



# Acceptability and efficacy of intra-gastric balloons (supported by a lifestyle programme) for the treatment of severe adolescent obesity and the metabolic effects of the associated weight loss -Balloons in Obesity (BOB) Study.

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There is no potential conflict of interest

## Background

A small number of adolescents have very severe obesity (typically weighing over >125 kg with BMI's between 40-50) with significant obesity-related health problems and psychological consequences as a result. These individuals also meet the NICE exceptionality criteria for bariatric surgery. Increasing numbers of severely obese adolescents undergo bariatric surgery in the USA with reports of substantial weight loss after one year. However, there are concerns from parents, commissioners and paediatricians regarding advocating permanent procedures with minimal long term data for young people. Pharmaceutical and lifestyle interventions alone are unfortunately often only of limited benefit.

## Rationale & hypothesis

We proposed a feasibility study of intra-gastric (stomach) balloons supported by a lifestyle programme to help severely obese adolescents lose weight. The balloon is placed in the stomach endoscopically and inflated - it can be left for 6 months. The rationale for proposing a trial was that in adults balloons have been shown to promote a clinically significant change in BMI of 4.0 - 9.0 kg/m<sup>2</sup>. As adults tend to regain weight post balloon removal, bypass surgery is often preferred. Balloons are a temporary measure and the risk of a serious complication is much lower (0.07%) compared to bariatric surgery (mortality 0.5-1%). Young people are more amenable to lifestyle change and we hypothesised that by using balloons to "kickstart" weight loss, supported by a lifestyle programme, we could provide a platform for longer term improvement in their weight.

## Objectives

- 1) To establish the potential of the intragastric balloon to support weight loss in adolescents with severe obesity
- 2) To ascertain the extent to which that weight loss is maintained 18 months later.
- 3) To examine the effect of the weight loss on biomedical outcomes such as glucose metabolism, lipid profiles, skeletal health as well as on psychosocial health including friendships and school.

## Methods

Cohort study of 12 adolescents (7 female, BMI >3.5 SD, Tanner stage 4 or above) (sample size based on statistical advice for a 'proof of concept' study) were recruited from the Children's hospital and peripatetic clinics with follow up for 2 years. (See table 1) The Sheffield Research Ethics Committee approved the project.

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A consultant paediatric gastroenterologist inserted the intra-gastric balloon endoscopically under general anaesthetic

## Results

Table 1 Demographics of recruited patients

Demographics					
No	Age/sex	Wt l year prior	Pre-op weight (kg)	Pre-op BMI(kg/m <sup>2</sup> )	Pre-op BMI SDS
1	16.3/F	122	130.9	46.8	+4.1
2	16.5/M	157.6	178.8	52.8	+4.3
3	15.3/M	130	145.9	49.3	+4.1
4	15.8/M	128.6	142.2	42.1	+3.7
5	15.0/M	137	154.9	51.6	+4.2
6	14.3/F	106.6	107.6	46.8	+4.1
7	16.0/F	121.4	116.9	41.8	+3.7
8	15.9/F	141.6	161.8	49.1	+4.2
9	14.6/M	112.6	118.9	44.1	+3.9
10	16/F	104.4	115.7	39.6	+3.6
11	15.3/F	146	170	56.3	+4.5
12	13.7/F	120.2	117.7	39.5	+3.6
Mean	15.3	127	138.45	47.5	+4.0

