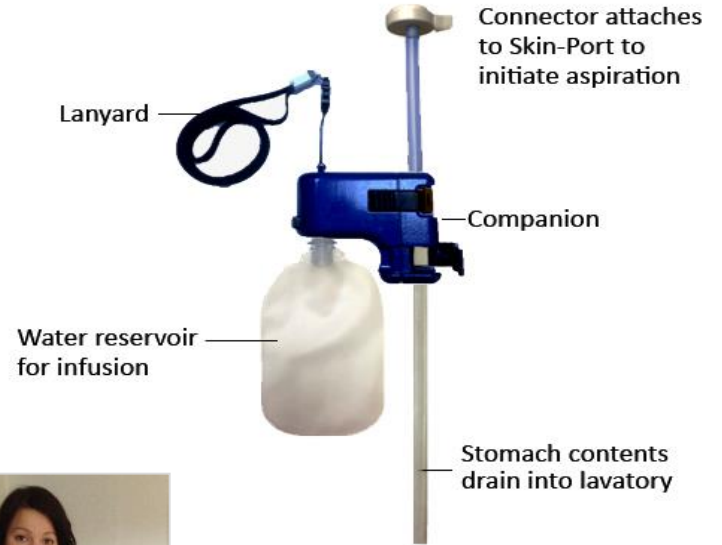
Aspiration System



Device in Use



Device Not in Use

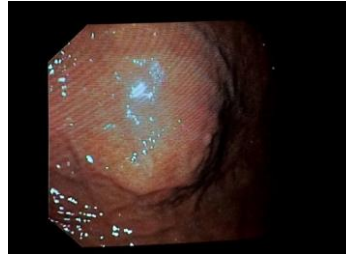


Placement: Standard PEG “pull” gastrostomy

Transillumination *is required**



Discrete finger indentation



Standard “pull” technique



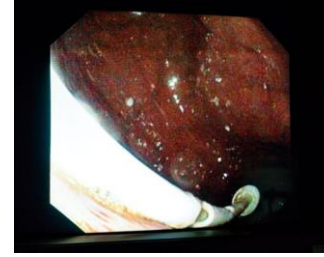
Intra-gastric “tail” on Aspire tube



External bolster for recovery



A-Tube curls into fundus



Transillumination successfully achieved in 99%* of patients

*One “failed” procedure where transillumination was not achieved initially, but was successfully achieved in a subsequent procedure via repositioning to Reverse Trendelenburg

Mechanisms of Action

Lifestyle Therapy and Aspiration Therapy Use

1

CALORIC DIVERSION

≤30% of calories drained by AspireAssist

* Responsible for 50-80% of weight loss

2

IMPROVED EATING BEHAVIOR

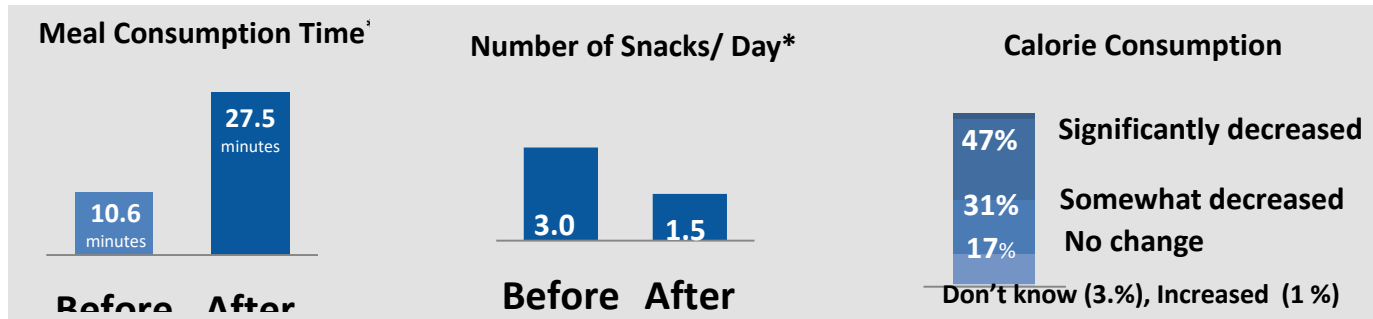
Thorough chewing/ slower eating

Increased water consumption

Less snacking

Mindful Eating

Meal Planning



PATHWAY Study Design (FDA Phase III Trial)

2:1 RANDOMIZATION

- 111 AspireAssist, 60 Lifestyle Therapy

INCLUSION CRITERIA

- Body Mass Index (BMI) 35 – 55
- Age 21-65
- Failed previous weight loss attempts

EXCLUSION CRITERIA

- GI disease/previous abdominal surg. that increases risk of A-Tube placement
- Previous bariatric surgery
- Serious cardiovascular disease
- History of major depressive or other severe psychiatric disorders
- Use of medications that cause clinically significant weight gain or loss
- Bulimia, Binge-eating, Night-Eating Syndrome

PRIMARY ENDPOINTS

- Mean percent Excess Weight Loss (EWL) >10% over control at 52 weeks
- At least 50% “Responder Rate” at 52-weeks (defined as 25% EWL)

Institutions

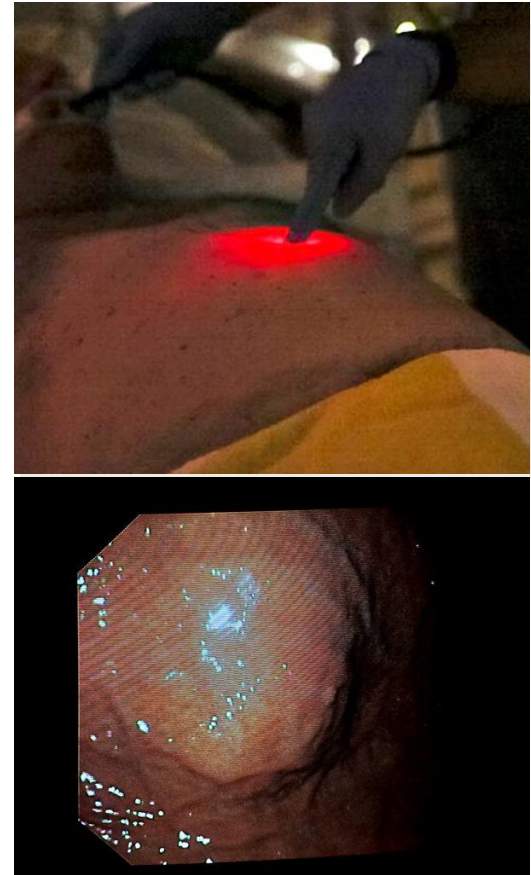
Boston Medical Center
Brigham & Women’s Hospital
Weill Cornell Medical College
St. Mary Medical Center
University of Pennsylvania
Howard University
Northwestern University
Mayo Clinic
Washington University
VA Center/ UC San Diego

Sponsor

Aspire Bariatrics, Inc.
King of Prussia, PA

Procedure Success/ Data

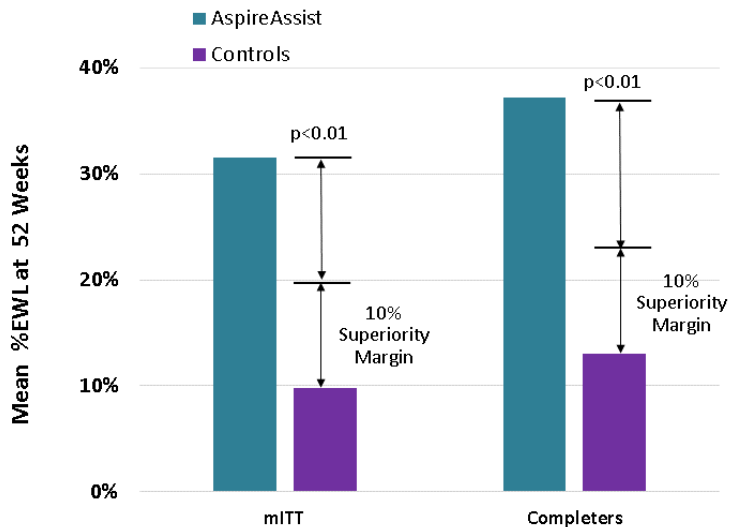
- Successful endoscopic placement in 111 of 114 endoscopies (97%) in 113 subjects
 - Endoscopy aborted in 1 subject because of suspected gastric varices
 - Endoscopy aborted in 1 subject because of previous (undisclosed) Roux-en-Y gastric bypass surgery
 - Endoscopy aborted in 1 subject because of inadequate transillumination, but later success in a re-attempt
- 89 of 111 (80%) AT placements done under conscious sedation
- Mean procedure time: 15 ± 7 minutes
- Mean recovery time: 106 ± 48 minutes