Figure 1 -Co-morbidities in severely obese adolescents related to their weight

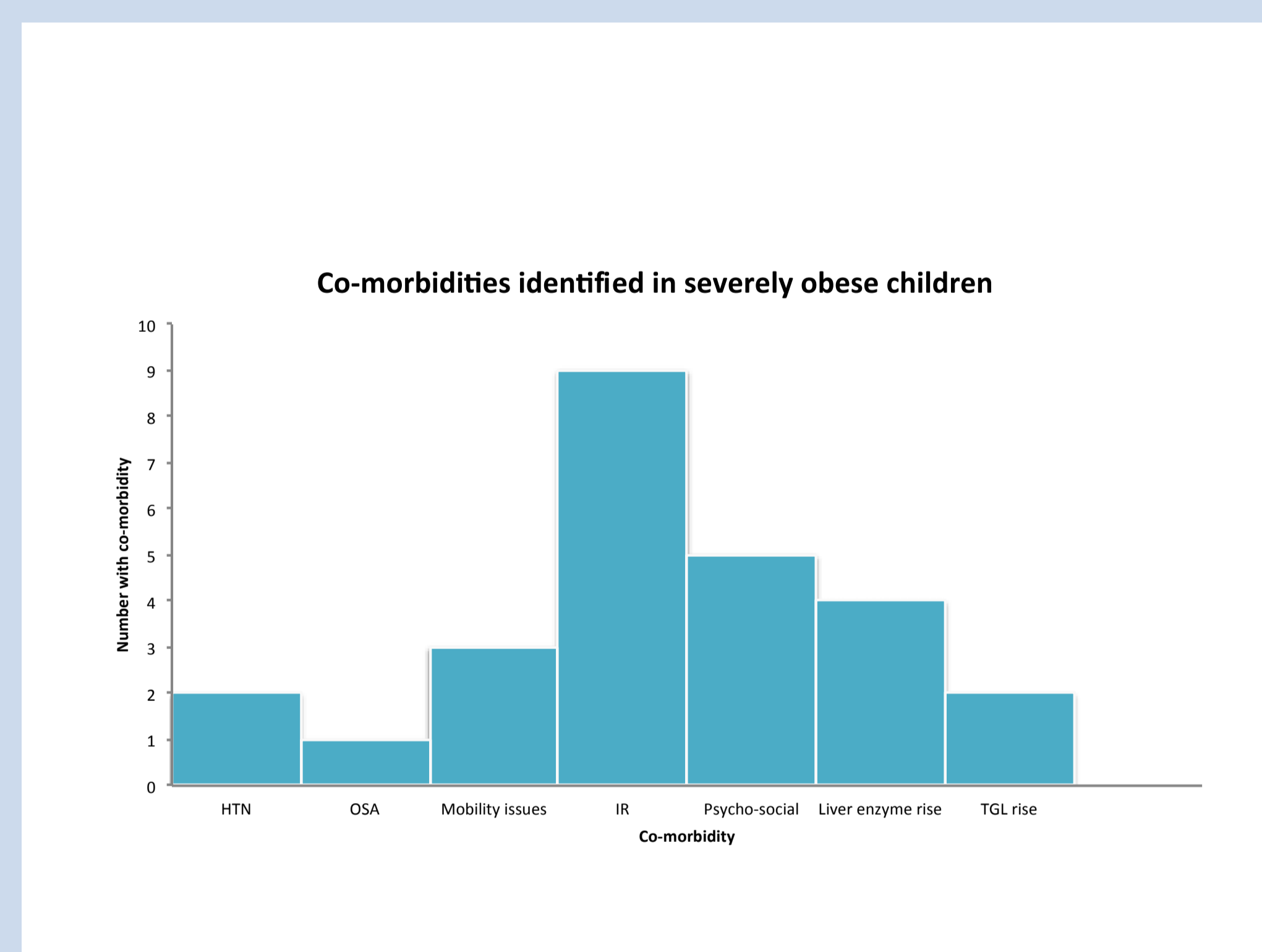
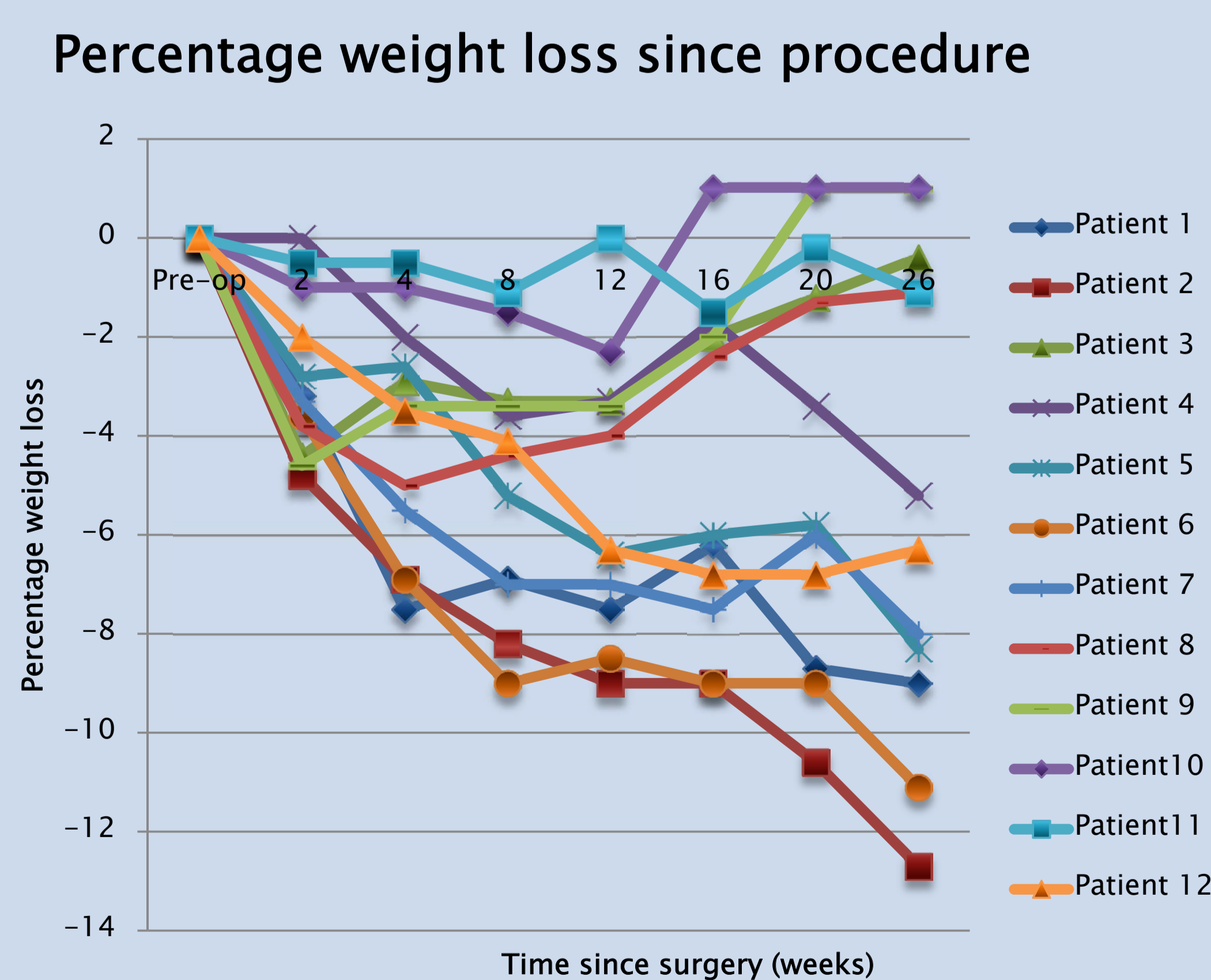