PATHWAY Study: Two Co-Primary Endpoints Met

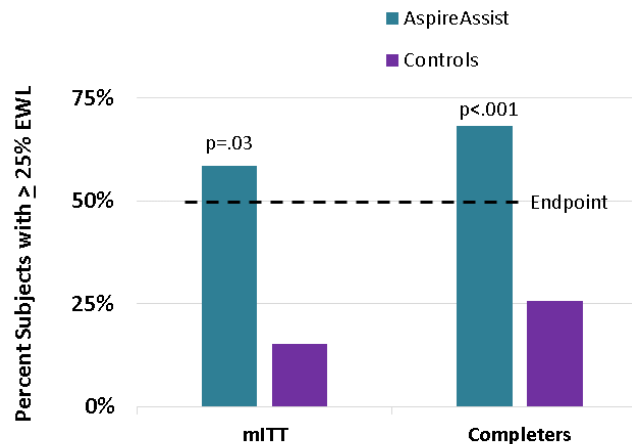
Co-Primary Endpoint #1

Mean %EWL at 52 Weeks of AT Group at least 10% greater than Control Group

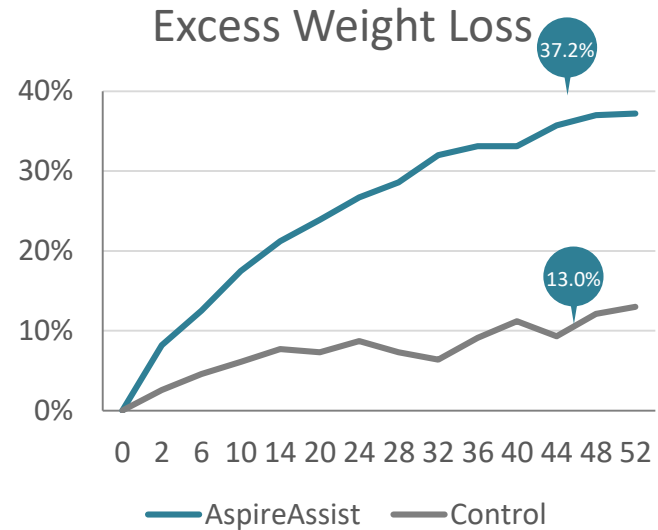
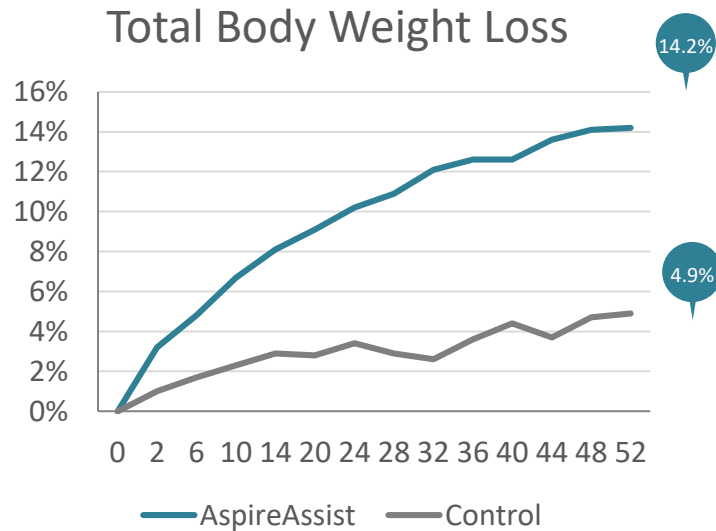


Co-Primary Endpoint #2

At least 50% of AT group achieves 25 %EWL or more at 52 Weeks



PATHWAY* Study: Weight Loss Results



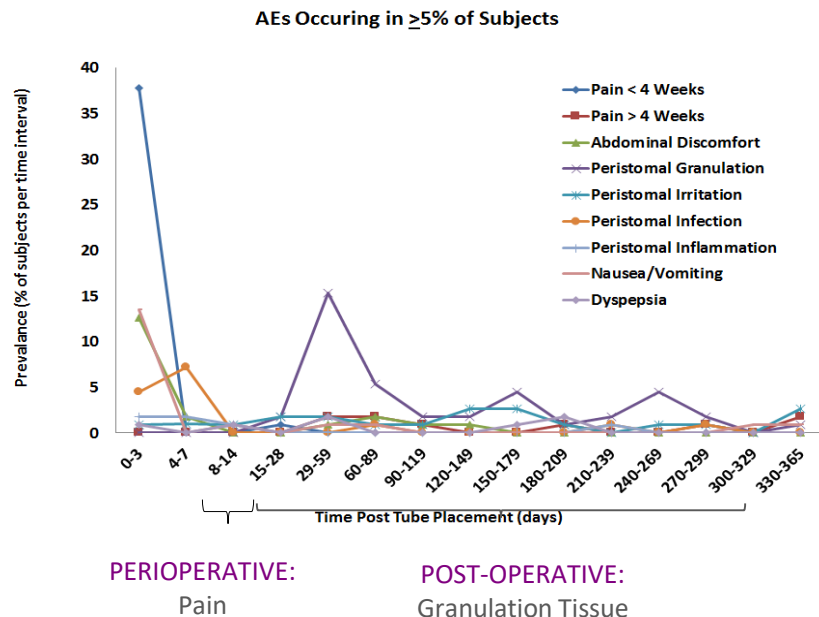
*US Data: Per Protocol. Thompson C et al. The AspireAssist Is an Effective Tool in the Treatment of Class II and Class III Obesity: Results of a One-Year Clinical Trial. Gastroenterology. April 2016 Volume 150, Issue 4, Supplement 1, Page S86. [Presented at DDW 2016]. N=171 Subjects.

Change in Cardiometabolic Factors & QoL

Endpoint	Baseline	52-week change**	P value
HbA1C (%)	5.7 ± 0.6	-0.36 ± 0.45	<0.001
Systolic BP (mm Hg)*	124.2 ± 13.3	-2.3% ± 15.7%	0.38
Diastolic BP (mm Hg)*	78.8 ± 8.1	-2.4% ± 9.7%	0.06
Total cholesterol (mg/dl)*	193.8 ± 37.4	-2.5% ± 12.9%	0.07
LDL-cholesterol (mg/dl)*	115.4 ± 32.8	-4.2% ± 19.4%	0.06
HDL-cholesterol (mg/dl)*	52.2 ± 14.4	+8.1% ± 18.1%	<0.001
Triglyceride (mg/dl)*	140.8 ± 81.7	-9.9% ± 36.2%	.02
IWQOL:			
Total IWQOL score	63.8±17.9	16.3±17.7	<0.001
Physical Function	60.2±20.4	18.7±20.6	<0.001
Self-Esteem	51.6±25.2	7.6 ± 17.3	<0.001
Sexual Life	70.5±28.1	13.4±24.4	<0.001
Public Distress	73.1±21.3	11.5±20.0	<0.001
Work	78.0±22.4	12.5 ± 20.1	<0.001

Safety

Few and relatively minor adverse events



Low Rate of Serious Adverse Events

Only 5 SAEs in 4 subjects, all easily resolved (**3.6% SAE rate**)

1. Perioperative pain, 1 night stay Resolved with pain medication
2. Perioperative mild peritonitis, 2 night stay. Resolved w/ IV antibiotics
3. Post-operative: Mild ulceration. Resolved w/ A-Tube removal
4. Postoperative: A-Tube fungal growth, resolved w/ A-Tube replacement