Figure 2 - Percentage weight loss over 6 months



## Results

All the young people took part in a medical, psychosocial, dietetic and physical assessment comprising of blood tests, bone scans, questionnaires and treadmill tests prior to the balloon going in and at 6 months at balloon removal. The young people had already developed significant co-morbidities related to their weight

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Average hospital stay was 24 hours. The balloon was tolerated well with minimal side effects such as nausea, vomiting and abdominal discomfort over the first few days. There were no significant complications and no early removals.

Patient engagement with the medical team was good with a mean of 6.5 visits out of a maximum of 8. However, attendance at the life style intervention package was sub optimal with only 37% of planned visits taking place.

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Mean total weight loss at 6 months was 7 kg (range +2 to -22.6, p=0.005) with an average percentage loss of 5% of total body weight (which is considered to be clinically significant for long term health).

An average of 9.55% (5.03-13.07 CI) of excess body weight was lost. BMI fell by 2.53 kg/m<sup>2</sup> (p<0.004) and BMI SDS reduced by 0.2 (p<0.002).

Waist circumference, a marker for visceral obesity, which correlates well with metabolic risk significantly reduced by 12.4 cm (p<0.016). Waist to hip ratio which is an even better predictor of cardiovascular health also improved into the normal range (0.91 to 0.85 in girls and 0.99 to 0.91 for boys)

No significant change was noted in HBA1c, lipid profiles, or blood pressure at balloon removal, although individual comorbidities improved. The study was not powered to detect significant differences.

DEXA showed an increase in TBLH (Total body less head) bone mineral content (BMC) and all the DEXA lumbar spine parameters, which are likely to be age related.

## Conclusion

This is the first feasibility study of this kind looking at the acceptability and efficacy of intragastric balloons in severely obese adolescents. The intra-gastric balloon has been generally well tolerated, is safe and acceptable to young people and results in significant weight loss with a number of clinical benefits. Follow-up is on-going.

Importantly the significant reduction in weight and truncal fat mass did not impact on bone mass accrual, allaying concerns that weight loss may adversely affect bone density in adolescents.