No Metabolic / Electrolytic Abnormalities

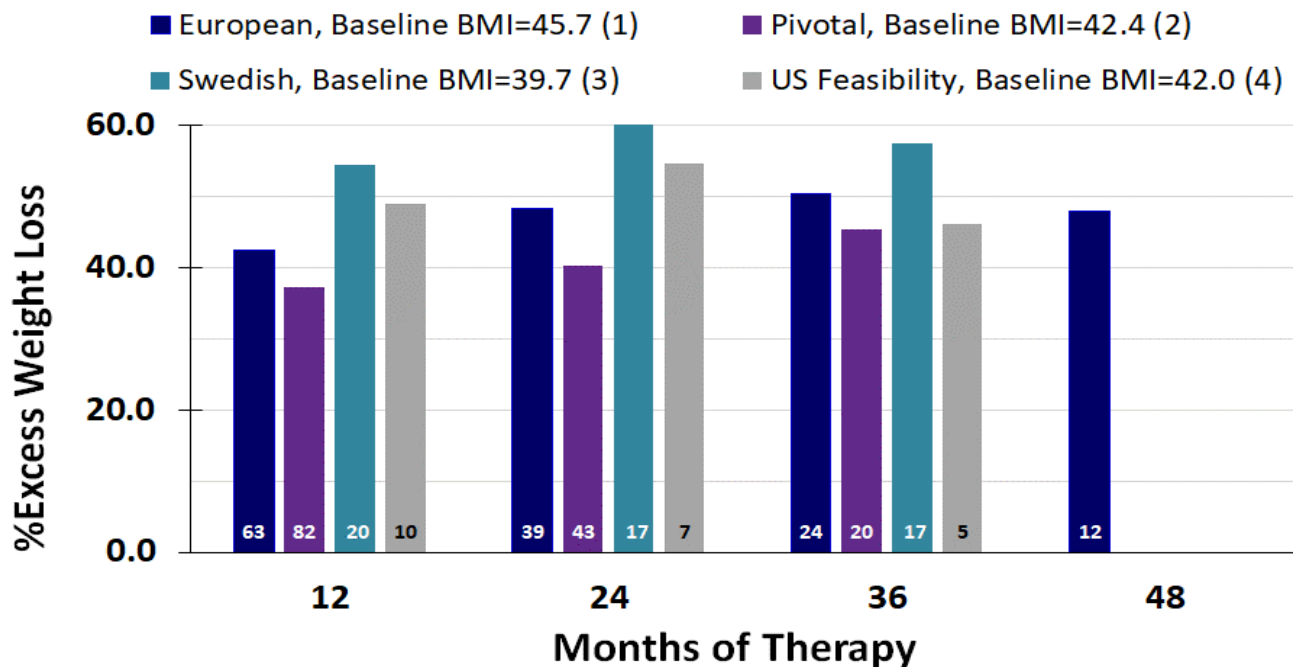
Effect on Eating Behaviors

- Subjects assessed for binge-eating, bulimia, & night-eating syndrome
 - Eating Behavior Assessment: Questionnaire on Eating and Weight Patterns-Revised (QWEPR) and the Eating Disorder Examination)
 - Assessments at Baseline, Week 14 (AT subjects only), Week 28, and Week 52
 - 1 Control subject developed binge-eating syndrome at Week 28 and was removed from study
 - No AT subject showed any evidence of worsening eating behaviors
- Frequency of aspiration monitored by Connector counts
 - No evidence of any subject excessively aspirating
- Self-reported data show an improvement in eating behaviors: more thorough chewing, more H2O consumption, less snacking, greater meal planning, mindful eating
 - Observed weight loss in AT subjects greater than can be explained through aspiration

Aspiration Therapy Studies

Study	Location	PI	Start Date, First Patient	Start Date, Last Patient	Number of Patients Enrolled
Controlled Studies					
RCT	St. Louis, MO	Steve Edmundowicz	3/2009	12/2009	18
RCT (“Pivotal Trial”)	USA (10 centers)	Chris Thompson Lou Aronne	12/2012	6/2014	171
Controlled AT vs RYGB	Karlskrona	Henrik Forssell	6/2015	1/2016	100
Adolescent Study	Ostrava, Czech Republic	Marek	7/2016	TBD	30
Observational Studies					
Pilot Study	Monterrey, Mexico	Fernando Lavalle	9/2007	2/2008	11
Post-Market	Karlskrona, Sweden	Henrik Forssell	6/2012	9/2012	25
Post-Market	Spain, CZ Republic, Austria, Germany, Italy, Denmark, Holland	Machytka, Turro, Bammer, Testoni, Fehlert, Forssell	10/2012	Ongoing	~300
Super-Obese	CZ Republic, Spain	Machytka, Turro	9/2013	8/2015	30

Durable Weight Loss Across 4 Studies



(1) Nystrom M, Machytka E, Forssell H, Noren E, R. Turro,, IFSO 2017.

(2) Thompson et al, Am. J. of Gastro., Dec 2016.

(3) Noren, Forssell, BMC Obesity, Dec. 2016

(4) Sullivan et al, Gastroenterology 2013; 145: 1245–1252

Long-term Results

- 85 patients enrolled from June 2012 to December 2016 in 3 centers(Ostrava, Czech Republic; Karlskrona, Sweden; Barcelona,Spain)
- Outcomes:

	1 yr	2 yrs	3 yrs	4 yrs
n	63	34	22	12
TBWL(±SD)	17.6%(8.6)	21.7%(10)	22.1%(9.7)	19.2(13.6)

Long Term Weight Loss Results

Mean Baseline BMI:
 $45.7 \pm 8.2 \text{ kg/m}^2$

Increasing weight loss through Year 3			
Time	%TWL Mean +SD 95% CI	%EWL Mean +SD 95% CI	AWL (kg) Mean +SD 95% CI
1 year	$18\% \pm 8\%$	$43\% \pm 23\%$	23 ± 13
2 Years	$22\% \pm 10\%$	$48\% \pm 27\%$	27 ± 15
3 Years	$22\% \pm 10\%$	$50\% \pm 26\%$	29 ± 17
4 years	$20\% \pm 14\%$	$48\% \pm 36\%$	25 ± 20

Results in Super Obese Patients

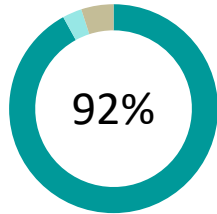
- 11 patients, mean age 44.9 (32-63); mean BMI 66.5 kg/m²(55-80.4)
- 100% successful placements; AE: Minor skin irritations in 3

- Results:

	1 yr	2 yrs	3 yrs
Kg lost	42.1 kg	45 kg	45.7 kg
TBWL, %	21.9%	25.5%	25.7%
EWL, %	34.1%	38.8%	39%

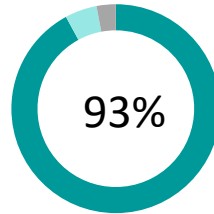
US Clinical Study Patient Experience Survey

Overall Satisfaction



■ Satisfied ■ Neutral ■ Dissatisfied

Would Recommend to a Friend



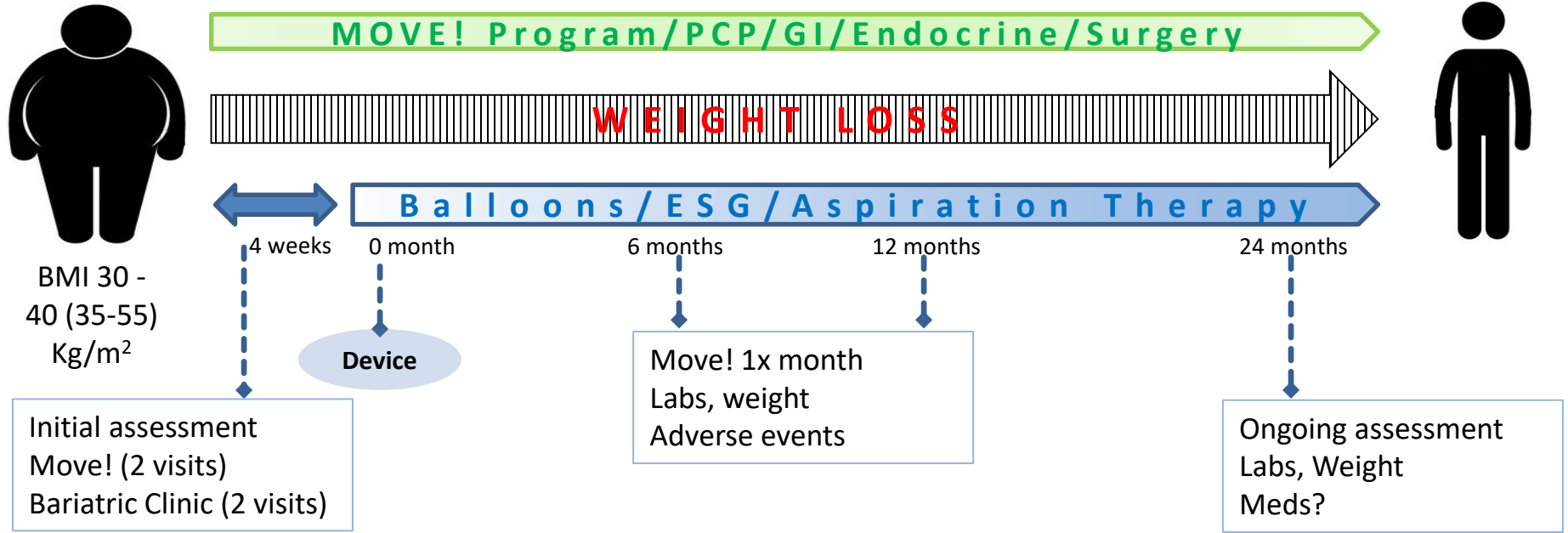
■ Likely ■ Neutral ■ Unlikely



Hanna, Age 35
Lost 77 pounds in 1 year

A Bariatric Endoscopy Program in Managed Care

12+ Month Program

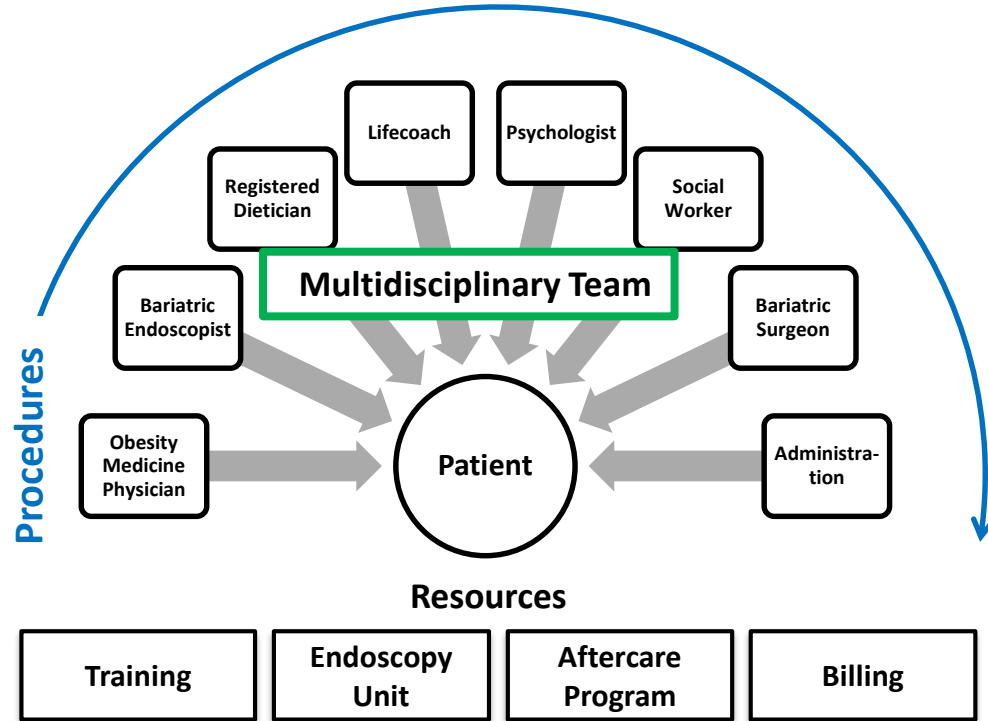


Patient Selection is Key

- Patient motivation important to success
- Poor candidates: people with highly chaotic/ difficult lives
- Successful aspiration requires thorough chewing
- If poor weight loss: either not aspirating regularly or poor chewing
- Improved methods of teaching chewing to patients
- Important ingredients to success: lifestyle counseling + group meetings

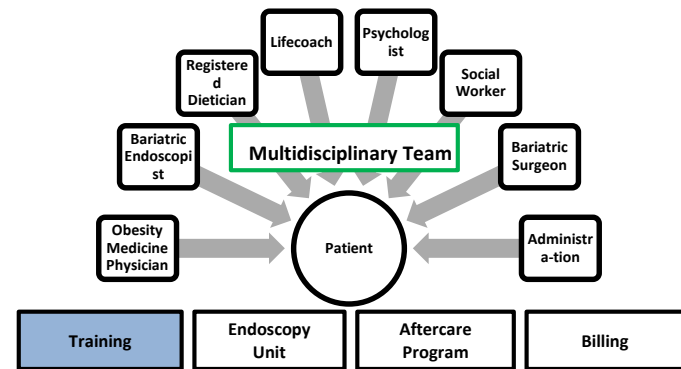
In screening process, patients should be able to articulate how they plan to fit aspiration therapy into their daily schedule

The Multidisciplinary Team

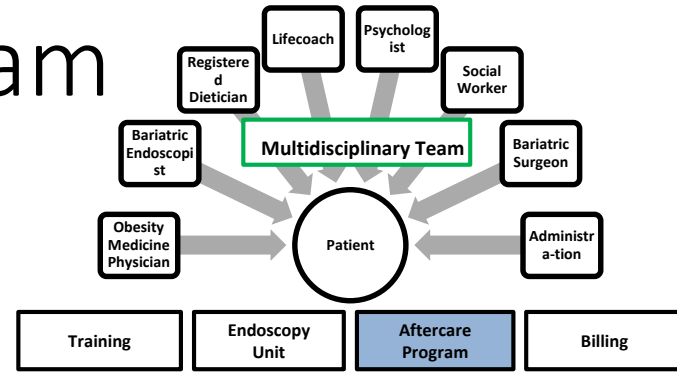


Resources: Training

- Physician credentialing:
 - Bariatric endoscopy fellowship
 - Board Certification in Obesity Medicine
 - Completed training at a certified course and approval of privileges at local hospital
 - Association for Bariatric Endoscopy
- Nurses training:
 - Protocols
 - Training courses for nurses:
 - Miami Flexible Endoscopic Surgery Course,
 - proctoring, etc



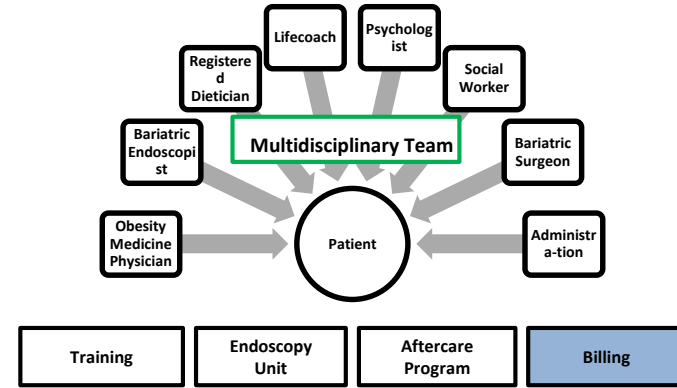
Resources: Aftercare Program



- Registered Dietitian:
 - Certified by the Academy of Nutrition and Dietetics
 - Training in Weight Management; Certified Specialist in Weight Management
- Lifestyle/Wellness Coach
- Support groups
- Shared visit

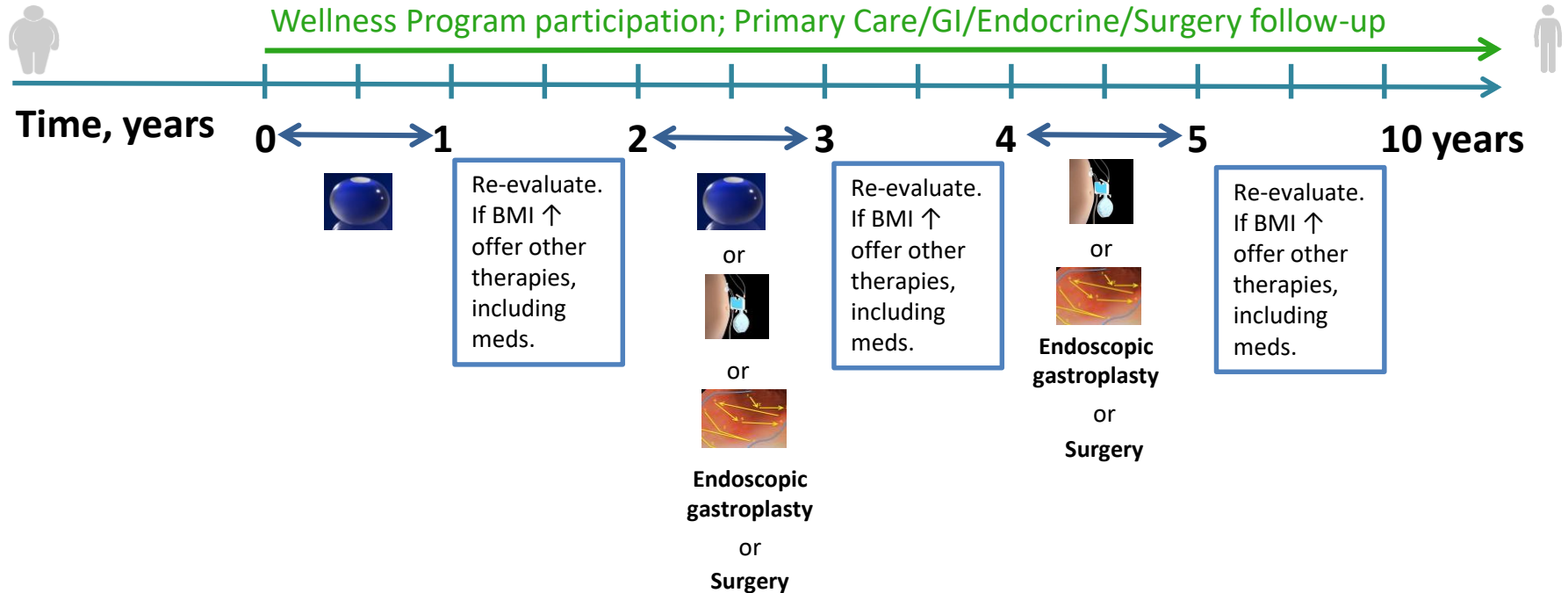
Billing

- Facility fee: hospital or office-based
- Anesthesiologist fee
- Nutritionist fee
- Device cost
- Complications
- Office-based IV hydration option
- Total cost should include facility, anesthesia and liability
- Cash-pay model

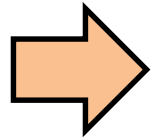
























Comprehensive approach

- Obesity is a chronic disease that requires long-term multidisciplinary management plan and standards of care.



New Treatment Paradigm



Intervention	BMI Category (kg/m)					Effectiveness	Complications
	25-26.9	27-29.9	30-34.9	35-39.9	≥40		
Diet, Exercise, Behavior Tx	✓ 	✓ 	✓ 	✓ 	✓ 		
Pharmacotherapy		With co-morbidities 	✓ 	✓ 	✓ 		
Endoscopic therapies			✓ 	✓ 	✓ 		
Surgery				With co-morbidities 	✓ 		

Thank you!

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